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ORIGINAL ARTICLE

High volume is the key for improving in-hospital outcomes after radical prostatectomy: a total population analysis in Germany from 2006 to 2013

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Abstract
Purpose Outcomes of radical prostatectomy are prone to publication bias, because most of the data originated from highly specialized centers. We assessed in-hospital outcomes of all radical prostatectomies in Germany from 2006 to 2013 focusing on caseload volume, surgical approach, and certification status.
Methods We analyzed the nationwide German hospital billing data covering 221,331 radical prostatectomies from 2006 to 2013. Outcomes were in-hospital mortality, surgical revision, and transfusion rates and the length of stay. Multivariate models described the impact of these factors.
Results The yearly number of radical prostatectomies declined from 28,374 to 21,850. While shares of all other approaches decreased, shares for robot-assisted prostatectomy increased from 0.6 to 25.2%. Hospitals with ≥100 cases a year reported lower in-hospital mortality with 0.08 versus 0.17% for hospitals with <50 cases a year. On multivariate analysis, the odds for an individual death were doubled in hospitals with <50 cases a year. All other factors showed no significant impact on mortality. Concerning blood transfusion, the surgical approach was the strongest predictor with minimally invasive surgery (26% of the odds of conventional surgery) followed by caseload volume. Surgical revision was frequent in hospitals with lower rates of minimally invasive approaches (OR 1.6) and smaller caseloads (OR 1.4). Length of stay was reduced by 3 days for caseloads ≥200 a year, 2 days with minimally invasive approaches, and 1 day in certified prostate cancer centers. Lacking clinical information is a major limitation.
Conclusions Annual caseload volume of hospitals is the most important factor for improved in-hospital outcomes.

Keywords Prostate cancer · Prostatectomy · Caseload · Robotics · Health services research

Abbreviations

ORPE	Retropubic radical prostatectomy
LRPE	Laparoscopic radical prostatectomy
RRPE	Robot-assisted radical prostatectomy
PRBC	Packed red blood cells
ICD	International classification of diseases
OPS	Classification of Operations and Procedures
Destatis	German Federal Statistical Office

Introduction

Radical prostatectomy is a standard procedure to treat non-metastatic prostate cancer [1]. Its high degree of standardization leads to moderate morbidity and low mortality. Two aspects that might further improve outcomes are the robot-assisted approach and an increased degree of specialization.

As part of the technical progress in minimally invasive surgery, robot-assisted radical prostatectomy (RRPE) has expanded the spectrum of surgical approaches. While it has already become the surgical standard in the USA [2–4], this trend seems to be delayed in other countries like Germany where open (retropubic) radical prostatectomy (ORPE) still

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dominates [5]. Several technological innovations promise better outcome like lower complication-rates and an accelerated healing process. With increasing surgical experience and more mature data, some of these promises have become evident in recent literature [6–8]. However, there are also studies with mixed results, especially regarding long-term outcomes [9–12].

Surgical expertise has been shown to be another important prerequisite for better outcomes after radical prostatectomy [13, 14]. Annual caseload per surgeon and institution can serve as a surrogate for this expertise. Other surrogate features are certification programs that often refer to a certain minimum caseload. Since 2007, a prostate cancer certification program has been established in Germany that requires a minimum of 50 radical prostatectomies and extensive additional quality assurance measures.

The aim of this study was to analyze the impact of surgical approach and degree of specialization on in-hospital outcomes after radical prostatectomy on a total population level.

Materials and methods

Since 2004 in Germany, reimbursement of inpatient treatment is based on an adapted version of the international diagnose-related groups coding diagnoses according to ICD-10 and medical procedures according to a German version of the international classification of operations and procedures. Records containing the diagnoses and procedures of each in-hospital case are transferred annually to the Institute of Hospital Remuneration and consecutively to the German Federal Statistical Office (Destatis). Because of German data protection requirements access to the raw data is prohibited and must be performed by remote data processing. Likewise, identification of single cases or hospitals is not possible and results which could allow identification are censored. With regard to our investigation, the data contained in the Destatis database are complete on a total population level.

Cases with a prostate cancer diagnosis (ICD-10: C.61) in combination with radical prostatectomy (OPS 5-604) were included. Moreover, OPS codes 5-987 (use of a surgical robot) and 8800c (transfusion of packed red blood cells) were assessed. Surgical revision was defined using either one of the OPS codes 5-6097 (surgical revision), 5-5410/5-5411 (explorative laparotomy), 5-5412/5-5413 (relaparotomy) during the same hospital stay.

The Destatis annual databases were complemented with additional hospital characteristics (e.g., the presence of a robotic surgical system and certification status) using the institute identification number.

Since 2007, the German Cancer Society encourages hospitals to acquire a voluntary certification as "prostate cancer center." Among others, requirements are a yearly minimum caseload of 50 radical prostatectomies per center, standardized processes of diagnosis, treatment evaluation, therapy, and a scheduled follow-up of patients. Effectively, this certificate has become standard throughout the last years with 86 certified centers in Germany in 2013 (Fig. 1). A competing and less accepted certification program by the German Federation of Prostate Centers was not included in our definition of certified "prostate cancer centers" because it included also benign prostatic diseases and missed minimum caseload requirements.

We performed all actions in accordance with the Declaration of Helsinki in its latest version. Analyzed data were

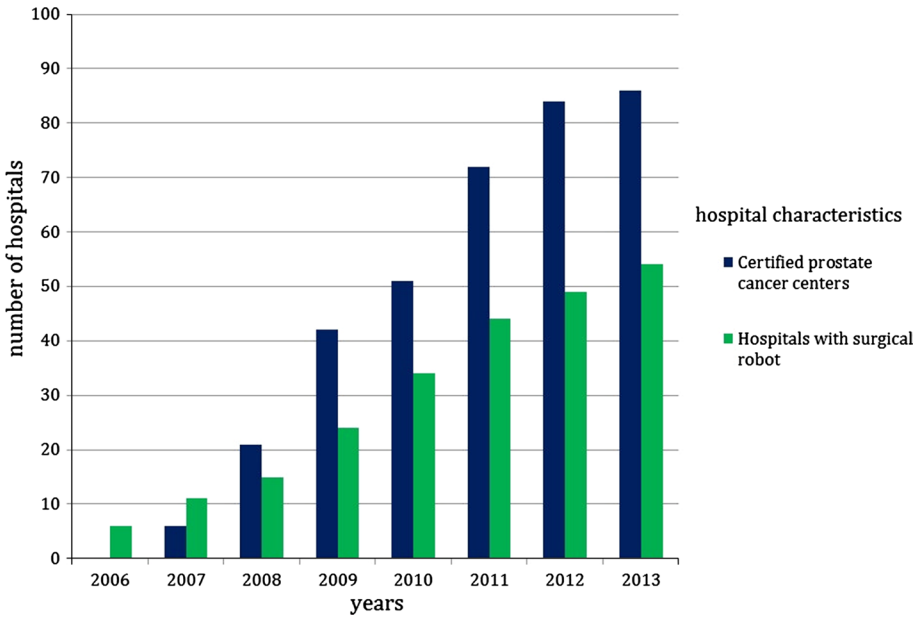


Fig. 1 Number of hospitals using a surgical robot and hospitals certified as prostate cancer center over time

Table 1 Multivariate logit-model displaying the rate of in-hospital mortality, transfusion, and surgical revision

Variables	Mortality Odds ratio (95% CI)	Transfusion Odds ratio (95% CI)	Surgical revision Odds ratio (95% CI)
Caseload			
0–19	2.26 (1.21–4.20)	2.81 (2.62–3.01)	1.42 (1.10–1.82)
20–49	2.11 (1.39–3.20)	2.01 (1.92–2.10)	1.21 (1.03–1.41)
50–99	1.64 (1.12–2.40)	1.61 (1.54–1.68)	1.21 (1.07–1.38)
100–199	1.22 (0.78–1.85)	1.29 (1.23–1.35)	1.10 (0.96–1.25)
200 + (reference)	1	1	1
Share of RRPE and LRPE of annual caseload			
<25%	0.84 (0.45–1.57)	1.58 (1.49–1.67)	1.56 (1.31–1.86)
50–25%	0.75 (0.42–1.34)	1.64 (1.55–1.74)	1.27 (1.06–1.51)
>50% (reference)	1	1	1
Hospital without certification	1.42 (0.97–2.09)	1.20 (1.16–1.25)	1.08 (0.96–1.22)
Prostate cancer center (Reference)	1	1	1
Individual surgery performed as RRPE or LRPE			
Yes	1.02 (0.58–1.79)	0.26 (0.24–0.28)	0.89 (0.75–1.06)
No (reference)	1	1	1

Table 2 Multivariate linear model for hospital stay (days)

Caseload category	Prostate cancer center			Hospital without certification		
	Share of LRPE and RRPE > 50%	Share of LRPE and RRPE 25–50%	Share of LRPE and RRPE <25%	Share of LRPE and RRPE >50%	Share of LRPE and RRPE 25–50%	Share of LRPE and RRPE <25%
0–19	10.72 (1.47) 12.66 (1.73)	10.55 (1.44) 12.49 (1.71)	10.76 (1.47) 12.70 (1.74)	11.84 (1.62) 13.79 (1.88)	11.67 (1.60) 13.62 (1.86)	11.88 (1.62) 13.83 (1.89)
20–49	10.69 (1.46) 12.64 (1.73)	10.52 (1.44) 12.47 (1.70)	10.73 (1.47) 12.68 (1.73)	10.73 (1.47) 12.68 (1.73)	11.65 (1.59) 13.59 (1.86)	11.86 (1.62) 13.80 (1.89)
50–99	10.21 (1.40) 12.16 (1.66	10.04 (1.37) 11.99 (1.64)	10.25 (1.40) 12.20 (1.67)	10.25 (1.40) 12.20 (1.67)	11.17 (1.53) 13.11 (1.79)	11.38 (1.56) 13.32 (1.82)
100–199	9.93 (1.36) 11.87 (1.62)	9.76 (1.33) 11.70 (1.60)	9.97 (1.36) 11.91 (1.63)	9.97 (1.36) 11.91 (1.63)	10.88 (1.49) 12.83 (1.75)	11.09 (1.52) 13.04 (1.78)
≥200	**7.31 (1.00)** reference 9.26 (1.27)	7.14 (0.98) 9.09 (1.24)	7.35 (1.01) 9.30 (1.27)	8.44 (1.15) 10.39 (1.42)	8.27 (1.13) 10.21 (1.40)	8.48 (1.16) 10.42 (1.43)

Row 1: Prostatectomy performed as RRPE or LRPE; Row 2: Prostatectomy performed as ORPE or perineal radical Prostatectomy. Ratio compared to reference in brackets

Reference with the ratio of 1.0 is marked in bold

completely anonymized and derived from an established database with rigorous data protection measures. Therefore, an additional ethics statement was not required. We followed the "REporting of studies Conducted using Observational Routinely collected health Data" statement [15].

Statistics

We determined absolute numbers of cases and radical prostatectomy rates for the hospital categories with corresponding median and 5, 25, 75, and 95 percentiles. For comparison of rates, we used the Wald test. We assessed the impact of hospital characteristics on outcomes with multivariate logit models including four factors (Table 1). A multivariate linear model of covariance analysis described the impact of the above named factors on the length of hospital stay (Table 2). We defined $p < 0.05$ to indicate significance. SAS 9.2 (SAS Institute GmbH, Heidelberg, Germany) was used for all analyses.

Results

The study population covers a total of 221,331 radical prostatectomies performed in Germany from 2006 to 2013. The total number of hospitals performing radical prostatectomy inclined from 396 in 2006 to 413 in 2008 and 415 in 2013.

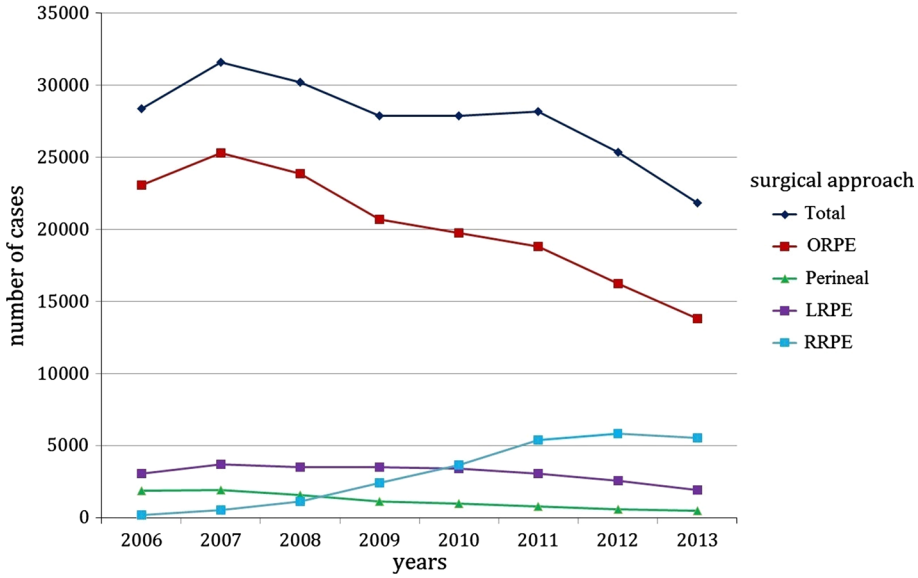


Fig. 2 Surgical approach (absolute number of cases)

The rise of hospitals with a surgical robot and certified prostate cancer centers during the study period is presented in Fig. 1. The mean age of patients was virtually stable at 65 years. Patients who received RRPE (64.2 ± 7.1 years) were younger than patients with ORPE (65.3 ± 6.5 years) and LRPE (64.7 ± 6.8 years; $p < 0.0001$).

The yearly number of radical prostatectomies declined from 28,374 in 2006 to 21,850 in 2013 (Fig. 2). During that time, the percentage of robot-assisted radical prostatectomy (RRPE) increased from 0.6 to 25.2%. Pelvic lymph node dissection was performed in 82.8% of all cases in 2006 and in 85.3% in 2013 ($p < 0.001$). A nerve-sparing procedure was performed in 35.0% of all cases in 2006 and in 54.4% in 2013 ($p < 0.001$). RRPE (62.5%) showed the highest rate of nerve-sparing procedures compared to ORPE (47.2%), LRPE (43.8%), and the perineal (39.4%) approach ($p < 0.001$).

The mean in-hospital mortality rate for ORPE was 0.12 versus 0.08% for RRPE ($p = 0.056$). Surgical revision during the same hospital stay had to be performed in 0.91% after ORPE versus 0.95% after RRPE ($p = 0.49$). Comparing overall transfusion in 2006 and 2013, the rates decreased from 12.1 to 7.2%. The transfusion rate was significantly higher for ORPE with 12.0% compared to 5.0% for LRPE, and 3.3% for RRPE ($p < 0.001$). The overall length of stay decreased from 13.5 days in 2006 to 10.6 days in 2013 ($p < 0.001$). It was distinctly longer for ORPE with 12.4 days versus 8.9 days for RRPE ($p < 0.001$).

Hospitals with ≥100 cases a year reported lower in-hospital mortality with 0.08% versus 0.17% for hospitals <50 cases a year ($p < 0.001$; Fig. 3a). The need for PRBC transfusion correlated significantly with the caseload volume ($p < 0.0001$; Fig. 3b). Hospitals with ≥100 cases a year reported a transfusion rate of 7.4 versus 15.5% in hospitals with <50 cases a year ($p < 0.001$). There was a tendency toward lower surgical revision rates with increasing caseloads without statistical significance ($p = 0.23$; Fig. 3c). Hospitals with ≥200 cases a year showed the shortest hospital stays with 9.5 days compared to 12.2 days (100–199 cases), 12.7 days (50–99 cases), 13.6 days (20–49 cases), and 13.7 days (<20 cases; Fig. 3d).

In prostate cancer centers, mean in-hospital mortality was 0.05 versus 0.12% in non-certified hospitals ($p < 0.001$). The surgical revision rate in prostate cancer centers was 0.86% compared to 0.97% in non-certified hospitals ($p = 0.02$). Certified centers showed significantly lower transfusion rates than non-certified hospitals with 7.0% receiving PRBC transfusions in prostate cancer centers versus 10.6% in not certified hospitals ($p < 0.001$). The length of stay decreased from 10.1 days in 2007 to 9.8 in 2013 in prostate cancer centers compared to 12.9–11.2 days in non-certified hospitals during the study period.

Table 1 shows multivariate logit models based on the complete dataset. Concerning in-house mortality higher caseloads had the strongest influence: The odds for an individual death were doubled in hospitals with less than 50 cases a year. All other variables did not have significant impact on mortality including the aspect of open vs. minimally invasive surgery. Concerning PRBC transfusion, the individual way of surgery was the strongest predictor with minimally invasive approaches reducing it to 26% of the odds of open surgery. Also smaller caseloads (OR 2.8), a lower rate of minimally invasive approaches (OR 1.6), and a lack of certification (OR 1.2) increased the risk of PRBC transfusion. Surgical revision was more likely in hospitals with a lower rate of minimally invasive approaches (OR 1.6) and smaller caseloads (OR 1.4). Table 2 shows a

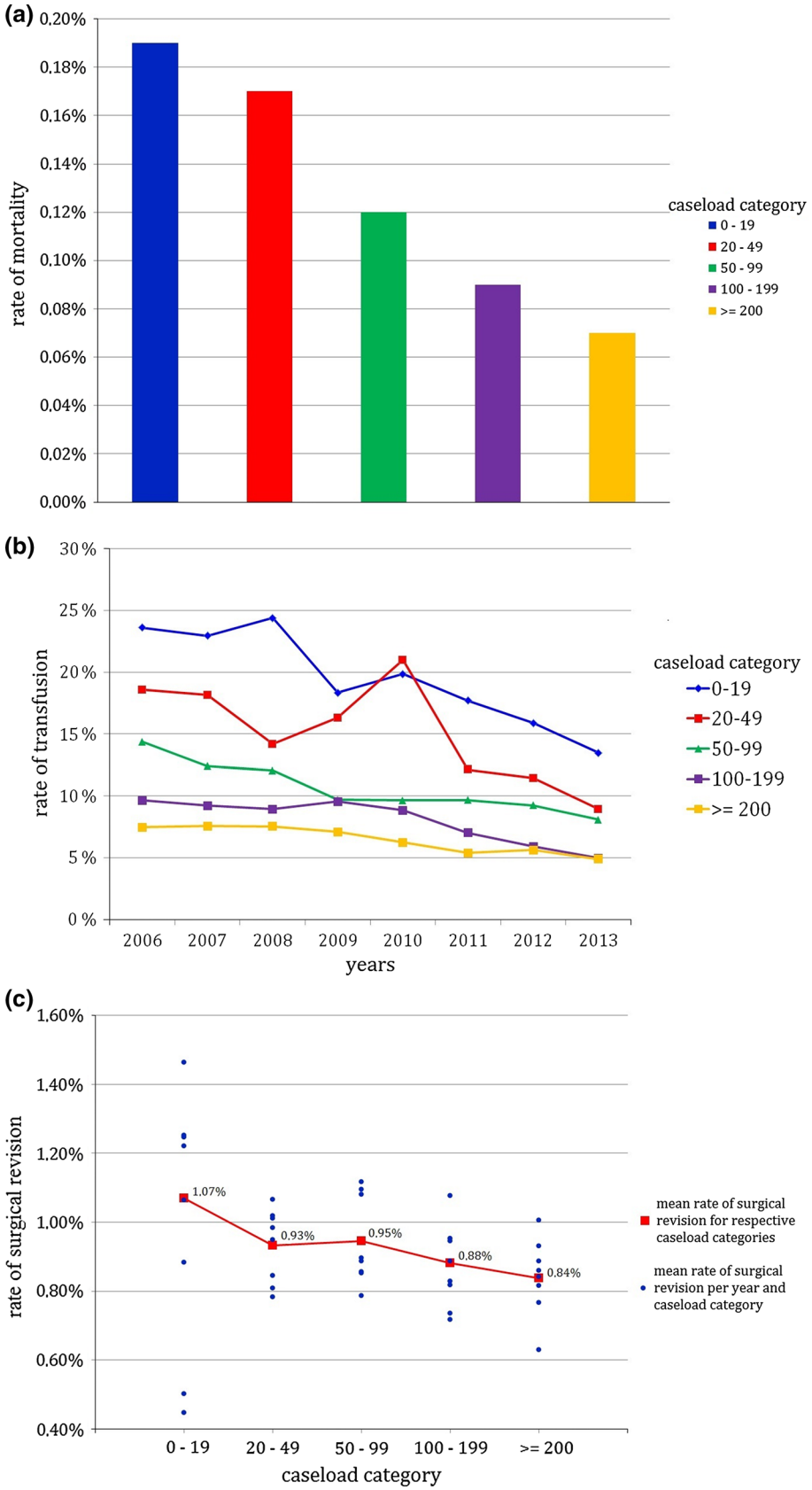
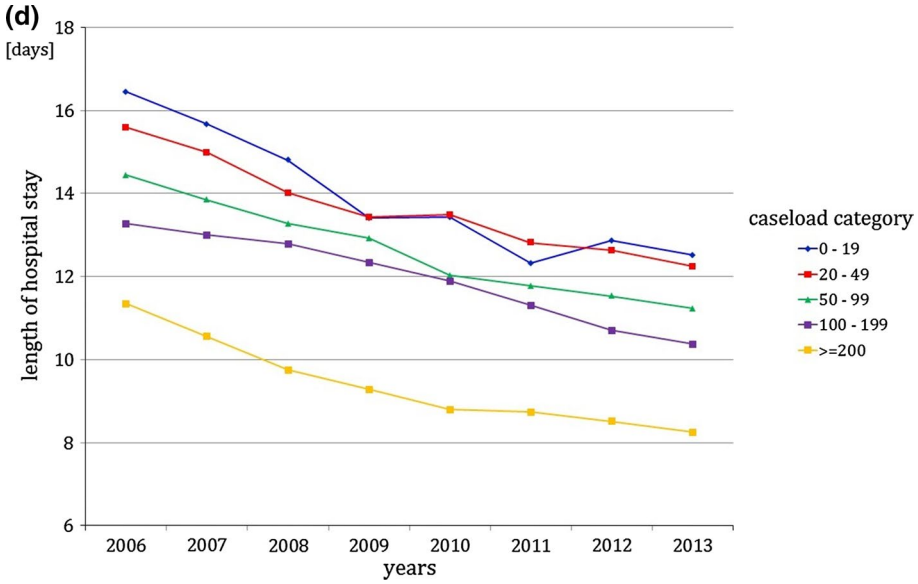


Fig. 3 Rate of mortality (**a**) transfusion, (**b**) surgical revision (**c**), and the length of hospital stay (**d**) stratified for caseload category

Fig. 3 continued



multivariate linear model for the mean length of the individual hospital stay. Roughly, caseloads ≥200 a year reduced it by 3 days in the mean, minimally invasive approaches reduced it by 2 days, and certification as a prostate cancer center reduced it by 1 day. There was no difference according to the share of minimally invasive surgery per hospital.

To better quantify the effect of increasing caseloads, we performed an additional analysis with hospital caseload as a continuous variable. This analysis corroborated the previous results: For every 10 cases performed per year the risk of in-hospital mortality decreased by OR 0.97 ($p = 0.014$). The risk of transfusion decreased by an OR of 0.97 ($p < 0.0001$) and the length of hospital stay by 0.13 days ($p < 0.0001$). The risk for surgical revision declined slightly by an OR of 0.995 without statistical significance ($p = 0.322$).

Discussion

Our longitudinal total population study with more than 220,000 cases showed clear advantages for hospitals with high annual caseloads concerning all four in-hospital outcomes: mortality, PRBC transfusion, surgical revision, and the length of stay. Remarkably, mortality was doubled in hospitals with less than 50 cases a year compared to ≥200 cases a year and it was independent of whether individual surgery was performed open or minimally invasive. However, minimally invasive procedures reduced the need for PRBC transfusion to 26% of the odds of open surgery and reduced the length of stay by 2 days. At the same time, patients undergoing RRPE were younger and received a higher rate of nerve-sparing procedures. Assumably, parts of these differences might result from relevant selection of healthier patients with less advanced disease for RRPE. A prostate cancer center certification also had some positive impact on the transfusion rate and the length of stay, but the effect size was smaller.

The patterns of care show an interesting diversity between different countries. Comparing the German situation to the current developments in Australia leads to similar findings: The yearly number of all radical prostatectomies is decreasing, and RRPE offers reduced blood loss and shorter hospital stays [16]. Moreover, improved surgical margin status was found for RRPE vs. ORPE and for hospitals with higher caseloads [17]. Although, whether this is due to a possible selection bias remains unclear. However, functional outcomes seem to be similar when surgical expertise is guaranteed [18]. In Australia and the USA [19], RRPE has become the standard of care, surpassing ORPE numbers. In Germany, RRPE has increased from 1% in 2006 to 25% in 2013, but it remains less frequent than in Australia and the USA. The main reason for this difference might consist in higher treatment costs [20] without adequate reimbursement in the German healthcare system.

The mean length of stay after radical prostatectomy in Germany is 8–13 days. This appears distinctly longer than data from other countries, e.g., 2 postoperative days in the US [7]. Because of the full coverage of hospitalization costs by German health insurances, patients usually stay until they are fully recovered. On the contrary, the US healthcare system encourages early dismissal to ambulatory care, because patients pay considerable sums for every extra inpatient day.

In the UK, health policy has aimed to centralize complex oncologic surgery since the turning of the century. The National Institute for Health and Care Excellence recommends that radical prostatectomy should not be executed in

teams performing less than 50 cases a year [21]. Recently a pre- and postintervention study showed improved surgical outcomes after centralizing radical prostatectomy at a pelvic surgical center in London [14]. High-volume centers might also be able to produce better results by offering improved training conditions and a steeper learning curve for inexperienced surgeons. RRPE numbers are rising in the UK, and the robot is predominantly used by surgeons performing at least 50 procedures a year [22].

Our study results show clear advantages for high-volume centers and thereby confirm previous evidence [7, 13, 19, 23]. But despite this fact, decentralization of radical prostatectomy is currently taking place in Germany [15].

However, what remained unclear was the role of quality management measures like the German certification model—another possible surrogate parameter for specialization. Recent study results have raised the question, whether a certification process improved structural and process quality, but there was no evidence for improved outcomes [24, 25]. We provide the first study quantifying comparative effects of caseload, certification status, share of minimally invasive surgery, and individual surgical approach in multivariate models. All in all the relative effects of the certification program were small. In hospitals without certification blood transfusion was more frequent (OR 1.2) and hospital stay was 1 day longer. However, the investigated outcomes are limited and other important aspects like functional results and patient satisfaction were not covered. Although the certification approach for "prostate cancer centers" is a German specialty, there are comparable activities in other countries [14, 26, 27]. Our findings suggest that defining a high minimal caseload might be the most powerful way of improving outcomes of radical prostatectomy.

Numerous international studies compared clinical outcomes of RRPE and ORPE. The vast majority showed reduced perioperative bleeding and a shorter hospital stay for RRPE [7, 8, 12, 28]. This is in line with our findings. Selection bias as a consequence of clinical decision making is a principal weakness of all non-randomized studies, because usually healthier and younger patients with less advanced cancer undergo RRPE. [10] Concerning long-term outcomes like biochemical recurrence [6], erectile function [11, 12], and urinary continence [6, 9], study results are contradictory. Finally, the surgeon's individual expertise might be more relevant for the long-term outcome than the surgical approach itself [29].

Studies conducted to date failed to show significant advantages in mortality rates for RRPE. And despite the huge number of cases in our analysis, there also was no significant difference. Furthermore, patients treated with RRPE were younger and nerve sparing was performed more frequently, implying that positive patient selection might be another relevant issue here.

This is the first study investigating in-hospital outcomes of radical prostatectomy in Germany using total population data. With 8 years the study period covers the longest possible timespan since the introduction of the DRG-system in Germany. These findings could also have distinct implications for the European healthcare systems in general. Since we exclusively analyzed billing data, the basic information presented can be regarded as highly accurate. The presented multivariate models enable a comparative judgment on the investigated parameters.

The lack of clinical information on tumor and patient characteristics is a major limitation, because we cannot control for selection bias caused by clinical decision making. Moreover, surgical revision could only be assessed during the same hospital stay. Because single cases or hospitals may not be identified from the database, it is not verifiable whether each dataset has been entered correctly and according to standard. As far as possible, we anticipated relevant issues in our analysis and given the huge case numbers these small irregularities appear negligible.

Conclusion

In comparison with ORPE minimally invasive and RRPE in particular showed improved rates of transfusion, surgical revision, and the length of stay. A prostate cancer center certification also had some positive impact on the transfusion rate and the length of stay. We found clear advantages for hospitals with high annual caseloads concerning all four in-hospital outcomes: mortality, blood transfusion, surgical revision, and the length of stay. Consequently, patients should be advised to undergo radical prostatectomy in large specialized centers. Still, there is a tendency toward decentralization of radical prostatectomy in Germany [15] and additional health-policy measures could be necessary to achieve centralization.

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Data source Research data centers of the federal and state statistical offices, DRG-statistics 2006 to 2013, own calculations. We thank Stefanie Uhrich for continuously supporting data retrieval.

Author contribution statement CG was involved in the project development, data collection, analysis and interpretation, manuscript writing, revision and final approval of the manuscript, obtaining funding, RK was involved in statistics, data collection, revision and final approval of the manuscript, MB was involved in graphics, statistical analysis, revision and final approval of the manuscript, MPW was involved in the project development, revising the manuscript for critically important intellectual content, revision and final approval of the manuscript, supervision, and JH was involved in the conception and design of the manuscript, revising it for critically important intellectual content, revision and final approval of the manuscript, obtaining funding.

Compliance of ethical standards

Conflict of interest There is no conflict of interest.

Human and animal participant No research involving human participants or animals was performed.

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