The 90-day cause-specific mortality after radical prostatectomy: a nationwide population-based study

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Objective
To investigate the cause-specific mortality in the postoperative period after radical prostatectomy (RP) for prostate cancer (PCa).

Methods
In the National Prostate Cancer Register of Sweden (NPCR), we identified all men who died within 90 days after RP performed 1998–2018 and we assessed cause of death in a chart review. We compared the adjudications of death from our medical record review with those in in the Swedish Cause of Death Registry (CDR).

Results
Out of 44 635, 58 (0.13%) men who had undergone RP from 1998 through 2018 died within 90 days after RP. Per medical record review the most common causes of death were cardiac disease (30%) and venous thromboembolic events (VTE; 21%). No men died of metastatic PCa as was first indicated in the CDR. After robot-assisted RP (RARP) or open retropubic RP (RRP), the postoperative mortality was 0.09% (19/21 520) and 0.19% (37/19 635), respectively. The effect off modality was confounded mainly by year of surgery, age at surgery, Charlson Comorbidity Index score and the concomitant pelvic lymph node dissection.

Conclusion
The validated absolute 90-day mortality after RP was 1.3/1000 during the 21-year study period. Cardiovascular diseases were the most common causes of death after RP. Our validation of the CDR refuted the occurrence of postoperative deaths from metastatic PCa. There were differences in rates and type of mortality between RRP and RARP, but the RARP cohort was more recent than the RRP cohort, which likely explain the differences.

Keywords
cause-specific mortality, 90-day mortality, #PCSM, prostate cancer, #ProstateCancer, radical prostatectomy, validation

Introduction
The postoperative 30-day mortality after radical prostatectomy (RP) has been reported to range between 0.07% and 0.6% [1–9]. We have previously reported a postoperative 90-day mortality rate of 0.17% in a nationwide Swedish cohort [10]. In that study and in the most other studies the cause of death was either not reported or based on administrative registries with potential systematic errors of the adjudication of the causes of death. Specific cause of death after RP has been reported in two previous studies, both focussing on 30-day cause of death after RP. One in the Swedish National Prostate Cancer Registry (NPCR) between the years 1997–2002 with only four deaths [9] and one in a Canadian registry in 2005 with high mortality rate, 0.5%, compared with more recent series and missing data on 47% of the deaths [11].

In general, the validity of cause-of-death data in the Swedish Cause of Death Registry (CDR) has been reported to be high among men with prostate cancer (PCa) [12]. This may not be true for early postoperative mortality after RP because of the general routine to upgrade the cause of death to the underlying cancer [13, 14]. Therefore, we reviewed medical records for all men who died within 90 days of RP during a 21-year period in order to validate the direct causes of death and to obtain an unbiased estimate of the postoperative mortality after RP. In addition, we also aimed to assess any
differences between different surgical techniques with regards to causes of postoperative deaths.

**Patients and Methods**

**NPCR and Prostate Cancer database Sweden (PCBaSe)**

The NPCR of Sweden is a clinical cancer register that captures 98% of all cases of PCa in Sweden compared to the Cancer Registry to which reporting is mandated by law [15]. The NPCR includes information on date of diagnosis, age, tumour stage, Gleason score and serum PSA levels at date of diagnosis, as well as primary treatment. The NPCR has been described in detail in previously [16–18]. The NPCR annually receives data on cause of death from the CDR.

In the PCBaSe, the NPCR has been linked to a number of nationwide healthcare and demographic registers at the National Board of Health and Welfare and Statistics Sweden. This linkage includes the Swedish National Cancer Register, the CDR, the Prescribed Drug Registry, the National Patient Registry, and multiple other registries and have been described in detail previously [18, 19].

**Study Population and Setting**

All men in the NPCR with localised PCa planned for a RP (clinical stage T1–T3, N0/NX, M0/MX with PSA levels of <50 μg/mL at the time of diagnosis), between the 1 January 1998 and the 30 July 2018, who died within 90 days from the RP were identified. We used the Swedish Personal Identity Number [20] to retrieve medical records from the hospital where the RP was performed and the hospital that reported the death. We reviewed the medical records including autopsy records for cause of death and compared with the cause of death in the CDR. We based the cause of death on autopsy results if available, otherwise from the clinical assessment by the physician who examined the man at the time of death. A cancer-specific death in the medical record review was defined as death with a metastatic burden of that specific cancer. The causes of death were divided into groups of similar aetiology (Appendix S1). All medical records were reviewed by J.B., M.A. and E.R. independently and then discussed to a consensus if there were disagreements. In addition to the cause of death, information on type of RP performed, pelvic lymph node dissection (PLND), pre-existing medical conditions, and hospital was extracted from the medical record review. Information on pre-existing medical conditions were used to create a Charlson Comorbidity Index (CCI) score for these patients.

We further identified all men in the PCBaSe who underwent RP during the same time period with the same inclusion criteria (clinical stage T1–T3, N0/NX, M0/MX with PSA levels of <50 μg/mL at the time of diagnosis). For these patients we collected information on type of RP, age at surgery, time of surgery, PSA at diagnosis, hospital, CCI, and death within 90-days of surgery from the PCBaSe. We collected this information from the PCBaSe as the type of RP (open retropubic RP [RRP], robot-assisted RP [RARP] and laparoscopic RP [LRP]) was not available from the NPCR directly. The patients with a death within 90 days according to the PCBaSe (n = 64) were excluded and replaced with the patients dying according to the chart review.

The study was approved by the Research Ethics Board at Uppsala University Hospital.

**Statistical Analysis**

Causes of death extracted from the CDR and via medical records review were described in terms of counts and frequencies.

The odds ratios (ORs) and 95% CI of the association between different surgical techniques and 90-day postoperative mortality were estimated using logistic regression. To allow for a direct comparison between different surgical techniques, this analysis was restricted to men treated after 2002, the year when RARP was introduced in Sweden. Given the low numbers of outcomes in men treated with LRP, this group was excluded from the analysis, and we compared RARP to RRP only. The confounders included in the model were year of surgery (categorised into quartiles: 2002–2007, 2008–2010, 2011–2014 and 2015–2018), age at surgery, hospital volume, CCI (categorised into 0, 1 and ≥2) [21], and a concomitant PLND. Hospital volume was defined as an average number of RPs per hospital per year during the study period and categorised into clinically meaningful groups i.e., small-volume (<30 RPs/year), medium-volume (30–100 RPs/year), and high-volume (>100 RPs/year) hospitals. As the medical review revealed that no cause of the death was directly attributable to progressive prostate cancer, tumour characteristics were not likely determinants of the 90-day mortality and were not included in the analysis as confounders. In addition to the all-cause 90-day mortality, we also evaluated the association between different surgical techniques and individual causes of 90-day mortality. Given the small numbers of the events, we performed only univariable analyses using logistic regression and Fisher’s exact test [22].

As a sensitivity analysis to the multivariable model, we also used the inverse probability of treatment weighting (IPTW) to adjust for confounding [23]. IPTWs were calculated for each subject as the inverse of their probability to receive the treatment they had. All of the abovementioned confounders were included in the propensity score model. We allowed a non-linear association between the age and the treatment by
modelling age using restricted cubic splines (with a knot at 64 years of age), and we included the interaction between the PLND and the age in the model.

All statistical analyses were performed in Stata (version 15.1, StataCorp., College Station, TX, USA).

**Results**

During the study period a total of 88 men died within 90 days of a RP for localised PCa and thus evaluated for the causes of death. We were able to retrieve medical records from time of surgery for all but two men. Among the remaining 86 men, we found that eight men had not undergone a RP, and 20 men had undergone a cystoprostatectomy for bladder cancer (Fig. 1). Of the eight men not undergoing RP, six of these men died while on the waiting list for RP, one man underwent radiotherapy, and one man had his operation cancelled due to rapidly progressing bladder cancer. Thus, 58 men who died within 90 days of RP remained for analysis (Fig. 1).

Of these 58 men, who truly died within 90 days after RP, we were able to retrieve the medical record from the actual time of death for 53 men (91%). Comorbidity was examined in the medical record review where 20/58 had no known comorbidity at the time of RP. In all, 14/58 men had a minor medical condition or had prior minor surgery, such as hypertension, appendectomy or hernia repair. In all, 24/58 had a major comorbidity or had undergone previous major surgery, such as diabetes, previous myocardial infarction, kidney failure or coronary artery bypass grafting. The median (interquartile range [IQR]) Gleason score was 7 (7–8), 38% had pT2 and 62% had pT3 on final pathology.

While the CDR had PCa as the most common cause of death (16/58, 28%), we did not identify any man who actually died with metastatic PCa in the postoperative 90-day period. After validation of the charts, the most common causes of death were instead cardiac disease (16/53, 30%) and venous thromboembolic disease (VTE; 11/53, 21%). Five men died of other cancers both according to the medical records and the CDR. These cancers, one bile duct cancer, one pancreatic cancer, one malignant melanoma, one lung cancer, and one cancer of unknown primary (on pathology deemed not of prostate origin) were all metastatic at the time of death but unknown at the time of RP. The comparison between the CDR and the medical records data is presented in Table 1 and a case-by-case matching is available in Appendix S2.

Most of the deaths, 31/58 (53%), occurred during the first month. The 30-day all-cause mortality was 0.07%. In all, 10 out of 11 (91%) of all thromboembolism-related deaths, half (eight of 16) of all heart-disease-related deaths, all (five of five) cerebrovascular-disease-related deaths, and five out of six (83%) of all ileus-related deaths occurred during the first month. In all, 12/58 (21%) deaths occurred in the second month and 15/58 (26%) in the third. The causes of death per month are presented in Appendix S3. The proportion of men having an autopsy was 83%, 80%, and 27% in the first, second, and third month, respectively.

With the comparison population from the PCBaSe 44 635 men underwent a RP for localised PCa during the study

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**Table 1** Comparison of cause of death recorded in the Swedish NPCR with the medical records review.

| Cause of death                             | Swedish NPCR | Medical records review |
|--------------------------------------------|-------------|-----------------------|
| Diabetes/metabolic disease                 | 3 (5)       | 0 (0)                 |
| Prostate cancer                            | 16 (26)     | 0 (0)                 |
| Gastrointestinal bleeding                  | 1 (2)       | 1 (2)                 |
| Postoperative haemorrhage                  | 1 (2)       | 1 (2)                 |
| Unknown                                    | 2 (3)       | 1 (2)                 |
| Other                                      | 3 (5)       | 1 (2)                 |
| Infection                                  | 1 (2)       | 2 (4)                 |
| Suicide                                    | 4 (7)       | 4 (6)                 |
| Cerebrovascular insult                     | 4 (7)       | 5 (9)                 |
| Ileus with aspiration                      | 3 (5)       | 6 (11)                |
| Other cancer                               | 5 (9)       | 5 (9)                 |
| Venous trombolic event                     | 1 (2)       | 11 (21)               |
| Cardiac disease                            | 14 (24)     | 16 (30)               |
| Total                                      | 58 (100)    | 53 (100)              |

Five men excluded from medical record analysis due to missing medical record at time of death.
period corresponding to a 90-day all-cause mortality of 0.13%. In all, 19,637 had a RRP, 21,517 a RARP, and 3,481 a LRP. RARP was primarily done in the latter part of the study period (2018 vs 2008), while RRP and LRP were more equally distributed (10,521 vs 9,116 and 1,798 vs 1,683), 1997–2007 vs 2008–2018. The baseline characteristics of the 90-day mortality cohort compared to the men without 90-day mortality extracted from the PCBaSe are presented in Table 2.

The absolute risk of 90-day postoperative mortality was 0.19%, 0.09%, and 0.06% for RRP, RARP, and LRP, respectively. In the multivariable analysis, comparing RRP and RARP, adjusted for year of surgery, age, CCI, hospital volume and concomitant PLND, there was no significant difference in the 90-day postoperative mortality between the different treatment modalities (OR 0.81, 95% CI 0.36–1.83; P = 0.618 for RARP vs RRP; Table 3). The results from the IPTW analysis were very similar, with non-statistically significant ORs in favour of RARP. Interestingly, being treated with RP after 2006, and in a large-volume hospital was associated with lower risk of 90-day postoperative mortality, whereas concomitant PLND, CCI score ≥2 and age were associated with an increased risk of 90-day postoperative mortality.

Causes of death was compared between RARP and RRP, full table in Appendix S4. VTE, cardiac disease, cerebrovascular insult and suicide were more common after RRP than after RARP but only VTE was statistically significant (OR 4.93, 95% CI 1.20–22.82; P = 0.032) in a univariable model.

### Discussion

In the present cohort of 44,635 men who underwent RP in Sweden between 1998 and 2018, 58 (0.13%) men died within 90 days. The most common causes of death after RP were cardiovascular disease, mainly cardiac disease and thromboembolism. Postoperative mortality was highest in the first month after surgery. None of the men who died within 90 days after RP died from metastatic PCa.

The main finding is consistent with the previous cause-specific mortality finding reported from the NPCR by Carlsson et al. [9] in 2009, with the addition of VTE as a major contributor to postoperative mortality. This was expected as we included most of the 3,800 patients evaluated in that study. It is also consistent with the Canadian register study from 2005 identifying cardiac disease and VTE as the main causes of death, 38% and 13% respectively, within 30 days; however, that study was a register-based study that only could examine the 53% who died in hospital, the 30-day mortality rate was also much higher at 0.5% compared 0.13% at 90-days in our present study [11]. Studies evaluating short-term complications after RP also report cardiovascular events...
and VTE as common major complications consistent with our present findings [24].

Our validation of the register data revealed limitations of the register data. Almost a quarter of the men dying within 90 days of surgery in the NPCR had in fact undergone a cystoprostatectomy for bladder cancer. These men had been registered in the NPCR after having undergone a cystoprostatectomy where concomitant PCa was diagnosed incidentally. This finding is consistent with a review of the NPCR by Tomic et al. [25] that suggested an overrepresentation of bladder cancer in the registry. Furthermore, eight out of 88 (9%) men had been registered as planned for surgery but did never in fact underwent the procedure for different reasons. Most of the men erroneously registered as undergoing a RP, can be excluded by linking the NPCR to the Swedish Inpatient Registry in order to cross-check for the correct surgical code. This is performed on a regular basis in the PCBaSe [19].

The cause of death in our present review of medical records for men who had undergone RP and that in the Swedish CDR differed for 34% (18/53) of the men. The reason for this discrepancy is that the CDR adjudicates death to the underlying cause as the immediate cause of death. For instance, a man who dies of a myocardial infarction as a complication to diabetes mellitus is recorded as dead from diabetes and a man who dies of a myocardial infarction in the postoperative period after PCa surgery is recorded as dead from PCa [13, 14]. None of the men with PCa as cause of death in the CDR had any signs of PCa metastases in the medical record up to the time of death.

These findings are consistent with a previous report from the Geneva Registry following breast cancer surgery [26]. According to the Swedish CDR the results that we found are a result of the WHO manual of attributing cause of death and are therefore likely to apply to other international cause of death registries using the WHO manual. In regard to cancers where the short-term postoperative risk of death from cancer is low this needs to be considered when studying causes of short-term postoperative mortality.

Difference in mortality between different surgical modalities has previously been studied in a similar Swedish setting [10]. The present study adds 6 years of study time and doubles the study cohort size. The present study also verifies the modality of surgery that was used in each patient that died within 90 days and ensures that the patient did indeed undergo RP for PCa and not RP as part of another surgical procedure such as cystoprostatectomy. Comparing the death rates, the absolute rate decreased and the absolute difference between the modalities increased compared to the earlier study. However, the difference was not statistically significant and other factors such as age, CCI, concomitant PLND and year of surgery were responsible for the majority of the difference in 90-day mortality.

As the frequency of RRP declined rapidly after the introduction of the RARP, we had limited possibilities to distinguish effects of time period from that of surgical modality. Our present analysis showed that time of surgery was a strong predictor of the lower absolute mortality rate after RARP. This is likely attributable to the year of surgery being a proxy of improvements in general surgical safety, introduction of VTE prophylaxis protocols, and others rather than the surgical technique itself. The analysis showed that it was mostly from 2006 that had a major impact indicating that the introduction of RARP during that period could have led to mortality improvements in both modalities.

We attempted to reduce the bias in the estimates of the association between treatment type and 90-day postoperative mortality by adjusting for known measured confounders and for proxies (i.e. year of surgery) of some unknown and unmeasured confounders. Assuming that the effect of the remaining unmeasured or unknown confounders is small, our present results suggest, although not statistically significantly, a lower risk of all-cause 90-day postoperative mortality for men treated with RARP vs RRP. This would be compatible with a lower 90-day postoperative mortality for laparoscopic vs open surgery in population-based comparisons in rectal cancer cohorts. Trends toward lower rates of cardiovascular events for laparoscopic surgery have also been seen in systematic reviews of randomised trials in colorectal cancer [27, 28]. The difference in the risk of a VTE-related death in RARP vs RRP is likely caused by the same confounders as when comparing the two modalities as a whole. This brings to light one of the major limitations in the present analysis, the rarity of the outcome of interest. Both the lack of power and the unknown or unmeasured confounders could influence the results, and they should, thus, be interpreted with care.

Finally, our present analysis also showed that age and PLND were strong predictors of increased risk of 90-day postoperative mortality. These results suggest that the indication for PLND should be carefully considered among elderly men who have lower chance of benefitting from the treatment altogether. The benefit vs risks of PLND in elderly males warrants further studies.

In conclusion, 90-day mortality after RP was 0.13% after exclusion of incorrectly adjudicated deaths in the register-based data. The most common cause of death after a RP was cardiac disease followed by thromboembolic events. No man in the cohort of operated men died of PCa in the postoperative period, in contrast to the official statistics.
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Conflict of Interest

None of the authors have anything to disclose.

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Abbreviations: CCI, Charlson Comorbidity Index; CDR, Swedish Cause of Death Registry; IPTW, inverse probability of treatment weighting; IQR, interquartile range; LRP, laparoscopic radical prostatectomy; NPCR, National Prostate Cancer Register of Sweden; OR, odds ratio; PCa, prostate cancer; PCaSe, Prostate Cancer Database Sweden; PLND, pelvic lymph node dissection; RARP, robot-assisted laparoscopic RP; RP, radical prostatectomy; OR, odds ratio; RRP, retropubic RP; VTE, venous thromboembolic events.
Supporting Information
Additional Supporting Information may be found in the online version of this article:

Appendix S1. International Classification of Diseases (ICD) codes used to group causes of death according to the similar aetiology.

Appendix S2. Matched comparison of cause of death in the Swedish CDR and the review of medical record for 53 men with known cause of death.

Appendix S3. The causes of death identified via medical records review at 1, 2 and 3 months after RP.

Appendix S4. Absolute 90-day risk of dying after RRP and RARP by cause of death according to the medical record review in number and percentage.