Definizione e stato dell’arte delle cure palliative precoci

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Cosa differenzia Early Palliative Care da End-of-Life Palliative Care ?

Cosa differenzia
(E) Palliative Care da terminal/hospice/EoL PC

- **Palliative care (ed EPC):** basata sui bisogni del paziente e della sua famiglia, (quasi) indipendentemente dalla prognosi

- **Terminal/hospice/EoL PC:** basata (principalmente) sulla prognosi

Palliative Care

- **Early Palliative Care**

(consulenze ai ricoverati? visite ambulatoriali?: quasi non c'è «capienza massima» e spesso CP simultanee, e non sempre presa in carico)

- **End-of-life palliative care**

(hospice? cure domiciliari?: c'è «capienza massima» e spesso [ma non sempre] «sole» CP, e presa in carico)

- **Fattori indicativi di bisogni di cure palliative**

- **Fattori prognostici**

Quale Early Palliative Care?

Generalist plus specialist palliative care -creating a more sustainable model

Quill TE Abernethy AP N Engl J Med.2013 Mar 28;368(13):1173-5

Representative Skill Sets for Primary and Specialty Palliative Care.

Primary Palliative Care

- Basic management of pain and symptoms
- Basic management of depression and anxiety
- Basic discussions about
  - Prognosis
  - Goals of treatment
  - Suffering
  - Code status

Specialty Palliative Care

- Management of refractory pain or other symptoms
- Management of more complex depression, anxiety, grief, and existential distress
- Assistance with conflict resolution regarding goals or methods of treatment
  - Within families
  - Between staff and families
  - Among treatment teams
- Assistance in addressing cases of near futility

Cure palliative precoci basiche o primarie o generaliste

Attori

- MMG
- Oncologi
- Geriatri
- Altri internisti
- Infermieri domiciliari di comunità o di strutture o di reparti

Azioni

- Identificazione «precoce» dei malati che «si avvicinano» alla fine della vita
- Screening sistematico dei bisogni
- Screening sistematico dei sintomi e della loro intensità
- Partecipazione alla formulazione di «pianificazione anticipata delle cure»
- Formazione da parte degli Specialisti

Perché è importante identificare i malati che si “avvicinano alla fine della vita”?

“La precoce identificazione delle persone vicine alla fine della vita e la loro inclusione in un registro conduce ad una precoce pianificazione delle cure e ad un loro migliore coordinamento.”

GSF National Primary Care Snapshot Audit 2010

the gold standards framework

4th Edition
October 2011

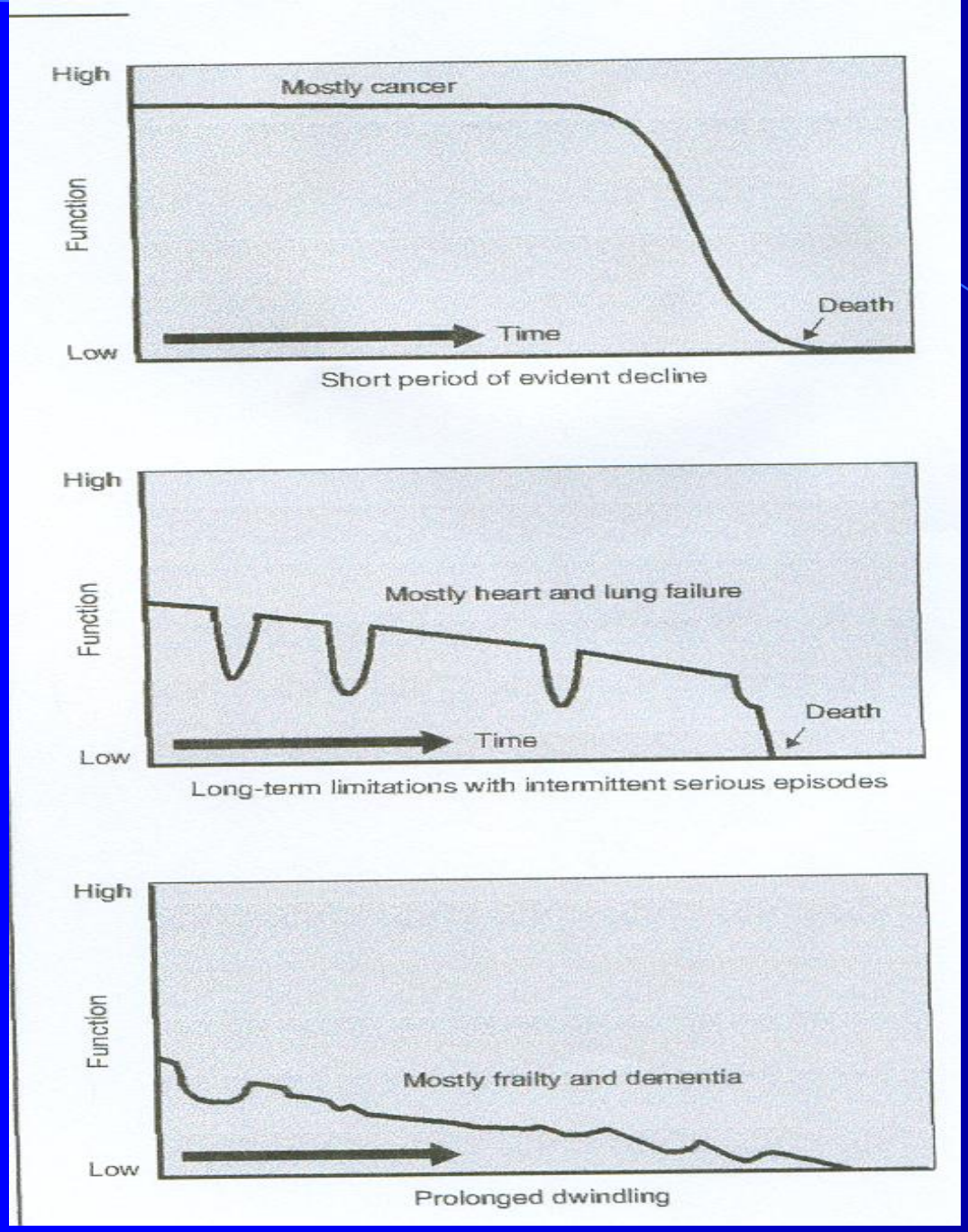
The GSF Prognostic Indicator Guidance

The National GSF Centre's guidance for clinicians to support earlier recognition of patients nearing the end of life

RCGP Royal College of General Practitioners

- *I malati "si avvicinano alla fine della vita" quando è probabile che essi muoiano entro i prossimi 12 mesi. In questa definizione sono inclusi i pazienti la cui morte è imminente (attesa entro poche ore o giorni) e quelli con:*
  - *Malattie inguaribili, progressive, in fase avanzata*
  - *Una condizione clinica di fragilità ("frailty") generale e patologie concomitanti per la quali è prevedibile una morte entro 12 mesi*
  - *Condizioni cliniche per le quali questi pazienti sono a rischio di morte per una crisi acuta ed improvvisa legata alla loro situazione*
  - *Condizioni acute a rischio per la vita, causate da eventi improvvisi e catastrofici*

Attenzione al «registro dei moribondi!»



Un periodo di rapido declino: il cancro

Un periodo più lungo di difficoltà, con peggioramenti ripetuti e una morte improvvisa: l'insufficienza cardiaca e respiratoria

Un periodo di peggioramento lento, continuo, fino alla morte: la demenza senile

J.Lynn, D.M. Adamson"Living well at the end of life" Rand Health 2003 www.rand.org

SIAARTI

PRO VITA CONTRA DOLOREM SEMPER

SOCIETÀ ITALIANA DI ANESTESIA ANALGESIA RIANIMAZIONE E TERAPIA INTENSIVA

GRANDI INSUFFICIENZE D'ORGANO "END STAGE": CURE INTENSIVE O CURE PALLIATIVE? "DOCUMENTO CONDIVISO" PER UNA PIANIFICAZIONE DELLE SCELTE DI CURA

Documento approvato e condiviso da:

- SOCIETÀ ITALIANA ANESTESIA ANALGESIA RIANIMAZIONE TERAPIA INITENSIVA (SIAARTI)
- ITALIAN RESUSCITATION COUNCIL (IRC)
- ASSOCIAZIONE NAZIONALE MEDICI CARDIOLOGI OSPEDALIERI (ANMCO)
- SOCIETÀ ITALIANA MEDICINA EMERGENZA URGENZA (SIMEU)
- SOCIETÀ ITALIANA CURE PALLIATIVE (SICP)
- SOCIETÀ ITALIANA NEFROLOGIA (SIN)
- ASSOCIAZIONE NAZIONALE INFERMIERI DI AREA CRITICA (ANIARTI)
- SOCIETÀ ITALIANA MEDICINA GENERALE (SIMG)
- ASSOCIAZIONE ITALIANA PNEUMOLOGI OSPEDALIERI (AIPO)

SIAARTI	Italian Resuscitation Council IRC	A.N.M.C.O. Associazione Nazionale Medici Cardiologi Ospedalieri
Società Italiana di Medicina d'Emergenza-Urgenza "SIMEU"	SICP Società Italiana di Cure Palliative	SOCIETÀ ITALIANA NEFROLOGIA SIN
aniarti Associazione Nazionale Infermieri di Area Critica	Società Italiana di Medicina Generale	AIPO Associazione Italiana Pneumologi Ospedalieri

Tre elementi “trigger” che suggeriscono che i malati si avvicinano alla fine della vita

- **1. La “domanda sorprendente”: saresti sorpreso se questo malato morisse nei prossimi mesi, settimane, giorni?**
- **2. La presenza di alcuni indicatori generali di deterioramento delle condizioni generali, di incremento dei bisogni o una scelta del malato di non essere più sottoposto a trattamenti “attivi”.**
- **3. Indicatori clinici specifici correlati ad alcune patologie.**

Integration of Oncology and Palliative Care: a systematic review

(Hui D, et al, *Oncologist* 2015; 20: 77-83)

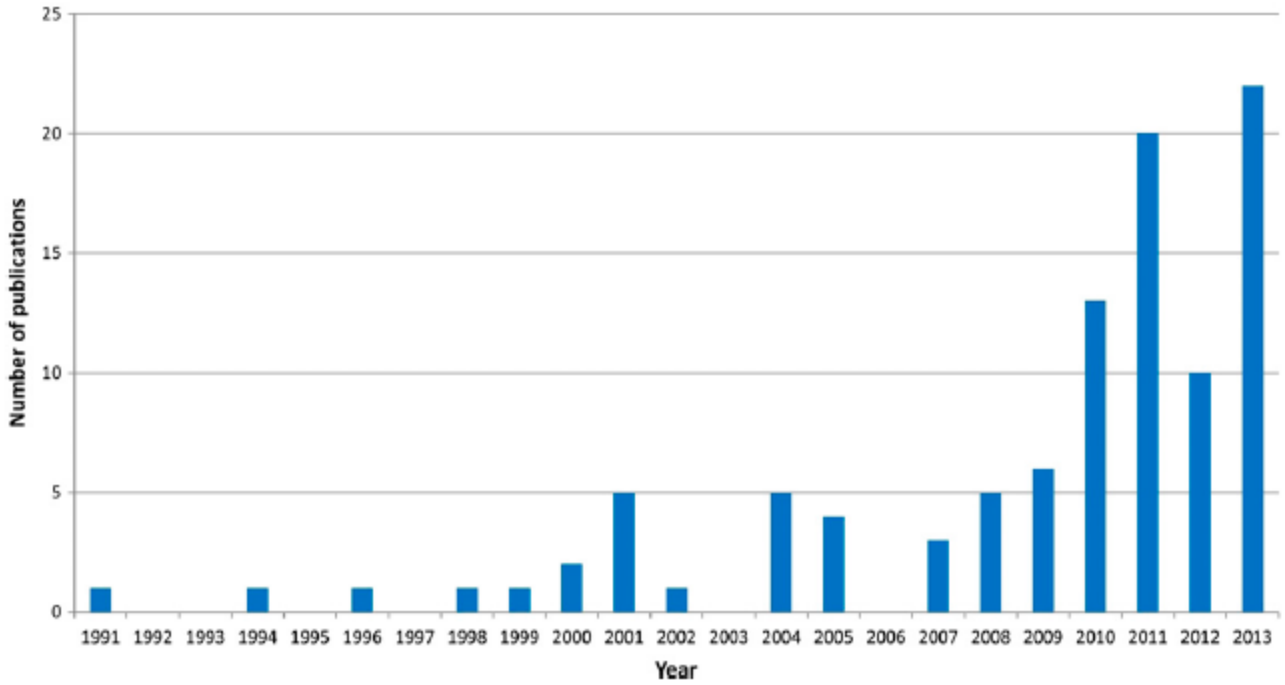


Figure 2. Increasing number of publications on integration of oncology and palliative care between 1999 and 2013 ($p < .001$). A total of 65 articles (64%) were published in 2010 or after.

Resource allocation issues concerning early palliative care

(Gaertner J, *Ann Palliat Med*, 2015; 4: 156-161)

Specialist Early Palliative Care

«early and routine integration of multiprofessional specialist palliative care service» (most often, in outpatient setting)

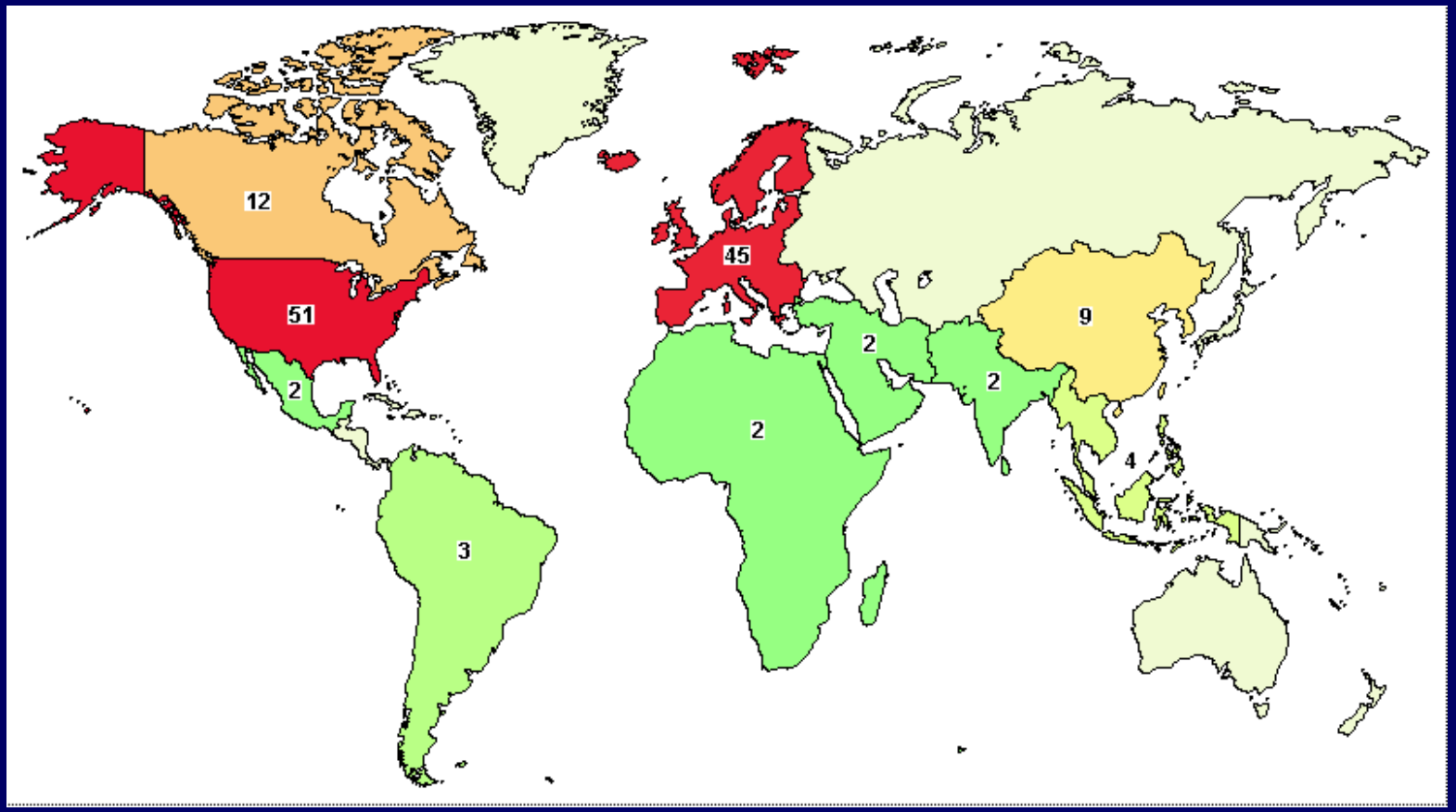
https://clinicaltrials.gov/:"early palliative care"

- **136 studi**

- **50 attivi (di cui 10 non ancora reclutanti e 40 reclutanti)**

- **86 non attivi**
- **completati**
- **attivi non reclutanti**
- **terminati**
- **stato non noto**
- **interrotti**

https://clinicaltrials.gov/:"early palliative care"



Early Specialty Palliative Care
Translating Data in Oncology into Practice

(Ravi B. Parikh, N Engl J Med 2013; 369:2347-2351)

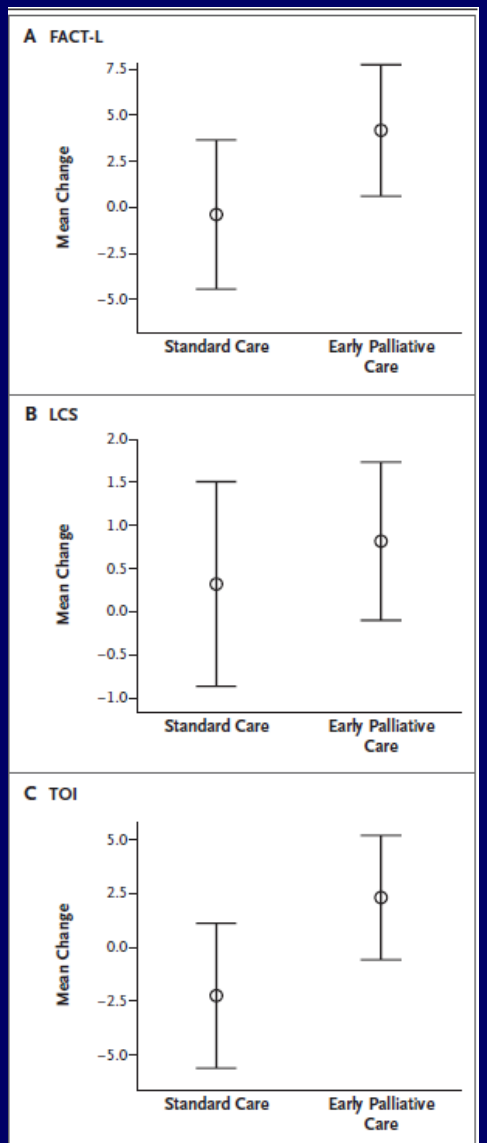
Triplo obiettivo delle cure palliative specialistiche precoci

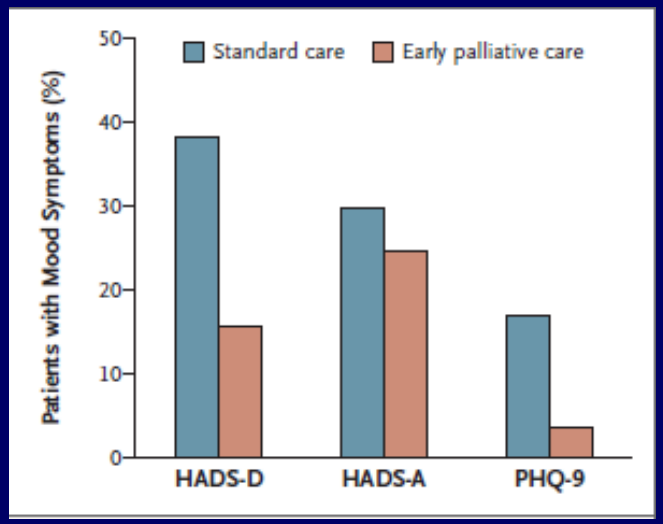
- **Migliore salute**
- **Migliore cura**
- **Costi inferiori**

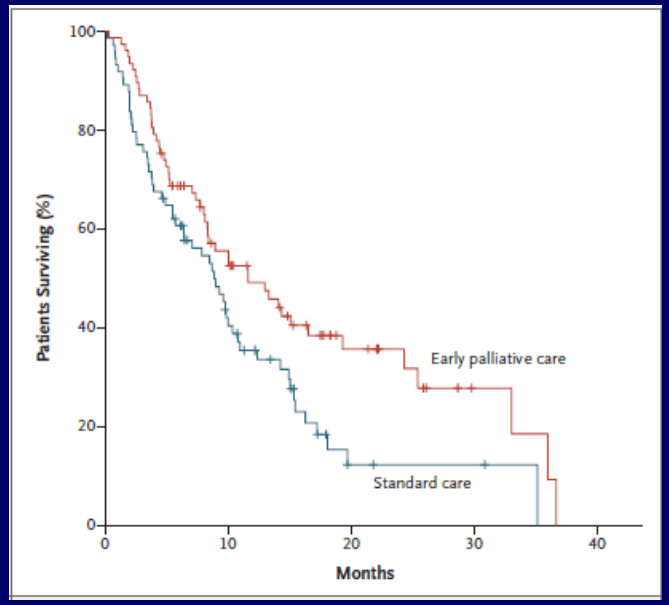
- Triple Aim initiative. Cambridge, MA: Institute for Healthcare Improvement, 2013 (http://www.ihi.org/offerings/Initiatives/TripleAim/Pages/default.aspx).

Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer

(Temel JS, N Engl J Med 2010;363:733-42)







Effect of early palliative care on chemotherapy use and end-of-life care in patients with metastatic non-small-cell lung cancer

(Greer JA, … Temel JS. J Clin Oncol. 2012 Feb 1;30(4):394-400)

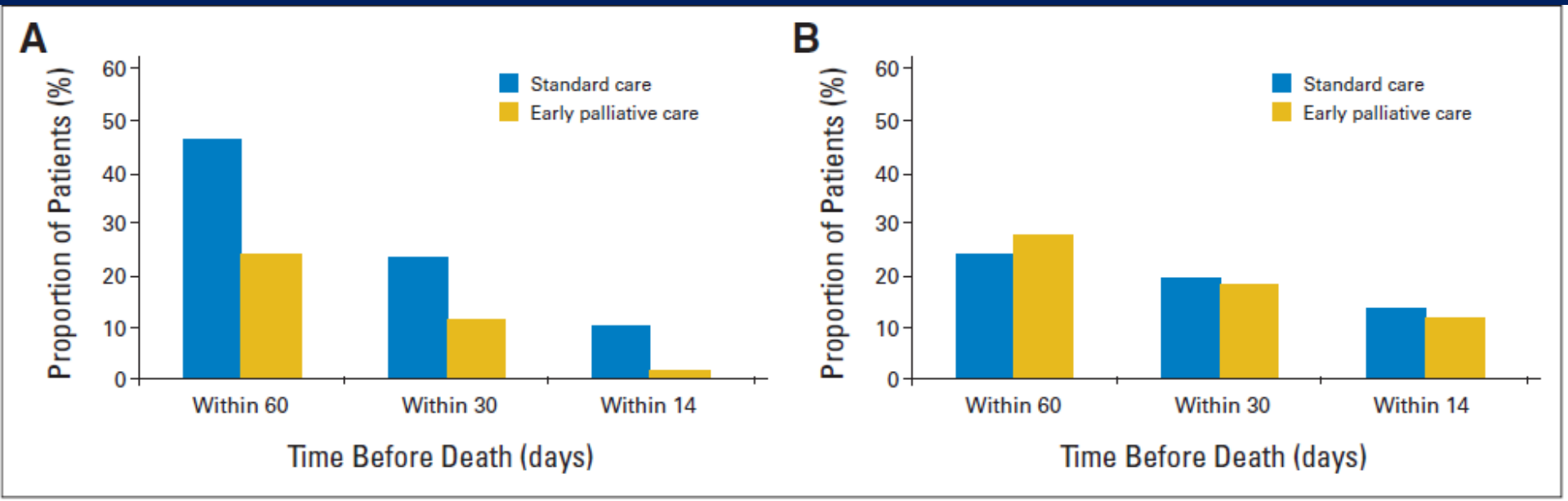


Fig 3. Administration of final regimen of (A) intravenous and (B) oral chemotherapy at end of life (n = 129). Within 60 days of death, a significantly greater percentage of patients were receiving intravenous chemotherapy as final regimen in standard-care (SC) group compared with early palliative care (PC) group (SC, 31 of 67 [46.3%] *v* early PC, 15 of 62 [24.2%]; $P = .01$). Finding remained similar within 30 days (SC, 16 of 67 [23.9%] *v* early PC, seven of 62 [11.3%]; $P = .07$) and 14 days of death (SC, seven of 67 [10.4%] *v* early PC, one of 62 [1.6%]; $P = .06$), although not quite meeting threshold for statistical significance. Percentages of patients receiving oral chemotherapy did not differ significantly between groups within each of three time frames (all *P* values ranging from .67 to > .99).

Supplemental Table 1: Ambulatory Palliative Care Guidelines

Illness understanding/education Inquire about illness and prognostic understanding Offer clarification of treatment goals
Symptom management – Inquire about uncontrolled symptoms with a focus on: Pain Pulmonary symptoms (cough, dyspnea) Fatigue and sleep disturbance Mood (depression and anxiety) Gastrointestinal (anorexia and weight loss, nausea and vomiting, constipation)
Decision-making Inquire about mode of decision-making Assist with treatment decision-making, if necessary
Coping with life threatening illness Patient Family/family caregivers
Referrals/Prescriptions Identify care plan for future appointments Indicate referrals to other care providers Note new medications prescribed

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Original Research

Systematic versus on-demand early palliative care: results from a multicentre, randomised clinical trial

Marco Maltoni [a], Emanuela Scarpi [b,*], Monia Dall'Agata [b], Vittorina Zagonel [c], Raffaella Bertè [d], Daris Ferrari [e], Chiara Maria Broglia [f], Roberto Bortolussi [g], Leonardo Trentin [h], Martina Valgiusti [i], Sara Pini [i], Alberto Farolfi [i], Andrea Casadei Gardini [i], Oriana Nanni [b], Dino Amadori [i] on behalf of Early Palliative Care Italian Study Group (EPCISG)

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Table 2
Mean change in QoL scores between T0 and T1.

	Mean change between T0 and T1		Difference between interventional and standard arm (95% CI)	p Value
	Standard arm, mean value (SD)	Interventional arm, mean value (SD)		
FACT-Hep score	−4.49 (17.68)	−0.92 (13.01)	3.57 (−1.02 to 8.15)	0.176
HCS score	−2.23 (7.70)	0.28 (6.47)	2.51 (0.40 to 4.61)	0.013
TOI score	−4.47 (14.12)	−0.63 (10.95)	3.83 (0.10 to 7.57)	0.041

Abbreviations: QoL = quality of life; CI = confidence interval; FACT-Hep = Functional Assessment of Cancer Therapy − Hepatobiliary; HCS = Hepatobiliary Cancer Subscale; SD = standard deviation; TOI = Trial Outcome Index.

Table 3
QoL outcomes at T1 (12 ± 3 weeks).

	Standard arm	Interventional arm	Difference between interventional and standard arms (95% CI)	*p* Value[a]	Effect size
		Mean value (SD)			
FACT-Hep score	113.0 (26.7)	119.6 (21.1)	6.63 (−0.47 to 13.73)	0.080	0.30
HCS score	48.2 (11.2)	52.0 (8.4)	3.78 (0.86 to 6.71)	0.008	0.42
TOI score	78.1 (21.3)	84.4 (16.3)	6.35 (0.75 to 11.95)	0.022	0.36

Abbreviations: QoL = quality of life; CI = confidence interval; FACT-Hep = Functional Assessment of Cancer Therapy − Hepatobiliary; HCS = Hepatobiliary Cancer Subscale; SD = standard deviation; TOI = Trial Outcome Index.

[a] Adjusted for baseline scores.

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Original Research

Systematic versus on-demand early palliative care: A randomised clinical trial assessing quality of care and treatment aggressiveness near the end of life

Marco Maltoni [a], Emanuela Scarpi [b,*], Monia Dall'Agata [b], Stefania Schiavon [c], Claudia Biasini [d], Carla Codecà [e], Chiara Maria Broglia [f], Elisabetta Sansoni [a], Roberto Bortolussi [g], Ferdinando Garetto [h], Luisa Fioretto [i], Maria Teresa Cattaneo [j], Alice Giacobino [k], Massimo Luzzani [l], Giovanna Luchena [m], Sara Alquati [n], Silvia Quadrini [o], Vittorina Zagonel [p], Luigi Cavanna [d], Daris Ferrari [e], Paolo Pedrazzoli [f], Giovanni Luca Frassineti [q], Antonella Galiano [p], Andrea Casadei Gardini [q], Manlio Monti [q], Oriana Nanni [b] on behalf of Early Palliative Care Italian Study Group (EPCISG)

Table 3

Use of healthcare services

	Standard arm N (%)	Interventional arm N (%)	P*
Chemotherapy administration			
Any chemotherapy ≤ 14 days before death	8/72 (11.1)	10/75 (13.3)	0.826
Any chemotherapy ≤ 30 days before death	20/72 (27.8)	14/75 (18.7)	0.036
Hospitalization			
Any admission from enrolment to death	53/72 (73.6)	51/75 (68.0)	0.417
Any admission ≤ 30 days before death	40/72 (56.3)	38/75 (50.7)	0.539
Emergency Department visits			
Any ED visit from enrolment to death	30/71 (42.2)	29/75 (38.7)	0.891
Any ED visit ≤ 30 days before death	20/71 (28.2)	20/75 (26.7)	0.729
Place of death			
Home	17/72 (23.6)	22/72 (30.6)	
Hospice	31/72 (43.0)	34/72 (47.2)	
Hospital	22/72 (30.6)	15/72 (20.8)	
Nursing home	2/72 (2.8)	1/72 (1.4)	0.702
Home + hospice	48/72 (66.7)	56/72 (77.8)	
Hospital + nursing home	24/72 (33.3)	16/72 (22.2)	0.102
Hospice Services			
No admission to hospice	40/73 (54.8)	42/76 (55.3)	
Admission to hospice ≤7 days before death	22/73 (30.1)	22/76 (28.9)	0.933
Admission to hospice >7 days before death	11/73 (15.1)	12/76 (15.8)	
Admission to palliative care program (home palliative care)	22/71 (31.0)	28/73 (38.4)	0.298
	Mean value (SD)	**Mean value (SD)**	
Admission to hospice before death			
Number of total admissions	0.97 (0.37)	1.38 (0.64)	0.001
Days in hospice	14.9 (11.1)	25.2 (24.0)	0.025
Admission to palliative care program (home palliative care)			
Days on palliative care program	29.0 (29.5)	43.2 (68.5)	0.380
	Median value (range)	**Median value (range)**	
Admission to hospice before death			
Number of total admissions	1 (0-2)	1 (1-3)	0.006
Days in hospice	14 (1-40)	20 (1-76)	0.025
Admission to palliative care program (home palliative care)			
Days on palliative care program	19 (1-105)	15 (1-289)	1.000

SD, standard deviation.

*Adjusted for age, gender, marital status and performance status

Systematic versus on demand early palliative care: a randomized clinical trial assessing quality of care and treatment aggressiveness near the end of life

	OD-EPC	Sys-EPC	
• 12-month OS probability	12.3% (95% CI 4.8-19.9)	22.4% (95% CI 13.0-31.7)	0.288
• Median OS	5.7 mo (95% CI 4.8-7.6)	6.6 mo (95% CI 4.4-8.1)	

Does palliative care improve outcomes for patients with incurable illness? A review of the evidence.

(El-Jawahri A, J Support Oncol 2011 May-Jun;9(3):87-94)

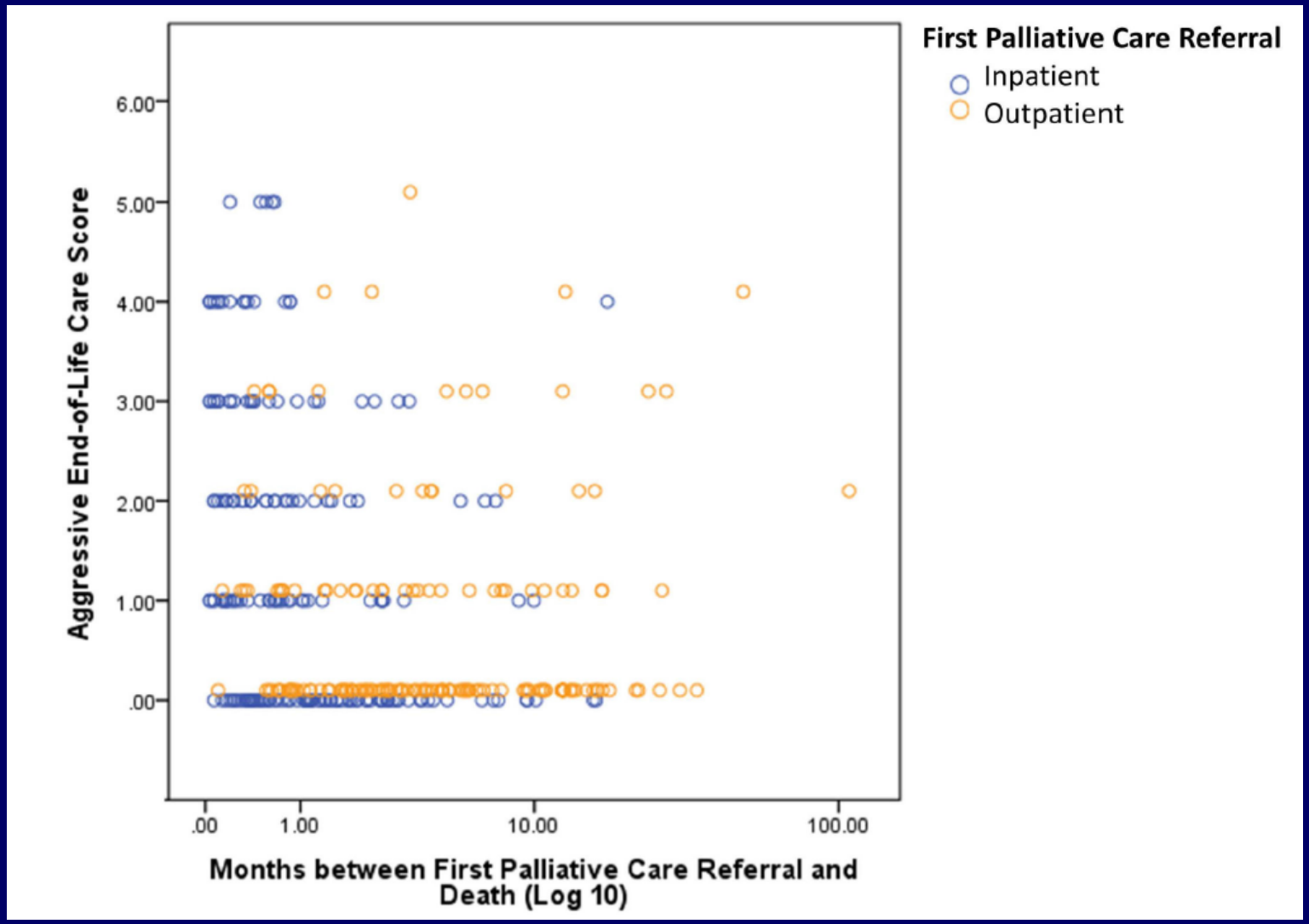
- **22 randomized studies about the efficacy of various palliative care interventions(14 + 8)**

- **5/7 studies quality of life as a primary outcome, and 5/6 with family caregivers outcomes, 7/10 patient and/or family caregiver satisfaction, and 9/13 health service use and EOL outcomes, favoured experimental arms**

- **Need for specialized standardized palliative care intervention**

Impact of timing and setting of Palliative care referral on Quality of End-of-Life care in cancer patients

(Hui D, et al, Cancer; 2014, 120: 1743-1749)



A review of the trials which examine early integration of outpatient and home palliative care for patients with serious illnesses

Davis M et al , *Ann Palliat Med* 2015;4(3):99-121

- ***Why are there differences in the benefits to palliative care in randomized control trials?***

- **Come è strutturato il team e l'intervento di cure palliative**
- **Compliance dei curanti alle raccomandazioni del team**
- **Definizione di cura «convenzionale» o «standard»**
- **Procedure e disegni: reclutamento non consecutivo, sbilanciamenti nella randomizzazione, non cecità dei rilevatori, non calcolo del potere dello studio, uscita pazienti e outcome multipli, timing delle valutazioni degli outcome, non analisi intention to treat, non menzione di come considerati i dati mancanti, utilizzo di termini quali «trend» o «vantaggio non significativo»**

Tabella 16. Proposta di screening per selezionare il paziente da avviare subito a supporto palliativo (22), elaborata da Zagonel. Un cut-off di 5 o superiore rende indicata l'attivazione delle cure palliative precoci.

	SCREENING ITEMS	Punteggio
1	Presenza di metastasi o malattia localmente avanzata	2
2	ECOG Performance Status	0-4
3	Presenza di una o più complicanze in genere associate a prognosi < a 12 mesi (metastasi cerebrali, ipercalcemia, delirio, compressione midollare, cachessia)	1
4	Presenza di una o più comorbidità gravi in genere associate a prognosi scarsa (moderata o severa insuff. cardiaca congestizia, malattia polmonare cronica ostruttiva, demenza, AIDS, insuff renale grave, cirrosi epatica conclamata)	1
5	Presenza di problemi che richiedono supporto palliativo	
	- Sintomi non controllati da terapie standard	1
	- Moderato o severo distress del paziente o familiari correlato alla diagnosi del cancro o alla terapia	1
	- Problemi del paziente o familiari correlati alla evoluzione del tumore e decisioni in merito	1
	- Richiesta del palliativista da parte del paziente o dei familiari	1
	- Richiesta del palliativista da parte del team per decisioni complesse o specifici obiettivi di cura	1
	TOTALE	0-13

Referral criteria for outpatient specialty palliative cancer care: an international consensus

(Hui D et al, Lancet Oncol 2016; 17: e552-e559)

	Category	Second-round agreement, n (%)	Third-round agreement, n (%)	p*
Needs-based criteria				
Severe physical symptoms (eg, pain, dyspnoea or nausea scored 7–10 on a ten-point scale)	Distress	55 (98%)	58 (100%)	>0·99
Severe emotional symptoms (eg, depression or anxiety scored 7–10 on a ten-point scale)	Distress	47 (84%)	56 (97%)	0·07
Request for hastened death	Distress	49 (88%)	55 (96%)	0·13
Spiritual or existential crisis	Distress	39 (71%)	53 (91%)	0·007
Assistance with decision making or care planning	Other	49 (88%)	55 (95%)	0·45
Patient request	Other	48 (86%)	55 (95%)	0·34
Delirium	Neurological	44 (79%)	51 (88%)	0·42
Brain or leptomeningeal metastases	Neurological	41 (73%)	43 (74%)	>0·99
Spinal cord compression or cauda equina	Neurological	41 (75%)	42 (72%)	0·85
Time-based criteria				
Within 3 months of diagnosis of advanced or incurable cancer for patients with median survival of 1 year or less	Disease trajectory	40 (71%)	51 (88%)	0·05
Diagnosis of advanced cancer with progressive disease despite second-line systemic therapy (incurable)	Disease trajectory	39 (70%)	51 (88%)	0·06

N=56 in the second round; N=58 in the third round. Because not all respondents answered all questions, in some instances the denominator used to calculate the percentages was different. * The McNemar test was used to examine the concordance in response between the second and third rounds.

Table 2: Major criteria for outpatient palliative care referral in third Delphi round

Conclusioni

- **L'integrazione precoce migliora gli outcomes clinici, la qualità della cura, riduce i costi, e probabilmente prolunga la sopravvivenza**

- **L'integrazione ottimale è quella precoce e che inizia nel setting ambulatoriale**

- **Ciascuna istituzione dovrebbe individuare la «soglia» per l'integrazione, in base al livello basico raggiunto e alle necessità cliniche**

Grazie per l’attenzione