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Utility of 30-day mortality as a quality metric for palliative radiation treatment: A population-based analysis from Queensland, Australia

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Abstract

Introduction: Palliative radiotherapy (PRT) is frequently used to treat symptoms of advanced cancer, however benefits are questionable when life expectancy is limited. The 30-day mortality rate after PRT is a potential quality indicator, and results from a recent meta-analysis suggest a benchmark of 16% as an upper limit. In this population-based study from Queensland, Australia, we examined 30-day mortality rates following PRT and factors associated with decreased life expectancy.

Methods: Retrospective population data from Queensland Oncology Repository was used. Study population data included 22,501 patients diagnosed with an invasive cancer who died from any cause between 2008 and 2017 and had received PRT. Thirty-day mortality rates were determined from the date of last PRT fraction to date of death. Cox proportional hazards models were used to identify factors independently associated with risk of death within 30 days of PRT.

Results: Overall 30-day mortality after PRT was 22.2% with decreasing trend in more recent years ($P = 0.001$). Male (HR = 1.20, 95% CI = 1.13–1.27); receiving 5 or less radiotherapy fractions (HR = 2.97, 95% CI = 2.74–3.22 and HR = 2.17, 95% CI = 2.03–2.32, respectively) and receiving PRT in a private compared to public facility (HR = 1.61, 95% CI = 1.51–1.71) was associated with decreased survival.

Conclusion: The 30-day mortality rate in Queensland following PRT is higher than expected and there is scope to reduce unnecessarily protracted treatment schedules. We encourage other Australian and New Zealand centres to examine and report their own 30-day mortality rate following PRT and would support collaboration for 30-day mortality to become a national and international quality metric for radiation oncology centres.

Key words: 30 day mortality; end of life; fractionation schedule; palliative radiotherapy.

Introduction

Palliative radiotherapy (PRT) is used to treat advanced cancer-related symptoms. Common indications for PRT include pain and fracture prevention from bone metastases,[1] neurological symptoms from spinal cord/cauda equina compression or nerve root compression,[2] symptoms from brain metastases,[3] soft tissue mass resulting in obstruction, fungation and bleeding.[4,5] The symptomatic benefit derived from PRT can take up to several weeks from the time of treatment, and so it is incumbent on treatment providers to ensure patients will survive long enough to receive benefit.[6] Evidence suggests that clinicians are prone to making overly-optimistic estimations of patient survival in the advanced cancer setting[7,8] resulting in some patients dying prior to deriving any benefit from PRT. Patients with advanced disease should be selected carefully before treatment with PRT, especially multi-fraction radiation treatments (RT), which may be futile close to end of life (EOL) and can increase patient burden and health care costs.[9,10] One evidence-based solution to this problem utilises shorter treatment courses (i.e. fewer RT fractions) for symptomatic patients with poorer prognoses.[7,10]

Thirty-day mortality following systemic therapy is routinely reported in the scientific literature,[11–13] and institutions such as England's National Health Service report on this metric for all of its trust hospitals.[14] It has been suggested the use of chemotherapy at EOL is a marker for poor-quality care.[15] Thirty-day mortality after PRT can also be used to audit how patients with advanced cancer are treated at EOL. To help establish a benchmark, Park *et al*.[16] in 2017 published a systematic review suggesting that more frequent use of shorter or single fraction treatment regimens may be preferrable, particularly for those patients with a poor performance status. The United Kingdom's Royal College of Radiologists suggested a level below 20% be used as a benchmark, although this was based on limited data.[17] More recently, a meta-analysis has provided a world-wide benchmark of 16% (95% CI = 14–18) for radiotherapy regulators to audit an individual centre's 30-day mortality rate after PRT. Subgroup analyses further highlighted several factors that may predict some patient populations as having a higher 30-day mortality rate after PRT.[18] These include: treatment at multiple body sites; treatment as an inpatient; ECOG status 3–4; hepatobiliary, melanoma and mesothelioma primary; presence of liver metastases, and country in which treatment is received.

The primary aim of this study was to report the 30-day mortality rate after PRT and the treatment fractionation schedules for patients undergoing PRT at all radiation oncology centres (public and private) in Queensland, Australia.

Methods

This retrospective population-based study used linked data from the Queensland Oncology Repository (QOR). QOR collates and matches data from the Queensland Cancer Register (QCR) together with all public and private hospitals admissions data, death data, treatment systems including public and private radiation therapy services, public and private pathology and hospital clinical data systems. Overall, there were 22 radiation oncology centres delivering PRT, of which five were public facilities and 17 were private.

To assign a PRT record to a diagnosis or death record, the PRT record closest to the death date is linked to the QOR diagnosis. For patients with a single cancer diagnosis, the last PRT to diagnosis was assigned. For patients with more than one cancer the last PRT to the diagnosis was assigned where: (i) the last PRT ICD10AM cancer site code was like the QOR ICD10AM primary site code; or (ii) last PRT cancer site group was like the QOR site group (e.g. primary site code is mesothelioma and the cancer site group is a higher level grouping of lung cancer) or (iii) cause of death code was similar to QOR ICD10AM primary site code; or (iv) last diagnosis before death.

Study population

The study population included 121,199 patients with a diagnosis of invasive cancer who died from any cause between 2008 and 2017. Patients who received PRT for a primary diagnosis of non-melanoma skin cancer were excluded (non-melanoma skin cancer is not notifiable to the QCR). From this population, we used treatment source data to identify 22,501 patients where RT closest to the date of death was of palliative intent (Fig. 1). Treatment was identified as palliative by the treating clinician and recorded in treatment source systems. Approximately 10% of patients did not have the intent of their RT recorded by the treating clinician; in these cases palliative intent was inferred based on the RT dose delivered which ranged from 8 to 30 Gy. For 675 (3%) of the patients studied, intent remained unknown and these cases were excluded from the study. The 30-day mortality rate after PRT was defined from date of last PRT fraction to date of death.

Variables included

The collected variables are shown in Table 1. Disease duration was measured from the date of initial diagnosis to date of death. Number of comorbidities was derived from hospital admissions data from 12 months before diagnosis to death. Residence at time of diagnosis was based on the Australian Geographical Classification,[19] and categorised into three groups: metropolitan, inner

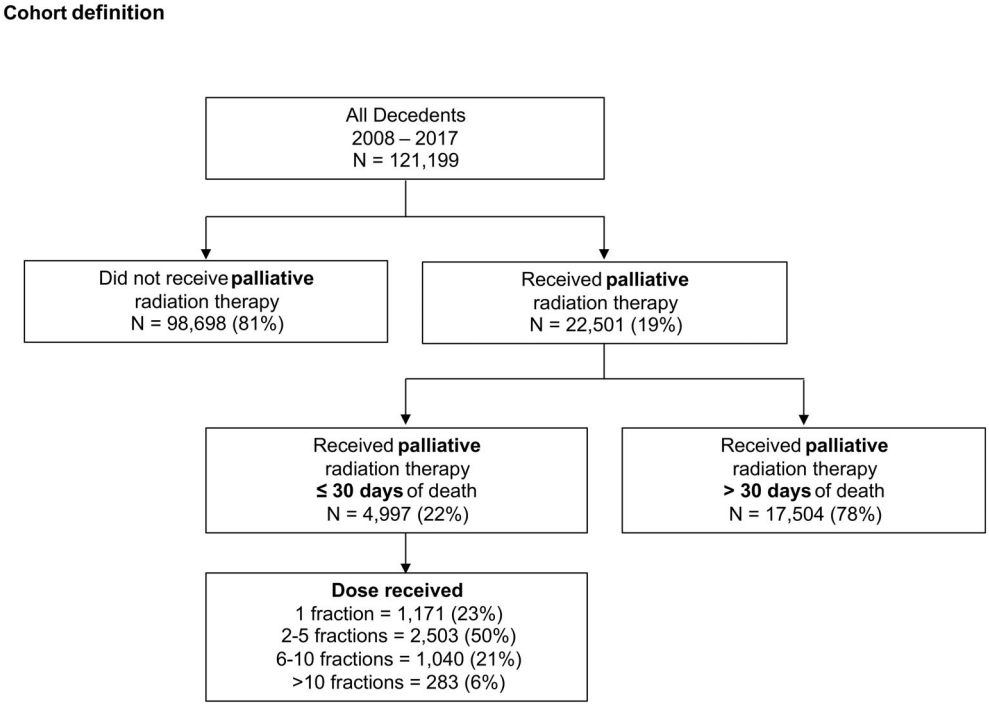

Fig. 1. Flowchart of cohort.

regional and rural (outer regional, remote and very remote combined due to small numbers). Socioeconomic status was assigned according to the Australian Bureau of Statistics Socio-Economic Indexes for Areas (SEIFA).[20] The number of RT treatments received were grouped as: single fraction, 2–5 fractions, 6–10 fractions and >10 fractions.

Statistical analysis

The statistical significance of bivariate comparisons between those who did and did not receive PRT within 30 days of death were estimated using chi-square or Kruskal–Wallis test. Cox proportional hazards model was used to identify factors independently associated with risk of death within 30 days of PRT. All analyses were conducted using Stata V19.0 (Stata Corp, College Station, TX, USA). Two-tailed $P < 0.05$ was considered statistically significant.

Results

Table 1 provides the sociodemographic and clinical characteristics of all patients receiving PRT and those who died within 30 days of PRT. The overall 30-day mortality after PRT in Queensland was 22.2% (4997/22,501) (95% CI = 21.7–22.8). There was a trend showing a decrease in 30-day mortality following PRT over 10-year timeframe of 2008–2017 from a high of 25% to 20% in 2017 ($P = 0.001$). The median time to death for patients receiving PRT within 30 days of death was 10 months.

Thirty-day mortality was significantly higher for males compared to females (23.5% and 20.3%, respectively) ($P < 0.001$) (Table 2), for those living in a metropolitan compared to inner regional or rural areas (22.8%, 20.6% and 22.1%, respectively) ($P = 0.006$), and for those whose treatment was at a private compared to public facility (24.4% and 20.6%, respectively) ($P < 0.001$). Patients with no comorbidity had a higher 30-day mortality compared to those with one or two or more comorbidities (23.7%, 22.5% and 19.5%, respectively) ($P < 0.001$). There was no significant difference in 30-day mortality according to socioeconomic status or First Nations status (Table 2).

In the fully adjusted model (Table 2), factors that remained significantly associated with an increased risk of death within 30 days of PRT included being male (HR = 1.20, 95% CI = 1.13–1.27 [$P < 0.001$]); receiving one or 2–5 fractions (HR = 2.97, 95% CI = 2.74–3.22 [$P < 0.001$] and HR = 2.17, 95% CI = 2.03–2.32 [$P < 0.001$], respectively); and having PRT in a private compared to public facility (HR = 1.61, 95% CI = 1.52–1.71 [$P < 0.001$]). The likelihood of dying within 30 days of PRT reduced as age increased ($P < 0.001$) and was approximately 20% lower for patients living in inner regional and rural areas compared to metropolitan (HR = 0.80,

Table 1. Sociodemographic and clinical characteristics of the study cohort

	Decedents receiving PRT *N*	Received PRT within 30 days of death *n* (%)
Total	22,501	4997 (22.2)
Sex		
Male	13,518	3172 (23.5)
Female	8983	1825 (20.3)
Age of death		
<18	66	21 (31.8)
18–44	914	232 (25.4)
45–54	2151	535 (24.9)
55–64	4716	1162 (24.6)
65–74	6939	1568 (22.6)
75–84	5442	1137 (20.9)
85+	2273	342 (15.0)
First nations people†		
First Nations	514	113 (22.0)
Non-first nations	21,985	4884 (22.2)
Location		
Metropolitan	14,573	3320 (22.8)
Inner regional	4901	1009 (20.6)
Rural‡	3027	668 (22.1)
Socioeconomic status		
Affluent	2272	524 (23.1)
Middle	14,267	3144 (22.0)
Disadvantaged	5962	1329 (22.3)
Comorbidities		
0	10,141	2400 (23.7)
1	6274	1410 (22.5)
≥2	6086	1187 (19.5)
Facility type		
Private	9500	2316 (24.4)
Public	13,001	2681 (20.6)
Cause of death		
Cancer	21,506	4869 (22.6)
Non-cancer	995	128 (12.9)
Median time to death (months)	25	10
Disease duration		
<1 month	321	319 (99.4)
1–3 months	1773	1047 (59.1)
3–6 months	2246	555 (24.7)
6–12 months	3748	834 (22.3)
1–2 years	4339	794 (18.3)
2–5 years	5279	823 (15.6)
>5 years	4795	625 (13.0)
Fractions received		
One	3591	1171 (32.6)
2–5	9591	2503 (26.1)
6–10	6161	1040 (16.9)
More than 10	3157	283 (9.0)
Primary site at death		
Lung	6661	1860 (27.9)
Prostate	2515	401 (15.9)
Breast	2172	336 (15.5)
Colorectal	1575	316 (20.1)
Melanoma	1432	328 (22.9)
Non-prostate urological	1374	317 (23.1)
Upper GI	1184	267 (22.6)
Haematological	897	184 (20.5)
Other cancers	4691	988 (21.1)

†First nations status unknown for two patients.

‡Rural includes outer regional, remote and very remote. PRT, palliative radiation therapy.

95% CI = 0.74–0.87 [$P < 0.001$] and HR = 0.83, 95% CI = 0.76–0.91 [$P < 0.001$], respectively).

30-day mortality by cancer

Of the 22,501 decedents receiving PRT, we inspected fractionation schedules for five common cancers (breast, colorectal, lung, prostate and melanoma), and whether PRT was delivered within 30 days of death (Table 3). Receipt of PRT within 30 days of death (all schedules) was highest in lung (28%) and melanoma (23%). Receiving PRT within 30 days of death was most common for those receiving a single fraction and lowest among those receiving more than five fractions. Among both those receiving a single fraction AND those receiving more than five fractions, receipt within 30 days of death was highest for people with lung cancer (45% and 17%, respectively) and lowest for prostate cancer (18%, 11%). Each of the five cancers considered showed that patients were less likely to receive radiation within 30 days of death as fractions increased.

Fractionation schedule

Table 4 shows the distribution of fractionation schedules delivered to patients who died within 30 days of receiving PRT according to facility type. There was a statistically significant difference ($P < 0.001$) in fractionation between public and private centres with patients treated in a private facility receiving fewer single fractions and more protracted fractionation schedules than public patients .

The distribution of 30-day mortality after PRT of both private and public facilities by centre volume compared with the Kutzko *et al*.[18] benchmark is shown in the funnel plot in Figure 2. This demonstrates that higher volume centres, particularly public centres have a 30-day mortality rate closer to the proposed benchmark of 16%. As several new private facilities opened during the study timeframe, we assessed treatment volume over the 10 years and found the volume of patients treated with PRT ranged from 6 to 3779 patients. Excluding low volume centres (i.e. treating less than 300 patients) from the analysis did not materially change the 30-day mortality which was 22.2% overall, but 22.1% with these centres excluded.

Table 2. Multivariate analysis examining factors associated with the likelihood of receiving PRT within 30 days of death in 22,501 decedents

Decedents receiving PRT	Received PRT within 30 days of death *N* (row%)	*P*-value	Adjusted Hazard ratio (95% CI)	*P*-value
Sex		<0.001		
Female (*n* = 8983)	1825 (20.3)		Ref	
Male (*n* = 13,518)	3172 (23.5)		1.20 (1.13–1.27)	<0.001
Age of death		<0.001		
<45 (*n* = 908)	253 (25.8)		Ref	
45–64 (*n* = 6867)	535 (24.9)		0.91 (0.80–1.04)	0.17
65–74 (*n* = 6939)	1162 (24.6)		0.80 (0.70–0.92)	0.001
75–84 (*n* = 5442)	1568 (22.6)		0.72 (0.63–0.83)	<0.001
85+ (*n* = 2273)	342 (15.0)		0.50 (0.42–0.59	<0.001
First Nations people		0.90		
Non-First Nations (*n* = 21,985)	4884 (22.2)		Ref	
First Nations (*n* = 514)	113 (22.0)		1.00 (0.83–1.20)	0.98
Location		0.006		
Metropolitan (*n* = 14,573)	3320 (22.8)		Ref	
Inner regional (*n* = 4901)	1009 (20.6)		0.80 (0.74–0.87)	<0.001
Rural† (*n* = 3027)	668 (22.1)		0.83 (0.77–0.91)	<0.001
Socioeconomic status		0.54		
Affluent (*n* = 2272)	524 (23.1)		Ref	
Middle (*n* = 14,267)	3144 (22.0)		0.90 (0.82–0.99)	0.02
Disadvantaged (*n* = 5962)	1329 (22.3)		1.00 (0.90–1.11)	0.99
Comorbidities		<0.001		
0 (*n* = 10,141)	2400 (23.7)		Ref	
1 (*n* = 6274)	1410 (22.5)		0.97 (0.91–1.03)	0.33
≥2 (*n* = 6086)	1187 (19.5)		0.86 (0.80–0.92)	<0.001
Fractions received		<0.001		
More than five (*n* = 9319)	1323 (14.2)		Ref	
Two to five (*n* = 9591)	2503 (26.1)		2.17 (2.02–2.32)	<0.001
One (*n* = 3591)	1171 (32.6)		2.97 (2.74–3.22)	<0.001
Facility type		<0.001		
Public (*n* = 13,001)	2681 (20.6)		Ref	
Private (*n* = 9500)	2316 (24.4)		1.61 (1.52–1.71)	<0.001

†Rural includes outer regional, remote/very remote. PRT, palliative radiation therapy.

Discussion

To our knowledge this is the first Australian population-based study evaluating 30-day mortality after PRT across all radiation oncology centres within a state or territory. The 30-day mortality rate after PRT of 22% for all Queensland patients is higher than the 16% benchmark suggested by Kutzko *et al*.[18] It is important to note that there was substantial heterogeneity between individual centres both geographically and by facility type. Several factors appeared to impact the 30-day mortality rate following PRT and are summarised below:

Age and comorbidities

In this study, older patients (i.e. those aged >65 years) were significantly less likely to die within 30 days of receiving PRT compared younger patients. While it is possible that older patients were potentially less likely to have received multiple fractions, our model was fully adjusted for varying fractionation schedules. To examine this further we conducted a stratified analysis and found no significant differences in fractions received according to age group ($P = 0.16$). We additionally found a lower 30-day mortality rate after PRT for patients with multiple comorbidities compared to those with none. One possible explanation for this is that clinicians are more likely to overestimate the prognosis and hence offer treatment to a younger, non-comorbid patient near EOL than an older comorbid patient. If true, our data emphasises the importance of using validated EOL prognostic tools in these patients to help reduce the 30-day mortality for patients under 65 years.

Residential location

After adjusting for clinical and socio-demographic characteristics patients living in regional and rural areas were 17% and 20% less likely to receive PRT in the last 30 days of their life than their metropolitan counterparts. A recent meta-analysis that focussed on geographical distance found patients living further away from

Table 3. Received PRT within 30 days of death by fraction schedule for five most common cancers

	Decedents 2008–2017 (*N*)	Received PRT		Single fraction		2–5 fractions		>5 fractions	
		n (%)	Died within 30 days	*n* (%)	Died within 30 days	*n* (%)	Died within 30 days	*n* (%)	Died within 30 days
Breast	4952	2172 (44%)	336 (15%)	362 (17%)	71 (20%)	924 (43%)	161 (17%)	886 (41%)	104 (12%)
Colorectal	9967	1575 (16%)	316 (20%)	190 (12%)	69 (36%)	672 (43%)	153 (23%)	713 (45%)	94 (13%)
Lung	16,742	6661 (40%)	1860 (28%)	1093 (16%)	495 (45%)	3133 (47%)	942 (30%)	2435 (37%)	423 (17%)
Prostate	6014	2515 (42%)	401 (16%)	686 (27%)	121 (18%)	1067 (42%)	194 (18%)	762 (30%)	86 (11%)
Melanoma	3392	1432 (42%)	328 (23%)	156 (11%)	61 (39%)	693 (48%)	181 (26%)	583 (41%)	86 (15%)

PRT, palliative radiation therapy.

Table 4. Distribution of fractions received by facility type for decedents who received PRT within 30 days of death

	Received PRT within 30 days of death			
	Qld (*n* = 4997) (%)	Public (*n* = 2681) (%)	Private (*n* = 2316) (%)	*P*-value
Number of fractions				<0.001
Single fraction	1171 (23.4)	810 (30.2)	361(15.6)	
2–5 fractions	2503 (50.1)	1443 (53.8)	1060 (45.8)	
>5 fractions	1323 (26.5)	428 (16.0)	895 (38.6)	

PRT, palliative radiation therapy.

radiotherapy centres were less likely to receive PRT and were more likely to receive single fractionation.[21] In Queensland, significant investment has been made in establishing many radiation facilities in inner regional areas over the period of this study with the aim of reducing the patients time spent travelling to RT centres and being away from home.[26] One explanation for the finding above may be that during this time these newer centres had shorter wait times for both clinic review and treatment delivery and by more rapid access treatment patients were less likely to die in the 30 days even if prognosis were the same as their metropolitan counterparts.

Public versus private RT facilities

In this study we found a 60% increase in the likelihood of patients receiving PRT in their last 30 days of life if they attended a private RT facility. The reasons why patients treated in the private system are more likely to receive PRT in the last 30 days of life are unknown. The majority (9/17) of private facilities included in our study were opened over a three-year span between 2014 and 2017. However, when comparing high volume established private centres and similar high volume established public centres (Fig. 2), we observe that in general, public facilities have the lowest proportion of patients receiving PRT within the last 30 days of life (three of the four public centres have lower proportions of patients treated in the final 30 days of life than all private facilities). One potential reason for this discrepancy may be financial, as private RT centres and their clinicians are more heavily compensated for active treatment, and not as well renumerated when only clinical review is undertaken. This contrasts with the remuneration practice of public RT centres and their clinicians. In Australia, Medicare rebates increase with the number of fractions and treatment complexities with approximately 80–90% of the fee rebated by Medicare for patients attending private facilities. Interestingly these results are in line with data seen in the recent meta-analyses, where 30 day mortality following PRT was highest in United States-based studies when compared as a subgroup to the rest of the world.[18] The renumeration system for the majority of centres in the United States is similar to the private RT centres in Australia, and health care studies in the United States have consistently reported disparities in rates of advanced cancer treatment use (including palliation) and access to hospice care between their public and private facilities.[11,22]

Fractionation

In this study prescribed fractionation schedule had a significant impact on 30 day mortality after PRT, with highest mortality observed for patients receiving single fractions. This is what we would expect to see if clinicians are accurately predicting prognosis and assessing the futility of longer treatment schedules in patients nearing EOL. We additionally found the rate of receiving a single fraction for patients treated in public facilities was double that observed for patients in private facilities with this difference remaining similar across the most common cancers in the cohort.

The reason why we observed such significant differences in fractionations received according to facility type is not evident, however, again as Medicare rebates increase with the number of fractions and treatment complexity, financial incentives may be a potential reason why private centres are more likely to use multiple fractions. It is also possible that the tendency to treat

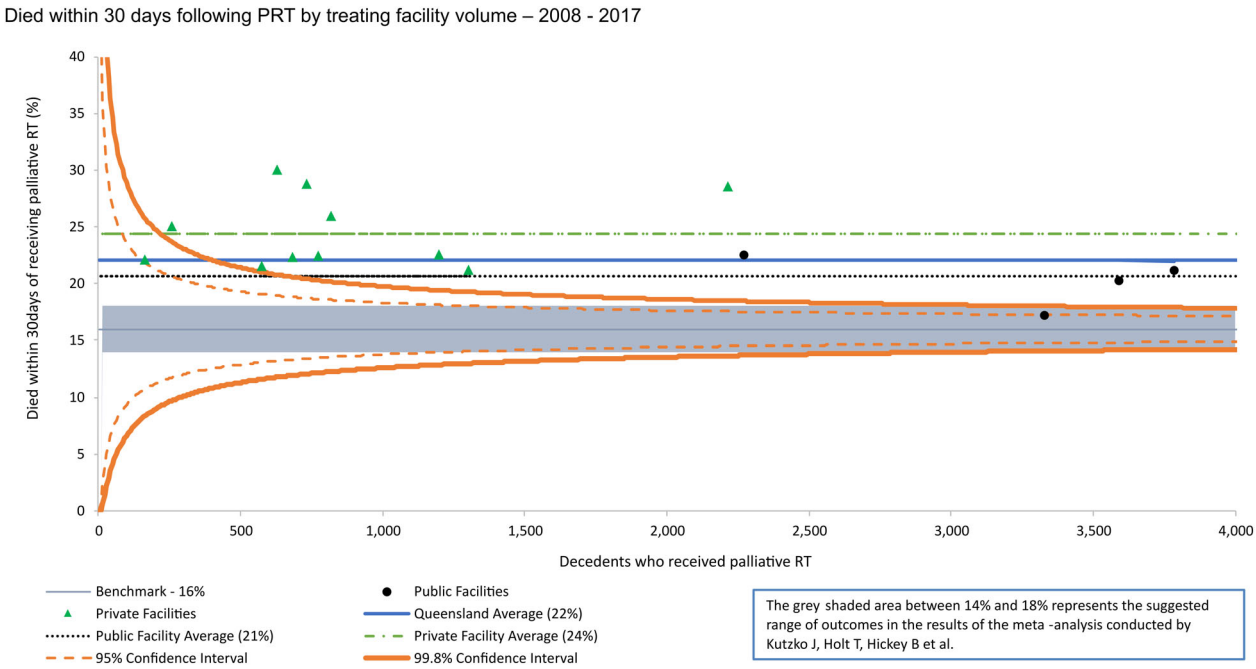

Fig. 2. Funnel plot of died within 30 days following PRT by facility.

with shorter fractions for patients in the public system reflects a different patient case mix. Several clinical practice guidelines recommend single fractionation schedules for patients with symptomatic bone metastases which has been shown to be as effective as multiple fractions, particularly in the setting of a predicted prognosis of less than 6 months where retreatment rates are less important.[1,23]

In this study, a disproportionately high number (26.5%) of patients who died within 30 days of completing PRT received a course of treatment of more than five fractions. Again, a significant discrepancy is evident between public and private facilities. It was beyond the scope of this study to further assess this subgroup of patients however it is important for individual centres where possible to audit and assess which patients may have been better served with shorter courses of treatment.

Where to from here?

Overall, the 30 day mortality for PRT in Queensland is above the global average and proposed benchmark of 16% as recommended in the recent meta-analysis of 30 day mortality after palliative radiotherapy[18] and above that reported in a recent New Zealand study (10%)[24] and from two other Australian-based studies which ranged from 8% to 15%.[25,26] There are multiple ways we can improve clinical management to reach this target. The first is through education of both existing radiation oncologists and radiation oncology trainees and encouraging the use of tools to aid in EOL prognostication and treatment decision making. Additionally, patient education regarding prognosis is an important part of clinical management to allow them to make informed treatment decisions weighing up potential benefit versus treatment time and toxicity. Several studies have reported clinical care is more aggressive near EOL for patients who are more optimistic of their life expectancy.[27,28]

The second is through clinical audit, to introduce this metric into all Queensland centres that provide RT services, with audits done at the individual site level, such as incorporating 30 day mortality into a regular morbidity and mortality meeting. Following a period of education and audit at the individual site level, the intention is to repeat the current central audit with a similar feedback process to all sites hoping to see with education an improvement in 30-day mortality rates and a reduction in the number of patients being treated with long fractionation schedules at EOL.

While the recent meta-analysis by Kutzko *et al*.[18] identified a 30 day mortality following PRT benchmark of 16%, given that several studies globally have reported 30-day mortality rates following PRT as low as 5–10%[24,25,30] we encourage individual RT centres throughout Australia and New Zealand to strive for as low a rate as possible taking into account each site's individual patient case mix, while being mindful of the potential for

underutilisation or overutilisation of PRT based on the adopted benchmark.

Limitations

While this was a large population-based study that included all radiation activity in Queensland over a 10-year period, there are some limitations. First, we did not have access to performance status, which has been shown to be a significant predictor for use of PRT. We did however have access to number of comorbidities and included this variable in our modelling. We additionally did not have access to details of individual clinician clinical experience nor patient preference. Further, we were unable to undertake any in depth analysis at an individual site level of reasons behind the differences observed between sites. These data comes from the period 2008–2017: it is possible that from 2018 to the present more sites have adopted the clinical guidelines that were published after 2017, which have recommended short fractionation schedules for poor prognosis patients.[9,23] Specific anatomic sites treated with radiotherapy were not differentiated and therefore the ability to examine the appropriateness of the fractionation schedule may also be limited. While there is evidence to support using 30 day mortality following PRT as a quality metric for centres, it remains that for some patients, single fraction PRT within 30 days of death will be appropriate to palliate pain or bleeding. This has been discussed in depth in a narrative review by Navarro-Domenech *et al*.[29] and case by case appropriateness of treatment can be easily evaluated in individual centres within morbidity and mortality meetings.

In conclusion, The 30-day mortality rate in Queensland is higher than expected and more can be done to reduce this, as well as increasing the use of short course and single fraction treatment schedules at EOL. Clinician and trainee education, better prognostication tools and ongoing audit are needed to achieve this goal in Queensland, and we encourage other Australian centres to look at their own rates and encourage collaboration for 30 day mortality to become a national and international quality metric.

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Conflict of interest

The authors have no relevant financial or non-financial interests to disclose.

Ethical approval

This study was conducted under the auspices of the Queensland Cancer Control Safety and Quality Partnership, a gazetted quality assurance committee under Section 82 of the Hospital and Health Boards Act (2011). This legislation allows The Partnership to access identifiable information to fulfil its functions including undertaking clinical research.

Data availability statement

The datasets generated during and/or analysed during the current study are not publicly available due to confidentiality but are available from the corresponding author on reasonable request.

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