Therapieverhalten bei Patienten

mit NSCLC

Assessment of Cost and ouTcomes of chemotherapy In an Observational setting in patients with advanced NSCLC

HG Bischoff

Thoraxklinik Heidelberg

14. Jahrestagung Deutsche Gesellschaft für Thoraxchirurgie

Workshop I: Integrierte Versorgung 2005

bei Patienten mit Lungenkarzinom – Quo Vadis ?

Berlin 02.06.2005

Lung cancer – overview

- Leading cause of death
- Number of new cases: 1.2 million/year worldwide
- 80% NSCLC
- > 50% advanced disease
- Few cost analyses available
- Only retrospective data from clinical trials

Rationale and objectives

Rationale:

- Need for ‘real-life’ data from routine clinical practice
- Need to assess ‘total’ treatment costs, in relation to QoL and outcomes

Primary objective:

- To identify the resources used and the outcomes of chemotherapy treatment following daily routine medical care in patients with advanced NSCLC outside clinical trial programmes

Study design and inclusion criteria

Countries: DE, NL, UK, PO, FI

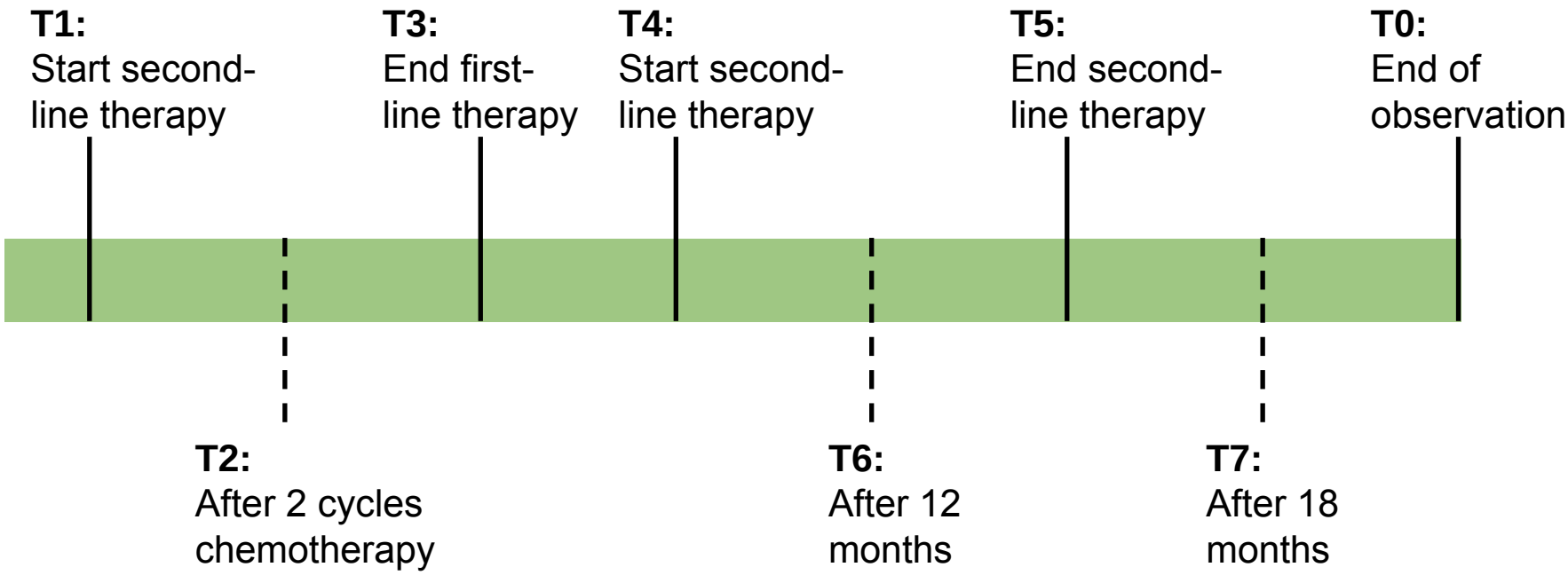
Patient numbers: 1200 planned

Follow-up: 18 months or death

Inclusion criteria:

- ≥ 18 years old
- Stage IIIb/IV disease
- Any NSCLC subtype
- Initiating first-line chemotherapy
- No clinical trial patients

Observations



Data collected

- Baseline demographics and clinical status
- Symptoms (Lung Cancer Symptoms Scale, weight loss > 10%)
- Physicians' treatment decisions
- Chemotherapies prescribed
- Toxicities
- Quality of life (EuroQoL)
- Outcomes
  - clinical: tumour response, time to disease progression
  - patient-related: days outside hospital, complication-free days etc
- Total costs: use of resources, medications, in- and outpatient days, physician visits, diagnosis, interventions

Data collected

	T1	T2	T3	T4	T5	T6	T7	T0
Informed consent document	X							
Review entry criteria	X							
Demographic data	X							
Diagnostic data	X			X				
Performance status	X	X	X	X	X			
Assessment of outcomes		X	X	X	X	X	X	X
Medical resource utilisation	X	X	X	X	X	X	X	X
LCSS	X	X	X	X	X	X	X	
EQ-5D questionnaire	X	X	X	X	X	X	X	

- 993 patients were recruited between April 2003 and June 2004
- Patients were ≥18 years old and receiving first-line chemotherapy for stage IIIB/IV NSCLC
- Choice of chemotherapy at discretion of treating physician
- Baseline data analyzed in terms of:
  - patient characteristics
  - diagnostic tests/pre-treatment interventions
  - reasons for chemotherapy choice

Baseline characteristics

967 evaluable patients

- Germany 571
- UK 193
- Finland 99
- Netherlands 69
- Portugal 35

Figure 1. Current stage of disease

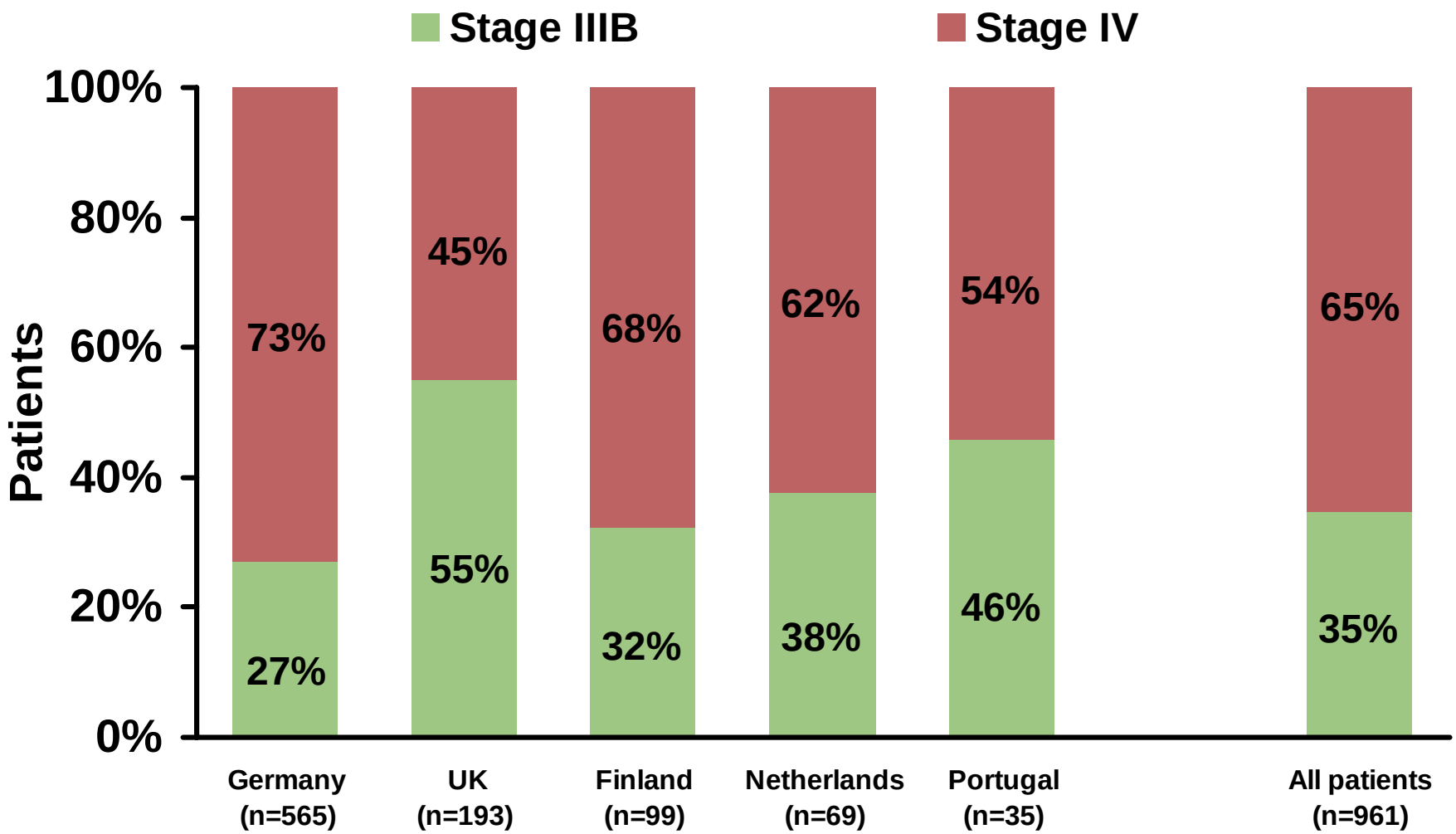


Table 3. Baseline clinical characteristics (evaluable patients)

Characteristic	Germany	UK	Finland	Netherlands	Portugal	All patients
Time since diagnosis, days						
Median	14	28	24	20	22	20
Range	0–165	6–182	4–176	0–155	0–95	0–182
n	523	182	95	65	35	900
Number of metastatic organs, n (%)						
0	89 (17)	94 (51)	31 (32)	18 (29)	11 (38)	243 (27)
1	261 (50)	70 (38)	49 (51)	30 (48)	14 (48)	424 (47)
2	116 (22)	17 (9)	11 (11)	11 (18)	2 (7)	157 (17)
3	40 (8)	4 (2)	3 (3)	3 (5)	2 (7)	52 (6)
≥4	20 (4)	1 (1)	2 (2)	0 (0)	0 (0)	23 (2.5)
Weight loss >10%, n (%)[a]						
Yes	117 (40)	31 (30)	7 (19)	9 (25)	7 (41)	171 (35)
No	120 (41)	59 (57)	26 (70)	25 (69)	5 (29)	235 (49)
Not known	54 (19)	13 (13)	4 (11)	2 (6)	5 (29)	78 (16)

[a] Among patients who had previously indicated they had experienced weight loss

Table 4. Pre-chemotherapy staging investigations (evaluable patients)

	Number of patients (%)					
Investigation	**Germany**	**UK**	**Finland**	**Netherlands**	**Portugal**	**All patients**
Bronchoscopy	**491 (87)**	**97 (50)**	**77 (79)**	**50 (74)**	**27 (77)**	**742 (78)**
Bone scan	**402 (72)**	**23 (12)**	**11 (11)**	**16 (25)**	**7 (20)**	**459 (49)**
Ultrasound	**511 (91)**	**20 (10)**	**37 (38)**	**24 (36)**	**13 (39)**	**605 (63)**
CT scan	**548 (96)**	**130 (67)**	**78 (79)**	**63 (93)**	**31 (91)**	**850 (88)**

Planned first-line medication

Medication prescribed at baseline visit

N = 967

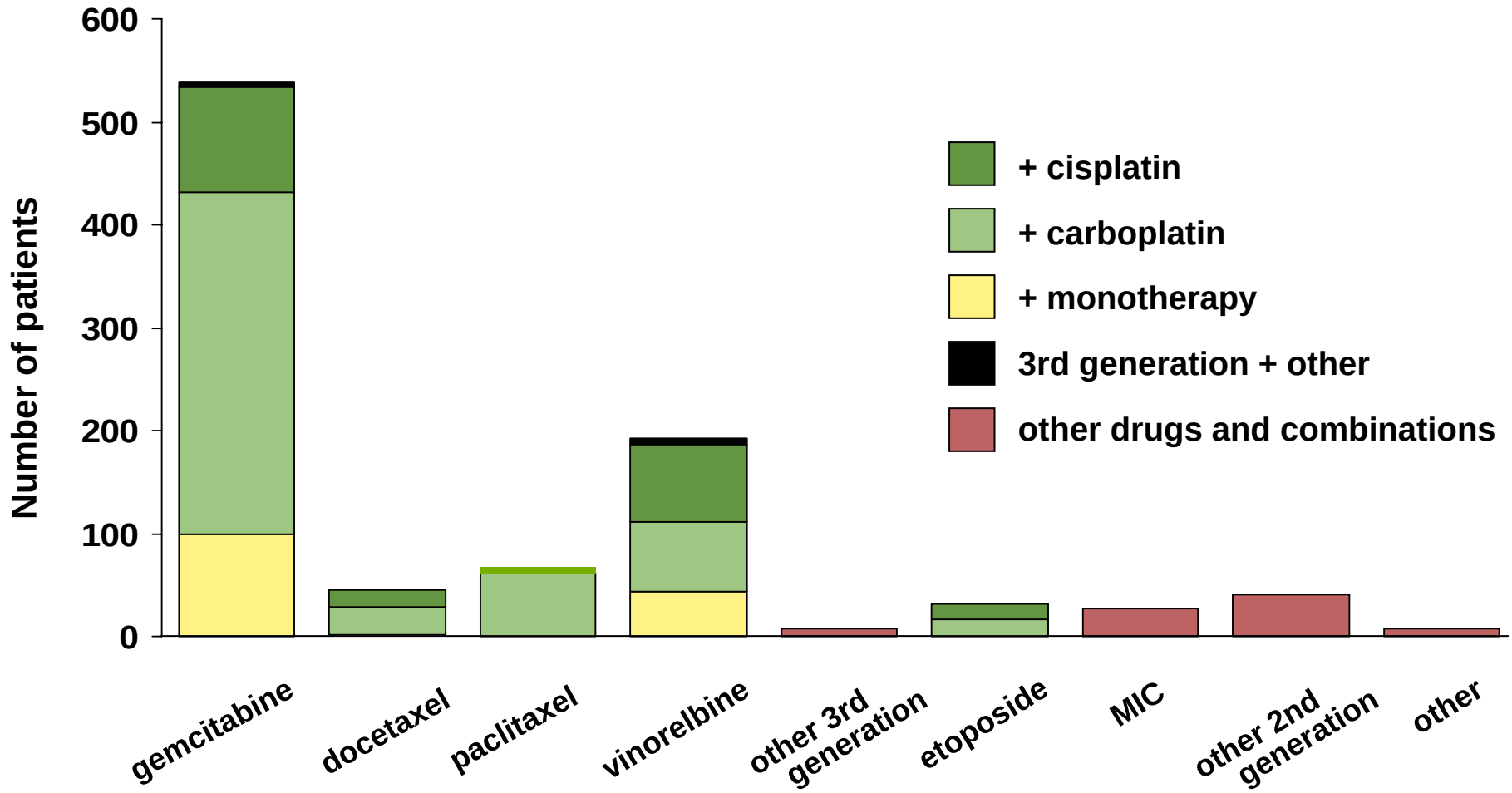


Figure 2. Third generation agents used

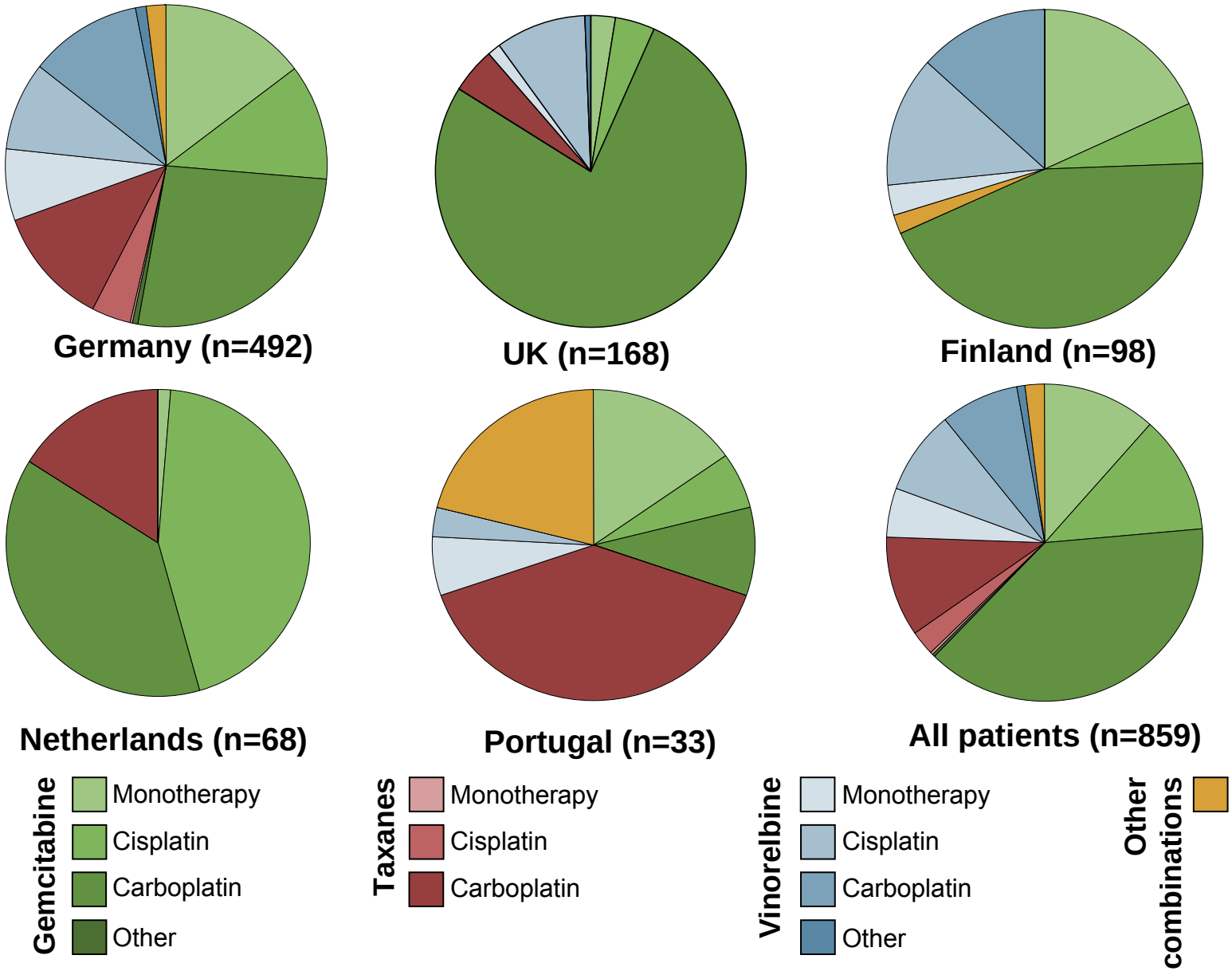


Table 5. Factors influencing treatment choice

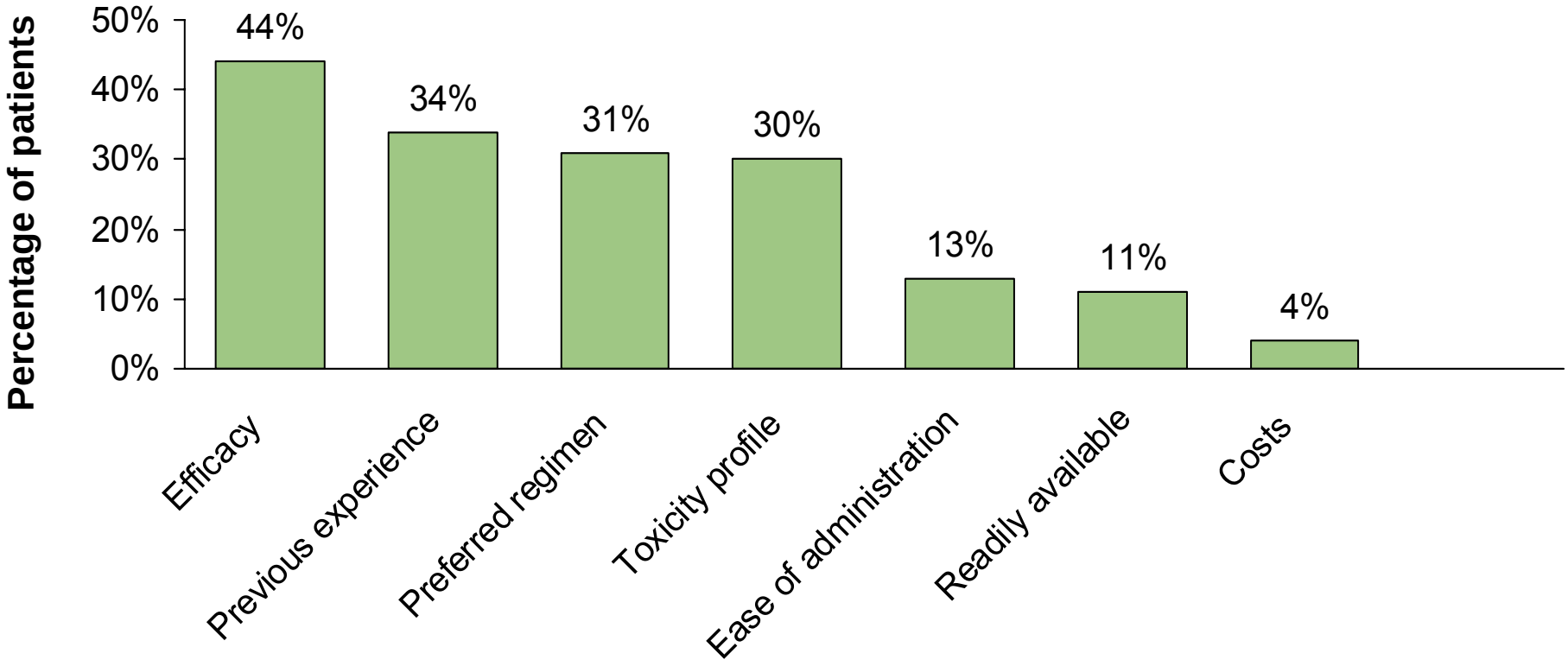
	Number of patients (%)					
Factor[a]	**Germany**	**UK**	**Finland**	**Netherlands**	**Portugal**	**All patients**
Toxicity profile	138 (24)	83 (43)	38 (38)	18 (26)	11 (31)	288 (30)
Ease of administration	41 (7)	57 (30)	10 (10)	18 (26)	3 (9)	129 (13)
Readily available	36 (6)	51 (26)	13 (13)	4 (6)	5 (14)	109 (11)
Efficacy	222 (39)	114 (59)	45 (45)	41 (59)	6 (17)	428 (44)
Preferred regimen	145 (25)	117 (61)	15 (15)	14 (20)	12 (34)	303 (31)
Previous experience	109 (19)	104 (54)	65 (66)	25 (36)	21 (60)	324 (34)
Costs	19 (3)	16 (8)	1 (1)	0	0	36 (4)

[a] More than one reason possible

In general, efficacy was the primary reason for choosing treatment regimen

Regimen selection

Reasons* for selecting regimen



*More than one answer possible

Summary

- Observational studies are a valuable adjunct to clinical trials
- The majority of patients treated in routine clinical practice are given 3rd generation agents
- The majority of patients are males > 60 years
- The majority have reasonable WHO performance status
- The majority have level 1 or 2 EuroQol domains
- Efficacy is the most common reason for treatment choice

Outlook

- The presented data are baseline data
- The follow-up period is 18 months
- The study will be completed in Autumn 2006
- The first cost analysis will be completed for the end of first-line treatment, scheduled for Summer 2005