

Time trends in prostate cancer surgery: data from an Internet-based multicentre database

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OBJECTIVES

- To report our experience with an Internet-based multicentre database that enables tumour documentation, as well as the collection of quality-related parameters and follow-up data, in surgically treated patients with prostate cancer.
- The system was used to assess the quality of prostate cancer surgery and to analyze possible time-dependent trends in the quality of care.

PATIENTS AND METHODS

- An Internet-based database system enabled a standardized collection of treatment data and clinical findings from the participating urological centres for the years 2005–2009.
- An analysis was performed aiming to evaluate relevant patient characteristics (age, pathological tumour stage,

What's known on the subject? and What does the study add?

Treatment recommendations such as interdisciplinary guidelines are always based on scientific publications. However, high-quality studies are very often focused on single-centre series of selected cases. Health care research has failed to provide comprehensive information that describes the clinical reality of prostate cancer management even in smaller centres.

This is a health care research study with 17 participating centres. Any prostate cancer centre can use the internet-based database <http://prostata-ca.net>, at no additional cost, to collect and analyze data for quality management, to conduct consecutive follow-up assessments, and to compare their data with the averages recorded by all other centres. The database also enables time trend analysis of certain quality parameters in an annual comparison.

preoperative International Index of Erectile Function-5 score), intra-operative parameters (operating time, percentage of nerve-sparing operations, complication rate, transfusion rate, number of resected lymph nodes) and postoperative parameters (hospitalization time, re-operation rate, catheter indwelling time).

- Mean values were calculated and compared for each annual cohort from 2005 to 2008. The overall survival rate was also calculated for a subgroup of the Berlin patients.

RESULTS

- A total of 914, 1120, 1434 and 1750 patients submitted to radical prostatectomy in 2005, 2006, 2007 and 2008 were documented in the database.
- The mean age at the time of surgery remained constant (66 years) during the study period.
- More than half the patients already had erectile dysfunction before surgery (median International Index of Erectile Function-5 score of 19–20).

- During the observation period, there was a decrease in the percentage of pT2 tumours (1% in 2005; 64% in 2008) and a slight increase in the percentage of patients with lymph node metastases (8% in 2005; 10% in 2008). No time trend was found for the operating time (142–155 min) or the percentage of nerve-sparing operations (72–78% in patients without erectile dysfunction).
- A decreasing frequency was observed for the parameters: blood transfusions (1.9% in 2005; 0.5% in 2008),

postoperative bleeding (2.6%; 1.2%) and re-operations (4.5%; 2.8%). The mean hospitalization time decreased accordingly (10 days in 2005; 8 days in 2008). The examined subcohort had an overall mortality of 1.5% (median follow-up of 3 years).

CONCLUSIONS

- An Internet-based database system for tumour documentation in patients with prostate cancer enables the collection and

assessment of important parameters for the quality of care and outcomes.

- The participating centres show an improvement in the quality of surgical management, including a reduction of the complication rate.

KEYWORDS

prostate cancer, radical retropubic prostatectomy, quality control, morbidity, quality of life, time trends

INTRODUCTION

Prostate cancer is the most common male malignancy in the Federal Republic of Germany and can be treated by a variety of methods [1]. Quality standards for prostate cancer surgery have not yet been adequately defined. The available data are essentially based on single-centre series, which are naturally prone to selection bias. Unselected data on current care practice are not available for this malignancy.

The present study aims to assess the quality of prostate cancer surgery at the participating centres. For this purpose, intra- and postoperative clinicopathological parameters and variables have been centrally collected in an Internet-based database since January 2005. Possible time trends are analyzed across the period covered thus far. The investigation is directed and coordinated by the Berlin Tumor Center, Inc. (a facility of the German Cancer Society).

PATIENTS AND METHODS

An Internet-based database (IOMTech GmbH, Berlin & Charité – Universitätsmedizin Berlin; <http://www.prostata-ca.net>) is used. Written informed consent is obtained from patients before starting the pseudonymized data collection. Various therapy-related areas are documented: epidemiological parameters (e.g. age, etc.), pre-, intra- and postoperative data, a detailed diagnosis (based on histological findings) and a follow-up.

The difference between the preoperative and discharge haemoglobin (Hb) levels was considered to be the actual Hb loss.

Transfusion was assumed to increase the recipient Hb level by 0.003 g/dL per mL of transfused erythrocyte concentrate. The transfusion rate is specified as a percentage of operated patients with peri-operative blood transfusions. The exact number of transfused concentrates or autotransfused volumes is not reported.

Serious complications (corresponding to Clavien classification [2] grade ≥ 3) were considered to be: intra-operative events such as rectal, neural or ureteral injury, re-operation in the postoperative phase (because of postoperative bleeding or lymphocele, etc.) or other severe peri-operative events (e.g. pulmonary embolism, myocardial infarction and apoplexy). All other intra- and postoperative events (e.g. wound infection, thrombosis, etc.) were considered to be mild complications (corresponding to Clavien classification grade 1–2).

The follow-up includes PSA levels over time, continence and potency (International Index of Erectile Function-5 with and without phosphodiesterase type 5 inhibitors).

Mortality analysis was possible for the subgroup of patients from Berlin. After obtaining consent from the centre involved, the Berlin Tumor Center addressed a central inquiry to the State Residency Office.

RESULTS

STATUS AT THE TIME OF ASSESSMENT IN JANUARY 2010

In total, 17 centres from various German federal states participated, and at least

10 patients were included from each of them (mean 334; median, 212). Radical prostatectomy was performed in 5218 of these patients (914 in 2005, 1120 in 2006, 1434 in 2007 and 1750 in 2008).

The parameters collected in assessable quality were: age, initial mean PSA, clinical tumour stage, International Index of Erectile Function-5, operating time, percentage of nerve-sparing operations, hospitalization time, catheter indwelling time, pathological tumour stage (including lymph node stage and number of resected lymph nodes), surgical margin status, specimen Gleason score, blood loss (Hb difference in g/dL), transfusion rate, rate of mild and severe complications, overall survival in relation to the biopsy Gleason score, clinical stage and lymph node status. Tables 1–3 show the time course of basic characteristics, peri-operative parameters and complications.

Open retropubic radical prostatectomy was performed in most (70.4%) of the 5218 interventions, perineal radical prostatectomy in 8.2% and laparoscopic radical prostatectomy in 8.7%. No distinction was made between conventional and robot-assisted laparoscopy. Data on the method of access were missing in 12.7%.

At the time of the intervention, 1507 of patients treated during the observation period were residing in Berlin. A central inquiry directed to the registration office of this federal state showed that 117 patients had moved and 21 had died. Overall survival after 48 months only differed significantly between advanced (T3, 91%) and localized tumour stages (T2, 98%; $P = 0.03$), as well as between node-positive (N+; 95%) and

Variable	2005	2006	2007	2008	TABLE 1 <i>Epidemiological parameters</i>
Age (years), median	66	66	66	66	
Initial mean PSA (ng/mL), median	7.0	7.0	7.1	7.4	
Percentage (clinical examination)	95.0	95.6	94.5	93.9	
Locally limited tumours < T3 (%)					<i>IIEF, International Index of Erectile Function.</i>
Preoperative IIEF-5 score, median	19	20	20	20	

Variable	2005	2006	2007	2008	TABLE 2 <i>Peri-operative parameters</i>
Operating time (min), median	140	131	137	145	
Nerve-sparing operations (%)	76	74	72	78	
Hospitalization time (days), median	10	10	10	8	
Catheter indwelling time (days), median	10	10	9	8	
Pathological examination	71	71	70	64	
Locally limited tumours < T3, N- (%)					
Lymph node metastases (%)	8	8	7	10	
R+ (%)	23	24	26	29	
R+ in pT2 (%)	12	14	16	16	
Gleason score in specimen, median	7	7	7	7	
Percentage of lymph nodes, median	10	10	9	10	

Variable	2005	2006	2007	2008	TABLE 3 <i>Morbidity</i>
Blood loss (transfusion-corrected Hb difference in g/dL), median	3.05	3.2	3.0	3.0	
Transfusion rate (%)	1.9	0.2	0.7	0.5	<i>*Clavien classification grade 1-2. †Clavien classification grade ≥3.</i>
Rate of mild complications (%)*	24.1	11.8	14.9	9.9	
Rate of severe complications (%)†	6.5	4.2	5.2	4.2	

node-negative patients (N-, 91%; $P = 0.05$) but not between various Gleason scores.

DISCUSSION

The Internet-based database (<http://www.prostata-ca.net>) permits centralized web-based documentation of quality-related data on all prostate cancer therapies, particularly radical prostatectomy. The database offers a benchmarking and statistics module that is easy to use without the requirement of extensive previous knowledge and readily enables a comparison any results obtained with the mean total values. This applies to both hospitals and individual surgeons. However, the present study does not consider such differences in terms of inter-individual benchmarking but reports total group results.

It enables a broad representative assessment of time trends in quality-related parameters of surgical therapy, which is essential

for monitoring care quality. During the analysis period, no trends were observed in the parameters: age at the time of therapy, pretherapeutic PSA, pretherapeutic International Index of Erectile Function-5 score, operating time and percentage of nerve-sparing operations. Pretreatment clinical tumour stages also showed no clear development pattern over time. However, evidence of time trends could be found for the parameters: percentage of pT2 tumours during the observation period (71% in 2005 and 64% in 2008) and percentage of patients with lymph node metastases (8% in 2005 and 10% in 2008). We attribute these trends to the increasing acceptance of surgery, even for locally advanced tumours [3], and to the variety of surgical techniques. The follow-up of these patients will show how these findings influence the biochemical freedom from relapse, particularly with respect to whether a higher rate of positive margins results in a higher biochemical relapse rate, as already reported in other series [4].

A trend towards greater surgical safety and quality is evident in the percentage of both severe and mild complications (6.5% and 24.1% in 2005 vs 4.2% and 9.9% in 2008). Especially noteworthy is the improvement in the parameters: transfusion rate (1.9% in 2005, 0.5% in 2008), postoperative hemorrhage rate (2.6%, 1.2%) and re-operation rate (4.5%, 2.8%). The overall complication rate of 20-30% is relatively high compared to that reported in monocentre studies [5-11].

However, it is difficult to make a direct comparison with similar unselected datasets such as the Cancer of the Prostate Strategic Urologic Research Endeavor registry [12] because their health-related quality-of-life questionnaire results after radical prostatectomy relate mainly to continence and potency and no information is provided on morbidity.

The oncosurgical quality is good throughout the entire documentation.

The median blood loss was lower for laparoscopic surgery than for the other two surgical methods (median transfusion-corrected Hb difference is 3.27 g/dL for open retropubic radical prostatectomy, 2.25 g/dL for laparoscopic radical prostatectomy and 2.7 g/dL for perineal radical prostatectomy). However, laparoscopic surgery was performed in only 8.7% of patients and perineal surgery in 4.3% of patients. This observation coincides with findings relating to various surgical methods reported in other series [11,13-18]. However, the detected difference of only 0.57 g/dL is of no clinical relevance, particularly with reference to the need for transfusion. None of the surgical methods showed a trend across annual cohorts.

The percentage of lasting anastomotic leaks is low for the total observation period and continues to decrease over the years (6.7% in 2005 and 2.6% in 2008). However, the catheter indwelling time remains stable at 10 days. The term 'anastomotic leak' is difficult to define. First, there is the problem of not knowing whether anastomotic tightness has been determined and, if so, what examinations were performed (X-ray/TRUS) on what day. Second, the indwelling catheter is already removed as early as the third postoperative day at some centres and not until the day 14 at others.

The mean number of resected lymph nodes was 10, which is the lower limit of the number recommended by the German Association of Urology in the Interdisciplinary S3 Guidelines (at least 10 lymph nodes) [19]. On the one hand, these results at the lower normal limit could imply a lower quality than that achieved in monocentre studies [20–22]. On the other hand, the guidelines were based mainly on monocentre series that may not be universally representative. The guidelines of the European Association of Urology do not specify a minimum number of lymph nodes to be resected [23] and the long-term clinical course remains to be assessed.

The present study has substantial limitations: the observation period is still short and does not permit an interpretation of long-term trends. However, the quality of care is relatively stable within this observation period.

Valid follow-up data are lacking regarding incontinence and potency, as well as the general health-related quality of life. They have been collected at several centres since 2008. In particular, the recovery of erectile function takes up to 2 years [24–26]. This will be assessed in future studies because long-term follow-up data are required.

For financial reasons, the present database operates without external quality assurance or external monitoring. The data density of such 'voluntary' documentation is naturally lower than in clinical studies with external sponsoring/monitoring. To maintain high-quality documentation, all participating centre directors signed a contract between themselves and the Berlin Tumor Center to record all their patients' data (particularly complications) in the system. The semi-automatic plausibility and validity check is jointly monitored during regular group meetings. As noted above, the system enables individual centres to compare their data with the mean total values, although public benchmarking with ranking does not take place. In this respect, the data can definitely be considered reliable.

Overall survival and tumour-specific survival of the Berlin patients have been analyzed during the period covered thus far. The results presented here coincide with those from other series [27,28]. Nevertheless, it is not yet advisable to assess the oncological

results for several reasons. A follow-up of no more than 4 years is generally inadequate for prostate cancer because, as a result of the slow progression of this tumour, typical prognostic factors such as the Gleason score can only predict overall and progression-free survival after many years. Moreover, survival data could only be obtained from the local cancer registries in one of the six participating federal German states. This may be attributed to the fact that registry management is still inconsistent in Germany. Ultimately, only the minority had a complete follow-up that included the PSA.

In conclusion, the documentation of quality-related parameters in prostate cancer therapy with the Internet-based system (<http://www.prostata-ca.net>) shows a high quality of care with a broad-based coverage. Centres have thus been provided with a tool that ensures adequate quality monitoring. Comparison of the annual cohorts from 2005 to 2008 showed no trends in most of the parameters. The care level is stable across all centres. Important quality-related parameters such as transfusion and re-operation rates show a trend toward quality improvement. However, there is an upward trend in the percentage of tumours with extracapsular extension, as well as in the percentage of positive surgical margins.

CONFLICT OF INTEREST

None declared.

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Abbreviation: Hb, haemoglobin.