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Assessment of palliative care for advanced non-small-cell lung cancer in France: A prospective observational multicenter study (GFPC 0804 study)☆

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ABSTRACT

Introduction: Few studies assessed, in real life, symptoms, specific interventions and factors influencing palliative care (PC) initiation for patients with advanced non-small-cell lung cancer (NSCLC). The objective of this study was to examine, in a prospective cohort of advanced NSCLC patients, PC use and factors associated with early (≤3 months after diagnosis) PC initiation.
Methods: It was an observational multicenter study. Each center included 10 consecutive patients with PC initiation.
Results: 514 patients were enrolled by 39 centers (age: 62.3 ± 10.7 years, performance status: 0/1; 68.6% cases). At baseline, the most frequent symptoms concerned pain (43.6%), malnutrition (37%) and psychological disorders (25.3%). Specific interventions were infrequent for pain control and malnutrition, but were more numerous for psychological and social problems and terminal care. Median time between diagnosis and PC initiation was 35 [13–84] days, median PC duration was 4.2 [0.6–9.3] months. Median overall survival was 8.6 [6.6–10.7] months; median survival after PC initiation was 3.6 [3.2–4.5] months. In multivariate analysis, only PS ≥2 was linked to early PC.
Conclusion: This study showed that early PC initiation is not a standard for patients with advanced NSCLC.

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1. Introduction

Advanced non-small-cell lung cancer (NSCLC), stages III and IV, still carries a poor prognosis despite recent therapeutic advances [1]. Some forms are particularly difficult to treat, and median survival has stagnated at about 10 months [2]. The respective roles of acute treatment and palliative care (PC) are difficult to define [3]. Symptomatic treatment, including multidisciplinary PC, is now an essential aspect of patient management [4]. PC has now international definition [5]. The objective is to ensure the best possible quality of life for patients and their families.

Patients rarely express a need for PC at the time of diagnosis [6,7]. However, two recent trials emphasize the value of early PC, introduced at the same time as standard treatment [8,9]. One of them [9], a phase III trial, showed that early PC improved quality of life, depression and survival compared with standard care. Two complementary publications showed that patients had a poor perception of NSCLC severity at diagnosis, and that early PC could not only improve their understanding of the disease [10] but also lead to significantly fewer chemotherapy cycles in the last part of life and to a longer period without chemotherapy before death [11]. Finally, PC appears to lessen costs by reducing hospitalization and ICU stays [12,13].

Recent publications deal with the type of PC [8,14–21]. The French NCI [22] considers that PC must cover several needs, including pain, fatigue, nutritional problems, digestive disorders, respiratory, genitourinary and dental problems, social difficulties, physical suffering, altered body image, and end-of-life support. PC should be developed together with pain control programs and be integrated in hospital programs and regional care organizations.

There are few published observational data in real life, which depicted the time of initiation of PC. A recent small, single-institution retrospective study [23] included 162 advanced NSCLC patients managed in 2005 in South Korea. Patterns of disease-related events requiring palliation were analyzed, along with palliative procedures and clinical outcomes. One-third of patients received PC at the time of diagnosis, and a further 36% at some stage of their management. Overall survival was similar in patients who started PC at the time of diagnosis and other patients.

The main objective of this prospective observational study was to examine PC use and factors associated with early (≤3 months after diagnosis) PC initiation. Secondary objectives were to assess needs and specific interventions used on PC setting.

2. Methods

2.1. Study and data collection

This was a prospective observational multicenter study of patients with advanced NSCLC who received PC. The participating centers belonged to the GFPC study group, all of which recruit more than 50 new cases of NSCLC each year. Each center was asked to enroll at least 10 and no more than 15 consecutive patients, with 1 year of follow-up.

Inclusion criteria were patients over 18 years of age with advanced NSCLC who started PC, defined as specifically organized pain management; nutrition; physiotherapy; prevention and treatment of anemia; social care; and physiotherapy.

Patients were not eligible if they were participating in a clinical trial that would modify the modalities of PC.

All the data were extracted from medical files (issued from investigators' declarations) and recorded by specifically trained clinical research assistants. As it was an observational study, no data were recorded on quality of life because it is not performed in the usual clinical practice. The analysis focused on the patients' clinical characteristics (age, sex, body weight and weight loss, performance status), cancer stage at diagnosis, type of treatment (surgery, radiotherapy, chemotherapy), the time between diagnosis and announcement, the time between diagnosis and PC initiation, symptoms present at PC initiation, symptom management, laboratory findings (serum calcium, albumin, creatinine), specific treatments (transfusions, erythropoietin (EPO), growth factors, antibiotics, enteral or parenteral nutrition, pain relief, corticosteroids), and the use of specific PC services (especially mobile PC and hospitalizations on a PC ward). For each patient, these data were collected at the time of treatment and then every 3 months or until death, for at least 1 year.

The protocol was approved by the Limoges University Hospital Ethics committee.

2.2. Statistical analysis

Continuous variables are expressed as the mean, standard deviation and median.

To identify variables associated with PC initiation, logistic regression was used to compare patients who received early PC (started within 3 months following diagnosis) to those who received PC more than 3 months after diagnosis. All variables significant in univariate analysis (≤20%) were included in the logistic regression model. Goodness-of-fit was verified by using the Hosmer and Lemeshow test. All calculations used SAS software (V9.2, SAS Institute, Cary, USA).

3. Results

Between 1 July 2009 and 30 June 2010, 514 patients were enrolled in 39 centers. Each center enrolled at least 10 consecutive patients, with gradual opening of recruitment over a 1-year period.

Mean age was 62.3 ± 10.7 years and 68.8% of patients had a PS of 0 or 1. The percentages of patients with weight loss exceeding 10% at 3, 6, 9 and 12 months were respectively 1.9%, 2.1%, 5.2%, and 3.1%. Nearly all the patients (95%) received chemotherapy, including a platinum salt in two-thirds of cases; 58.6% of patients had received radiotherapy and 11.7% had undergone surgery (Table 1). Number and type of metastatic sites are depicted in the Table 1.

Median survival after diagnosis was 8.6 [6.6–10.7] months; median survival after PC initiation was 3.6 [3.2–4.5] months; survival rate at 1 year was 26.4%. The time between diagnosis and announcement of the disease was 10 [4–19] days. The time between diagnosis and PC initiation was 35 [13–84] days. The duration of PC was 4.2 [0.6–9.3] months.

Table 2 shows the prevalence of symptoms according each time period and the percentages of patients who received a specific intervention for these symptoms. At baseline, the main symptoms were pain (43.6%), malnutrition (37%) and psychological disorders (25.3%). Symptoms declined with time, according to specific interventions. However, intervention rate varied greatly depending on the symptom. Interventions for pain and malnutrition management were largely under the needs with nearly 50% of patients with these symptoms who did not receive specific management. In contrast, psychological disorders, social needs and terminal care appeared to be better dispensed. Regardless of the study period, between 23.4% and 36% of patients complained of noteworthy fatigue (Table 2). Hematological disorders (anemia, thrombocytopenia and febrile neutropenia) affected 29.7% to 54.8% of patients during follow-up (Table 3). The principal specific medical treatments were erythropoietin, transfusions, growth factors and antibiotics (Table 4). A significant number of patients (5.5–15.9%) received enteral or parenteral nutrition at some phase of their management (Table 4).

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Table 1
Characteristics of the patients.

	n	%
Sex (n = 514)		
Male	362	70.4
Female	152	29.6
Age (n = 514)	62.3 ± 10.7	
PS at the inclusion (n = 444)		
0	90	20.8
1	212	47.8
2	98	22.1
3/4	41	9.3
Number and type of metastatic sites (n = 352)		
One site	56	16.0
≥Two sites	296	84
Brain	152	29.12
Lung	198	37.93
Bone	232	44.44
Adrenal gland	113	21.65
Kidney	12	2.3
Other	135	25.86
Previous surgery (n = 514)	62	11.7
Chemotherapy after inclusion (n = 514)	492	95.7
With cisplatin	307	62.4
Without cisplatin	185	37.6
Number of cycles		
With platinum	3.3 ± 2.3	
Without platinum	3 ± 1.6	
Radiotherapy after inclusion (n = 514)	310	58.6
Brain	103	33.3
Bone	125	40.45
Lung	43	13.9
Others	38	12.3

Two hundred twelve (51%) patients began early (≤3 months after diagnosis) PC initiation. In univariate analysis (Table 5), factors associated with early PC were PS ≥ 2, early death (within 3 months after diagnosis), and the need for terminal care. Chemotherapy was not significant ($p = 0.41$) according to its correlation with other variables like PS. Use of erythropoietin, parenteral nutrition, and hospitalization to a PC ward were significantly associated with late (>3 months after diagnosis) PC initiation. In multivariate analysis (Table 6), only PS ≥ 2 remained associated with early PC initiation, while erythropoietin administration, parenteral nutrition and hospitalization in terminal care unit, remained significantly associated with late PC initiation.

4. Discussion

This observational, multicenter study, in a population of patients with advanced NSCLC, gave detailed information about PC in a routine setting. It underlined an under management for some symptoms like pain or malnutrition. The rate of specific interventions was far from optimal, in comparison of French NCI guidelines [22]. The average time between diagnosis and PC initiation was long and the only factor significantly associated with early PC was poor PS, whereas international guidelines recommend early PC for all patients. There was also marked heterogeneity in the interventions against symptoms: in this study, social, psychological interventions and terminal care were the more frequent, while pain management and nutritional support were lower.

Inadequate pain relief has also been observed in other studies [17,18,23,24]. In a recently published article, among 3123 ambulatory patients with cancer of the breast, prostate, colon/rectum or lung, 67% reported pain or required analgesics at their initial assessment and 33% of them received inadequate pain relief.

Table 2
Symptoms and palliative interventions.

Periods	Symptoms (%)	Interventions (%)
Pain		
0–3 months (n = 490)	43.6	22.1
3–6 months (n = 286)	36.4	21.7
6–9 months (n = 171)	31	16.2
9–12 months (n = 128)	28.9	16.4
Malnutrition		
0–3 months (n = 490)	37	27.1
3–6 months (n = 286)	25.5	12.2
6–9 months (n = 171)	19.9	8.7
9–12 months (n = 128)	16.4	8.6
Psychological disorders		
0–3 months (n = 490)	25.3	29.5
3–6 months (n = 286)	16.8	15.7
6–9 months (n = 171)	8.8	14
9–12 months (n = 128)	7	7.8
Social difficulties		
0–3 months (n = 490)	10.8	10.6
3–6 months (n = 286)	9.4	8
6–9 months (n = 171)	8.8	7
9–12 months (n = 128)	6.3	7.3
Terminal care		
0–3 months (n = 490)	17.3	14.4
3–6 months (n = 286)	18.9	8.1
6–9 months (n = 171)	12.9	12.3
9–12 months (n = 128)	7.8	6.2
Fatigue		
0–3 months (n = 490)	36	NA
3–6 months (n = 286)	31.1	NA
6–9 months (n = 171)	27.5	NA
9–12 months (n = 128)	23.4	NA
Other symptoms[a]		
0–3 months (n = 490)	60.1	59.2
3–6 months (n = 286)	47.9	43
6–9 months (n = 171)	44.4	36.8
9–12 months (n = 128)	36.1	36.7

[a] Respiratory, digestive, ondotology,

Predictors of inadequate pain relief were good performance status, management at a minority treatment site, and non-advanced disease without concurrent treatment. In another database review of 1476 lung cancer patients, only 8% received palliative care, usually late in the hospital stay or when death was imminent [25].

In a Norwegian study in the general population, the likelihood of in-hospital death was dependent of the rate of chemotherapy administration during the last 3 months of life [26]. In our study,

Table 3
Clinically significant biological disorders.

Hypercalcemia (>2.6 mmol/l)	
0–3 months (n = 490)	0.8%
3–6 months (n = 286)	0%
6–9 months (n = 171)	1.2%
9–12 months (n = 128)	1.5%
Hypoalbuminemia (<30 g/l)	
0–3 months (n = 490)	4.9%
3–6 months (n = 286)	3.8%
6–9 months (n = 171)	2.3%
9–12 months (n = 128)	3.1%
Renal failure (creatinemia > 125 μmol/l)	
0–3 months (n = 490)	6.3%
3–6 months (n = 286)	5.1%
6–9 months (n = 171)	5.8%
9–12 months (n = 128)	2.3%

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Table 4
Principal specific medical treatments.

Erythropoietin	
0–3 months (n = 490)	31.4%
3–6 months (n = 286)	17.8%
6–9 months (n = 171)	16.4%
9–12 months (n = 128)	11%
Transfusion	
0–3 months (n = 490)	28%
3–6 months (n = 286)	22.7%
6–9 months (n = 171)	12.3%
9–12 months (n = 128)	14.1%
Growth factor	
0–3 months (n = 490)	21.8%
3–6 months (n = 286)	14%
6–9 months (n = 171)	7%
9–12 months (n = 128)	9.4%
Antibiotics	
0–3 months (n = 490)	39.4%
3–6 months (n = 286)	22.4%
6–9 months (n = 171)	17.6%
9–12 months (n = 128)	19.5%
Parenteral nutrition	
0–3 months (n = 490)	15.9%
3–6 months (n = 286)	14.7%
6–9 months (n = 171)	6.4%
9–12 months (n = 128)	5.5%

Table 5
Univariate analysis of factors associated with early (≤3 months (0) and >3 months from diagnosis) palliative care.

Item	OR	95% CI	P
Patient characteristics			
Age	0.99	[0.98–1.01]	0.7
Sex (F/M)	0.82	[0.56–1.19]	0.29
Performance status			
≤1	1	-	0.019
≥ 2	0.61	[0.41–0.92]	
Weight loss (Y/N)	0.73	[0.45–1.20]	0.22
Chemotherapeutic treatment	1.16	[0.83–1.64]	0.41
Death (<3 months, Y/N)	0.17	[0.11–0.26]	0.0001
Symptoms			
Pain	0.88	[0.61–1.25]	0.46
Fatigue	1.24	[0.86–1.80]	0.25
Malnutrition	0.60	[0.32–1.09]	0.70
Other symptoms	1.25	[0.70–2.21]	0.09
Odontologic symptoms	1.18	[0.67–2.09]	0.56
Social difficulties	0.89	[0.30–2.69]	0.83
Psychological disorders	0.93	[0.62–1.40]	0.72
Palliative care symptoms	0.42	[0.25–0.69]	0.0006
Specific medications			
Recombinant human erythropoietin	2.25	[1.44–3.51]	0.0003
Transfusion	1.46	[0.97–2.21]	0.07
Antibiotics	0.97	[0.67–1.39]	0.85
Enteral nutrition	0.89	[0.30–2.69]	0.84
Parenteral nutrition	1.91	[1.17–3.10]	0.0095
Palliative care interventions			
Psychological support	1.25	[0.70–2.21]	0.45
Pain team support	1.70	[0.97–2.97]	0.06
Social support	1.87	[1.08–3.25	0.02
Physiotherapy	1.14	[0.77–1.66]	0.51
Dietary support	1.11	[0.72–1.72]	0.61
Palliative care ward admission	2.34	[1.38–4.18]	0.002

OR, odds ratio; CI, confidence interval.

Table 6
Multivariable analysis of PC initiation ≤3 months (0) vs >3 months (1).

Items	OR	CI 95%	P
Performance status			0.0049
≤1	1		
≥2	0.53	[0.34–0.82]	
Admission in PC unit	2.85	[1.54–5.27]	0.0080
Recombinant human erythropoietin	2.05	[1.24–3.39]	0.0053
Parenteral nutrition	2.08	[1.20–3.61]	0.0092

PC, palliative care; OR, odds ratio; CI, confidence interval.

chemotherapy was not significant in relation to its correlation to clinical items like PS.

In the published studies, few data assess in real life the use of PC interventions [23], but the Korean study did not analyze the procedures and the needs of PC.

The main limitation of our study is its observational, non-randomized nature, which rules out firm conclusions on symptom prevalence and the proportion of patients who received PC, even though each center was asked to include consecutive patients.

Another limitation is that the data were dependent on the quality of the medical records, but, in general, the majority of specific interventions were recorded in medical files, because in France specific fees are given to hospitals according to their management.

There were no information about comorbidity, but the main objective of the study was PC initiation. Comorbidities are predictive of poor outcomes and PS is a better prognosis factor of patient's alterations and health status [27]. Probably, as for chemotherapy, PS could be predominant vs comorbidities in the multivariate analysis. This study was designed before the generalization in France of biomarkers assessment: these criteria could change the PC initiation, according to different management. It has to be studied in the future.

Despite these limitations, this study provides important information on the needs and modalities of PC in a large population of patients with advanced NSCLC. It clearly shows the lower rate of specific interventions for some issues, particularly pain and malnutrition. It also demonstrates the role of performance status in the initiation of PC. In patients with good PS, palliative care was started probably too late, only when appear indications for EPO parenteral nutrition, or admission to a terminal care ward. In the other hand, altered PS, when it was found at the diagnosis, was the best predictive factor of early PC, induced by physicians.

In conclusion, large international studies are needed to better identify needs and palliative interventions in different countries with a view to preparing international guidelines.

Conflicts of interest and source of funding

No conflicts of interest are declared by the authors.

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None.

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