Early Palliative Care for Patients with Advanced NSCLC Lung Cancer

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Quality Cancer Care at the End-of-Life

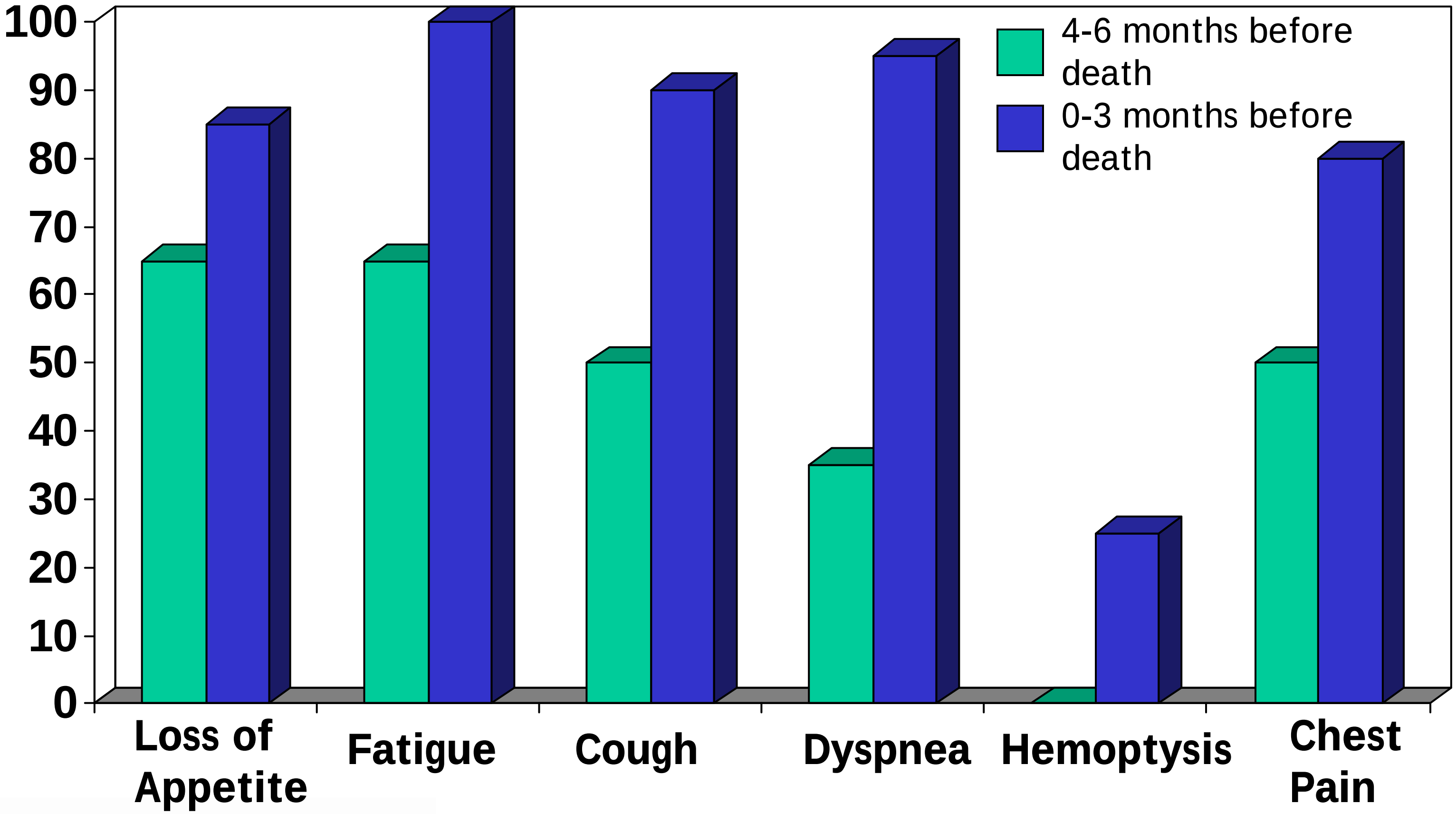
- Assess and address pain & dyspnea
- Documented discussions about EOL care
- Palliative care referral
- Hospice (and its timing)
- Chemotherapy within last two weeks of life

ASCO QOPI

Early Palliative Care for Patients with Advanced Lung Cancer

- Metastatic lung cancer:
  - High symptom burden
  - Suffering for *both* patients and families
  - Limited understanding of illness/ prognosis
  - Complex decision-making regarding treatment and end-of-life care

Symptoms in Advanced Lung Cancer



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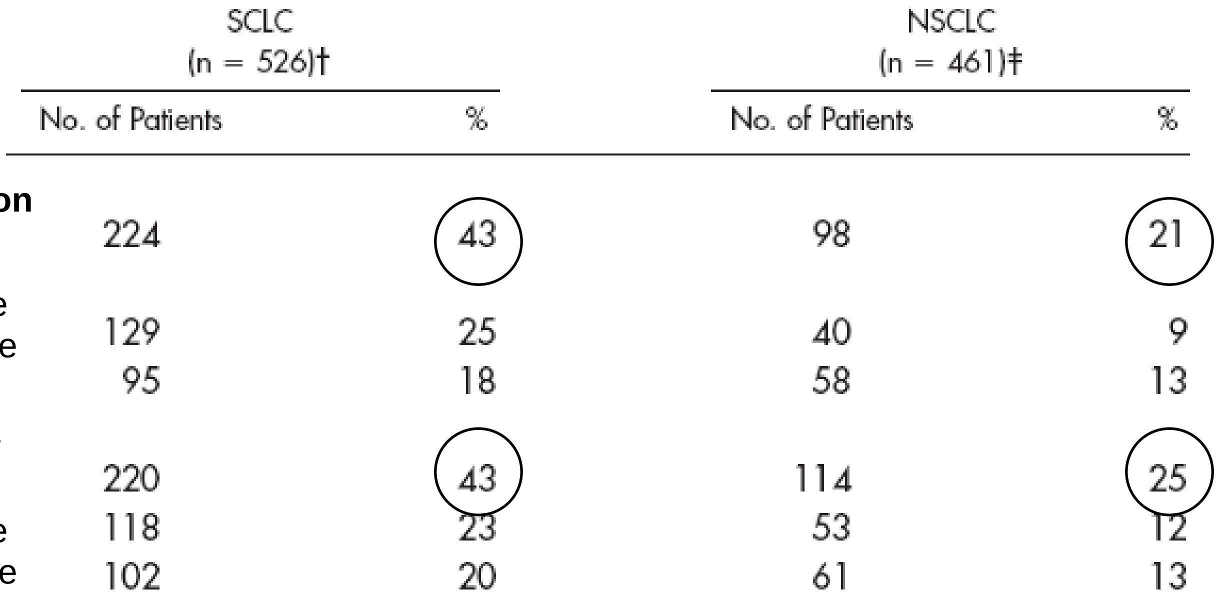
Lutz et al., J of Pall Med. 2001; 4(2)

Psychological Distress in Patients with Lung Cancer



	SCLC (n = 526)†		NSCLC (n = 461)‡	
	No. of Patients	%	No. of Patients	%
Depression				
Total	224	43	98	21
Probable	129	25	40	9
Borderline	95	18	58	13
Anxiety				
Total	220	43	114	25
Probable	118	23	53	12
Borderline	102	20	61	13

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Hopwood et al., JCO. 2000; 18(4)

Challenge

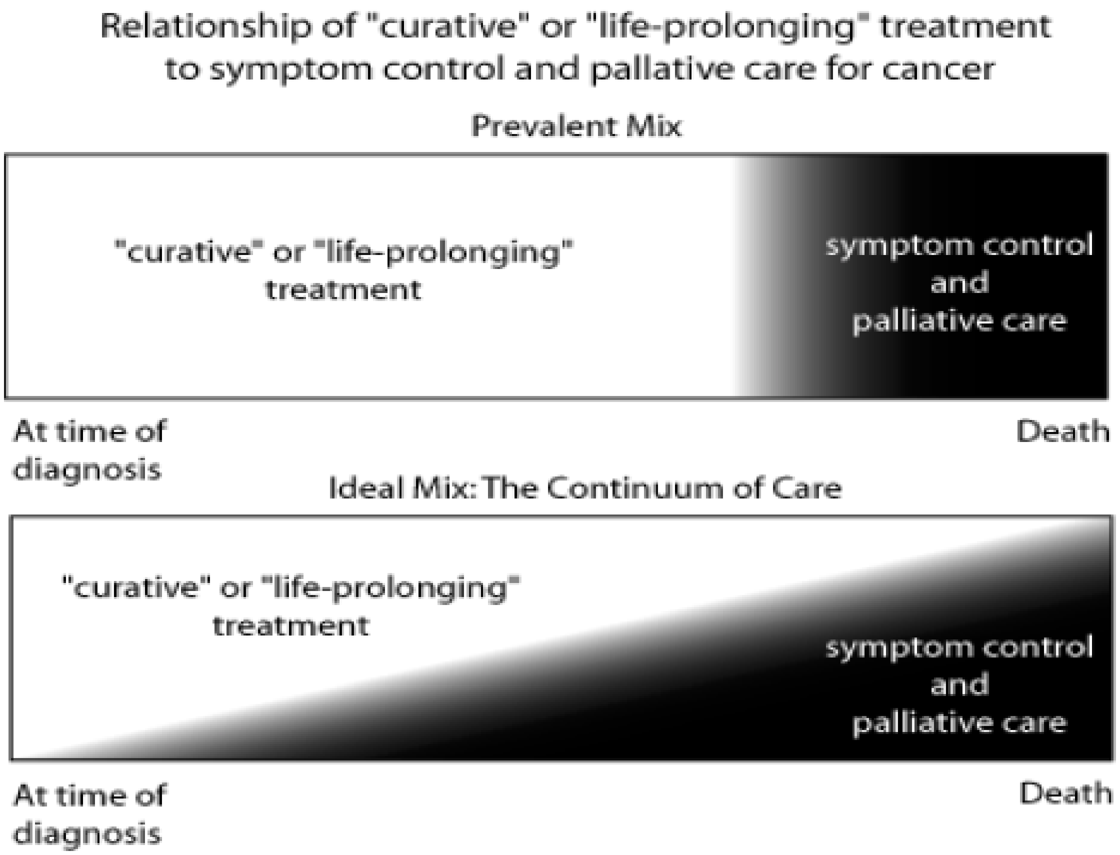
How can we…

1. Improve symptoms
2. Enhance communication and decision-making
3. Provide high quality care at the EOL

<u>while</u> patients are receiving cancer therapy?

Bridging the divide…

Integrating Palliative & Oncology Care



Relationship of "curative" or "life-prolonging" treatment to symptom control and pallative care for cancer

Prevalent Mix

Ideal Mix: The Continuum of Care

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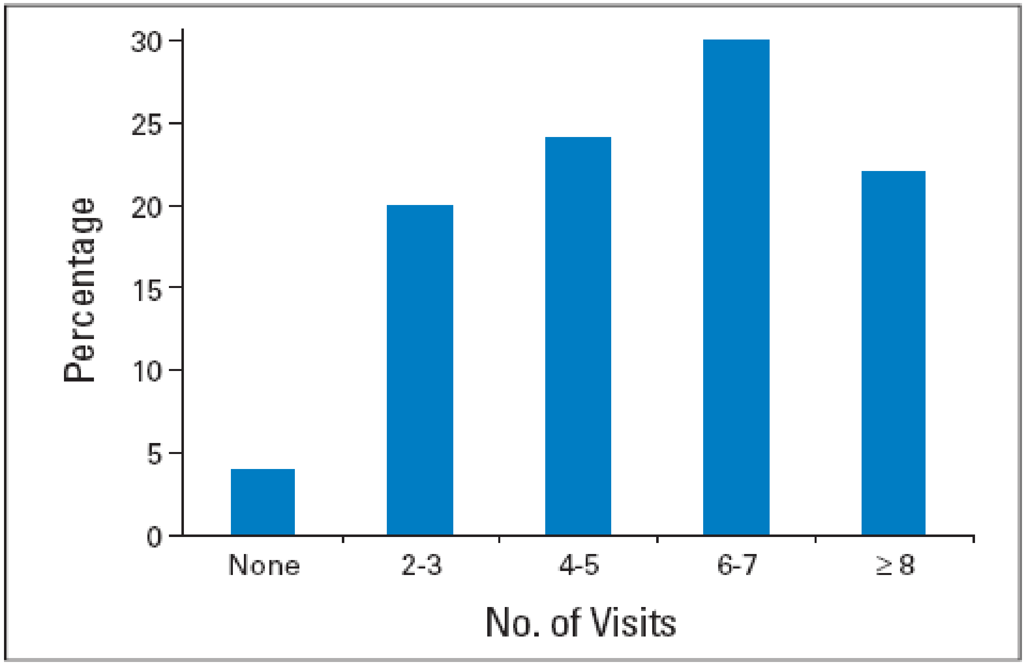
Novel Approach to Integrated Care

Can oncology and palliative care be integrated to provide simultaneous and comprehensive cancer care?

50 patients with newly diagnosed advanced NSCLC

↓

Meet with palliative care at least monthly during routine cancer care



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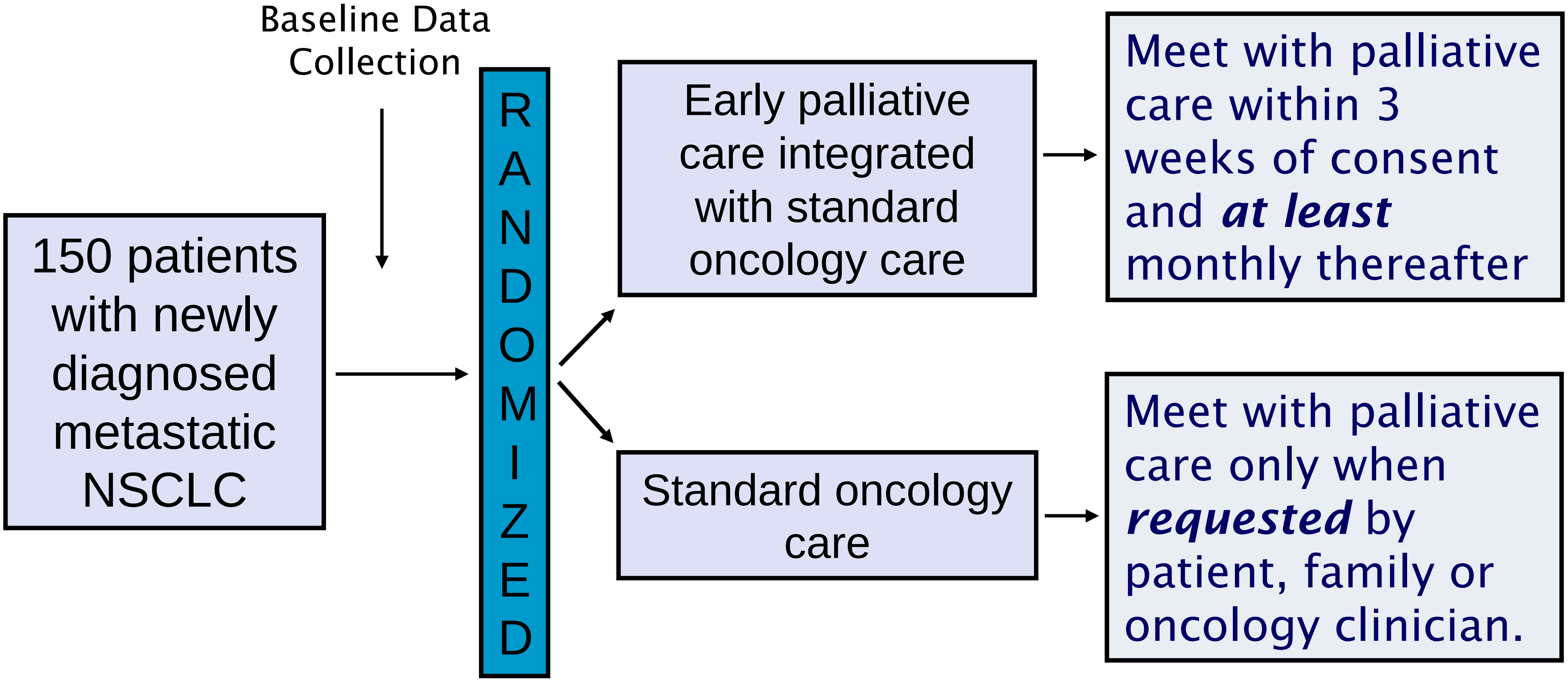
Temel et al., JCO. 2007; 25(17)

Study Design



Baseline Data Collection

150 patients with newly diagnosed metastatic NSCLC

RANDOMIZED

Early palliative care integrated with standard oncology care

Meet with palliative care within 3 weeks of consent and ***at least*** monthly thereafter

Standard oncology care

Meet with palliative care only when ***requested*** by patient, family or oncology clinician.

Study Intervention

Palliative Care Guidelines

Illness understanding and education
- Inquire about illness and prognostic understanding
- Offer clarification regarding treatment goals

Symptom management
- Pain
- Pulmonary symptoms (cough, dyspnea)
- Fatigue and sleep disturbance
- Mood (depression, anxiety)
- Gastrointestinal (anorexia, weight loss, nausea & vomiting, constipation)

Decision-making
- Assess mode of decision-making
- Assist with treatment decision-making

Coping with life-threatening illness
- Provide support and counseling for patients and families/caregivers

Referral/Prescriptions
- Identify care plan for future appointments
- Indicate referrals to other care providers
- Note new medications prescribed

Study Objectives

Primary Objective:

- To measure the difference between study groups with respect to the change in QOL from baseline to 12 weeks

Secondary Objectives:

- Psychological distress at 12 weeks
- Resource utilization at the end-of-life
- Documentation of resuscitation preferences in the medical record

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Study Eligibility Criteria

1. Metastatic NSCLC diagnosed within the previous 8 weeks
2. ECOG performance status 0-2
3. Ability to read and respond to questions in English
4. Planning to receive care at Massachusetts Hospital Cancer Center

Study Outcome Measures

Quality of Life

- **FACT-Lung** - Lower scores indicative of worse physical, social, emotional, and functional wellbeing
  - Lung Cancer Symptom (**LCS**): lung cancer specific symptoms
  - Trial Outcome Index (**TOI**): LCS plus physical and functional wellbeing subscales

Psychological Distress

- Hospital Anxiety and Depression Scale (**HADS**)
  - Score of $\geq$ 8 on each subscale indicative of symptoms of depression or anxiety
- Patient Health Questionnaire-9 (**PHQ-9**)
  - Evaluates major depressive syndrome using DSM-IV criteria

Study Outcome Measures

Illness Understanding

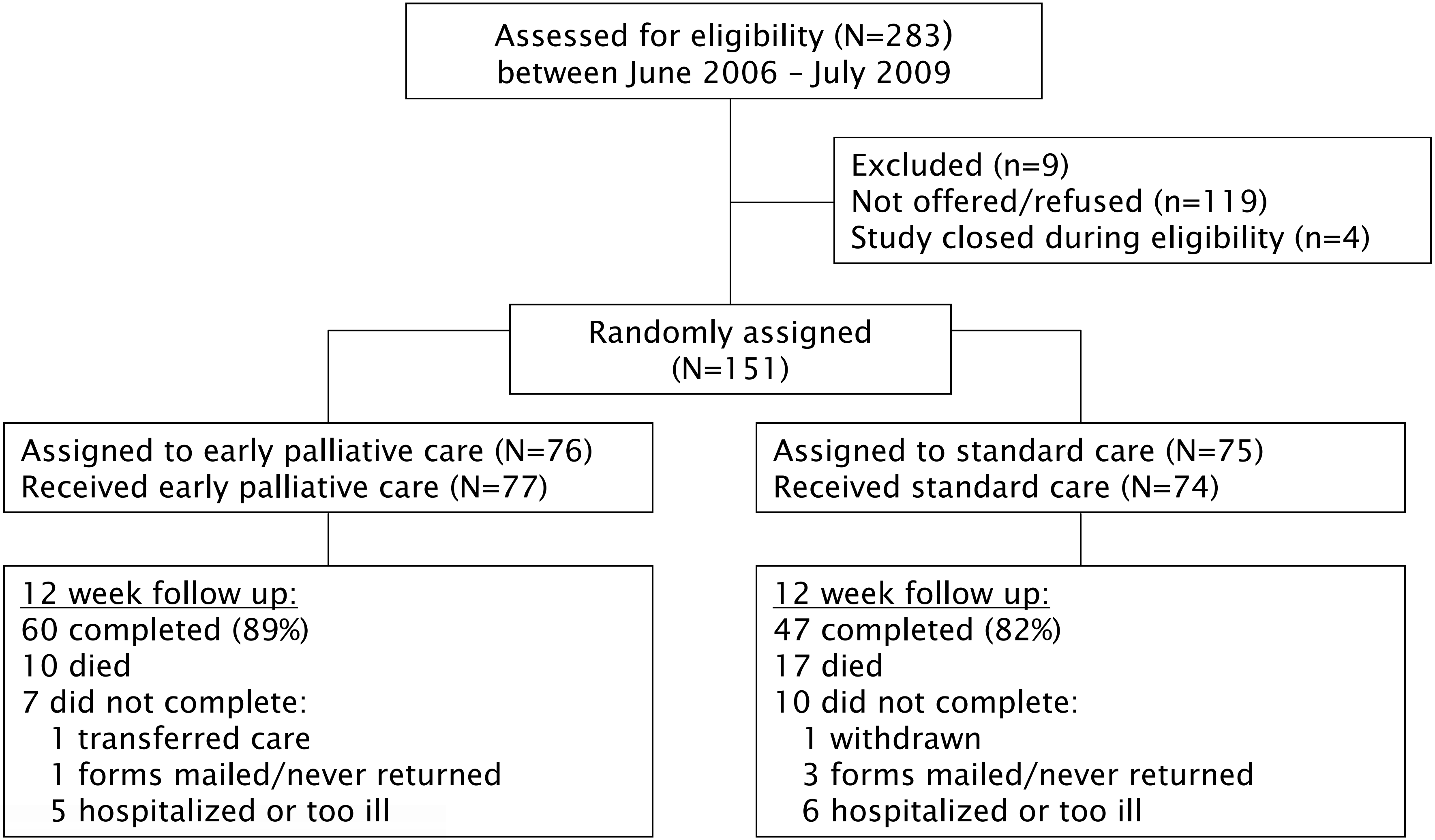
- "My cancer is curable." (Yes/No)

End-of-Life Care Measures

1. Documentation of resuscitation preferences in the electronic medical record

2. Medical care at the EOL
   - Chemotherapy utilization
   - Hospital admissions/emergency department visits
   - Hospice care prior to death
     - Length of stay on hospice
   - Date and location of death

Study Flow



Assessed for eligibility (N=283)
between June 2006 – July 2009

Excluded (n=9)
Not offered/refused (n=119)
Study closed during eligibility (n=4)

Randomly assigned
(N=151)

Assigned to early palliative care (N=76)
Received early palliative care (N=77)

Assigned to standard care (N=75)
Received standard care (N=74)

<u>12 week follow up:</u>
60 completed (89%)
10 died
7 did not complete:
  1 transferred care
  1 forms mailed/never returned
  5 hospitalized or too ill

<u>12 week follow up:</u>
47 completed (82%)
17 died
10 did not complete:
  1 withdrawn
  3 forms mailed/never returned
  6 hospitalized or too ill

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Temel, Greer et al., NEJM. 2010; 363(8)

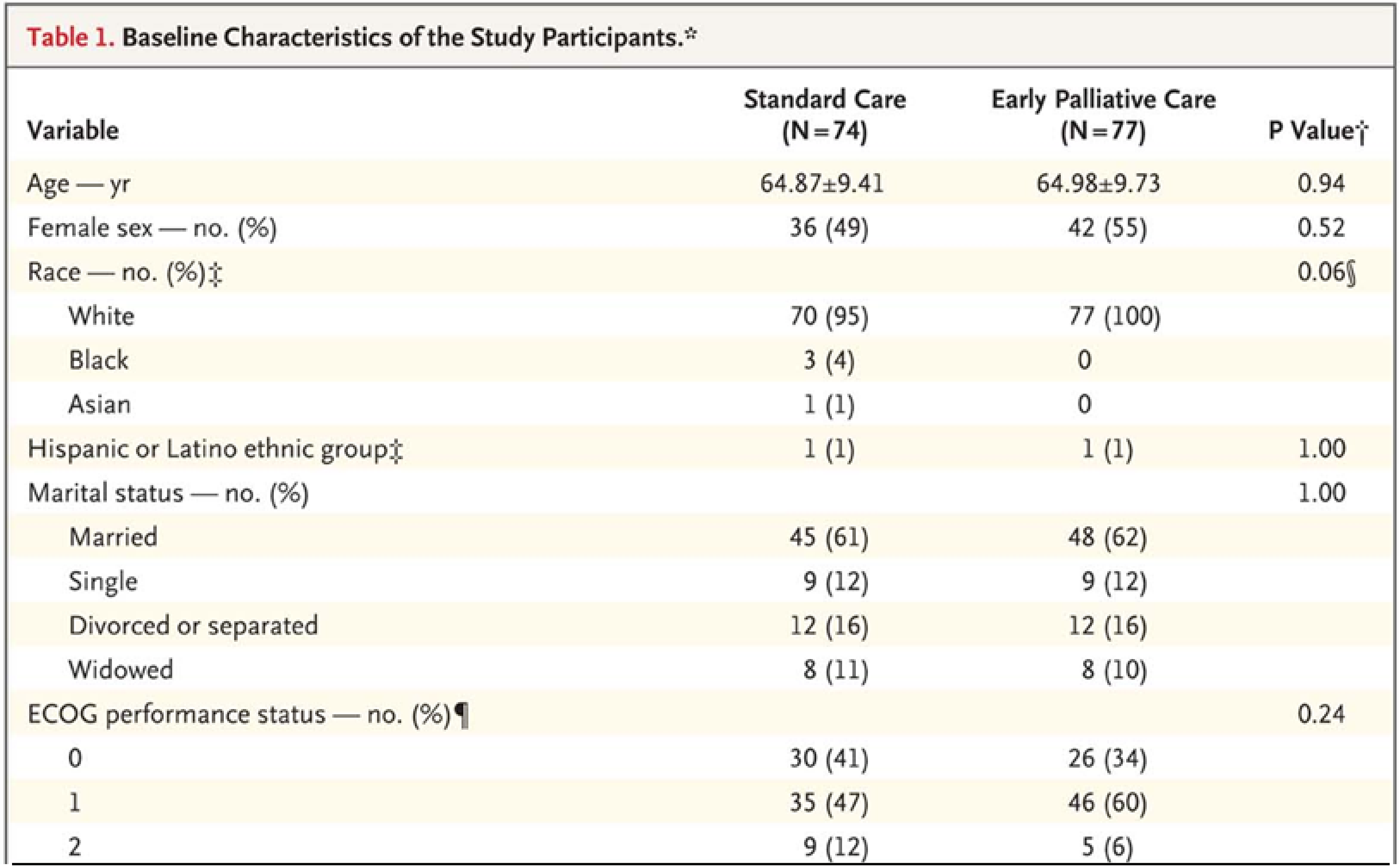

Table 1. Baseline Characteristics of the Study Participants.*

Variable	Standard Care (N=74)	Early Palliative Care (N=77)	P Value†
Age — yr	64.87±9.41	64.98±9.73	0.94
Female sex — no. (%)	36 (49)	42 (55)	0.52
Race — no. (%)‡			0.06§
White	70 (95)	77 (100)	
Black	3 (4)	0	
Asian	1 (1)	0	
Hispanic or Latino ethnic group‡	1 (1)	1 (1)	1.00
Marital status — no. (%)			1.00
Married	45 (61)	48 (62)	
Single	9 (12)	9 (12)	
Divorced or separated	12 (16)	12 (16)	
Widowed	8 (11)	8 (10)	
ECOG performance status — no. (%)¶			0.24
0	30 (41)	26 (34)	
1	35 (47)	46 (60)	
2	9 (12)	5 (6)	

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Temel, Greer et al., NEJM. 2010; 363(8)

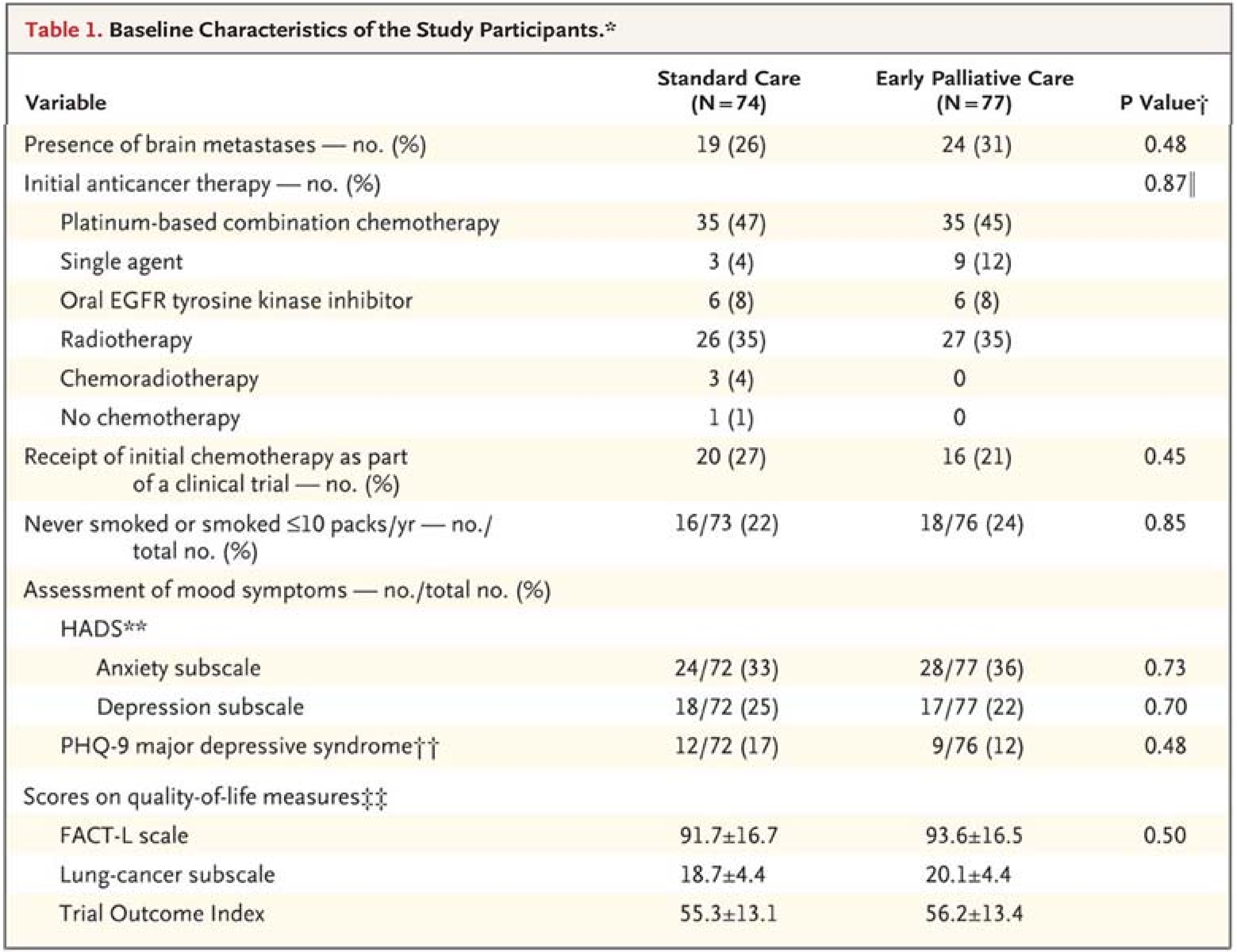

Table 1. Baseline Characteristics of the Study Participants.*

Variable	Standard Care (N=74)	Early Palliative Care (N=77)	P Value†
Presence of brain metastases — no. (%)	19 (26)	24 (31)	0.48
Initial anticancer therapy — no. (%)			0.87‖
Platinum-based combination chemotherapy	35 (47)	35 (45)	
Single agent	3 (4)	9 (12)	
Oral EGFR tyrosine kinase inhibitor	6 (8)	6 (8)	
Radiotherapy	26 (35)	27 (35)	
Chemoradiotherapy	3 (4)	0	
No chemotherapy	1 (1)	0	
Receipt of initial chemotherapy as part of a clinical trial — no. (%)	20 (27)	16 (21)	0.45
Never smoked or smoked ≤10 packs/yr — no./total no. (%)	16/73 (22)	18/76 (24)	0.85
Assessment of mood symptoms — no./total no. (%)			
HADS**			
Anxiety subscale	24/72 (33)	28/77 (36)	0.73
Depression subscale	18/72 (25)	17/77 (22)	0.70
PHQ-9 major depressive syndrome††	12/72 (17)	9/76 (12)	0.48
Scores on quality-of-life measures‡‡			
FACT-L scale	91.7±16.7	93.6±16.5	0.50
Lung-cancer subscale	18.7±4.4	20.1±4.4	
Trial Outcome Index	55.3±13.1	56.2±13.4	

Temel, Greer et al., NEJM. 2010; 363(8)

Palliative Care Visits by 12 Weeks

Palliative Care Visits	Standard Care (N=74) N (%)	Early Palliative Care (N=77) N (%)
None	64 (87)	1 (1)*
1	7 (9)	0
2	3 (4)	8 (10)
3	0	18 (23)
4	0	26 (34)
≥ 5	0	24 (31)

* Died within 2 weeks of enrollment

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Temel, Greer et al., NEJM. 2010; 363(8)

Components of Initial Outpatient Palliative Care Visit

Median Time of Consultation
Total Time 55 minutes (Range: 20-120)
Symptom management 20 minutes (Range: 0-75)
Coping with life-threatening illness 15 minutes (Range: 0-78)
Illness understanding and education 10 minutes (Range: 0-35)

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Jacobsen et al., JPM. 2011; in press

Comparison of QOL at 12 Weeks

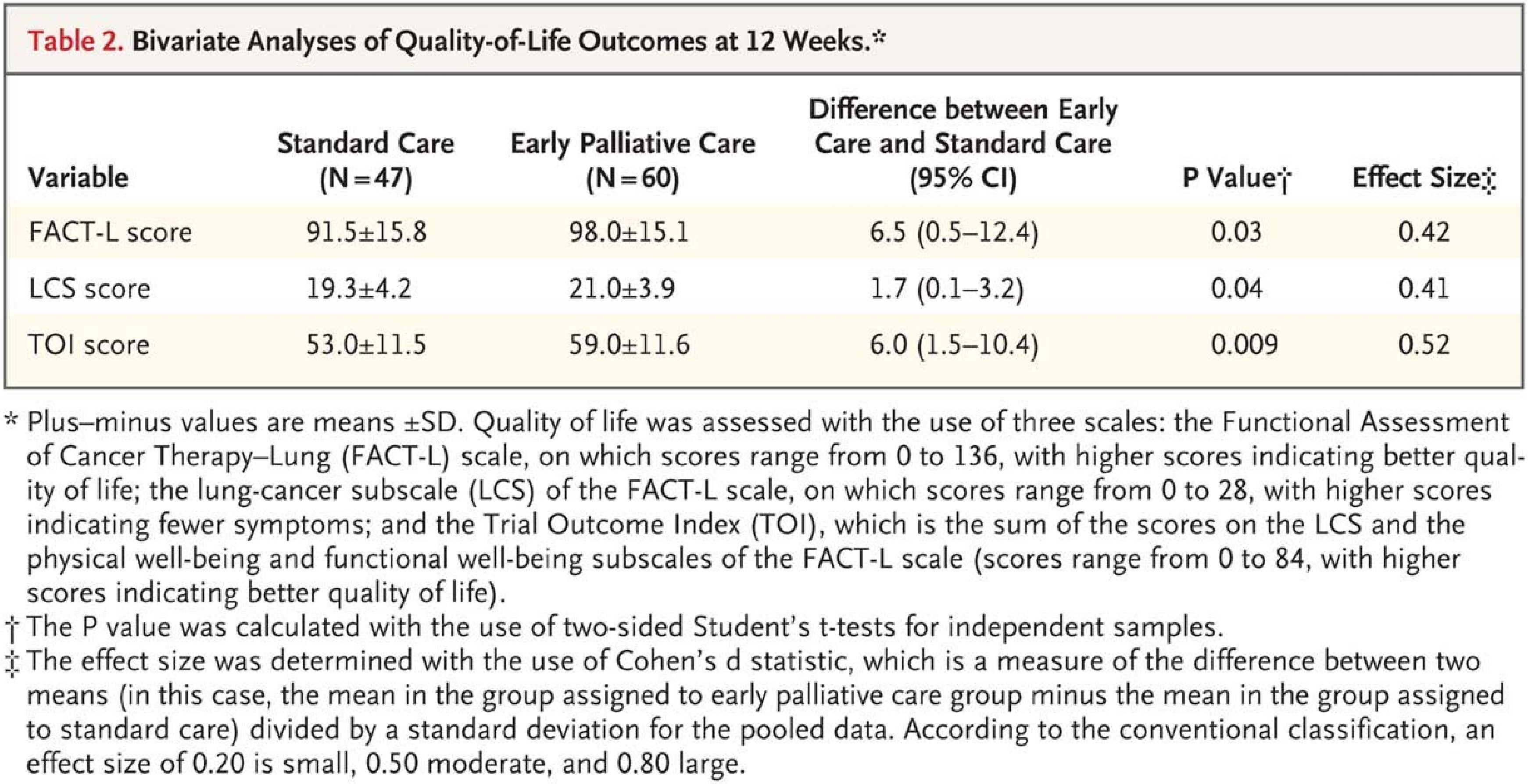

Table 2. **Bivariate Analyses of Quality-of-Life Outcomes at 12 Weeks.***

Variable	Standard Care (N=47)	Early Palliative Care (N=60)	Difference between Early Care and Standard Care (95% CI)	P Value†	Effect Size‡
FACT-L score	91.5±15.8	98.0±15.1	6.5 (0.5–12.4)	0.03	0.42
LCS score	19.3±4.2	21.0±3.9	1.7 (0.1–3.2)	0.04	0.41
TOI score	53.0±11.5	59.0±11.6	6.0 (1.5–10.4)	0.009	0.52

* Plus–minus values are means ±SD. Quality of life was assessed with the use of three scales: the Functional Assessment of Cancer Therapy–Lung (FACT-L) scale, on which scores range from 0 to 136, with higher scores indicating better quality of life; the lung-cancer subscale (LCS) of the FACT-L scale, on which scores range from 0 to 28, with higher scores indicating fewer symptoms; and the Trial Outcome Index (TOI), which is the sum of the scores on the LCS and the physical well-being and functional well-being subscales of the FACT-L scale (scores range from 0 to 84, with higher scores indicating better quality of life).

† The P value was calculated with the use of two-sided Student's t-tests for independent samples.

‡ The effect size was determined with the use of Cohen's d statistic, which is a measure of the difference between two means (in this case, the mean in the group assigned to early palliative care group minus the mean in the group assigned to standard care) divided by a standard deviation for the pooled data. According to the conventional classification, an effect size of 0.20 is small, 0.50 moderate, and 0.80 large.

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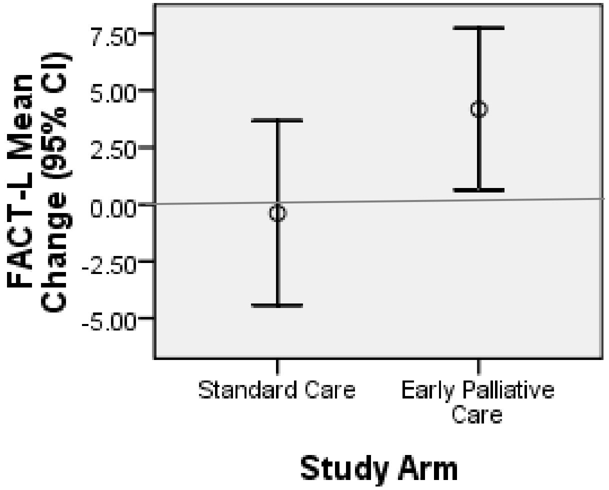
Temel, Greer et al., NEJM. 2010; 363(8)

Change in QOL from Baseline to 12 Weeks

FACT-Lung

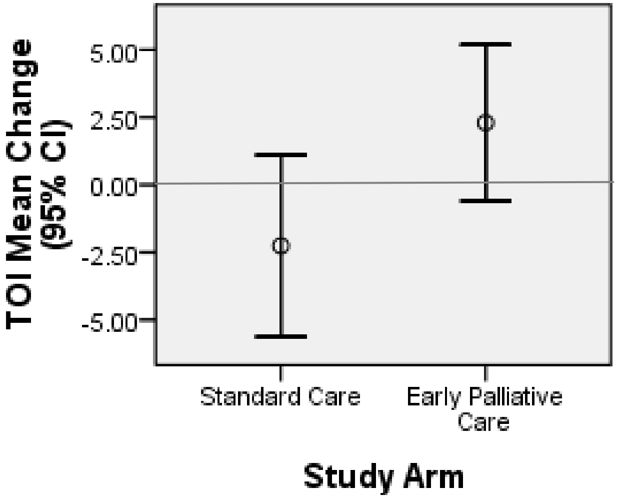


Mean change Early Palliative Care = + **4.2**

Mean change Standard Care = - **0.4**

p=0.09

FACT- Lung TOI



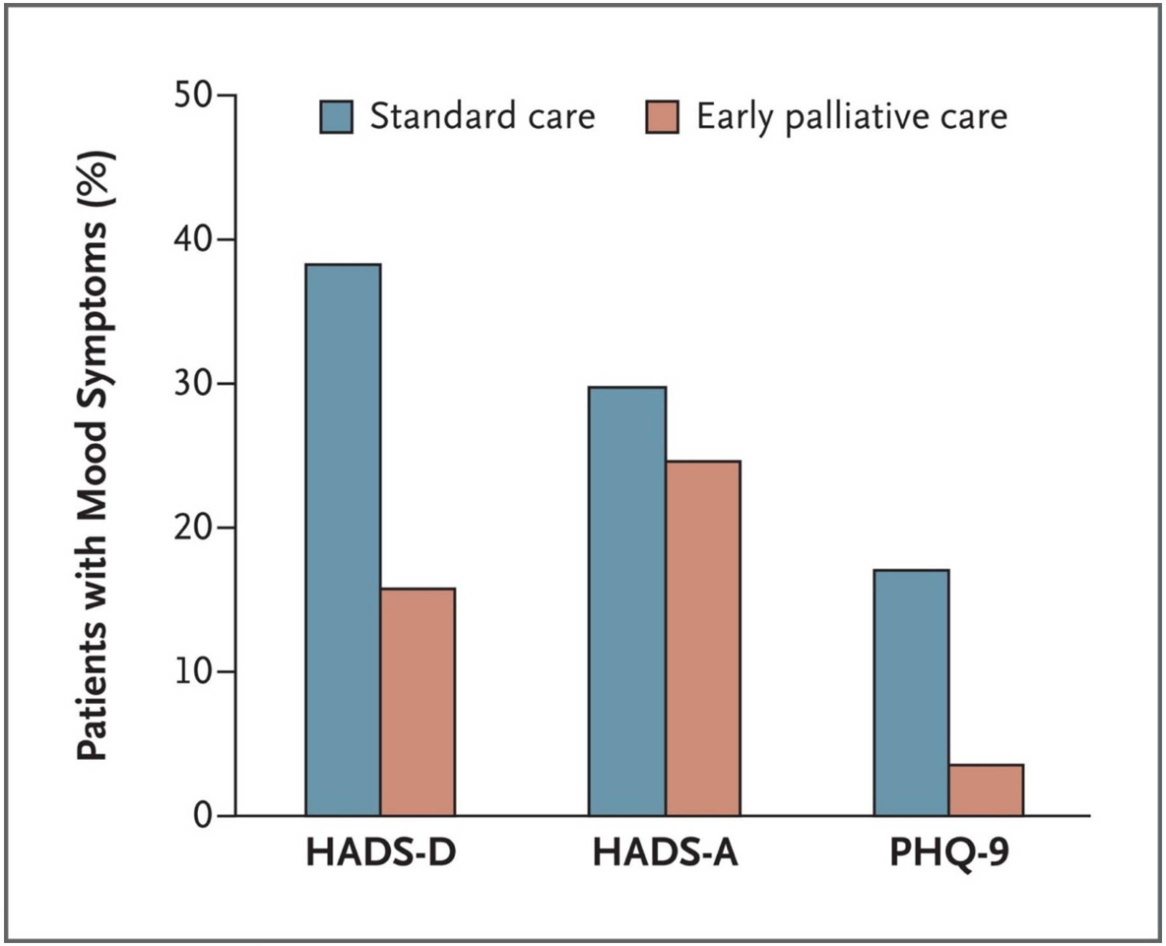
Mean change Early Palliative Care = + **2.3**

Mean change Standard Care = - **2.3**

p=0.04

Temel, Greer et al., NEJM. 2010; 363(8)

Effect of Early PC on 12-week Mood Symptoms



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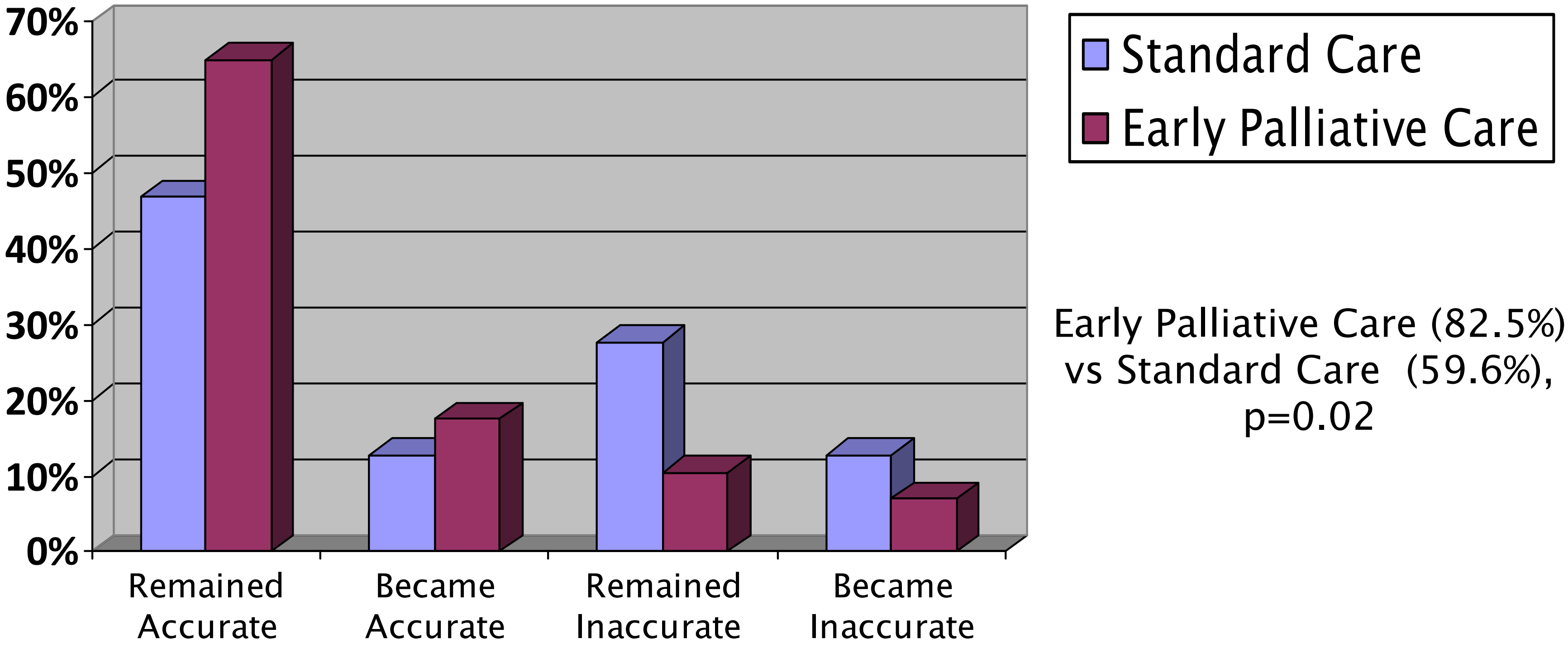
Changes in Perceptions of Cancer Curability



Early Palliative Care (82.5%)
vs Standard Care (59.6%),
p=0.02

Quality of EOL Care

ASCO Quality Measures

1. No hospice
2. Enrolled in hospice $\leq$ 3 days before death
3. Chemotherapy within 14 days of death (DOD)

Measure	Standard Care N (%) or Median	Early Palliative Care N (%) or Median	*p*-value
Aggressive EOL Care	**30 (54)**	**16 (33)**	**0.05**
No hospice	22 (39)	15 (31)	
Hospice $\leq$ 3 days	5 (15)	1 (3)	
Chemo within 14 DOD	12 (24)	7 (18)	
Hospital/ER Admits within 30 DOD	**31 (55)**	**19 (39)**	**0.12**
Days on hospice	**4 (0-269)**	**11 (0-117)**	**0.09**
Documented Resuscitation Preference	**11 (28)**	**18 (53)**	**0.05**

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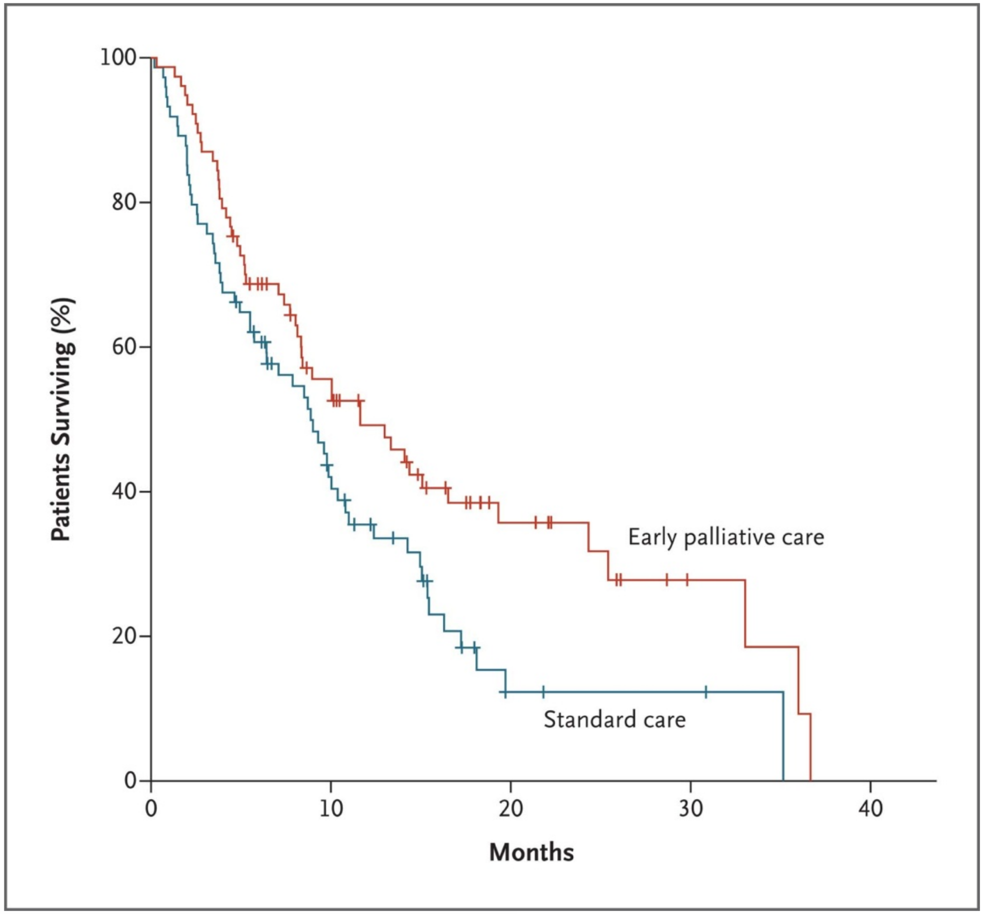
Temel, Greer et al., NEJM. 2010; 363(8)

Survival Analysis



- Usual Care=8.9 months
- Palliative Care=11.6 months
- Entire Sample=9.8 months

***Log Rank p=0.02**

Controlling for age, gender and baseline PS, adjusted **HR=0.59 (0.40-0.88), p=0.01**

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Temel, Greer et al., NEJM. 2010; 363(8)

Summary

- Compared with standard oncology care, integrated palliative care led to:
  - Improved QOL
  - Decreased psychological distress
  - More accurate illness understanding
  - Greater documentation of resuscitation preferences
  - Less aggressive care at the end of life
  - Longer survival (requires replication)

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