Urologia Internationalis

Research Article

Urol Int 2023;107:949–958
DOI: 10.1159/000534486

Received: July 28, 2023
Accepted: September 2, 2023
Published online: November 6, 2023

Patient Benefits of Radical Prostatectomy in Certified Prostate Cancer Centers: Comparative Results from the Multicenter IMPROVE Study

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Keywords
Prostate cancer · Radical prostatectomy · Patient-reported outcome · German cancer society · Certification

Abstract
Introduction: We investigated differences in treatment outcomes following radical prostatectomy (RP) between certified centers (CCs) and noncertified centers (nCCs) within the IMPROVE study group. ***Methods:*** A validated survey assessing various factors, including stress urinary incontinence (SUI) and decision regret (DR), was administered to 950 patients who underwent RP across 19 hospitals (12 CCs and 7 nCCs) at a median follow-up of 15 months after RP (interquartile range: 11–20). The response rate was 74%, with 703 patients participating, including 480 (68%) from CCs. Multivariate binary regression models were used to analyze differences between CCs and nCCs regarding the following binary endpoints: nerve-sparing (NS), positive surgical margins (PSM), SUI (defined as >1 safety pad), complications based on the Clavien-Dindo classification (grade ≥1, grade ≥3) and DR (>15 points indicating critical DR). ***Results:*** Considering the multivariate analysis, the rate of NS surgery was lower in CCs than in nCCs (OR = 0.52; $p = 0.004$). No significant differences were observed in the PSM rate (OR = 1.67; $p = 0.051$), SUI (OR = 1.03; $p = 0.919$), and DR (OR = 1.00; $p = 0.990$). SUI (OR 0.39; $p < 0.001$) and DR (OR 0.62; $p = 0.026$) were reported significantly less frequently by patients treated with robotic-assisted RP, which was significantly more often performed in CCs than in nCCs (68.3% vs. 18%; $p < 0.001$). The total complication rate was

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45% lower in CCs (OR = 0.55; p = 0.004), although the number of complications requiring intervention (Clavien-Dindo classification ≥3) did not differ significantly between CCs and nCCs (OR = 2.52; p = 0.051). ***Conclusion:*** Within the IMPROVE study group, similarly favorable outcomes after RP were found in both CCs and nCCs, which, however, cannot be transferred to the general treatment landscape of PCA in Germany. Of note, robotic-assisted RP was more often performed in CCs and associated with less SUI and DR, while open prostatectomy was the treatment of choice in low-volume nCCs. Future prospective and region wide studies should also investigate the surgeon caseload and experience as well as a spillover effect of the certification process on nCCs.
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Introduction

In Germany, prostate cancer (PCA) is the most common type of cancer in men, accounting for 24.6% of all newly diagnosed cases, and is the second leading cause of cancer-related death (12%) [1]. Radical prostatectomy (RP) is considered the gold standard therapy for localized PCA. Despite the increasing popularity of robotic-assisted RP (RARP) over open RP (ORP) as the preferred surgical approach, patients still experience side effects such as stress urinary incontinence (SUI) or erectile dysfunction [2–5].

In an effort to improve the quality of PCA treatment, the German Cancer Society (DKG) began certifying PCA centers based on specific criteria in 2008 [6, 7]. In 2020, 146 PCA centers in Germany, Austria, Switzerland, and Luxembourg have been certified by the DKG [8]. The certification criteria are based on national cancer guidelines and include both quantitative aspects (e.g., the number of annual RPs) and qualitative measures (e.g., positive surgical margin (PSM) rate, nerve-sparing (NS) rate), as well as defined structural requirements (e.g., weekly cancer board meetings, appropriate technical equipment).

Most cancer studies primarily focus on patient survival rates. However, due to the relatively low mortality rates and longer mean survival associated with PCA compared to other types of cancer, patients are at a higher risk of experiencing significant functional and psychological impairments resulting from treatment side effects [5]. Consequently, the importance of functional outcomes, such as urinary continence and erectile function, has increased in patients' perception of treatment quality. Interestingly, these functional outcomes are not mandatory criteria for PCA center certification.

The "Importance of various supportive measures in the context of radical prostatectomy from the patient's perspective" (IMPROVE) study addresses patient-reported outcomes as a key parameter for measuring treatment quality. The study aims to determine whether patients benefit from being treated at a certified center (CC).

Materials and Methods

A total of 20 urological clinics (12 CCs and 8 noncertified centers [nCCs]) participated in the IMPROVE study collaboration group. From April to June 2021, a survey was sent to a total of 1,000 patients (50 patients per center) who had undergone RP in their facility between 2018 and 2020. Each center contacted only the latest 50 consecutive patients who had received RP at least 6 months before the survey was sent out. The survey included perioperative, personal, and functional criteria as follows:

SUI was assessed using a validated questionnaire [9–11]. Decision regret (DR) was measured using the Decision Regret Scale [12, 13], consisting of five questions that resulted in a score ranging from 0 (no regret) to 100 (highest regret). To ensure comparability with previous studies [14, 15], a cutoff score of >15 was set to define relevant DR. Patients were also asked to report the decision-making process regarding the surgical approach, including decisions made solely by the physician, consensual decision-making, or active decision-making by the patient alone. The median time interval between RP and completion of the questionnaire by patients was 15 months, with an interquartile range of 11–20 months.

Furthermore, the participating centers provided corresponding clinical and pathological data for each patient. This included information on the surgical approach, TNM classification, RP caseload per year, International Society of Urological Pathology (ISUP)-Group, presurgery prostate-specific antigen (PSA) value, surgery date, information about relationship status (fixed partnership vs. no fixed partnership), information about retirement status (professionally active vs. retired), details on NS (bilateral NS, unilateral NS, or no NS), surgical margin status (PSM vs. negative surgical margin), and complications recorded according to the Clavien-Dindo classification (CDC) [16, 17]. Complications were categorized as the total complication rate (CDC grades 1–5 vs. CDC grade 0) and complications requiring intervention (CDC grades 3–5 vs. CDC grades 0–2). Delayed catheter removal was defined as CDC grade 1 d [18].

Descriptive statistical analyses were performed using the Mann-Whitney U test for comparisons between groups with metric variables. The Fisher's exact test was used for dichotomized categorical variables (2 × 2), and the Pearson χ^2-test was used for other categorized variables (>2 × 2). Multivariate binary-regression models (enter method) were employed to calculate differences between CC and nCC in relation to the following binary endpoints: NS surgery, PSM, SUI requiring more than one safety pad, complications based on the CDC (≥ grade 1, ≥ grade 3) and DR (using the cutoff of >15 points to define critical DR). IBM SPSS Statistics v. 28 (Armonk, NY, USA) was used for all statistical analyses. The reported p values are two-sided, and statistical significance was set at $p < 0.05$.

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Results

Out of the 1,000 patients contacted, 750 (75%) returned a completed survey and provided informed consent. One nCC was excluded due to missing clinical follow-up data, resulting in a final study group of 703 patients treated in 19 PCA centers, with 480 (68.3%) patients treated in 12 CCs and 223 (31.7%) patients treated in 7 nCCs.

The clinical and histopathological criteria are presented in Table 1 for group comparison. Comparing CCs and nCCs, it was found that patients in CCs were significantly younger, with a mean age of 67 compared to 69 in nCCs ($p < 0.001$). The annual RP caseload was lower in nCCs, with a median of 29 RPs compared to 125 in CCs ($p < 0.001$). Regarding the surgical approach, RARP and laparoscopic RP (LRP) were more frequently performed in CCs than in nCCs, while ORP was more common in nCCs (RARP: 328 vs. 40, LRP: 42 vs. 15, ORP: 110 vs. 168; $p < 0.001$).

In the univariate group comparison, NS surgery occurred significantly less frequently in CCs (58.3% vs. 66.4%; $p = 0.046$). On the other hand, there were significantly fewer overall complications (CDC grades ≥1) in CCs (28.1% vs. 48%; $p < 0.001$). There were no significant group differences observed in PSM (26.7% vs. 23.8%; $p = 0.459$), the occurrence of SUI (18.8% vs. 24%; $p = 0.130$), complications requiring intervention (CDC grades ≥3) (6.9% vs. 3.6%; $p = 0.087$), and the presence of critical DR (33.9% vs. 39.2%; $p = 0.202$; Table 1). Furthermore, the independent impact of certification as a PCA center on the five endpoints was examined (Tables 2–6).

Ad (1) In CCs, NS surgery was significantly less frequently performed than in nCCs (OR 0.52; $p = 0.004$). Patients with advanced tumor stages (pT stages ≥3) also had significantly lower rates of NS surgery (OR 0.43; $p < 0.001$; Table 2).

Ad (2) There was a trend toward higher PSM rates in CCs, although it was not statistically significant (OR 1.67; $p = 0.051$). Patients with advanced tumor stages (pT stages ≥3) had over 4 times higher odds of RP with PSM (OR 4.13; $p < 0.001$; Table 3).

Ad (3) There was no significant difference in SUI rates between CCs and nCCs (OR 1.03; $p = 0.919$). Patients without a partnership were more likely to experience SUI (OR 1.93; $p = 0.034$). RARP was associated with significantly lower SUI rates (OR 0.39; $p < 0.001$; Table 4).

Ad (4) CCs had a relative 45% lower rate of overall complications (CDC 1–5) (OR 0.55; $p = 0.004$; Table 5a). However, there was a trend toward more complications requiring intervention in CCs (CDC 3–5) (OR 2.52; $p = 0.051$; Table 5b). Advanced tumor stages were associated with higher overall complication rates (OR 2.01; $p < 0.001$; Table 5a) and complications requiring intervention (OR 2.73; $p = 0.003$; Table 5b).

Ad (5) The PCA certification state did not have a significant influence on the critical DR of RP patients (OR 1.00; $p = 0.990$). Notably, the NS rate did not influence DR, but SUI (OR 2.67; $p < 0.001$) and ORP+LRP (OR 0.62; $p = 0.026$) were associated with significantly higher DR rates (Table 6).

Discussion

The healthcare system is constantly striving for progress in order to improve quality and reduce treatment costs. Alongside technological, pharmaceutical, and structural advancements, the certification of centers has emerged as a method to ensure adherence to specific treatment criteria for diseases and enhance transparency in treatment quality for patients and physicians [19, 20], OnkoZert, the most well-established institution for center certification in Germany, granted certification for the treatment of PCA since 2008, making it one of the first cancers to receive such recognition. This certification brings visibility to a center and can attract patients, but it also involves high costs and bureaucratic efforts, often limiting certification to large institutions like maximum-care hospitals or university hospitals. Currently, there are 146 certified PCA centers in Germany, while many clinics intentionally choose not to undergo certification due to the additional burden it entails. Thus, the crucial question for patients and referring physicians alike is whether there are significant differences in treatment quality between CCs and nCCs.

OnkoZert has established various criteria for PCA center certification, encompassing clinical, oncological, and operative aspects. These include the establishment of a structured network among specialized departments, transferring doctors, encounter groups, and the clinic. Additionally, supportive measures such as psycho-oncological support, outreach services, and rehabilitation programs must be provided for the patients [21]. To enhance surgical outcomes, oncological criteria such as the annual caseload of RPs, PSM rate, and NS rate are evaluated. However, the current certification process does not require patient-reported or functional outcome parameters, despite their critical importance to patients with localized PCA due to the high survival rates after curative treatment [22, 23]. Therefore, the multicentric IMPROVE study aimed to assess the quality of clinical, oncological, and patient-reported outcomes in patients

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Table 1. Descriptive statistics of the whole IMPROVE study cohort and divided based on treatment of prostate cancer in a certified center or noncertified center

Variable	Whole study group (n = 703)	CC (n = 480)	nCC (n = 223)	p value
Age (n = 703), median (IQR) in years	68 (63–72)	67 (62–71)	69 (64–74)	<0.001
Personal relationship status (n = 700), n (%)				0.072
Fixed partnership	633 (90.4)	440 (91.9)	193 (87.3)	
No fixed partnership	67 (9.6)	39 (8.1)	28 (12.7)	
Professional status (n = 698), n (%)				0.120
Professionally active or with professional activity rescheduled	189 (27.1)	138 (28.9)	51 (23.2)	
Retired	509 (72.9)	340 (71.1)	169 (76.8)	
Time interval between RP and survey (n = 703), median (IQR) in month	15 (11–20)	14 (11–21)	16 (11–20)	0.187
Center's level of care (n = 703)				<0.001
Nonuniversity center	385 (54.8)	162 (33.7)	223 (100)	
University center	318 (45.2)	318 (66.3)	0	
Center's RP-caseload per annum in 2018-2020 (n = 703), median (IQR) in cases	92 (49–134)	125 (67–150)	29 (19–92)	<0.001
Surgical approach (n = 703), n (%)				**<0.001**
Open radical prostatectomy (ORP)	278 (39.5)	110 (22.9)	168 (75.3)	
Laparoscopic radical prostatectomy (LRP)	57 (8.1)	42 (8.8)	15 (6.7)	
Robotic-assisted radical prostatectomy (RARP)	368 (52.4%)	328 (68.3)	40 (18.0)	
Preoperative PSA level (n = 703), median (IQR) in ng/mL	7.9 (5.6–12.1)	7.7 (5.4–12.3)	8.4 (6–12)	0.224
Gleason ISUP group (n = 703), n (%)				0.564
ISUP Group 1 (Gleason score 3+3 = 6)	72 (10.2)	49 (10.2)	23 (10.3)	
ISUP Group 2 (Gleason score 3+4 = 7a)	326 (46.4)	213 (44.4)	113 (50.7)	
ISUP Group 3 (Gleason score 4+3 = 7b)	173 (24.6)	124 (25.8)	49 (22.0)	
ISUP Group 4 (Gleason score 4+4 = 8, 3+5 = 8, and 5+3 = 8)	48 (6.8)	33 (6.9)	15 (6.7)	
ISUP Group 5 (Gleason score 4+5 = 9, 5+4 = 9, and 5+5 = 10)	84 (12.0)	61 (12.7)	23 (10.3)	
pT stage (n = 703), n (%)				0.934
≤pT2c	435 (61.9)	296 (61.7)	139 (62.4)	
≥pT3a	268 (38.1)	184 (38.3)	84 (37.6)	
pN stage (n = 702), n (%)				0.070
pN0/x	636 (90.6)	441 (92.1)	195 (87.4)	
pN1	66 (9.4)	38 (7.9)	28 (12.6)	
Surgical margin status (n = 703), n (%)				0.459
Negative surgical margins	522 (74.3)	352 (73.3)	170 (76.2)	
Positive surgical margins	181 (25.7)	128 (26.7)	53 (23.8)	
Adjuvant radiotherapy (n = 699), n (%)				0.999
No adjuvant local radiation	568 (81.3)	389 (81.2)	179 (81.4)	
Adjuvant local radiation	131 (18.7)	90 (18.8)	41 (18.6)	
Nerve-sparing surgery (n = 703), n (%)				0.046
No nerve-sparing	275 (39.1)	200 (41.7)	75 (33.6)	
Nerve-sparing (uni- and bilaterally)	428 (60.9)	280 (58.3)	148 (66.4)	
Complications according to the Clavien-Dindo classification in grades (n = 703), n (%)				<0.001
0	461 (65.6)	345 (71.9)	116 (52.0)	
≥1	242 (34.4)	135 (28.1)	107 (48.0)	
Complications according to the Clavien-Dindo classification grades (n = 703), n (%)				0.087
0–2	662 (94.2)	447 (93.1)	215 (96.4)	
≥3	41 (5.8)	33 (6.9)	8 (3.6)	

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Table 1 (continued)

Variable	Whole study group (n = 703)	CC (n = 480)	nCC (n = 223)	p value
Stress urinary incontinence (n = 700), n (%)				0.130
1-1 safety pad/day	557 (79.6)	389 (81.2)	168 (76.0)	
>1 pad/day	143 (20.4)	90 (18.8)	53 (24.0)	
Patient's decision regret (DR) (n = 691), median (IQR) in points	10 (0–20)	10 (0–20)	10 (0–26)	0.727
Patient's decision regret/DR (n = 691), n (%)				0.202
0–15 points (no critical DR)	445 (64.4)	310 (66.1)	135 (60.8)	
>15 points (critical DR)	246 (35.6)	159 (33.9)	87 (39.2)	

CC, certified center; nCC, noncertified center; *n,* number of patients; IQR, interquartile range; RP, radical prostatectomy; ORP, open radical prostatectomy; LRP, laparoscopic radical prostatectomy; RARP, robotic-assisted radical prostatectomy; PSA, prostate specific antigen; ISUP, International Society of Urological Pathology; DR, decision regret.

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Table 2. Odds ratio of nerve-sparing surgery (NS vs. no NS) based on clinical and personal parameters

Variable	OR (95% CI)	p value
Age in years	0.95 (0.92–0.97)	<**0.001**
RP median caseload per year (2018–2020)	1.00 (1.00–1.00)	0.142
pT-stage: pT≥3 (reference: pT≤2)	0.43 (0.30–0.63)	<**0.001**
pN-stage: pN1 (reference: pN0/pNx)	0.66 (0.35–1.25)	0.202
Preoperative PSA level in ng/mL	0.95 (0.93–0.98)	<**0.001**
Gleason-Score: ISUP 3–5 (reference: 1–2)	0.78 (0.54–1.11)	0.166
Surgical approach: RARP (reference: ORP + LRP)	1.46 (0.99–2.17)	0.059
Partnership: no partnership (reference: fixed partnership)	0.57 (0.32–1.02)	0.057
Center's level of care: CC (reference: nCC)	0.52 (0.33–0.81)	**0.004**

OR, odds ratio; CI, confidence Interval; RP, radical prostatectomy; PSA, prostate-specific antigen; ISUP, International Society of Urological Pathology; RARP, robotic-assisted radical prostatectomy; ORP, open radical prostatectomy; LRP, laparoscopic radical prostatectomy; CC, certified center; nCC, noncertified center.

Table 3. Odds ratio of postoperative resection status (positive surgical margin vs. negative surgical margin) based on clinical parameters

Variable	OR (95% CI)	p value
Age in years	1.02 (0.98–1.05)	0.337
RP median caseload per year (2018–2020)	1.00 (1.00–1.00)	**0.019**
pT-stage: pT≥3 (reference: pT≤2)	4.13 (2.68–6.37)	<**0.001**
pN-stage: pN1 (reference: pN0/pNx)	2.28 (1.24–4.21)	**0.008**
Preoperative PSA level in ng/mL	1.01 (1.00–1.03)	0.077
Gleason-Score: ISUP 3–5 (reference: 1–2)	1.11 (0.73–1.68)	0.619
Surgical approach: RARP (reference: ORP + LRP)	0.99 (0.62–1.59)	0.997
Nerve-sparing: NS (reference: non-NS)	0.53 (0.36–0.80)	**0.002**
Center's level of care: CC (reference: nCC)	1.67 (1.00–2.80)	0.051

OR, odds ratio; CI, confidence interval; RP, radical prostatectomy; PSA, prostate-specific antigen; ISUP, International Society of Urological Pathology; RARP, robotic-assisted radical prostatectomy; ORP, open radical prostatectomy; LRP, laparoscopic radical prostatectomy; NS, nerve sparing; CC, certified center; nCC, noncertified center.

treated with RP for localized PCA, comparing CCs and nCCs, as well as evaluating the potential benefits of certification.

In our cohort, CCs exhibited a significantly higher median annual caseload (125 vs. 29) compared to nCCs. Notably, 5 out of 7 collaborating nCCs did not meet the 50 RP caseload criteria required for certification as a PCA center. Surprisingly, we observed significantly lower NS rates in CCs, which may initially seem contradictory given that OnkoZert mandates an 80% NS rate for suitable patients. However, OnkoZert does not provide a detailed definition of suitability for NS, unlike the PSM rates, which should not exceed 15% in (y)pT2 c/pN0 or Nx M0 stages. This suggests a potential prioritization of negative surgical margins over NS, which becomes evident when considering that patients without NS in our cohort did not express postoperative regrets, regardless of whether NS was performed. These patients were likely to have erectile dysfunction or large tumors, indicating that the absolute number of NS procedures alone cannot be used to draw conclusions about differences in treatment quality between CCs and nCCs.

A low rate of complications is a crucial criterion for successful surgical treatment. As expected, patients with higher tumor stages experienced significantly more postoperative complications. Interestingly, patients who underwent RARP demonstrated significantly fewer complications compared to those treated with ORP or LRP. This could be attributed to the increased availability and experience with RARP in recent years. A recent comparative study showed that long-term quality of life is similar between RARP and ORP, while RARP is associated with significantly fewer postsurgical complications such as pain, venous thrombosis, infections, or blood transfusions [24]. However, it is important to consider the potential selection bias against RARP in patients with unfavorable clinical or oncological features, which may influence these results.

Another intriguing finding is the approximately 45% lower overall postoperative complication rate in CCs compared to nCCs, despite a strong trend toward a higher incidence of more severe complications rated as CDC ≥3 in CCs (OR 2.52; $p = 0.051$). This discrepancy might be attributed to preoperative patient assessment and selection. Patients with adverse clinical traits such as multimorbidity or frailty, which increase the risk of postoperative complications, are more likely to be referred to CCs. This explanation is supported by the slight yet significant age difference between patients treated in CCs and nCCs (67 years vs. 69 years, $p < 0.001$).

Furthermore, patient selection might also explain the results regarding postoperative surgical margin status. Both CCs and nCCs appeared to offer equal quality in terms of oncological outcomes for the patients referred to them.

Although OnkoZert requires parameters such as caseload, surgical margin status, and NS rate during the certification process, our study also focused on functional and patient-reported outcomes. SUI is a highly important outcome parameter for patients' quality of life after RP. Our study group has previously demonstrated an association between SUI and a threefold increased presence of critical DR after RP [25]. While no significant difference in postoperative SUI was observed between CCs and nCCs in the current study, patients who underwent RARP experienced significantly less SUI (OR 0.39; $p < 0.001$) compared to those treated with ORP or LRP. Again, this can be explained by patient selection prior to surgery and increased experience with RARP. Notably, RARP was performed significantly more frequently in CCs than in nCCs (68.3% vs. 18%; $p < 0.001$).

Finally, no difference in critical DR after RP was observed, irrespective of the certification status of the clinic performing the treatment. Interestingly, patients who underwent RARP were significantly less likely to regret their decision to undergo surgery compared to patients receiving ORP and LRP. It is possible that the latter patients perceived that they did not receive the best available therapy, despite an overall positive experience with their treatment and outcome.

Our findings, which demonstrate no significant differences in SUI and PSM between CCs and nCCs, are partially in contrast to a recent publication that analyzed 22,649 patients treated at a German rehabilitation center [26]. The authors observed a higher frequency of SUI and PSM in patients treated at nCCs, while NS was significantly more common in CCs. These contradictory results could be attributed to several factors. The study population of Butea-Bocu et al. [26] consisted of patients admitted to the rehabilitation center within 35 days after RP, comparing CCs and nCCs at an early postoperative stage. In contrast, the IMPROVE study focused on mid-term effects at a median time of 15 months after RP.

Additionally, the patient cohort of Butea-Bocu et al. [26] included individuals treated between 2008 and 2017, during which there was a significant shift in surgical techniques from ORP to RARP, resulting in an inhomogeneous study population, particularly due to the lack of differentiation between different surgical approaches. The increasing dissemination of robotic technology throughout Germany, mainly driven by consumer demand and increased market competition among hospitals [27], also resulted in a wider distribution of RARP in low-volume hospitals. However, previous studies demonstrated significantly more complications, perioperative blood transfusions, and longer

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Table 4. Odds ratio of postoperative stress urinary incontinence (>1 pad vs. ≤1 safety pad) based on clinical and personal parameters

Variable	OR (95% CI)	*p* value
Age in years	1.03 (0.99–1.06)	0.200
RP median caseload per year (2018–2020)	1.00 (1.00–1.00)	**0.041**
pT-stage: pT≥3 (reference: pT≤2)	1.33 (0.84–2.09)	0.225
pN-stage: pN1 (reference: pN0/pNx)	1.06 (0.55–2.05)	0.868
Preoperative PSA level in ng/mL	1.01 (1.00–1.02)	0.122
Gleason-Score: ISUP 3–5 (reference: 1–2)	0.88 (0.57–1.35)	0.553
Surgical approach: RARP (reference: ORP + LRP)	0.39 (0.24–0.65)	<**0.001**
Nerve-sparing: NS (reference: non-NS)	0.79 (0.52–1.21)	0.281
Partnership: no partnership (reference: fixed partnership)	1.93 (1.05–3.54)	**0.034**
Professional status: retired (reference: professionally active)	1.60 (0.90–2.86)	0.110
Time interval between RP and survey (in months)	0.95 (0.91–0.98)	**0.003**
Center's level of care: CC (reference: nCC)	1.03 (0.62–1.69)	0.919

OR, odds ratio; CI, confidence interval; RP, radical prostatectomy; PSA, prostate specific antigen; ISUP, International Society of Urological Pathology; RARP, robotic-assisted radical prostatectomy; ORP, open radical prostatectomy; LRP, laparoscopic radical prostatectomy; NS, nerve sparing; CC, certified center; nCC, noncertified center.

Table 5. Odds ratio of postoperative complications (Clavien-Dindo classification) based on clinical parameters

Variable	OR (95% CI)	*p* value
(a) CDC grades 1–5 versus CDC grade 0		
Age in years	1.04 (1.01–1.06)	**0.013**
RP median caseload per year (2018–2020)	1.00 (1.00–1.00)	0.148
pT-stage: pT≥3 (reference: pT≤2)	2.01 (1.43–2.82)	<**0.001**
Surgical approach: RARP (reference: ORP + LRP)	0.50 (0.34–0.72)	<**0.001**
Center's level of care: CC (reference: nCC)	0.55 (0.36–0.82)	**0.004**
(b) CDC grades 3–5 versus CDC grades 0-2		
Age in years	1.06 (1.00–1.12)	0.052
RP median caseload per year (2018–2020)	1.00 (1.00–1.00)	0.624
pT-stage: pT≥3 (reference: pT≤2)	2.73 (1.40–5.32)	**0.003**
Surgical approach: RARP (reference: ORP + LRP)	0.99 (0.47–2.05)	0.969
Center's level of care: CC (reference: nCC)	2.52 (1.00–6.35)	0.051

CDC, Clavien-Dindo classification; OR, odds ratio; CI, confidence interval; RP, radical prostatectomy; RARP, robotic-assisted radical prostatectomy; ORP, open radical prostatectomy; LRP, laparoscopic radical prostatectomy; CC, certified center; nCC, noncertified center.

hospitalization in patients treated by RARP in low-volume clinics, when compared to high-volume hospitals performing approximately 100 RARPs per year [27]. On the other hand, a wide body of evidence exists showing improved outcome after ORP when performed by experienced high-volume surgeons. It is noteworthy that most of our nCCs performed ORP rather than RARP [28].

Lastly, the specific composition of the IMPROVE study group has to be considered when interpreting our results. Only 7 collaborating nCCs were included in our analysis, all of which were managed by highly experienced surgeons. This is crucial since surgeon experience is a major factor associated with treatment quality [29, 30]. In a recent systematic review, Van der Broeck et al. [31] found that hospitals with a high caseload of >86 (interquartile range 35–100) RPs per year have better outcomes in terms of cancer recurrence and complications during or after hospitalization. Nevertheless, the authors also concluded that experienced surgeons can still achieve similar or even better outcomes in hospitals with lower annual operations.

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Table 6. Odds ratio of postoperative decision regret (sum score >15 vs. 0–15) based on clinical, personal, and functional parameters

Variable	OR (95% CI)	*p* value
Age in years	0.98 (0.95–1.01)	0.191
RP median caseload per year (2018–2020)	1.00 (1.00–1.00)	0.278
pT-stage: pT≥3 (reference: pT≤2)	1.39 (0.92–2.10)	0.116
pN-stage: pN1 (reference: pN0/pNx)	1.82 (0.98–3.35)	0.056
Surgical margin status: R1 (reference: R0)	1.09 (0.71–1.67)	0.690
Preoperative PSA level in ng/mL	1.00 (0.99–1.01)	0.650
Gleason-Score: ISUP 3–5 (reference: 1–2)	0.64 (0.44–0.93)	**0.018**
Surgical approach: RARP (reference: ORP + LRP)	0.62 (0.40–0.94)	**0.026**
Nerve-sparing: NS (reference: non-NS)	0.99 (0.68–1.43)	0.935
Partnership: no partnership (reference: fixed partnership)	1.39 (0.80–2.44)	0.244
Professional status: retired (reference: professionally active)	1.43 (0.89–2.30)	0.136
Complications: CDC 3–5 (reference: CDC 1–2)	1.07 (0.52–2.19)	0.857
Time interval between RP and survey (in months)	1.01 (0.98–1.04)	0.455
SUI: >1 pad/day (reference: max. 1 pad/day)	2.67 (1.78–4.00)	<**0.001**
Center's level of care: CC (reference: nCC)	1.00 (0.65–1.54)	0.990

OR, odds ratio; CI, confidence interval; RP, radical prostatectomy; PSA, prostate specific antigen; ISUP, International Society of Urological Pathology; RARP, robotic-assisted radical prostatectomy; ORP, open radical prostatectomy; LRP, laparoscopic radical prostatectomy; NS, nerve sparing,; CDC, Clavien-Dindo classification; SUI, stress urinary incontinence; CC, certified center; nCC, noncertified center.

This is also the case with our collaborating nCCs, where RPs are usually performed by only one or two experienced surgeons, therefore ensuring high and consistent treatment quality. In contrast, many large centers or university hospitals are obliged to train up-and-coming surgeons, which naturally is associated with a learning curve.

When taking these factors into account, the similar results between CCs and nCCs within our IMPROVE study group seem reasonable. Compared with our study, the cohort of Butea-Bocu et al. [26] consisted of over 22,000 patients treated at 290 different hospitals, including small hospitals with lower caseloads and less experienced surgeons than those in our nCCs, which could lead to fewer routine procedures and worse outcomes for nCCs in their study. The widespread approach by Butea-Bocu et al. [26] might better reflect the general treatment landscape of PCA in Germany than the focused analysis of specific centers within the IMPROVE study.

The comparable outcomes of nCCs and CCs in our study might also be attributed to the increasingly competitive situation in the healthcare system. In Germany, there are 146 clinics certified for PCA treatment competing against approximately 250 nCCs, with the majority of the latter group also performing RPs. In other words, almost every nCC has a CC in close proximity. Due to the complete performance transparency required by OnkoZert, a spillover effect occurs even in nCCs. Consequently, nCCs continually monitor the outcomes of their RP patients through constant feedback from urologists, general practitioners, patients, and their families. As a result, the quality of treatment provided in nCCs aligns with the treatment standards of CCs and ultimately improves, even without transparent evidence of performance through certification.

The current study has several limitations that have to be considered. As mentioned above, the limited number of participating centers prohibits any generalized conclusions regarding the differences between CCs and nCCs. Given that only 7 out of approximately 250 nCCs in Germany participated in the current study, our results cannot be representative of the treatment quality in nCCs. In contrast to CCs, nCCs are not bound to any quality standards defined by certifying institutions, therefore allowing for a much wider range of the treatment quality than is the case in CCs. Also, no actual data on individual surgeon caseload were available. Moreover, data on preoperative sexual function as well as the type and extent of preoperative diagnostic measures were not available, which might help improve the interpretation of our results. Also, some differences between CCs and nCCs could not always be perfectly adjusted for in multivariate analyses, like the 6% higher prevalence of PCAs graded Gleason >7a in CCs or the longer timespan in nCCs needed to recruit the 50 most recent patients for study inclusion. The 50 recruited patients were scattered over a timespan of several years at some

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nCCs, while it took only several weeks in some high-volume CCs to accumulate the same number of patients. This might have an influence on treatment quality if these patients were recruited during the training phase of a surgeon at a CC. Finally, we investigated the differences between CCs and nCCs based on six endpoints. Given the exploratory nature of our study, no statistical controlling procedures were applied to counteract the problem of multiple testing.

Conclusion

The certification criteria serve as a benchmark for optimal treatment quality, and the certification itself ensures adherence to these standards, providing the CCs with increased visibility and market positioning. Interestingly, from the patients' subjective perspective, nCCs demonstrated comparable results to CCs. Notably, oncological and functional outcomes were similar between the two groups and did not impact DR of the patients. The comparable outcomes might be due to ORP being the treatment of choice in low-volume nCCs, while RARP was performed only by high-volume hospitals. However, patients were more likely to express dissatisfaction with their therapy if they did not receive RARP. Nonetheless, it is important to consider the specific characteristics of the IMPROVE cohort, particularly the limited number of included nCCs, all of which are managed by highly experienced surgeons. Despite the wide-ranging evidence of a volume-outcome relationship demonstrated in numerous studies, our research findings indicate that selective clinics with case volumes below the threshold set by OnkoZert can achieve oncological and functional outcomes in RP patients that are comparable to those of clinics with higher RP case volumes. The causal factors for this phenomenon are likely attributed to the individual expertise of the often sole surgeon performing the RP in the smaller clinic, knowledge transfer from these colleagues trained in clinics with higher RP case volumes, and the previously discussed spillover effect. Future prospective studies should encompass smaller regional clinics and examine the surgeon caseload and experience as well as the quality of the preoperative diagnostic assessment to further investigate the potential spillover effect of the certification process on nCCs.

Appendix

Collaborators of the IMPROVE Study

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Acknowledgments

We would like to thank Steffen Lebentrau at the Department of Urology, Werner Forßmann Hospital Eberswalde, Eberswalde, Germany, for his support concerning the conceptualization of this study. We thank American Journal Experts for editing the manuscript.

Statement of Ethics

The study was conducted in accordance with the Declaration of Helsinki and approved by the Leading Ethics Committee of Medizinische Hochschule Brandenburg Theodor Fontane (ethical approval E-01-20200805, date of approval: August 17, 2020). Study registration: DRKS-ID: DRKS00023765 (German register of clinical studies). The return of the questionnaire was regarded as informed consent in accordance with the Leading Ethics Committee of Medizinische Hochschule Brandenburg Theodor Fontane.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

This research received no external funding.

Author Contributions

Conceptualization and software: M.M. Methodology: D.S., C.F., I.W., J.P., M.M., and C.G. Validation: I.W. and M.M. Formal analysis: D.S. and C.F. Investigation: D.S., C.F., B.W., I.W., B.H., A.M., R.G., M.B., J.S., N.H., N.L., F.A.D., M.M., J.P., and C.G. Data curation: D.S., C.F., B.W., I.W., B.H., A.M., R.G., M.B., J.S., N.H., N.L., F.A.D., M.M., J.P., and C.G. Manuscript writing: D.S. and C. F. Visualization: D.S., C.F., B.W., I.W., B.H., A.M., R.G., M.B., J.S., N.H., N.L., F.A.D., M.M., J.P., and C.G. Supervision: I.W., M. M, and C. G.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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References

1 Erdmann F, Spix C, Katalinic A, Christ M, Folkerts J, Hansmann J, et al. Krebs in Deutschland für 2017/2018. Robert Koch-Institut; 2021. p. 24.
2 Ficarra V, Novara G, Artibani W, Cestari A, Galfano A, Graefen M, et al. Retropubic, laparoscopic, and robot-assisted radical prostatectomy: a systematic review and cumulative analysis of comparative studies. Eur Urol. 2009 May;55(5):1037–63.
3 Carlsson S, Nilsson AE, Schumacher MC, Jonsson MN, Volz DS, Steineck G, et al. Surgery-related complications in 1253 robot-assisted and 485 open retropubic radical prostatectomies at the Karolinska University Hospital, Sweden. Urology. 2010 May;75(5):1092–7.
4 Rabbani F, Yunis LH, Pinochet R, Nogueira L, Vora KC, Eastham JA, et al. Comprehensive standardized report of complications of retropubic and laparoscopic radical prostatectomy. Eur Urol. 2010 Mar;57(3):371–86.
5 Resnick MJ, Koyama T, Fan KH, Albertsen PC, Goodman M, Hamilton AS, et al. Long-term functional outcomes after treatment for localized prostate cancer. N Engl J Med. 2013 Jan 31;368(5):436–45.
6 Kowalski C, Ferencz J, Albers P, Fichtner J, Wiegel T, Feick G, et al. Quality assessment in prostate cancer centers certified by the German Cancer Society. World J Urol. 2016 May;34(5):665–72.
7 Griesshammer E, Adam H, Sibert NT, Wesselmann S. Implementing quality metrics in European Cancer Centers (ECCs). World J Urol. 2021 Jan;39(1):49–56.
8 Burchardt M, Fichtner J, Wesselmann S, Rückher J, Utzig M, Jörg V, et al. Kennzahlenauswertung. 2022. Jahresbericht der zertifizierten Prostatakrebszentren. Auditjahr 2021/Kennzahlenjahr 2020. Deutsche Krebsgesellschaft eV. 2022. p. 5.
9 Szymanski KM, Wei JT, Dunn RL, Sanda MG. Development and validation of an abbreviated version of the expanded prostate cancer index composite instrument for measuring health-related quality of life among prostate cancer survivors. Urology. 2010 Nov;76(5):1245–50.
10 Beyer B, Huland H, Feick G, Graefen M. ["Expanded Prostate cancer Index Composite" (EPIC-26): results of functional treatment in patients with localized prostate cancer]. Urologe. 2015 Nov;54(11):1591–5.
11 Sibert NT, Dieng S, Oesterle A, Feick G, Carl G, Steiner T, et al. Psychometric validation of the German version of the EPIC-26 questionnaire for patients with localized and locally advanced prostate cancer. World J Urol. 2021 Jan;39(1):11–25.
12 Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. Med Decis Making. 2003 Jul-Aug;23(4):281–92.
13 van Tol-Geerdink JJ, Leer JW, Wijburg CJ, van Oort IM, Vergunst H, van Lin EJ, et al. Does a decision aid for prostate cancer affect different aspects of decisional regret, assessed with new regret scales? A randomized, controlled trial. Health Expect. 2016 Apr;19(2):459–70.
14 Baunacke M, Schmidt ML, Groeben C, Borkowetz A, Thomas C, Koch R, et al. Decision regret after radical prostatectomy does not depend on surgical approach: 6-year followup of a large German cohort undergoing routine care. J Urol. 2020 Mar;203(3):554–61.
15 Lindsay J, Uribe S, Moschonas D, Pavlakis P, Perry M, Patil K, et al. Patient satisfaction and regret after robot-assisted radical prostatectomy: a decision regret analysis. Urology. 2021 Mar;149:122–8.
16 Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004 Aug;240(2):205–13.
17 Hiess M, Ponholzer A, Lamche M, Schramek P, Seitz C. [The Clavien-Dindo classification of complications used for radical prostatectomy]. Wien Med Wochenschr. 2014 Aug;164(15–16):297–301.
18 Constantinides CA, Tyritzis SI, Skolarikos A, Liatsikos E, Zervas A, Deliveliotis C. Short- and long-term complications of open radical prostatectomy according to the Clavien classification system. BJU Int. 2009 Feb;103(3):336–40.
19 Borkowetz A, Linxweiler J, Fussek S, Wullich B, Saar M; German Prostate Cancer Consortium DPKK. The role of PSMA PET imaging in prostate cancer theranostics: a nationwide survey. Urol Int. 2022;106(11):1126–35.
20 Cetin B, Wabl CA, Gumusay O. Optimal treatment for patients with oligometastatic prostate cancer. Urol Int. 2022;106(3):217–26.
21 Wolff I, Burchardt M, Peter J, Thomas C, Sikic D, Fiebig C, et al. Patient's desire and real availability concerning supportive measures accompanying radical prostatectomy: differences between certified prostate cancer centers and non-certified centers based on patient-reported outcomes within the cross-sectional study improve. Cancers. 2023 May 19;15(10):2830.
22 De Angelis R, Sant M, Coleman MP, Francisci S, Baili P, Pierannunzio D, et al. Cancer survival in Europe 1999-2007 by country and age: results of EUROCARE--5-a population-based study. Lancet Oncol. 2014 Jan;15(1):23–34.
23 Barocas DA, Alvarez J, Resnick MJ, Koyama T, Hoffman KE, Tyson MD, et al. Association between radiation therapy, surgery, or observation for localized prostate cancer and patient-reported outcomes after 3 years. JAMA. 2017 Mar 21;317(11):1126–40.
24 Chang P, Wagner AA, Regan MM, Smith JA, Saigal CS, Litwin MS, et al. Prospective multicenter comparison of open and robotic radical prostatectomy: the PROST-QA/RP2 consortium. J Urol. 2022 Jan;207(1):127–36.
25 Wolff I, Burchardt M, Gilfrich C, Peter J, Baunacke M, Thomas C, et al. Patients regret their choice of therapy significantly less frequently after robot-assisted radical prostatectomy as opposed to open radical prostatectomy: patient-reported results of the multicenter cross-sectional IMPROVE study. Cancers. 2022 Oct 30;14(21):5356.
26 Butea-Bocu MC, Muller G, Pucheril D, Kroger E, Otto U. Is there a clinical benefit from prostate cancer center certification? An evaluation of functional and oncologic outcomes from 22,649 radical prostatectomy patients. World J Urol. 2021 Jan;39(1):5–10.
27 Gershman B, Meier SK, Jeffery MM, Moreira DM, Tollefson MK, Kim SP, et al. Redefining and contextualizing the hospital volume-outcome relationship for robot-assisted radical prostatectomy: implications for centralization of care. J Urol. 2017 Jul;198(1):92–9.
28 Trinh QD, Bjartell A, Freedland SJ, Hollenbeck BK, Hu JC, Shariat SF, et al. A systematic review of the volume-outcome relationship for radical prostatectomy. Eur Urol. 2013 Nov;64(5):786–98.
29 Begg CB, Riedel ER, Bach PB, Kattan MW, Schrag D, Warren JL, et al. Variations in morbidity after radical prostatectomy. N Engl J Med. 2002 Apr 11;346(15):1138–44.
30 Bandin A, Staff I, McLaughlin T, Tortora J, Pinto K, Negron R, et al. Outcomes over 20 years performing robot-assisted laparoscopic prostatectomy: a single-surgeon experience. World J Urol. 2023 Apr;41(4):1047–53.
31 Van den Broeck T, Oprea-Lager D, Moris L, Kailavasan M, Briers E, Cornford P, et al. A systematic review of the impact of surgeon and hospital caseload volume on oncological and nononcological outcomes after radical prostatectomy for nonmetastatic prostate cancer. Eur Urol. 2021 Nov;80(5):531–45.

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