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Ninety-Day Postoperative Mortality after Robot-assisted Laparoscopic Prostatectomy and Retropubic Radical Prostatectomy. Nation-wide population-based study

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Abstract

Objective—To assess 90-day postoperative mortality after Robot assisted laparoscopic Radical prostatectomy (RARP) and retropubic radical prostatectomy (RRP) by use of nationwide population-based registry data.

Patients and methods—Cohort study in the National Prostate Cancer Register (NPCR) of Sweden of 22 344 men with prostate cancer in clinical local stage T1-T3, PSA <50 µg/ml who had undergone primary RP in 1998 - 2012. Vital status was ascertained through the Total Population

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Conflicts of Interest

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Register. 90-day postoperative mortality was analysed by use of logistic regression analysis and comparison of 90-day mortality with the background population were made using standardised mortality ratios (SMR).

Results—29 out of 14820 men (0.20%) died after RRP and 10 out of 7524 men (0.13%) died after RARP. Mortality during the 90-day postoperative period in the cohort was lower than in an age-matched background population, SMR 0.57 (CI 95% 0.39-0.75). There was no statistically significant difference in 90-day mortality according to surgical method, RARP vs. RRP (odds ratio, OR 1.14; 95% CI, 0.46-2.81). Postoperative 90-day mortality decreased over time, 2008-2012 vs. 1998-2007 (OR 0.44; 95% CI, 0.21-0.95), mainly due to decreased mortality after RARP. Limitations of our study include the non-randomised design and that more RARP were performed in recent years compared to RRP.

Conclusion—90-day postoperative mortality was low after RARP and RRP and there was no statistically significant difference between the methods. Given the long life expectancy among men with low and intermediate risk prostate cancer, very low postoperative mortality is a prerequisite for RP which was fulfilled by both RRP and RARP. The selection of healthy men for RP is highlighted by the lower 90-day mortality after RP compared to the background population.

Keywords

Prostate Cancer; Radical Prostatectomy; Retropubic Prostatectomy; Robot assisted Laparoscopic Prostatectomy; Mortality; 90-day postoperative

Introduction

Radical prostatectomy prevents death from prostate cancer in the long-term and therefore, only very low postoperative mortality is acceptable (1, 2). In the modern era, retropubic radical prostatectomy (RRP), has been documented to have low postoperative mortality (3-7). In Sweden, the number of RP's increased until reaching a plateau in 2010. The number of robot-assisted laparoscopic prostatectomy (RARP) surpassed those of RRP in 2009 (8). There has been no indication that RARP is less safe than RRP. Some studies have suggested lower in-hospital postoperative mortality after RARP than after RRP, but there is no previous population-based study comparing RARP and RRP with respect to perioperative mortality. The aim of this study was to assess the 90-day postoperative mortality after RARP and RRP in a large representative cohort, also comparing the mortality with the background population to account for baseline mortality.

Patients and methods

Study population and setting

The National Prostate Cancer Register (NPCR) of Sweden captures 98% of all incident cases of prostate cancer in Sweden in comparison with the Swedish Cancer Registry to which registration is mandated by law (9). The NPCR includes information on date of diagnosis, age, tumour stage, Gleason score, serum levels of prostate specific antigen (PSA) at date of diagnosis as well as primary treatment. Men in NPCR diagnosed with localised prostate cancer (clinical stage T1-T3, N0/NX, M0/MX and PSA <50 µg/ml at the time of

diagnosis) who had undergone a RARP or a RRP, between January 1998 and September 2012 were identified and included in this study.

In the Prostate Cancer database (PCBaSe), NPCR has been linked to a number of nationwide healthcare registers and demographic databases. By use of data in the Patient Register, comorbidity was assessed by use of the Charlson Comorbidity Index (CCI) based on discharge diagnoses for hospital admissions, with CCI 0 denoting no comorbidity, CCI mild comorbidity and CCI2+ moderate to severe comorbidity as previously described (10, 11). Data on pelvic lymph node dissection (PLND) were extracted from the Patient Register. Information on vital status and cause of death were collected from the Cause of Death Register, and educational level and marital status from the LISA database (Swedish acronym for Longitudinal Integration Database for Health Insurance and Labor Market Studies) (12). We extracted the following variables from PCBaSe: demographics (age, comorbidity, educational level, marital status), clinico-pathologic features (serum PSA level, TNM stage, Gleason score or WHO tumour grade), and surgical data (date of RP, type of surgical technique, receipt of pelvic lymph node dissection, and hospital surgical volume). Prostate cancer risk categories was defined according to a modification of the NCCN guidelines 2015 edition for prostate cancer low-risk (T1–T2a, Gleason score ≤ 6 and PSA < 10 µg/l), intermediate-risk (T2b–T2c and/or Gleason score 7 and/or PSA 10–19.9 µg/l), and high-risk (T3 and/or Gleason score 8–10 and/or PSA ≥ 20 µg/l). (13)

We divided the study population in to two groups according to date of surgery, 1998-2007 vs. 2008-2012. The cutoff was chosen a priori based solely on the sizes of the groups.

To accommodate that increasing hospital volume improves outcome (14) we categorised hospital volume into low-volume, less than 61 cases (lowest to 74th percentile), intermediate-volume, 61-108 cases (75th to 89th percentile), and high volume, more than 109 cases per year (90th to highest percentile). The cutoff was chosen a priori based solely on the sizes of the groups.

Statistical Analysis

We calculated odds ratios (OR) and 95% confidence intervals (CIs) for 90-day postoperative mortality using logistic regression adjusting for age, treatment year, marital status, educational level, Charlson Comorbidity Index (CCI), tumour risk category, pelvic lymph node dissection, and prostatectomy volume at the hospital. In order to detect possible issues with overfitting, we began with a univariable model to which each multivariable model was compared.

We assessed standardised mortality ratio (SMR) using an age-matched male background-population data from The Total Population Register as the basis for the expected mortality. The study was approved by the Research Ethics Board at Umeå University Hospital.

Results

In total, 22 344 men underwent RP in Sweden between January 1998 and September 2012 out of whom 14 820 (66%) underwent RRP and 7 524 (34%) underwent RARP.

Men undergoing RARP had a higher educational level than those who underwent RRP (**Table 1**). The number of RRP per year increased from 1998 until 2004 and decreased after that date, while the number of RARP continued to increase. Pelvic lymph node dissection was done more frequently in conjunction with RRP, (28%), than with RARP, (14%). RARP was mainly performed in high-volume centers (59%), while RRP were mainly performed in low-volume centers (61%).

Overall 39 men (0.17%) died within 90 days after surgery, which was significantly lower than in the background population, (SMR, 0.57; 95% CI 0.39-0.75).

Figure 1 presents the cumulative 90-day mortality by surgical technique. The 90-day postoperative mortality was 29/ 14 820 (0.20 %) after RRP and 10/ 7 524 (0.13%) after RARP (crude odds ratio; OR, 0.68; 95% CI, 0.33-1.39 for RARP vs. RRP; adjusted OR, 1.15; 95% CI, 0.47-2.83) in multivariable analysis (**Table 2**). All estimates were similar in direction and magnitude, thus indicating no strong overfitting in the model.

There was an increase in 90-day mortality with age at surgery (OR, 1.07; 95% CI, 1.00-1.13 per one year increase) and the 90-day postoperative mortality decreased significantly in recent years (OR, 0.45; 95% CI, 0.21-0.96 for 2008-2012 vs. 1998-2007). In stratified analysis, the decrease in risk over time remained significant after RARP, (OR, 0.25; 95% CI, 0.07-0.92) but not after RRP (OR, 0.60; 95% CI, 0.27-1.36).

Among men who underwent a RP with a simultaneous pelvic lymph node dissection, 15 men (0.29%) died within 90 days after surgery. Men who underwent a PLND in combination with RP did not have a significantly increased 90-day postoperative mortality (OR, 1.37; 95% CI, 0.67-2.79).

Discussion

In this large, representative cohort of men who underwent prostatectomy 1998 – 2012 in Sweden, 90-day postoperative mortality was low, with no statistically significant difference between RRP (0.20%) and RARP (0.13%). The 90-day mortality after RARP decreased significantly over time, while no decrease was observed after RRP. A simultaneous pelvic lymph node dissection did not significantly affect the risk of 90-day mortality. Finally, 90-day mortality after RP was lower than in the background population, indicating a selection of healthy men for RP.

This is the first large population-based study that compares compare 90-day mortality after robotic and retropubic prostatectomy, but despite the large number of study subjects, the confidence intervals remained wide due to the rarity of postoperative death. Another advantage of our study design was the use of a comparison population matched by age, sex, county of residency, and time period to examine background mortality risk.

Limitations of our study include the non-randomised design and that a larger proportion of RARP were performed in more recent years compared to RRP. Moreover, RARP was predominantly performed in high volume centers while the majority of RRP were performed in low-volume centres. A large randomised trial would eliminate these biases as well as

potential unmeasured confounders - however at the cost of the population-based design of the present study.

Several previous studies have compared the outcomes of RRP and RARP in terms of duration of hospital stay, need of blood transfusion, and intra- or postoperative complications, but less is known regarding mortality (15-17).

Sammon et al reported significantly lower mortality during the postoperative hospital stay associated with RARP among 77 616 patients (18). In a partly overlapping study population, Trinh et al found lower mortality after RARP among 19 462 patients in the univariable analysis but the association was not significant after adjustment for covariates (19). Liu et al compared minimally invasive radical prostatectomy (MIRP, encompassing both laparoscopic and RARP), with open radical prostatectomy (ORP) and found, based on seven deaths, significantly lower 30-day mortality after MIRP (20). Apart from not distinguishing between RARP and traditional laparoscopic procedures, the study was not population-based. Kowalczyk et al investigated 78 232 patients and found that RRP was associated with a twofold higher 30-day mortality than after MIRP. Similar to Liu et al, this study did not separate laparoscopic from robot-assisted procedures and also did not account for tumor grade or stage in the analysis (21). The absolute 30 day mortality in the Kowalczyk et al study was around three times higher than our 90-day mortality, so it is difficult to compare the results from RARP and RRP between these two studies.

Thus, our finding of similar postoperative mortality between RRP and RARP is in contrast with previous studies; however, the differences in study design and population might explain these differences. Also, in some studies follow-up ended at discharge after the surgery, and none had a follow-up beyond 30 days.

In our study, there was a significant decrease in 90-day postoperative mortality during the study period, mainly attributable to a decline in mortality after RARP. This might reflect the RARP learning curve and increasing experience with this technique during the study period. In Sweden, RARPs were introduced in the university hospitals and subsequently adopted by smaller hospitals, so there was no trend in centralization that could account for the decreased mortality (8). There was no significant difference in mortality according to hospital surgical volume, although the risk estimates were consistently above one for low and intermediate volume centers compared with high volume centers.

Our finding of an almost tripled 90-day postoperative mortality among men with high-risk prostate cancer is surprising, but may be spurious due to the low number of events and wide confidence intervals. Apart from the lymphadenectomy, which we could adjust for, the surgery of locally advanced disease is more technically demanding with but not to the extent that it should explain such a strong increase in risk of death. Speculatively, surgery may be offered to men with more significant comorbidity and advanced tumours, and some residual confounding by comorbidity beyond what was accounted for by the Charlson Comorbidity Index could be a partial explanation.

In conclusion, there was no difference in 90-day postoperative mortality between men treated by RRP or RARP in Sweden in 1998-2012. Men who underwent RARP or RRP had

a very low risk of death within 90 days after surgery and mortality was lower than in an age-matched background population, highlighting the selection of healthy men for RP.

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Abbreviations

RP	Radical Prostatectomy
RRP	Radical Retropubic Prostatectomy
RARP	Robot Assisted Laparoscopic Radical Prostatectomy
NPCR	National Prostate Cancer Register
PLND	Pelvic Lymph Node Dissection
SMR	Standardised mortality ratio
CCI	Charlson Comorbidity index
PSA	Prostate-specific antigen
IQR	Interquartile Range
OR	Odds Ratio
CI	Confidence interval
NCCN	National Comprehensive Cancer Network
PCBaSe	Prostate Cancer data Base Sweden

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Figure 1.
Cumulative 90-day mortality after retropubic radical prostatectomy (RRP) and robot-assisted laparoscopic radical prostatectomy (RARP)

Table 1

Demographics and tumor characteristics of men with localized or locally advanced prostate cancer who underwent a primary radical prostatectomy in Prostate Cancer data Base Sweden (PCBaSe) 3.0 between January 1, 1998 and September 30, 2012,

	RRP	(%)	RARP	(%)	All men	(%)
All men	14820	(100)	7524	(100)	22344	(100)
PLND						
RP without PLND	10690	(72)	6463	(86)	17153	(77)
RP with PLND	4130	(28)	1061	(14)	5191	(23)
Treatment year						
1998-2007	9550	(64)	2015	(27)	11565	(52)
2008-2012	5270	(36)	5509	(73)	10779	(48)
Age at RP (years)						
Median (IQR)	63.7	(60-67)	63.5	(59-67)	63.6	(59-67)
<60	3914	(26)	2310	(31)	6224	(28)
60-64	4795	(32)	2236	(30)	7031	(31)
65-69	4524	(31)	2158	(29)	6682	(30)
70+	1587	(11)	820	(11)	2407	(11)
Marital status						
Married	11012	(74)	5388	(72)	16400	(73)
Not married	3711	(25)	2132	(28)	5843	(26)
Missing data	97	(1)	4	(0)	101	(0)
Educational level*						
High	3848	(26)	2923	(39)	6771	(30)
Middle	6050	(41)	3059	(41)	9109	(41)
Low	4767	(32)	1508	(20)	6275	(28)
Missing data	155	(1)	34	(0)	189	(1)
Charlson comorbidity						
CCI 0	13131	(89)	6747	(90)	19878	(89)
CCI 1	1078	(7)	446	(6)	1524	(7)
CCI 2+	611	(4)	331	(4)	942	(4)
Risk category						
Low risk	6404	(43)	3194	(42)	9598	(43)
Intermediate risk	6358	(43)	3435	(46)	9793	(44)
High risk	2058	(14)	895	(12)	2953	(13)
Center volume**						
1-75%	8984	(61)	1723	(23)	10707	(48)
76-90%	3616	(24)	1381	(18)	4997	(22)
91-100%	2220	(15)	4420	(59)	6640	(30)

RP = Radical prostatectomy, RRP = Retropubic radical prostatectomy, RARP = Robot-assisted laparoscopic prostatectomy, PLND = Pelvic lymph node dissection, IQR = Interquartile range,

CCI = Charlson Comorbidity Index: CCI 0 no comorbidity, CCI 1 mild comorbidity CCI 2+ moderate to severe comorbidity,

* Educational level: low = compulsory school (<10 years), upper secondary school (10-12 years), college or university (>12 years),

** Based on percentiles of RPs performed in Sweden in 2005, with the following cut-offs: 75% = 61, 90% = 109

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Table 2

Adjusted odds ratios of death within 90 days after radical prostatectomy in Prostate Cancer data Base Sweden (PCBaSe) 3.0 between January 1, 1998 and September 30, 2012

	Events	OR	95% CI
Type of RP			
RRP	29	1.00	(Ref.)
RARP	10	1.14	(0.46-2.81)
PLND			
RP without PLND	24	1.00	(Ref.)
RP with PLND	15	1.37	(0.67-2.78)
Treatment year			
1998-2007	26	1.00	(Ref.)
2008-2012	13	0.44	(0.21-0.95)
Age at RP			
1-year increase		1.07	(1.00-1.13)
Marital status			
Married	25	1.00	(Ref.)
Not married	14	1.76	(0.91-3.41)
Educational level			
High	14	1.00	(Ref.)
Middle	10	0.49	(0.22-1.11)
Low	15	0.88	(0.42-1.85)
Charlson comorbidity			
CCI 0	32	1.00	(Ref.)
CCI 1	3	1.02	(0.31-3.36)
CCI 2+	4	2.23	(0.77-6.40)
Risk category			
Low risk	11	1.00	(Ref.)
Intermediate risk	15	1.23	(0.55-2.74)
High risk	13	2.89	(1.18-7.06)
Center volume			
1-75%	20	1.00	(Ref.)
76-90%	10	0.93	(0.43-2.02)
91-100%	9	0.65	(0.26-1.62)

RP = Radical prostatectomy, RRP = Retropubic radical prostatectomy, RARP = Robot-assisted laparoscopic prostatectomy, PLND = Pelvic lymph node dissection, IQR = Interquartile range

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* Educational level: low = compulsory school (<10 years), upper secondary school (10-12 years), college or university (>12 years)

** Based on percentiles of RPs performed in Sweden in 2005, with the following cut-offs: 75% = 61, 90% = 109