An update of patterns of care and outcomes for men diagnosed with prostate cancer in Victoria

Running head: Patterns of care for men with prostate cancer

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Abstract:

Backgrounds:

To update patterns of care for men diagnosed with prostate cancer in Victoria, Australia, between 2008 and 2015.

Materials and methods:

From August 2008 to December 2015, 14,025 men diagnosed with prostate cancer were included. These data were obtained from the Prostate Cancer Outcome Registry – Victoria (PCOR-Vic). Frequencies were used to describe hospital and patient characteristics and treatment types. Comparisons were made between previous period of analysis (2008-2011) to the most recent period (2011-2015). Survival analysis using a stepwise Cox proportional hazards regression model was performed.

Results:

Mean age of diagnosis was 66.5 years and 44% of patients were diagnosed with Gleason 7 prostate cancer. Majority of notifications (63.6%) were received from a private institution and 70.2% of patients were diagnosed at a metropolitan institution. Most patients (95.3%) were diagnosed with clinically localised disease. Within 12 months of diagnosis, 55.9% of patients with low risk disease received no active treatment. Radical prostatectomy (RP) was the most common primary treatment with curative intent (47%). When comparing of patterns of care between 2008-2011 and 2011-2015, the proportion of patients diagnosed with Gleason 9-10 disease increased, as has the proportion of patients diagnosed with metastatic disease.

Conclusion:

With the PCOR-Vic, we were able to identify that increasing number of patients were diagnosed with high-risk and metastatic disease. There has been an overall decrease in radical treatment rates, likely due to active surveillance playing a significant role especially in patients with low risk prostate cancer.

Keywords: prostate cancer, patterns of care, registry, health services research

Introduction

Australia has one of the highest incidences of prostate cancer in the world¹, representing a major public health issue and placing a significant burden on health resources. Between 2008 and 2012, the Australian Institute of Health and Welfare² estimated that there were over 94,000 men living with prostate cancer.

In 1993, the epidemiology and management of prostate cancer in Victoria were first reported through a large population-based survey³. To more comprehensively and prospectively monitor treatment and outcomes for men

following a prostate cancer diagnosis, the Prostate Cancer Outcome Registry-Victoria (PCOR-Vic, formally known as the Victorian Prostate Cancer Registry (Vic-PCR)) was established in 2009. Evans et al⁴ first reported the patterns of care for men with prostate cancer from this population-based registry. Further analysis of PCOR-Vic has described the use of active surveillance for localised prostate cancer⁵, positive surgical margins in men undergoing radical prostatectomy⁶, and quality improvements seen in both of these areas over the duration of PCOR-Vic⁷.

Of note, since the inception of PCOR-Vic, there have been significant developments in prostate cancer diagnosis and management in relation to PSA screening^{8,9}, randomised trials comparing prostatectomy to observation^{10,11,12}, or comparing radical prostatectomy to radiation or active monitoring¹³. Finally, we have also seen an increase in the utilisation of active surveillance as a management strategy for low risk disease^{7,14,15}. The grade D recommendation of the United States Preventive Services Taskforce (USPSTF) against PSA testing in 2012 resonated very strongly, and despite efforts to mitigate the negative messaging regarding early detection of prostate cancer¹⁶, there has been a significant reduction in PSA testing, prostate biopsies, and diagnoses of prostate cancer, not just in the USA¹⁷, but also in Canada¹⁸ and Australia¹⁹.

In this rapidly shifting landscape of prostate cancer management, we aim to update the patterns of care and outcomes in Victorian men with prostate cancer. By comparing patterns of care in 2008-2011 to 2011-2015, shifting trends influenced by new guidelines and evidence may be identified.

Methods

The purpose of the PCOR-Vic is to monitor patterns of care and outcomes of men diagnosed with prostate cancer in Victorian hospitals. Details of PCOR-Vic and methods of data collection have been previously described²⁰. We analysed data in PCOR-Vic to determine patterns of care of men diagnosed with prostate cancer between 2008 and 2015, and to identify temporal changes during this period.

Inclusion and exclusion criteria

Patients were included in this study if they had a statutorily-required notification to the Victorian Cancer Registry of a histological diagnosis of prostate cancer between 1st August 2008 and 31st December 2015, and had also attended at a participating hospital with both ethical approval from the recruiting hospital's human research ethics committee and consent from clinicians to include all their patients in the registry.

Recruitment and data collection

Notifications from 33 public and six private institutions were progressively added to PCOR-Vic. Following notification of prostate cancer diagnosis, an explanatory statement was sent to the patient approximately 10 months after diagnosis explaining that their information would be included in the registry unless they chose to opt off.

Clinical details and histopathological data were collected from medical records, or extracted from hospital information systems and pathology reports prior to the 12-month telephone follow-up. The phone call was used to administer a quality of life tool and confirm PSA levels and treatment details. Treatments provided within 12 months of diagnosis were included in the analysis.

Statistical Analysis

Frequencies were used to describe hospital and patient characteristics. Proportions were also used to describe treatment types according to National Comprehensive Cancer Network (NCCN) risk of disease progression categories. The very low risk NCCN category was not used because PCOR-Vic does not collect PSA density, necessary for this assignment. If a patient had a Gleason score ≤ 6 and a PSA level $<10\text{ng/ml}$ at diagnosis but there was no clinical T stage

recorded, they were classified as having low risk disease. For treatment analysis, patients who were recorded as 'active surveillance' or 'watchful waiting', and patients who had no documentation of treatment, were recorded as having no active treatment within 12 months of their diagnosis.

A multivariate logistic regression analysis was also undertaken using these categorical predictor variables to assess the odds of not receiving treatment. Furthermore, for the descriptive characteristics, treatment frequencies, analysis compared the previous period of analysis (2008-2011) to the most recent period (2011-2015).

Survival analysis using a stepwise Cox proportional hazards regression model (probability of inclusion = 0.05) was undertaken to assess characteristics associated with mortality. All statistical analyses were performed using STATA/IC version 14.2 (StataCorp, College Station, TX), and a two-sided P value < 0.05 was considered statistically significant.

Ethics Approval

Institutional review board approval for this project was obtained from Monash University's Human Research Ethics Committee (Review reference 2016-0999-1070).

Results

Recruitment

The recruitment of patients into PCOR-Vic are summarised in FigureS1. A total of 19,319 prostate cancer notifications were assessed for eligibility by PCOR-Vic. In total, 2,975 men (15.4%) were ineligible. Of the 16,344 who were eligible, 426 patients did not provide consent for participation and 185 consents were pending. Of the 15,733 men who did not opt out of the registry, treatment details were collected on 14,025 (89%) men.

Hospital and patient characteristics

Hospital and patient characteristics are summarised in Table 1. The majority of patients were diagnosed at metropolitan hospitals (70.2%) and there were more than twice the number of notifications from the private sector (63.6%) compared to that of the public (31%). Years with the highest number of notifications of diagnosis were in 2011 and 2012, accounting for 17.3 and 17.7% respectively. Mean age at diagnosis was 66.5 years (SD=8.99). Median PSA level was 6.8 (interquartile range = 4.8-11ng/mL). The majority of the patients

(13,366, 95.3%) were classified as having clinically localised disease, and 43.3% (6070) of the patients were classified as being at intermediate risk of disease progression.

Management details

Management types and their breakdown according to risk of disease in the initial 12 months following diagnosis are summarised in Table 2. A total of 3349 (23.9%) patients received no active treatment. Of the 3466 patients with low risk disease, 1937 (55.9%) received no active treatment. Comparing public and private sectors, 25.4% and 24.1% of patients received no active treatment, respectively; 24.5% of patients from metropolitan and 24.6% of regional patients received no active treatment. Radical prostatectomy (RP) was the most common primary treatment with curative intent (47%). Of the patients who underwent RP, 2.3% did not have an approach recorded. Of those that did, 55.7% of the cases were robotic-assisted RP, 38.2% had open RP and 6.1% had laparoscopic approach. Comparing public and private, 28.7% and 50.2% of patients underwent RP, respectively; 46.5% of patients from metropolitan and 34% of regional patients underwent RP. Overall, 2990 (21.3%) cases of radiation treatment with curative intent were recorded; this includes external beam radiation therapy (EBRT) (15.7%), brachytherapy (BT) (4.8%) and combination

EBRT and high dose BT (0.9%). Further details of management are listed in Table 2.

Multivariable logistic regression analysis of factors associated with men not receiving active treatment within 12 months of diagnosis is shown in TableS1. Being over the age of 75 at diagnosis was associated with reduced likelihood of receiving active treatment and being diagnosed with higher risk disease was associated with increased likelihood of receiving active treatment.

Mortality

There was a total of 402 prostate cancer-related deaths in the period between diagnosis and follow-up in the study period of 2008-2015. Over half of the mortality notifications were from metropolitan institutions (247 [61.4%]) and 223 (55.5%) patients who died were diagnosed in a public hospital (TableS2). Stepwise multivariate Cox regression analysis of factors associated with mortality is shown in TableS3. Patients diagnosed with a Gleason score >6 were 2.1 times more likely to die (95% CI: 1.78-2.41, $p<0.001$) as compared to those with Gleason scores ≤ 6 , after accounting for other significant risk factors. Other factors significantly associated with increased risk of prostate cancer mortality are: diagnosis made in a regional hospital (HR 1.42; 95% CI:1.09-1.84; $p=0.010$), age >55 years at diagnosis (HR 1.49; 95% CI:1.31-1.69; $p<0.001$), PSA >10 ng/ml

at diagnosis (HR 1.52;95% CI 1.27-1.81; $p<0.001$), Gleason score (HR 2.07;95% CI 1.78-2.41; $p<0.001$),and NCCN risk category higher than low risk of disease progression (HR 2.22;95% CI 1.92-2.56; $p<0.001$).

Comparison of patterns of care between 2008-2011 and 2011-2015

Comparisons of hospital characteristics and patient demographics data are shown in TableS4. There was an increase in the proportion of notifications received from private as well as regional hospitals, in the period from 2011-2015, reflecting the patterns of recruitment to the PCOR-Vic. The proportion of patients diagnosed with Gleason 9-10 disease increased, as has the proportion of patients diagnosed with metastatic disease in the same time period.

Discussion

By increasing coverage of the Victorian health network, PCOR-Vic provides potential for high quality data in a clinician-led governance framework to monitor care and outcomes. Here we documented an update to the previous patterns of care publication. It was noted that the majority of the prostate cancer notifications were from metropolitan hospitals and the private sector. The majority of patients were classified as having clinically localised disease, and

intermediate risk of disease progression was the most commonly reported NCCN risk category. Regarding prostate cancer treatment, RP was the most common primary treatment with curative intent, and active surveillance has played a bigger part in the management of patients with low-risk of disease.

Localised prostate cancer makes up most of all diagnosed prostate cancers. Approximately 18% of localised prostate cancers are graded as low risk in the PCOR-Vic. From 1990 to 2010, more than 90% of patients diagnosed with low-risk prostate cancer received radical treatment²¹. Subsequent evidence regarding the indolent nature of low-grade disease (15-year mortality risk of 2-3%²²) as well as the favourable outcome with conservative management resulted in the increased uptake in AS. AS has also become an important management option for prostate cancer patients in Victoria as we have identified that 55.89% of the low risk disease group received AS or watchful waiting.

Overall, surgical management remained the most common primary treatment with curative intent and the robotic RP has become the most common approach. This is likely partly because PCOR-Vic did not receive notifications from facilities performing robot-assisted RP (RARP) before December 2010 but also represents the growth of robotic surgery in Australia. The level of usage in Victoria, however, is still low compared to counterparts in USA, where in some regions >75% of all RP's are performed using robotic approach²³. It is clear from our

data that RARP has superseded open surgery as the most common surgical option for prostate cancer in Victoria.

Since early 1990, PSA testing represents the mainstay of screening for prostate cancer. In October 2011, the U.S. Preventive Services Task Force (USPSTF) reviewed available evidence and concluded that PSA testing resulted in a negligible reduction in prostate cancer-related mortality²⁴. In the final recommendation in May 2012, the USPSTF issued grade D recommendation against PSA screening⁸. In 2016, the new Australian guidelines were published²⁵. Similarly, the guidelines do not recommend a population-based screening program for prostate cancer. The key recommendations are to offer evidence-based decisional support to men considering a PSA test accounting for benefits and harms. Most recently, the USPSTF has released a draft recommendation statement, issuing grade C recommendation for screening in men aged 55-69⁹. This recommendation encourages individualized and informed decision-making about screening after discussion with a clinician⁹.

In Australian, we have seen a clear decline of prostate cancer incidence over the last few years, which may be attributed to a decrease in PSA screening rates. Lo et al²⁶ examined health service data from 2001 to 2014 to study prostate cancer screening rates in Australia. Findings suggest that PSA screening rates in Australia have been in decline since 2008, with highest rates of screening seen in

patients aged 65-74 years (an annual average of 21,453 per 100,000 men)²⁶.

These findings were similar to the results from USA databases. Jemal et al²⁷ analysed Surveillance, Epidemiology and End Results (SEER) data, and found an 18% relative decrease in PSA testing, from 37.8% in 2010 to 30.8% in 2013.

We have noted the proportion of patients diagnosed with Gleason 9-10 disease has increased, as has the proportion of patients diagnosed with metastatic disease in the period of 2011-2015 compared to 2008-2011. This corresponds to some of the current available evidence. A number of studies utilised the National Cancer Database (NCDB) and reported increased diagnoses of clinical stage T3a or higher, including metastatic disease^{28,29}. Other studies of the NCDB data also showed a decrease in low-risk cases, from 31.9% in 2011 to 25.9% in 2013, and a corresponding increase in intermediate- risk (43.5% to 45.1%) and high-risk (24.5% to 29%) cases²⁸. We suspect this finding could be due to the fact that the screening rates in younger men, who are more likely to harbour lower grade and stage of disease, have decreased more than the screening rates of elderly men. This could have caused a shift to higher proportion of high risk and metastatic disease. This is supported Lo et al²⁶, whose results demonstrated significant downward trend of PSA screening rates since 2008 for all age groups except for men aged over 85 years.

We assessed whether patient demographics were associated with different outcomes. The majority of notifications received by PCOR-Vic came from metropolitan institutions and the private sector. These patterns were similar compared to the previous period of analysis. We also noted that a higher percentage of prostate cancer specific mortality occurred in the public sector compared to private. Our findings were similar to a Western Australian population-based study examining the effects of demographic, geographical and socio-economic factors, and the influence of private health insurance, on prostate cancer care and 3-year survival³⁰. Results demonstrated poorer 3-year survival in men from socioeconomically and geographically disadvantaged backgrounds, particularly those admitted to regional or public hospitals³⁰. Interestingly, our data did not demonstrate regional hospitals having higher rates or significant association with mortality. This could be partly explained by the significantly higher notification rate from the metropolitan hospitals.

The limitations of our study need to be acknowledged. The PCOR-Vic does not have 100% population coverage (current population coverage is 75%); therefore, it is not possible to extract accurate incidence data. There are a proportion of patients with incomplete data and this contributes to the inaccuracies of interpretations. In our dataset, a proportion of clinical T-stage data was missing. This is because it is not routinely recorded in some practices or hospitals. Regarding analysis of predictor of survival, year of diagnosis was

explored to be a predictor, however due to its collinearity with the multivariate cox regression model, this was unable to be assessed fully. As the PCOR-Vic records treatment information in 12-monthly intervals, patients initially on AS progressing to active treatment within 12 months may not be recorded as initially being on AS. This could lead to underestimation of the number of patients on AS. Lastly, the registry does not collect information regarding medical co-morbidities or frailty indices.

Conclusion

With the PCOR-Vic, we were able to identify that increasing number of patients were diagnosed with high-risk and metastatic disease. There has been an overall decrease in radical treatment rates, especially in patients with low risk prostate cancer, likely due to active surveillance playing a significant role. This update of patterns of care for Victorian prostate cancer patients is important for monitoring trends over time to ensure quality of care, especially in the rapidly changing landscape of prostate cancer management.

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Supporting information:

TableS1

Multivariable logistic regression analysis of factors associated with men not receiving active treatment within 12 months of diagnosis (2008-2015)

TableS2

Comparison of proportions of prostate cancer specific mortality by hospital and risk of disease progression between Aug 2008-Feb 2011 and Mar 2011-Dec 2015.

TableS3

Stepwise multivariate cox regression analysis of factors associated with mortality.

TableS4

Comparisons of hospital characteristics and patient demographics between Aug 2008-Feb 2011 and Mar 2011-Dec 2015.

FigureS1

Patient recruitment for the PCOR.

Tables:**Table 1: Hospital and patient characteristics**

Number (%) of patients	
Hospital Characteristics	
Type of Hospital	
Public	4,350 (31%)
Private	8,923 (63.6%)
Interstate/Overseas	189 (1.4%)
Unknown	563 (4%)
Location of Hospital	
Metro	9,847 (70.2%)
Regional	3,318 (23.7%)
Interstate/Overseas	189 (1.4%)
Unknown	671 (4.8%)
Patient Characteristics-Age	
<55 years	1,689 (12%)
55-64 years	5,083 (36.2%)
65-74 years	5,231 (37.3%)

75-84 years	1,722 (12.3%)
>=85 years	300 (2.1%)
Gleason Score	
6 or less	4,472 (31.9%)
7	6,171 (44%)
8	1,367 (9.8%)
9	1,407 (10%)
10	121 (0.9%)
Unknown	487 (3.5%)
Prostate-specific antigen (PSA) level	
<=10 ng/mL	9,693 (69.1%)
10.01-20 ng/mL	2,226 (15.9%)
>20 ng/mL	1,614 (11.5%)
Unknown	492 (3.5%)
Risk of disease progression	
Low risk (clinically localised)	3,466 (24.7%)
Intermediate risk (clinically localised)	6,070 (43.3%)
High risk (clinically localised)	3,024 (21.6%)
Very high risk (locally advanced)	149 (1%)
Metastatic disease	875 (6.2%)
Unknown	441 (3.1%)
cT Stage	
T1	5,772 (41.2%)

T2	3,702 (26.4%)
T3	1,053 (7.5%)
T4	147 (1.1%)
Unknown	3,351 (23.9%)
cN Stage	
1 – NX	95 (0.7%)
2 – N0	13,271 (94.6%)
3 – N1	437 (3.1%)
4 – Unknown	222 (1.6%)
cM Stage	
MX	68 (0.5%)
M0	12,995 (92.7%)
M1	202 (1.4%)
M1a	23 (0.2%)
M1b	481 (3.4%)
M1c	48 (0.3%)
Unknown	208 (1.5%)

Table 2: Overall treatment in the initial 12-month period following diagnosis according to NCCN risk category (2008-2015).

Frequency of principal treatment types according to risk of disease progression at diagnosis (n=14,025) - Treatments occurring within 12months of diagnosis								
	Low Risk	Intermediate Risk	High Risk	Total (clinically localised categories)	Very High Risk	Metastatic Disease	Unable to Classify (likely low risk)	Total (all risk categories)
No Active Treatment	1937 (55.89%)	932 (15.35%)	260 (8.60%)	3129 (24.91%)	4 (2.68%)	21 (2.40%)	195 (44.22%)	3,349 (23.88%)
Radical Prostatectomy	1136 (32.78%)	3551 (58.50%)	1144 (37.83%)	5831 (46.43%)	24 (16.11%)	82 (9.37%)	129 (29.25%)	6066 (43.25%)
Radical Prostatectomy and External Beam Radiation Therapy	30 (0.87%)	210 (3.46%)	235 (7.77%)	475 (3.78%)	11 (7.38%)	22 (2.51%)	11 (2.49%)	519 (3.70%)
External Beam Radiation Therapy	105 (3.03%)	835 (13.76%)	890 (29.43%)	1830 (14.57%)	69 (46.31%)	258 (29.49%)	40 (9.07%)	2197 (15.66%)
Brachytherapy-Unknown	16 (0.46%)	35 (0.58%)	7 (0.23%)	58 (0.46%)	0 (0.00%)	1 (0.11%)	12 (2.72%)	71 (0.51%)
Low Dose Rate Brachytherapy	212 (6.12%)	334 (5.50%)	7 (0.23%)	553 (4.40%)	0 (0.00%)	1 (0.11%)	7 (1.59%)	561 (4.00%)
High Dose Rate Brachytherapy	2 (0.06%)	24 (0.40%)	8 (0.26%)	34 (0.27%)	2 (1.34%)	0 (0.00%)	0 (0.00%)	36 (0.26%)
External Beam Radiation Therapy and High Dose Rate Brachytherapy	0 (0.00%)	38 (0.63%)	81 (2.68%)	119 (0.95%)	3 (2.01%)	1 (0.11%)	2 (0.45%)	125 (0.89%)
Androgen Deprivation Therapy	14 (0.40%)	96 (1.58%)	384 (12.70%)	494 (3.93%)	35 (23.49%)	421 (48.11%)	38 (8.62%)	988 (7.04%)

HIFU	12 (0.35%)	12 (0.20%)	1 (0.03%)	25 (0.20%)	0 (0.00%)	1 (0.11%)	0 (0.00%)	26 (0.19%)
Chemotherapy	1 (0.03%)	2 (0.03%)	4 (0.13%)	7 (0.06%)	1 (0.67%)	66 (7.54%)	6 (1.36%)	80 (0.57%)
Other	1 (0.03%)	1 (0.02%)	3 (0.10%)	5 (0.04%)	0 (0.00%)	1 (0.11%)	1 (0.23%)	7 (0.05%)
Total (all treatment categories)	3466 (24.71%)	6070 (43.28%)	3024 (21.56%)	12560 (89.55%)	149 (1.06%)	875 (6.24%)	441 (3.14%)	14,025(100%)

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