Survival after radical prostatectomy and radiotherapy for prostate cancer: a population-based study

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Abstract

Objective: Based on the natural history of localized prostate cancer, the life expectancy (LE) of men treated with either radical prostatectomy (RP) or definitive external-beam radiotherapy (EBRT) should exceed 10 years. To test this hypothesis, we examined overall survival rates after RP or EBRT in a contemporary population–based cohort.

Methods: Within a population-based cohort we assessed crude survival in 17 570 men diagnosed with prostate cancer who were either treated with RP (n = 9678) or definitive EBRT (n = 7892) between 1989 and 2000. Age and Charlson Comorbidity Index (CCI) score at treatment represented covariates. In order to control for prostate cancer–related mortality, we repeated analyses for 9131 men who did not receive any secondary treatment for prostate cancer.

Results: In the entire cohort, the actuarial 10-year survival probability after RP was 75.3%, versus 36.7% after EBRT ($p < 0.001$). In those who did not receive any secondary treatment, the actuarial 10-year survival probability after RP was 81.1%, versus 30.4% after EBRT ($p < 0.001$). In multivariate Cox regression models, EBRT was associated with a 2.8-fold ($p < 0.001$) and 3.9-fold ($p < 0.001$) higher risk of mortality in the entire cohort and in the cohort without secondary treatment, respectively. Increased CCI score and increased age were also associated with a higher risk of mortality ($p < 0.001$).

Conclusion: Some men treated with EBRT and, to a lesser extent, those treated with RP may have insufficient LE to warrant therapy with curative intent. More stringent selection criteria are necessary to avoid overtreatment.

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Résumé

Objectif : Si on se fie à l'évolution naturelle du cancer localisé de la prostate, l'espérance de survie après une prostatectomie radicale (PR) ou une radiothérapie externe (RE) définitive devrait être supérieure à 10 ans. Pour vérifier cette hypothèse, nous avons examiné les taux de survie globaux après ces deux types d'interventions dans une cohorte représentative récente.

Méthodologie : Dans une cohorte représentative, nous avons évalué le taux brut de survie chez 17 570 hommes atteints d'un cancer de la prostate ayant subi une PR (n = 9678) ou une RE définitive (n = 7892) entre 1989 et 2000. L'âge et l'Indice de comorbidités de Charlson (ICC) en cours de traitement étaient les covariables examinées. Afin de mesurer la mortalité attribuable au cancer de la prostate, les analyses ont été répétées chez 9131 hommes n'ayant reçu aucun traitement secondaire pour leur cancer.

Résultats : La probabilité actuarielle de survie après 10 ans était de 75,3 % pour la PR contre 36,7 % pour la RE définitive ($p <$ 0,001) dans la cohorte entière et de 81,1 % pour la PR contre 30,4 % pour la RE définitive ($p < 0,001$) chez les patients n'ayant reçu aucun traitement secondaire. Dans des modèles de régression multivariable de Cox, la RE a été associée à un risque 2,8 fois ($p < 0,001$) et 3,9 fois ($p < 0,001$) plus élevé de mortalité dans la cohorte entière et dans la cohorte n'ayant reçu aucun traitement secondaire, respectivement. On a aussi établi un lien entre un risque plus élevé de mortalité d'une part, et un ICC plus élevé et un âge plus avancé d'autre part ($p < 0,001$).

Conclusion : L'espérance de survie de certains hommes traités par RE et, dans une moindre mesure, de certains hommes traités par PR pourrait être trop faible pour justifier un traitement à but curatif. Des critères de sélection plus rigoureux sont donc requis afin d'éviter tout traitement excessif.

Introduction

Radical prostatectomy (RP) and definitive external-beam radiotherapy (EBRT) represent the principal treatment modalities with curative intent for men with localized prostate cancer. The main alternative consists of brachytherapy, active surveillance, observation followed by androgen withdrawal, observation alone or androgen withdrawal alone.[1–3] The most recent decision analysis of alternative treatment modalities for localized prostate cancer suggests that potentially curative therapy results in a life expectancy (LE), as well as a quality-adjusted LE gain, up to the age of 80 years in men with poorly differentiated (Gleason score 7–10) prostate cancer.[4,5] In the presence of moderately differentiated prostate cancer (Gleason score 5–6), LE and quality-adjusted LE gains can be expected up to the age of 75 years.[4] These estimates are different from those suggested in a previous decision analysis, where potentially curative therapy was no longer suggested to men aged 70 years or older.[6]

In Canada, the average LE of men aged 65 years is 16.5 years. For men aged 75 years, it is 10 years, and for men aged 80 years it is 7.5 years.[7] In men with prostate cancer, LE is modified by the severity of general comorbidities.[2,8] Albertsen and colleagues,[2] in their series of men treated with watchful waiting or with androgen withdrawal alone, demonstrated that 63% of those with intermediate grade (Gleason score sum 6) prostate cancer, aged 65 to 69 years at diagnosis, die of noncancer causes. Therefore, recommendations favouring therapy with curative intent in older patients may result in significant overtreatment, as the LE of these patients may be undermined by age and comorbidity. To explore the issue of potential overtreatment, we examined crude survival in 17 570 men treated with either RP or definitive EBRT, between 1989 and 2000.

Methods

Study cohort

The Quebec Health Insurance Plan (Régie de l'assurance maladie du Quebec [RAMQ]) represents the exclusive insurer in the province of Quebec. Its database allows ascertainment of all health services covered by the plan and provided in Quebec. These include all treatment modalities for prostate cancer, including definitive EBRT, RP, bilateral orchiectomy and hormonal therapy (HT). Specific diagnostic codes were used to define the therapy delivered to patients with localized prostate cancer versus that delivered to patients with palliative intent. The number of radiotherapy sessions was used to further validate definitive from palliative radiation. Moreover, the RAMQ relies on the International Classification of Diseases, ninth revision, (ICD-9) codes and their respective dates, which allow defining the Charlson Comorbidity Index (CCI) scores at the time of definitive therapy.[9] The CCI quantifies important comorbidities and has been successfully used for risk-adjustment in health outcomes research.[10,11] We used the score specification of the CCI developed by D'Hoore and colleagues[11] to adapt it for the use of data relying on ICD-9 diagnostic codes. Finally, the plan provides crude survival data for all enrollees.

The RAMQ database allowed us to identify all men treated with either RP or definitive EBRT, between Jan. 1, 1989, and Dec. 31, 2000. All men were diagnosed with prostate cancer (ICD-9 185–9). Each record included the region of residence, the type of treatment, the date of RP or definitive EBRT, age at treatment, vital status up to July 31, 2004, as well as the CCI score. Patients who left Quebec were censored at the time of their last follow-up. The RAMQ records contain no information on stage, grade or serum prostate-specific antigen levels. The analyses targeted 17 570 evaluable patients, of which 9678 were treated with RP and 7892 received definitive EBRT. The data set used for the comparisons represents claim files and were provided by the RAMQ. The mortality rates within this data set reflect mortality rates that are used by the Quebec Institute of Statistics. Unfortunately we have no means to test the validity of the Quebec Institute of Statistics mortality rates. To the best of our knowledge, no random sample of RAMQ records has ever been validated against data from patient charts.

To exclude the influence of prostate cancer–specific mortality on overall survival, all analyses were repeated in a subgroup of men who did not receive any secondary treatment. Secondary treatment was defined as either EBRT after RP or RP after EBRT. Alternatively, any type of HT after either RP or definitive EBRT was considered secondary therapy. Hormonal therapy consisted of either medical castration, including steroidal or nonsteroidal antiandrogens or bilateral orchiectomy (ICD-9 624). Finally, we excluded patients with EBRT who had received androgen deprivation therapy in an adjuvant setting. This may account for the lower than expected proportion of EBRT patients.

In the restricted analyses, we also excluded records of men treated with any form of HT before, during or immediately after RP (0–6 mo) or EBRT (0–12 mo). Hormonal therapy during that period may confound the relation between primary treatment and the need for secondary treatment. It is also difficult to establish whether HT within 0 to 12 months after EBRT or within 0 to 6 months after RP is based on adjuvant or salvage criteria. Based on the same considerations, we also excluded men treated with bilateral orchiectomy before or at any point after EBRT or RP.

Statistical analyses

The statistical analyses relied on χ^2 test, independ-

ent sample *t* test, Kaplan–Meier method, life table and Cox regression analyses, which targeted overall mortality. In univariate and multivariate Cox regression models the covariates included age at treatment, CCI score and treatment type. All statistical tests were performed using S-PLUS Professional, version 1 (MathSoft, Inc.). All tests were 2-sided with significance level set at $p = 0.05$.

Results

In the province of Quebec, between 1989 and 2000, 17 570 patients were treated with either RP or definitive EBRT for prostate cancer (Table 1). Radical prostatectomy was performed for 9678 (55.0%) patients and definitive EBRT was delivered to 7892 (45.0%) patients. Follow-up ranged from 0.1 to 15.5 (mean 6.3, median 5.9) years. The median actuarial survival for the entire cohort was 12.1 (mean 10.2) years. Mean follow-up of RP and EBRT patients was, respectively, 7.5 (median 7.2) years and 4.8 (median 4.4) years. The median actuarial survival was not reached in the RP cohort (mean 12.4) and was 7.3 (mean 6.8) years in the EBRT cohort. The median age at the time of treatment was 68 years, for the entire cohort (RP: 65 yr; EBRT: 71 yr) and the median CCI score was 1 (RP: 1; EBRT: 2; $p < 0.001$).

Figure 1 shows the Kaplan–Meier plot of overall survival in the cohort of 17 570 men. The treatment-specific survival curves differed in a statistically significant fashion (log rank $p < 0.001$; Fig. 2). In life table analyses, at 1, 5, 10 and 15 years after RP, the survival probability estimates were, respectively, 98.5%, 90.7%, 75.3% and 52.3%. For the same time points after EBRT, the survival probability estimates were 80.3%, 57.8%, 36.7% and 19.8%.

Table 2 shows the univariate and multivariate Cox regression models addressing crude survival in the overall population of 17 570 men. In univariate analyses, the rate of overall mortality was 4.2-fold higher if definitive EBRT was delivered instead of RP ($p < 0.001$). After adjustment for age and CCI the rate of overall mortality remained 2.8-fold higher for those treated with EBRT versus RP ($p < 0.001$). The multivariate effect of age indicated that relative to the youngest category of men (55–59 yr), the mortality rate was 1.3- to 7.3-fold higher in older men. The multivariate effect of CCI also indicated that relative to men with a score of 0, the mortality rate was 1.3- to 3.3-fold higher in men with scores of 1 and above.

The 9131 patients (RP: $n = 5955$; EBRT: $n = 3176$) who did not receive secondary treatment represent the focus of the second analysis (Table 3). Follow-up ranged from 0.1 to 15.5 (medians: overall 5.9, RP 7.0, EBRT 3.9) years. Median actuarial survival was 13.8 (mean 10.7) years. The median actuarial survival was not reached in the RP cohort (mean 13.0 yr) and was 4.7 (mean 6.4) in the EBRT cohort. Age and CCI score had a similar distribution as in the entire cohort.

Figure 3 shows the overall survival Kaplan–Meier plot in the cohort without secondary treatment. The treatment-specific survival curves differed in a statistically significant fashion (log rank $p < 0.001$; Fig. 4). In life table analyses, at 1, 5, 10 and 15 years after RP, the survival probability estimates were, respectively, 98.1%, 92.0%, 81.1% and 61.9%. For the same time points after EBRT, the survival probability estimates were 74.2%, 48.8%, 30.4% and 17.9%.

Table 4 shows univariate and multivariate Cox regression models in the cohort of 9131 patients, who did not receive secondary treatment. Overall mortality was 6.6-fold higher after EBRT versus RP ($p < 0.001$) and remained 3.9-fold higher in multivariate analyses ($p < 0.001$). The direction and the magnitude of age and CCI were virtually the same as for the entire cohort (Table 4).

Discussion

In this analysis we address the issue of LE after therapy for prostate cancer with curative intent. The descriptive analyses of the overall cohort (Table 1) show that men treated with EBRT were older than their surgical counterparts (71 v. 65 yr, $p < 0.001$). This finding is consistent with data from the United States, where EBRT is delivered more frequently than RP in older men.[12] Moreover, EBRT recipients had more baseline comorbidities, evidenced by a median CCI score of 2 versus 1 for men treated with RP ($p < 0.001$). The life table analysis indicates median survival of 12.1 years. This is worrisome, as it implies that 50% of the cohort died at the 12.1-year time point (Fig. 1). Stratification according to treatment type indicates that men treated with RP exhibit substantially better survival than their counterparts treated with EBRT (log rank $p < 0.001$). The median survival of the surgical

cohort was not reached. Conversely that of the EBRT cohort was only 7.3 years. In life table analyses, the 10-year actuarial survival of men treated with RP was 75.3% versus only 36.7% for those treated with EBRT. Age and comorbidity characteristics of EBRT patients did account for these differences. In multivariate Cox models (Table 2), increasing age and higher CCI score represented independent predictors of overall mortality. The effect of age ranged from a 1.3-fold ($p < 0.001$) up to a 7.3-fold ($p < 0.001$) increase in mortality relative to men in, respectively, the youngest age category (55–59 yr) and those with a CCI score of 0. It could be postulated that age and comorbidity differences that exist between the RP and EBRT cohorts underlie the observed striking survival differences. However, the assessment of the variable defining treatment type indicates that variables other than age and comorbidities may account for this difference. Those may include socioeconomic status as well as disease characteristics. This is based on the results of the multi-

Table 1. Descriptive analysis for 17 570 patients treated with radical prostatectomy and external-beam radiotherapy

Variables	No. (%) of patients* RP, *n* = 9678	EBRT, *n* = 7892	Total, *n* = 17 570
Age at treatment, yr			
Mean (median)	65 (65)	71 (71)	68 (68)
Range	45–89	42–95	42–95
40–44	— —	3 (0.0)	3 (0.0)
45–49	3 (0.0)	8 (0.1)	11 (0.1)
50–54	14 (0.1)	20 (0.3)	34 (0.2)
55–59	1664 (17.2)	341 (4.3)	2005 (11.4)
60–64	2887 (29.8)	870 (11.0)	3757 (21.4)
65–69	3519 (36.4)	2058 (26.1)	5577 (31.7)
70–74	1414 (14.6)	2548 (32.3)	3962 (22.5)
75–79	144 (1.5)	1467 (18.6)	1611 (9.2)
80–84	27 (0.3)	430 (5.4)	457 (2.6)
≥ 85	6 (0.1)	147 (1.9)	153 (0.9)
CCI score			
Mean (median)	1.1 (1.0)	1.9 (2.0)	1.5 (1.0)
Range	0–11	0–12	0-12
0	4434 (45.8)	2199 (27.9)	6633 (37.8)
1–2	3897 (40.3)	3193 (40.5)	7090 (40.4)
3–4	1118 (11.6)	1717 (21.8)	2835 (16.1)
5–6	198 (2.0)	600 (7.6)	798 (4.5)
> 6	31 (0.3)	183 (2.3)	214 (1.2)
Follow-up time, yr			
Mean (median)	7.5 (7.2)	4.8 (4.4)	6.3 (5.9)
Range	0.1–15.5	0.1–15.5	0.1–15.5
Deaths	1941 (20.1)	4243 (53.8)	6184 (35.2)
Actuarial survival, yr			
Mean (median)	12.4 (NR)	6.8 (7.3)	10.2 (12.1)

*Unless otherwise indicated.
CCI = Charlson Comorbidity Index; EBRT = external-beam radiotherapy; NR = not reached; RP = radical prostatectomy.

variate analysis, in which EBRT was associated with a 2.8-fold higher mortality rate than RP ($p < 0.001$), after accounting for age and comorbidities.

In the absence of cancer-specific mortality data, we repeated the analyses in a restricted cohort, where only those who did not require secondary therapies were included. The overall Kaplan–Meier plot demonstrated lower mortality, especially past the 10-year mark. After stratification according to treatment modality, the survival pattern of the RP subgroup improved (81.1% v. 75.3%). However, the survival pattern of the EBRT subgroup did not improve (30.4% v. 36.7%). In the multivariate analyses, the effect of age was more pronounced than in the entire cohort (rate ratios 1.5–7.7 v. 1.3–7.3). Similarly, the effect of most, but not all, comorbidity categories was stronger

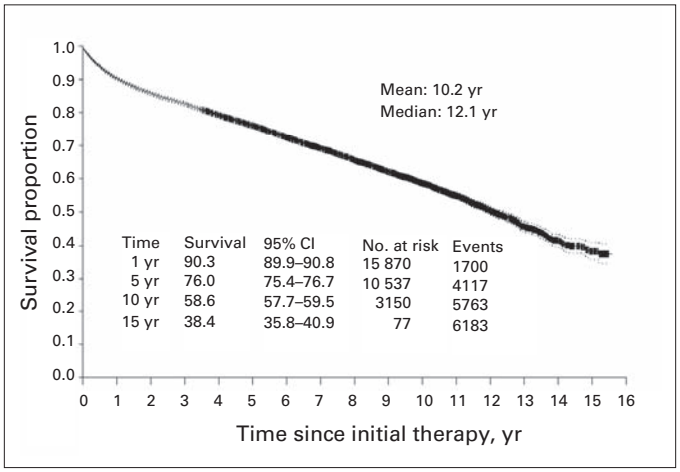

Fig. 1. Overall survival after radical prostatectomy and radiotherapy (17 570 cohort). CI = confidence interval.

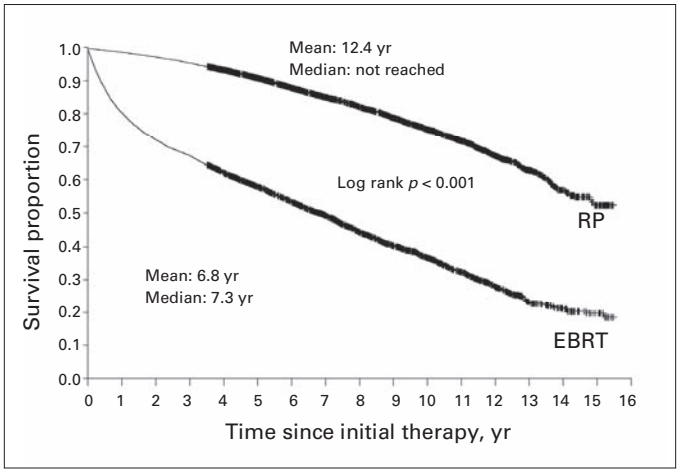

Fig. 2. Overall survival after radical prostatectomy (RP) and external-beam radiotherapy (EBRT) stratified according to treatment type (17 570 cohort).

Table 2. Univariate and multivariate analyses of the relation of age, Charlson Comorbidity Index score, and treatment type to overall mortality after radical prostatectomy and external-beam therapy (17 570 data set)

	Rate ratio; p value < 0.001	
Predictors	Univariate	Multivariate
Age at treatment, yr		
60–64 v. 40–59	1.4	1.3
65–69 v. 40–59	2.4	1.8
70–74 v. 40–59	3.6	2.0
75–79 v. 40–59	6.6	2.9
80–84 v. 40–59	12.1	4.9
≥ 85 v. 40–59	19.0	7.3
CCI		
1–2 v. 0	1.6	1.3
3–4 v. 0	2.7	1.9
5–6 v. 0	4.0	2.3
> 6 v. 0	6.3	3.3
Treatment type		
EBRT v. RP	4.2	2.8

CCI = Charlson Comorbidity Index; EBRT = external-beam radiotherapy, RP = radical prostatectomy.

than in the overall analysis. Finally, the effect of treatment type, after adjusting for the effect of age, comorbidity and region of residence increased from 2.8 ($p < 0.001$) to 3.9 ($p < 0.001$).

Our findings are in agreement with previous studies. For example, in a series of 276 patients treated with either RP (138) or EBRT (138), Fowler and colleagues[13] demonstrated that the effect of the same comorbidity score had a stronger effect in EBRT patients than in those treated with RP. A comorbidity score of 1 was associated with 77% 10-year survival after RP versus 27% in the EBRT group. The age-adjusted mortality risk was 3.8 times greater ($p = 0.02$) in men treated with EBRT versus RP. The survival estimates virtually replicate our findings, as in the restricted cohort of 9131 men the 10-year survival after RP was 81% and that of men treated with EBRT was only 30%. Moreover, the variable defining the treatment modality in our cohort also increased the risk of mortality by a factor of 4.1, which is comparable to 3.8 reported by Fowler and colleagues.[13] Several other series also assessed the relation between treatment assignment and age and comorbidity.[12–17]

From a societal perspective, our findings indicate that the perception of definitive EBRT as a treatment modality for localized prostate cancer may require an adjustment, where age, comorbidi-

Table 3. Descriptive analysis for 9131 patients who did not receive secondary treatment after radical prostatectomy and external-beam radiotherapy

Variables	No. (%) of patients*		
	RP, $n = 5955$	EBRT, $n = 3176$	Total, $n = 9131$
Age at treatment, yr			
Mean (median)	64 (64.0)	71 (71.0)	66 (66.0)
Range	55–89	55–93	55–93
55–59	1189 (20.0)	184 (5.8)	1373 (15.0)
60–64	1944 (32.6)	419 (13.2)	2363 (25.9)
65–69	1941 (32.6)	751 (23.6)	2692 (29.5)
70–74	777 (13.0)	941 (29.6)	1718 (18.8)
75–79	78 (1.3)	611 (19.2)	689 (7.5)
80–84	20 (0.3)	205 (6.5)	225 (2.5)
≥ 85	6 (0.1)	65 (2.0)	71 (0.8)
CCI			
Mean (median)	1.1 (1.0)	2.3 (2.0)	1.5 (1.0)
Range	0–11	0–12	0–12
0	2704 (45.4)	685 (21.6)	3389 (37.1)
1–2	2421 (40.7)	1252 (39.4)	3673 (40.2)
3–4	693 (11.6)	809 (25.5)	1502 (16.4)
5–6	117 (2.0)	322 (10.1)	439 (4.8)
> 6	20 (0.3)	108 (3.4)	128 (1.4)
Follow-up time, yr			
Mean (median)	7.4 (7.0)	4.3 (3.9)	6.3 (5.9)
Range	0.1–15.5	0.1–15.5	0.1–15.5
Deaths	903 (15.2)	1972 (62.1)	2875 (31.5)
Actuarial survival, yr			
Mean (median)	13.0 (NR)	6.4 (4.7)	10.7 (13.8)

*Unless otherwise indicated.
CCI = Charlson Comorbidity Index; EBRT = external-beam radiotherapy; NR = not reached; RP = radical prostatectomy.

ties and LE in general are interpreted in the same fashion as when the use of RP is contemplated. The survival data in the entire cohort of 17 570 men, as well as in the cohort restricted to 9131 men, demonstrated that about 1 in 3 men survive the 10-year mark if they are treated with EBRT. This implies that only 1 in 3 men benefit from EBRT as a definitive treatment modality for localized prostate cancer. The remaining two-thirds possibly could have been treated with either immediate androgen withdrawal or with watchful waiting with possible delayed androgen withdrawal.

From a practical perspective, our data indicate that radiation oncologists, as well as urolo-

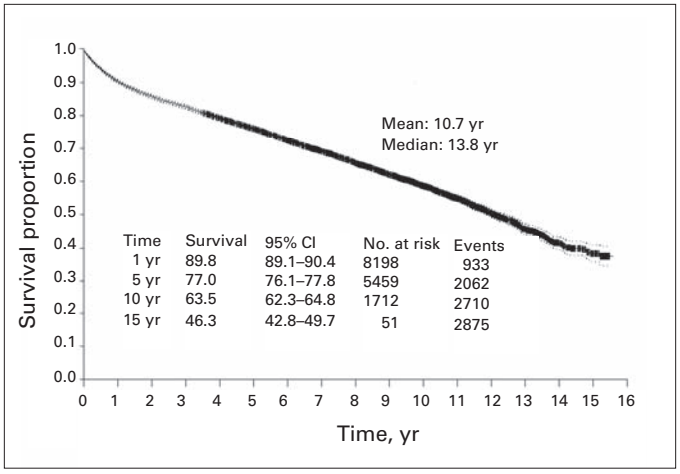

Fig. 3. Overall survival in men who did not receive secondary treatment after radical prostatectomy and radiotherapy (9131 cohort). CI = confidence interval.

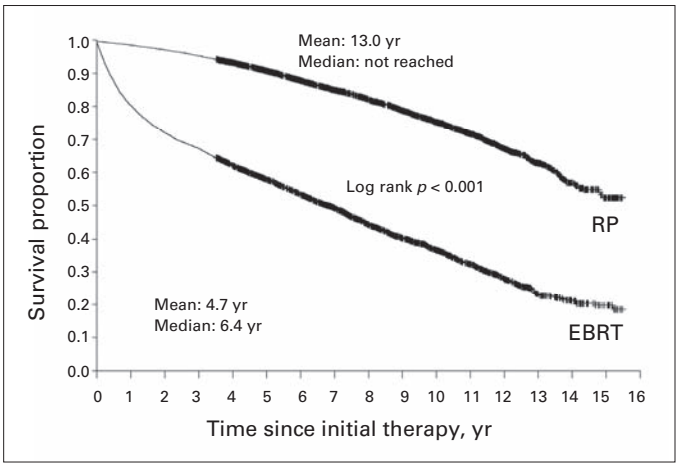

Fig. 4. Overall survival in men who did not receive secondary treatment after radical prostatectomy (RP) and external-beam radiotherapy (EBRT) stratified according to treatment type (9131 cohort).

Table 4. Univariate and multivariate analyses of the relation of age, Charlson Comorbidity Index score, and treatment type to overall mortality in men who did not receive secondary treatment after radical prostatectomy and external-beam therapy (9131 data set)

	Rate ratio; *p* value < 0.001	
Predictors	Univariate	Multivariate
Age at treatment, yr		
60–64 v. 55–59	1.7	1.5
65–69 v. 55–59	3.5	2.6
70–74 v. 55–59	5.9	3.0
75–79 v. 55–59	12.1	4.0
80–84 v. 55–59	17.7	5.3
≥ 85 v. 55–59	25.2	7.7
CCI		
1–2 v. 0	1.9	1.4
3–4 v. 0	3.6	2.0
5–6 v. 0	6.2	2.5
> 6 v. 0	9.3	3.4
Treatment type		
EBRT v. RP	6.6	3.9

CCI = Charlson Comorbidty Index; EBRT = external-beam radiotherapy, RP = radical prostatectomy.

gists, oncologists and all health professionals should be more conservative when EBRT is considered as a definitive treatment modality for localized prostate cancer. Better selection of RP candidates should also represent a priority, as 25% of men treated with RP do not survive past the 10-year mark.

From the academic perspective, our findings suggest caution when results of decision analyses are interpreted. Decision analyses represent extremely valuable aids, especially when randomized trials are limited or unavailable.[4,6,18] However, their findings may not always be applicable to all clinical scenarios. For example, the recommendation of potentially curative therapy up to the age of 80 or 75 years, in presence of, respectively, high or intermediate grade prostate cancer does not appear to fit our data, at least those for men treated with EBRT. It is noteworthy that these recommendations were not consistent with data from the randomized trial of RP and watchful waiting, in which the treatment with curative intent resulted in greatest benefit in men aged 65 years or younger.[18]

Our study is not devoid of limitations. The completeness of RAMQ comorbidity data has not been validated. The recorded comorbidities are based on diagnostic codes from inpatient and outpatient data files. Moreover, the data did not allow inferences about cancer-specific versus overall survival. All our results pertain to overall survival. Lack of cancer-specific mortality represents one of the main limitations. Cancer-specific and/or crude survival rates ideally require adjustment for treatment- and health-related quality-of-life detriments. Lack of clinical and pathological characteristics of the treated cancers represents another potential weakness. Therefore the effect of grade and stage was not and could not be assessed. The efficacy of the surgical interventions, measured by rates of biochemical or clinical cancer relapse should ideally be known. Similarly, the type and dose of delivered EBRT was unavailable. Moreover, treatment selection is not based only on LE and cancer characteristics. Quality-of-life considerations, patient and physician preferences and treatment availability all add to the complexity of treatment selection. Therefore, our findings certainly have weaknesses. However, it is unlikely that the detailed knowledge of all these variables would have drastically changed our findings. Moreover, the availability of large sample sizes, as was the case in our study, is virtually always associated with less detailed data. Finally, it remains to be seen whether the same applies to the United States or Europe. Fowler and colleagues' report suggests that the situation is similar in the United States, at least when veteran's administration data are compared.[19]

Conclusion

Men treated with definitive EBRT are older and sicker than their counterparts treated with RP. Only one-third of EBRT patients survive 10 years after therapy, even when analyses are restricted to men without evidence of disease relapse. Conversely, three-quarters of patients subjected to RP survive 10 years after therapy. These data suggest that more stringent criteria should be applied to EBRT candidates to improve the efficacy of this treatment modality.

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