Morbidity and All-Cause Mortality Following Radical Prostatectomy Compared with Observation for Localized Prostate Cancer in Chinese Men: A Non-Randomized Retrospective Study

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABF 1 Xi Zhang*
ABF 1 Xiang Li*
BDF 1 Qiwei Yu
CDF 1 Jun Ma
BCF 1 Xuemin Zeng
DEF 2 Li Xue

1 Department of Urology, Kunshan Hospital of Traditional Chinese Medicine, Kunshan, Jiangsu, P.R. China
2 Department of Urology, The Second Affiliated Hospital of Xi'an Jiaotong University, Xi'an, Shaanxi, P.R. China

Corresponding Author:
Source of support:

* Xi Zhang and Xiang Li contributed equally to this work
Li Xue, e-mail: li.xue7e7@gmail.com
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Background: The Chinese 2018 guidelines and the current 2014 Chinese Urological Association guidelines for prostate cancer recommend radical prostatectomy for Chinese men with localized prostate cancer as the first choice, but it has treatment-related adverse effects. This study aimed to study morbidity and all-cause mortality following radical prostatectomy compared with observation for localized prostate cancer in Chinese men from a single center.

Material/Methods: Men diagnosed (histologically) as stage T1-T2N×M0 prostate cancer of any grade with 1-year history were included in the analysis. A total of 201 men underwent radical prostatectomy (RP cohort) and 209 men did not undergo radical prostatectomy (OS cohort).

Results: During follow-up (17-24 years), 135 (67%) men died in the RP cohort and 156 (75%) men died in the OS cohort (P=0.103). All-cause mortality was lower for men with prostate-specific antigen level >10 ng/mL (P<0.0001), Gleason score ≥7 (P=0.004), and high D'Amico tumor risk scores (P=0.007) if they underwent radical prostatectomy. Age ≥65 years (P=0.041), Gleason score ≥7 (P=0.049), and tumor stage ≥2c (P=0.045) were associated with all-cause mortality.

Conclusions: The findings from this study showed that radical prostatectomy has no significant beneficial effects when compared with observation for Chinese men with localized prostate cancer, unless they had a prostate-specific antigen level >10 ng/mL, Gleason score ≥7, and high D'Amico tumor risk scores.

Keywords: Erectile Dysfunction • Mortality • Neoplasm Grading • Prostate-Specific Antigen • Prostatectomy • Prostatic Neoplasms

Abbreviations: AUA/ASTRO/SUO – The American Urological Association and Society of Urologic Oncology; CAPRA score – Cancer of Prostate Risk Assessment score; CUA – Chinese Urological Association; EAU-ESTRO-SIOG – The European Association of Urology-European Society for Radiotherapy & Oncology-International Society of Geriatric Oncology; OS cohort – men who did not undergo radical prostatectomy; PIVOT – Prostate Cancer Intervention versus Observation Trial; RP cohort – men who underwent radical prostatectomy; TNM stage – tumor, nodule, and metastasis stage

Full-text PDF: https://www.medscimonit.com/abstract/index/idArt/928596

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Background

Prostate cancer is a common tumor in Chinese men [1] and 30% of newly diagnosed Chinese men with prostate cancer have a clinically localized stage of cancer [2]. At present, limited information is available on prostate cancer in Chinese men concerning race-based pathological differences [3]. The randomized trials on North American men [4] and English men [5] with localized prostate cancer showed that radical prostatectomy does not reduce mortality, but has treatment-related adverse effects, as compared with active monitoring. However, randomized trials involving Scandinavian men [6] and North American men (PIVOT: Prostate Cancer Intervention versus Observation Trial) [7,8] reported that men with localized prostate cancer benefit from radical prostatectomy. Guidelines like the European Association of Urology-European Society for Radiotherapy & Oncology-International Society of Geriatric Oncology (EAU-ESTRO-SIOG) guidelines part I [9] and the American Urological Association and Society of Urologic Oncology (AUA/ASTRO/SUO) guideline part II [10] for the management of localized prostate cancer have recommended a risk-stratified clinical framework, but the Chinese Urological Association (CUA) has no clear guidelines [2] of risk stratification for localized prostate cancer, and the current 2014 CUA guidelines for prostate cancer [11] are based on the European and American guidelines and are not suitable for the actual situation of Chinese men with localized prostate cancer [12]. However, the Chinese guidelines 2018 [2] and the current 2014 CUA guidelines for prostate cancer [11] recommend radical prostatectomy for localized prostate cancer as the first choice for low-, intermediate-, and high-risk prostate cancer in Chinese men. The 2018 Chinese guidelines [2] recommended watchful waiting for patients with life expectancy ≤10 years and active surveillance for patients with life expectancy >10 years, but it is difficult to estimate life expectancy of patients. The EAU-ESTRO-SIOG guidelines part I [9] recommend watchful waiting for all stages of localized prostate cancer and radical prostatectomy for intermediate- and high-risk prostate cancer. AUA/ASTRO/SUO guideline part II [10] recommends radical prostatectomy for patients with life expectancy >10 years and age <65 years, but the same question remains of how to calculate life expectancy of patients. The AUA/ASTRO/SUO guideline part II also recommends watchful waiting for patients with all pathological and radiological diagnoses at regular time intervals during follow-up, but does not give limits for life expectancy and age for localized prostate cancer patients if they are put on watchful waiting. All of these guidelines were developed in White patients, not for Chinese, especially Han Chinese, patients with localized prostate cancer.

The objective of the present non-randomized retrospective study was to study morbidity and all-cause mortality following radical prostatectomy compared with observation for localized prostate cancer in Chinese men from a single center. We also assessed the risk factors for all-cause mortality among the enrolled men.

Material and Methods

Ethics Approval and Consent to Participate

The designed protocol (2018YBXM-SF-13-5, dated 19 August 2020) was approved by the Review Boards of the Kunshan Hospital of Traditional Chinese Medicine, Kunshan, China, the Second Affiliated Hospital of Xi'an Jiaotong University, Xi'an, China, and the Chinese Urological Association. The study adhered to the laws of China and the 2008 Helsinki Declaration. The enrolled men provided signed informed consent regarding pathology and surgery (if performed) during hospitalization. Data of men were retrospectively collected from the institutes after obtaining written consent from authorities.

Study Population

Men (age >40 years) with histologically confirmed stage T1-T2N×M0 prostate cancer of any grade and with a 1-year history were included in the analyses. Data of men who had incomplete information available in the institutes' records were excluded from analyses.

Data regarding baseline tumor characteristics, age, all-cause mortality, and health problems during follow-up of the included patients were collected from the medical records of the institutes.

Comorbidities

Comorbidities were assessed using the Charlson score, which ranges from 0 to 4, with 0 indicating fully active. The higher score, the poorer the functional status [13].

Tumor risk

Tumor risk was assessed using the D'Amico tumor risk scores. The D'Amico risk groups were stratified into low-, intermediate-, or high-risk of biochemical recurrence after surgery according to the clinical TNM stage (tumor, nodule, and metastasis stage), the biopsy Gleason score, and the preoperative prostate-specific antigen level [14,15]. Low-risk was defined as tumor stage 2a or less, prostate-specific antigen level less than 10 ng/mL, and Gleason score 6 (3+3) or less. Intermediate-risk was defined as tumor stage 2b, prostate-specific antigen level 10-20 ng/mL, and Gleason score 7 (4+3 or 3+4). High-risk was defined as tumor stage 2c or more, prostate-specific antigen level more than 20 ng/mL, and Gleason score 8 or more [16].
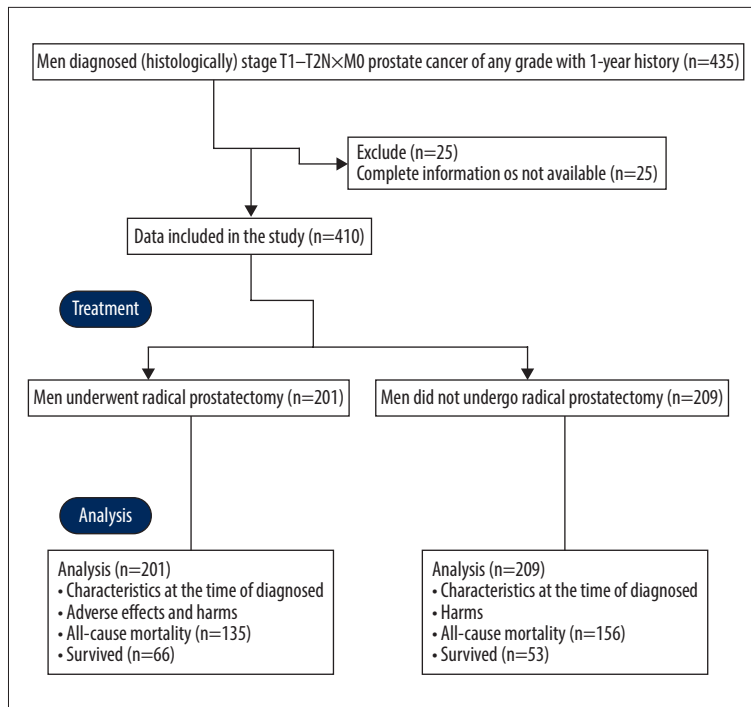
Figure 1. The study protocol to evaluate the morbidity and all-cause mortality following radical prostatectomy compared with observation for localized prostate cancer in Chinese men.

Prostate Cancer Risk Assessment (CAPRA) Scores

CAPRA was assessed according to the guidelines of the University of California, San Francisco, Cancer of the Prostate Risk Assessment score in the range of 0-10 using Gleason score, positive biopsies, age, and the clinical TNM stage [17]. For men with Gleason score ≤6 (3+3), the assigned CAPRA points for Gleason score were zero and for men with Gleason score 8-10, the assigned CAPRA points for Gleason score were 3. It was classified as low-risk, intermediate-risk, and high-risk [7,8].

Adverse Effects and Health Problems

Radical proctectomy (all surgeries were performed by urologist(s) with a minimum of 3 years of experiences of the institutes)-related complications within 1 month after surgery and health problems within 2 years after diagnosis (self-reported) for all enrolled men were collected and analyzed.

Statistical Analysis

The study assumed that a minimum of 35±5% men would survive the follow-up period (17-24 years). The sample size was calculated on the basis of 80% power and 5% two-sided type-I error (α=0.05 and β=0.2) at a 95% confidence level. The minimum number of men required in each cohort (the sample size) was 199. SPSS V25.0 IBM Corporation, Armonk, NY, USA was used for statistical analysis. The Fisher exact test was performed to assess differences between constant data, and an unpaired *t* test was used to compare differences between continuous data. Univariate and multivariate analyses were performed for the detection of correlations between the characteristics of men at the time of diagnosis and all-cause mortality during follow-up (17-24 years). The results were considered significant at *P*<0.05.

Results

Study Population

From 15 November 1995 to 12 February 2003, a total of 435 men (age >40 years) were diagnosed (histologically) as having stage T1-T2N×M0 prostate cancer of any grade with a 1-year history at the Department of Urology of the Kunshan Hospital of Traditional Chinese Medicine, Kunshan, China and the Second Affiliated Hospital of Xi'an Jiaotong University, Xi'an, China. Among them, complete information of 25 men was not available in the patients' records of the institutes; therefore, these data were excluded from the study. Among the 410 included men, 201 men underwent radical prostatectomy (RP cohort) and 209 men did not undergo radical prostatectomy (OS cohort). The men decided on their own either to undergo radical prostatectomy or not to receive any surgery. Data regarding baseline tumor characteristics, age, comorbidities, health status, all-cause mortality during follow-up period, tumor risk, and CAPRA scores were collected from medical records of the institutes and were analyzed (**Figure 1**).

Table 1. Characteristics of men at the time of diagnosis.

Characteristics		Cohort		Comparisons between cohorts
		RP	OS	
Treatment		Radical prostatectomy	Observation	
Men included in analysis		201	209	p-Value
Age (years)	40-64	129	133	0.072
	≥65	72	76	
	Mean±SD	61.15±10.14	59.41±9.41	
Ethnicity	Han Chinese	183 (91)	190 (91)	0.096
	Mongolian	14 (7)	16 (7)	
	Tibetan	2 (1)	2 (1)	
	Uighurs Muslim	1 (1)	1 (1)	
Prostate specific antigen level (ng/mL)	≤10	149 (74)	152 (73)	0.823
	>10	52 (26)	57 (27)	
Charlson score	0	123 (61)	136 (65)	0.474
	≥1	78 (39)	73 (35)	
Gleason score	<7	100 (50)	118 (56)	0.198
	≥7	101 (50)	91 (44)	
D'Amico tumor risk scores	Low	91 (45)	84 (40)	0.567
	Intermediate	67 (33)	78 (37)	
	High	43 (22)	47 (23)	
CAPRA scores	Low	84 (42)	106 (51)	0.158
	Intermediate	96 (48)	81 (39)	
	High	21 (10)	22 (10)	

Categorial and ordinal variables are presented as frequency (percentages). Continuous variables are presented as mean±standard deviation (SD). Fischer exact test was performed between constant and ordinal variables and an unpaired *t*-test was used between continuous variables. If *p*<0.05 was considered significance. CAPRA scores – Cancer of Prostate Risk Assessment scores.

Characteristics at the Time of Diagnosis

There were no significant differences in the characteristics of men at the time of diagnosis between the 2 cohorts (*P*>0.05 for all, **Table 1**).

All-cause Mortality

As of 1 August 2020, a total of 291 (71%) men had died. The minimum follow-up time was 17 years and the maximum follow-up time was 24 years. A total of 135 (67%) men had died in the RP cohort and 156 (75%) men had died in the OS cohort. The number of deaths was not significantly different (*P*=0.103) between the 2 cohorts. Mean survival was 15 years in the RP cohort and 14 years in the OS cohort. There was a 4% reduction in all-cause mortality and an increase in survival 1 year after radical prostatectomy at 24 years of follow-up. All-cause mortality was lower in men with prostate-specific antigen level >10 ng/mL (*P*<0.0001), Gleason score ≥7 (*p*=0.004), and high D'Amico tumor risk scores (*P*=0.007) if they underwent radical prostatectomy, irrespective of the other characteristics at the time of diagnosis (**Table 2**).

Risk Factors for All-cause Mortality

Univariate analysis showed that age ≥65 years (*P*=0.012), prostate-specific antigen level >10 ng/mL (*P*=0.023), Charlson score ≥1 (*P*=0.045), Gleason score ≥7 (*P*=0.041), tumor stage ≥2c (*P*=0.035), and high CAPRA scores (*P*=0.042) were associated with all-cause mortality. Multivariate analysis showed that age ≥65 years (*P*=0.041), Gleason score ≥7 (*P*=0.049), and tumor stage ≥2c (*P*=0.045) were associated with all-cause mortality (**Table 3**).

Table 2. All-cause mortality during follow-up time according to characteristics of men.

Characteristics		Cohort		Comparisons between cohorts
		RP	OS	
Treatment		Radical prostatectomy	Observation	
Men included in analysis		201	209	p-Value
Age (years)	40-64	90 (67)	106 (68)	0.901
	≥65	45 (33)	50 (32)	
	Mean±SD	62.04±10.42	61.12±10.15	
Ethnicity	Han Chinese	125 (93)	145 (93)	0.998
	Mongolian	8 (5)	9 (5)	
	Tibetan	1 (1)	1 (1)	
	Uighurs Muslim	1 (1)	1 (1)	
Prostate specific antigen level (ng/mL)	≤10	120 (89)	108 (69)	<0.0001
	>10*	15 (11)	48 (31)	
Charlson score	0	81 (60)	97 (62)	0.719
	≥1	54 (40)	59 (38)	
Gleason score	<7	101 (75)	91 (58)	0.004
	≥7 (3+4 or 4+3)*	34 (25)	65 (42)	
D'Amico tumor risk scores	Low	74 (55)	69 (44)	0.007
	Intermediate	49 (36)	52 (33)	
	High*	12 (9)	35 (22)	
CAPRA scores	Low	77 (57)	77 (49)	0.154
	Intermediate	51 (38)	62 (40)	
	High	7 (5)	17 (11)	

Categorial and ordinal variables are presented as frequency (percentage). Continuous variables are presented as mean±standard deviation (SD). Fischer exact test was performed for statistical analysis. If *p*<0.05 was considered significance. * Significant lower number than OS cohort. CAPRA scores – Cancer of Prostate Risk Assessment scores.

Table 3. Risk factor for all-cause mortality.

Men died in the follow-up	291		
Characteristics at the time of diagnosing	Odd ratio	95% confidence limit	p-Value
Age (≥65-year* vs <65 years)	2.451	0.451-0.982	0.041
Prostate specific antigen level (>10 ng/mL vs ≤10 ng/mL)	1.052	0.681-0.941	0.053
Charlson score (≥1 vs 0)	0.893	0.611-0.872	0.098
Gleason score (≥7* vs <7)	1.151	0.511-0.852	0.049
Tumor stage (≥2c* vs tumor stage ≤2b)	1.892	0.482-0.912	0.045
CAPRA scores (high vs low and intermediate)	1.031	0.512-0.895	0.058

Multivariate analysis. Data of survived men (n=119) were considered the reference standard. Odd ratio >1 and *p*-value <0.05 were considered significant. * Significant risk factor associated with all-cause mortality. CAPRA scores – Cancer of Prostate Risk Assessment scores.

Table 4. Adverse effects reported in men of the RP cohort within 1 month after radical prostatectomy.

Adverse effect	Men (%)	
Men subjected to radical prostatectomy	**201**	
Wound infection	9	(4)
Urinary tract infection	7	(2)
Bleeding requiring transfusion	2	(1)
Bowel dysfunction	2	(1)
Sepsis	1	(1)
Additional surgical repair	9	(4)
Urinary catheterization	20	(10)
Pneumonia	2	(1)
Deep-vein thrombosis	1	(1)
Stroke	1	(1)
Renal failure	2	(1)
Need of dialysis	2	(1)
Other surgery-related complications	10	(5)
Death	1	(1)

Data are presented as frequency (percentages).

Adverse Effects of Radical Prostatectomy

Within 1 month after radical prostatectomy, wound infections had occurred in 9 (4%) men, urinary tract infection occurred in 7 (2%) men, bleeding requiring transfusion was reported in 2 (1%) men, bowel dysfunction was reported in 2 (1%) men, and urinary catheterization was required in 20 (10%) men. The details of the adverse effects that occurred in men in the RP cohort within 1 month after radical prostatectomy are reported in **Table 4**. After 2 years, rates of urinary incontinence (P=0.001), erectile dysfunction (P<0.0001), and bowel dysfunctions (P=0.034) were significantly higher among men of

the RP cohort than those of the OS cohort. The detailed self-reported health problems among men 2 years after diagnosis are reported in **Table 5**. However, there were no significant differences in anxiety and depression (developed from the hospital anxiety and depression scale) between men in the 2 cohorts during the follow-up period.

Discussion

We found that during a 24-year follow-up, radical prostatectomy had no significant beneficial effects when compared with observation. The results of the current study agree with the those of randomized trials on North American men [4,7,8], Scandinavian men [6], and English men [5] with localized prostate cancer. The PIVOT trial [7,8] had type II error and reported that 74% of patients with low-grade localized prostate cancer without prostatectomy survived the follow-up period [18]. In general, radical prostatectomy has no beneficial effects on Chinese men with localized prostate cancer compared to observation.

We found that all-cause mortality was lower in men with prostate-specific antigen level >10 ng/mL, Gleason score ≥7, and high D'Amico tumor risk scores if they underwent radical prostatectomy, irrespective of the other characteristics of men at the time of diagnosis. Our findings for all-cause mortality agreed with the those of randomized trials on North American men [4,7,8] and English men [5] with localized prostate cancer. Radical prostatectomy was beneficial in Chinese men who had prostate-specific antigen levels >10 ng/mL, Gleason score ≥7, and high D'Amico tumor risk scores.

Age ≥65 years, Gleason score ≥7, and tumor stage ≥2c were independently associated with all-cause mortality. The results of risk factor analysis for all-cause mortality of the current study agreed with those of randomized trials in North American

Table 5. Self-reported health problems in men 2 years after diagnosis.

Harms	Cohort		Comparisons between cohorts
	RP	OS	
Treatment	Radical prostatectomy	Observation	
Men included in analysis	**201**	**209**	**p-Value**
Urinary incontinence	35 (17)*	11 (5)	0.001
Erectile dysfunction	154 (77)*	81 (39)	<0.0001
Urinary catheterization	7 (3)	5 (2)	0.569
Bowel dysfunction	32 (16)*	18 (9)	0.034

Variables are presented as frequency (percentage). Fischer exact test was performed for statistical analysis. If p<0.05 was considered significant. * Significant higher number than OS cohort.

men [4,7,8], Scandinavian men [6], and English men [5] with localized prostate cancer. We found no significant difference between watchful waiting and radical prostatectomy in Chinese men with localized prostate cancer with age ≥65 years, Gleason score ≥7, and/or tumor stage ≥2c.

The general surgical issues, urinary incontinence, and erectile dysfunction were assessed among men who underwent radical proctectomy. The results concerning adverse effects of radical proctectomy and health problems during the follow-up period of the current study agreed with those of randomized trials on North American men [4,7,8], Scandinavian men [6], and English men [5], as well as with results from a non-randomized prospective study of English men [19], and a retrospective study of Chinese men [20] with localized prostate cancer. Proctectomy has been reported to be associated with clinically worse outcomes [21], while radical prostatectomy is associated with more adverse effects and health problems than observation in Chinese men.

The present study has certain limitations, such as the small sample size, the use of a single center, and a focus on disease progression and tumor progression, which requires surgery, and distant metastases were not considered. The expertise of surgeons has effects on surgery-related outcomes [7], but we did not assess the effect of urologists' experiences during the follow-up. In addition, retrospective analysis leads to selection bias. The mortality included in the study was all-cause mortality; therefore, patients who died due to only prostate cancer were not considered separately. The D'Amico tumor risk scores and the CAPRA scores parameters used in the study were based on studies of White patients with localized prostate cancer. These parameters need to be validated for Chinese populations before being used for research in China.

Conclusions

The findings from this study showed that radical prostatectomy has no significant beneficial effects when compared with observation for Chinese men with localized prostate cancer, unless they have a prostate-specific antigen level >10 ng/mL, Gleason score ≥7, and high D'Amico tumor risk scores. Age ≥65 years, Gleason score ≥7, and tumor stage ≥2c were independently associated with all-cause mortality. Also, radical prostatectomy has adverse effects related to surgery and significant health problems related to the urogenital system during follow-up. The 2018 Chinese guidelines and the current 2014 Chinese Urological Association guidelines for prostate cancer need to be updated to develop clear recommendations for management of localized prostate cancer in Chinese men.

Acknowledgments

Conflict of Interest

None.

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