to assess the accuracy of SCORTEN in predicting in-hospital mortality. These studies overall have shown that the SCORTEN performance during the first five days of hospitalization was excellent and is best on Day 3.[4] The most recent accuracy study was a retrospective study that included adult and pediatric patients admitted to a burn center with biopsy-confirmed SJS/TEN. SCORTEN scores were calculated on Day 1 and Day 3 of hospital admission, and they compared predicted with actual mortality in these patients. This study, however, claims that the accuracy of the SCORETEN model remains unclear and could be more precise, therefore encouraging future studies to explore other variables and a possible reformulated SCORTEN.[5] These studies exemplify that like many things in medicine, mortality probability models cannot 100% predict outcomes in individual patients.

That said, the presence of palliative medicine is increasing in ICU settings, and there is an increasing need for prognostic tools and evidence-based practice to help facilitate GOC discussion. In support of the traditional palliative care philosophy, recent findings show that aggressive end-of-life care does not correlate with improved perception of the medical care received near time of death and that many patients near the end of life often prefer palliative treatments over aggressive life-extending therapies.[6] Because the SCORTEN assessment was available and done quickly, we were able to present this patient's family members with an accurate prognostication of their loved one's in-hospital mortality. With these data, we were able to have a more direct GOC discussion, and the patient was able to die with care in accordance with her wishes.

This case study and discussion demonstrates the acuity of decision making necessary in a patient with severe integument injury with a >90% in-hospital mortality likelihood. It additionally provides palliative care providers with the knowledge of the SCORTEN illness severity and in-hospital mortality scale, demonstrating how having such a tool can aid in expediting GOC discussions, leading to improved patient end-of-life care.

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Comparability of the Australian National Cancer Symptom Trials (CST) Group's Study Populations to National Referrals to Non-CST Specialist Palliative Care Services Participating in the Palliative Care Outcomes Collaboration

Introduction

Using the results of Phase III studies in clinical practice depends on how representative study participants are of the clinical population to whom the results will be applied. The closer the characteristics between the subgroup who participate in a clinical trial and the whole population, the easier it is for clinicians to apply the results directly to the patient that he/she is treating. Trial participation is generally more happenstance than a systematic sampling of a population and is limited by eligibility criteria that do not reflect the entire clinical population.[1]

Phase III study populations tend to be younger with fewer comorbidities and not represent the gender and ethnicity of the target population, limiting generalizability of results.[1,2] When moving from Phase III studies to Phase IV postmarketing studies, there will

be differences in the populations prescribed the medications and the outcomes achieved,[3] highlighting the gap between gold-standard evidence from Phase III randomized studies and the application of that evidence in real-world practice. Palliative care services are referral based, yet there are no standard national or international referral criteria. As such, the populations served by specialist palliative care services are ill defined, complicating the problem of defining a "representative" population even further. Key characteristics have been suggested to aid generalizability of research findings in palliative care,[4] although these are poorly reported.

In palliative care, large-scale Phase III, symptom control effectiveness studies are being conducted successfully. This includes the work of the Australian National Cancer Symptom Trials (CST) group.[5–10] Can the findings from these studies be generalized to the broader palliative cancer care population in the same health system?

The aim of this analysis was to compare key demographic factors between participants with cancer in these Phase III studies and people referred to nontrial specialist palliative care services using standard prospective data collection. The null hypothesis was that there was no difference between participants' characteristics.

Methods and Analysis

This is a comparison of two independent but complementary consecutive cohorts generated contemporaneously through clinical trials and clinical quality initiatives nationally in Australia. This study compared age, sex, cancer diagnosis, language, socioeconomic status (using the Index of Relative Advantage and Disadvantage[11]), and Australian-modified Karnofsky Performance Status[12] in people with cancer enrolled in CST Phase III clinical studies[5–10] in people with cancer registered by the Australian National Palliative Care Outcomes Collaboration (PCOC) during the period 2013–2016 from sites not participating in CST.

Statistical Considerations

Demographic data were summarized using counts, percentages, medians, and interquartile ranges. Median ages and functional status were compared using the Wilcoxon rank sum test, whereas differences between the distribution of gender, language, and socioeconomic status were compared using Pearson's chi-squared test. Analyses were performed using R (Version 3.4.0, 2017; Auckland, New Zealand). No missing data were imputed. This study is reported using the STROBE framework for observational studies.[13]

Anonymized, deidentified data in secondary analysis required no further ethical review. Primary data collection was covered by relevant Human Research Ethics Committees.

Results

Nine hundred two people with cancer participated in six Phase III placebo-controlled, randomized controlled trials across 17 sites (Table 1). A consecutive cohort of 75,240 patients with a cancer diagnosis seen in 117 non-CST sites were the comparator population.

The CST cohort were younger (median age 71 [interquartile range {IQR} 62–79]) than the PCOC population (median 73 [IQR 63–81]; $P = 0.003$). There was no difference in sex between the groups (56.1% male in CST; 54.8% PCOC; $P = 0.483$), but the CST cohort had a higher proportion of English speakers (CST 95.0%; PCOC 92.2%; $P = 0.004$). The most frequent four diagnoses in the CST cohort were as follows: lung, colorectal, gynecological, and prostate cancers. For PCOC, this was as follows: lung, colorectal, other gastrointestinal tract, and breast cancers (Table 2). Functional status, unlike the parameters reported in Table 3, changes over time in life-limiting illnesses so the decision was made to report the first Australian-modified Karnofsky Performance Status in each database for each person. The studies on delirium and inoperable malignant bowel obstruction tended to be later in people's clinical course, while studies on breathlessness tended to be in people with better levels of function (Table 3). Overall, people in CST studies tended to have a better level of function with a median score of 60 (IQR 50–70) than people referred to PCOC (median 50 [IQR 30–60]; $P < 0.001$).

Table 1
Double-Blind, Parallel-Arm, Multisite, Placebo-Controlled, Phase III Studies for Symptom Control in People With Advanced Cancer

Study Drug	People With Cancer Randomized	Total Randomized	Percentage of Cancer
Sertraline	75	223	33.6
Extended-release morphine	122	284	43.0
Megestrol or dexamethasone	190	190	100
Ketamine	185	185	100
Octreotide	112	112	100
Risperidone or haloperidol	218	247	88.3
Total	902	1241	72.7

Table 2

Comparison of the Fixed Characteristics of Participants in National, Multisite Phase III Controlled Clinical Studies for Symptom Control (Cancer Symptom Trials [CST] Group) With the Specialist Palliative Care Population in Nonparticipating Sites that were Part of the Palliative Care Outcomes Collaboration (PCOC)

Population Characteristics	Population	
	PCOC (n = 75,240)	CST (n = 902)
Age (median; IQR)[a]	73.0 (63–81)	71.0 (62–79)
Sex, n (%)[b]		
Men	41,257 (54.8)	498 (56.1)
Women	33,967 (45.2)	390 (43.9)
Language[c]		
English	68,115 (92.2)	774 (95.0)
Non-English	5782 (7.8)	41 (5.0)
Socioeconomic status, n (%)[d]		
Index of Relative Socio-economic Advantage and Disadvantage (quintile)		
1	13,241 (17.7)	149 (17.0)
2	10,877 (14.5)	136 (15.5)
3	14,106 (18.8)	136 (15.5)
4	15,366 (20.5)	212 (24.1)
5	21,326 (28.5)	246 (28.0)

Population Characteristics	Population					
	PCOC (n = 75,240)			CST (n = 902)		
		Med. Age	% Male		Med. Age	% Male
Diagnosis						
Lung	16,425 (21.8)	72	59.4	261 (28.9)	72	61.7
Colorectal	8540 (11.4)	73	54.9	125 (13.9)	71	48.0
Other GIT	7140 (9.4)	72	62.1	57 (6.3)	68	68.4
Breast	5535 (7.4)	67		55 (6.1)	67	
Pancreatic	5044 (6.7)	73	51.8	35 (3.9)	68	54.3
Prostate	4994 (6.6)	79		82 (9.1)	77	
Hematological	4938 (6.6)	76	56.1	27 (3.0)	74	74.1
Head and neck	4006 (5.3)	68		13 (1.4)	[e]	
Gynecological	3578 (4.8)	70		85 (9.4)	[e]	
Other urological	3275 (4.4)	76	67.8	34 (3.8)	75	74.4
Other primary	2997 (4.0)	72		6 (0.6)	[e]	
Skin	2971 (3.9)	72	67.7	40 (4.4)	71	77.5
Unknown primary	2077 (2.8)	77		6 (0.7)	[e]	
CNS	1611 (2.1)	65		4 (0.4)	[e]	
Bone and soft tissue	1171 (1.6)	71		10 (1.1)	[e]	
Malignant—other	974 (1.3)	74		62 (6.9)	[e]	

IQR = interquartile range; GIT = gastrointestinal tumor; CNS = central nervous system.
[a]Age difference between groups: $P = 0.003$.
[b]16 (0.02%) missing PCOC; 14 (1.6%) missing CST: $P = 0.483$ for between-group comparison.
[c]1343 (1.8%) missing PCOC; 87 (9.6%) missing CST; $P = 0.004$ for between-group comparison.
[d]324 (0.4%) missing PCOC; 23 (2.5%) missing CST; $P = 0.022$ for between-group comparisons.
[e]Cell count <25 so not calculated.

Service delivery models were similar between the cohorts (Table 4).

Patients referred to PCOC are more likely to have a higher socioeconomic status than the general Australian population. The highest two Index of Relative Advantage and Disadvantage quintiles are overrepresented in both cohorts, with this being even greater in CST (52.1%; PCOC 49.0%; $P = 0.022$).

Discussion

This study found demographic differences between a Phase III study cohort and the general palliative care population consistent with differences described in other clinical specialties. Despite these statistical differences, the findings of these Phase III studies are likely to be able to be applied to the broader palliative care population.

Differences in cancer diagnoses almost certainly reflect the symptoms explored: breathlessness and anorexia are both prevalent in lung cancer [5,6]; bowel obstruction is prevalent in gynecological cancers[9]; and pain is frequently encountered in late-stage metastatic breast and prostate cancers.[8]

In efficacy studies that have the most stringent eligibility criteria, the population is likely to be healthier with fewer comorbidities, often reflecting only the index clinical presentation. By contrast, effectiveness studies have broader eligibility criteria, more closely reflecting day-to-day practice. This study demonstrates that for the criteria compared, CST studies are effectiveness studies maximizing their generalizability.

Table 3
Comparison of Variable Factors (Functional Status) of People Participating in Cancer Symptom Trials (CST) Studies Group With the Population in Non-CST Sites that were Participating in the Australian National Palliative Care Outcomes Collaboration (PCOC)

	PCOC (%)	CST (%)
AKPS	$N = 75{,}240$	$N = 902$
Median (IQR)	50 (30–60)	60 (50–70)
10	2.4	0.0
20	10.6	4.4
30	9.6	5.4
40	15.3	14.2
50	22.7	23.4
60	21.2	26.1
70	10.9	19.2
80	3.8	5.4
90	1.2	0.8
100	0.1	0.0
Missing	2.3	1.1

AKPS = Australian-modified Karnofsky Performance Status; IQR = interquartile range.
$P < 0.001$ (Wilcoxon rank sum test).

In palliative care, a framework for classifying research subpopulations to which the research findings are being applied by clinicians, health planners, and funders in real-world settings has been suggested.[14] Existing literature often inadequately describes the characteristics of patients, limiting the utility of results. Hjermstad et al. identified wide variation in palliative care services and patients.[15] Patients' characteristics differed when compared across predefined categories of participating centers.

Detailed characterization is the first step in improving use of palliative care research. Palliative care cancer populations are inconsistently and insufficiently described when reporting randomized controlled trials requiring investigators to improve this aspect of trial reporting.[16–18]

Table 4
Comparison of the Sites' Characteristics in National, Multisite Phase III Controlled Clinical Studies for Symptom Control (Cancer Symptom Trials [CST] With the Specialist Palliative Care Population in Non-CST Sites that were Participating in the Palliative Care Outcomes Collaboration [PCOC])

Item	PCOC ($n = 75{,}240$) 117 Sites	CST ($n = 902$) 17 Sites
Inpatients/consults	55 (47%)	9 (53%)
Community only	34 (29%)	1 (6%)
Consult only	4 (3%)	3 (18%)
Inpatients and community	16 (14%)	2 (12%)
Community and consult	5 (4%)	0 (0%)
Inpatients and community and consult	3 (3%)	2 (12%)

Limitations

The data from the PCOC cohort do not contain comorbidity data, and the research database has comorbidities only relevant to each individual study. Stage of disease was also not available. Future work in this area should collect such data prospectively.

Strengths

All data in this data set were generated prospectively with high levels of completeness. The use of the data in this secondary analysis is directly in keeping with the purposes for which the data were collected.

Clinical Implications

The CST has run effectiveness studies with the widest possible eligibility criteria to ensure that the generalizability of the findings is maximized. The findings in this study are that the CST cohort largely mirrors the palliative care population that we serve. This gives confidence for clinicians to explore applying the findings from these studies to their own setting, as many have done given demonstrated changes in practice.[19,20]

Research Implications

Continuing to refine the evidence base for therapeutic interventions in palliative care is paramount if we are to realize the vision to personalize care. Palliative care Phase II and III studies need to be effectiveness studies built on the broadest possible population of palliative care patients.

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Ethical approval: The Palliative Care Outcomes Collaboration is run under a Human Research Ethics Approval (2006/046) of the combined University of Wollongong/Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee. Patients were not required to provide written informed consent. Only aggregated deidentified data were used in this analysis. As noted previously, a waiver for written informed consent was granted by the Human Research Ethics Committee.

Data sharing statement: Data can be made available to bona fide researchers.

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When We Document End-of-Life Care, Words Still Matter

To the Editor:

In the September 2018 edition of the *Journal of Pain and Symptom Management*, the study "Language used by health care professionals to describe dying at an acute care hospital" focused on specific word choices when documenting end-of-life care.[1] They accurately note that, in acute care settings, the patient's medical record often becomes the primary mechanism for communication between providers. Imprecise documentation can lead to poor transfer of knowledge and even implicit bias.[2] Wentlandt et al. describe the "implied state" category as most frequently used by nonpalliative care providers, which labels patients by the care they receive (e.g., "he receives comfort care") without clearly indicating estimated prognosis. Specific terms such as "dying," "die," and "passing" (a word that many would characterize as an inexact euphemism) were only documented 24.7% of the time.

Words still matter. Provider discomfort compassionately employing clear, direct terms (e.g., "your father is dying") has been well described.[3,4] The unintended consequences of using oblique terminology (e.g., "your father is transitioning") certainly include miscommunication ("you mean my father has been moved to a different room?") and missed or delayed opportunities to engage in the grieving process. What this study underlines is the remarkable extent to which provider discomfort talking about death and dying extends away from the patient/family encounter to the clinical chart: we are anxious to say these things even to each other.

We applaud the efforts of Dr. Wentlandt and colleagues to shine the light onto our communication practices within the medical record. Perhaps, these findings offer the opportunity for our own hospice and palliative care field to clearly define best communication practices. For example, the *Journal of the American Geriatrics Society* recently took a stance on language by requiring its authors to use the term "older adult" when referring to someone aged 65 years or older rather than seniors or elderly.[5] We suggest *JPSM*, and other discipline-specific journals consider adopting similar word choice policies related to terminology of death and dying—let's set a standard for others to follow.

Sincerely,

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Response to Hyoscine Butylbromide for the Management of Death Rattle: Sooner Rather Than Later

Dear Editor:

I read the recent paper regarding death rattle treatment with great interest.[1] The authors are commended for giving consideration to this naturally occurring patient noise that is distressing to clinicians and families.

Clinicians have largely believed there is no patient distress as death rattle develops in the context of declining consciousness. We established that there is no patient distress associated with the development