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## ORIGINAL ARTICLE

# Multicentric experience in Retzius-sparing robot-assisted radical prostatectomy performed by expert surgeons for high-risk prostate cancer

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## ABSTRACT

**BACKGROUND:** The study aim was to report the results of Retzius-Sparing robot-assisted radical Prostatectomy (RSP) in high-risk prostate cancer (HR-PCa) patients in a multicentric setting of expert surgeons and to analyze predictors of positive surgical margins (PSMs) and urinary continence recovery.

**METHODS:** We retrospectively evaluated all consecutive HR-PCa patients who underwent RSP by expert surgeons in 7 centers. Pre-, peri- and postoperative features were collected. Minimum surgical experience required was 100 RSP cases. The oncological outcomes evaluated were PSMs and biochemical relapse (BCR). Urinary continence was defined as no pad or safety pad. Erectile function was defined as erections sufficient for intercourse.

**RESULTS:** We collected 579 patients operated by 9 surgeons. Median age was 66, median PSA was 9,6 ng/mL. ISUP biopsy was 1 in 3,8%, 2 in 23%, 3 in 32,6%, 4 in 19,9%, 5 in 20,7; median surgical time was 195 minutes. Pathological stage was pT2 in 40,1%, pT3a in 35,9%, pT3b in 23,1%, and pT4 in 0,9% of cases. PSMs were present in 31,3% of cases. Urinary continence was achieved in 66,8% of cases one week after catheter removal. At 22 months (median follow-up), 89,1% patients were continent, BCR occurred in 27,5% patients. In multivariate analysis, PSA, prostate volume, surgical time were independent predictors of PSMs; ASA score and PSMs predicted urinary continence.

**CONCLUSIONS:** We report the first multicentric experience of RSP for HR-PCa. Considering HR cases as those with the worst functional results, 89% of continent patients confirms that RSP helps achieve good functional results.

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**KEY WORDS:** Prostatectomy; Robotics; Prostatic neoplasms.

In 2020, Retzius-Sparing robot-assisted radical prostatectomy (RSP) was mentioned for the first time by the European Association of Urology Guidelines as a possible surgical approach for prostate cancer. However, the panelists expressed some concerns regarding the choice of

RSP in special situations, such as high-risk prostate cancers (HR-PCa), post-BPH surgery or salvage prostatectomy, in which good quality data are still lacking.<sup>1</sup> On the contrary, good data exist for anterior prostatectomy in similar situations.<sup>2</sup>

RSP was successfully attempted in early 2010<sup>3</sup> in highly selected patients. Since then, in our center, the indications for RSP have gradually widened, and since 2011, we began performing RSP in all radical prostatectomy indications, demonstrating its feasibility in several contexts.<sup>4</sup> By now, RSP has been performed in many centers throughout the world,<sup>5</sup> and many publications have confirmed the superiority of the approach in terms of higher urinary continence recovery, especially in the early periods after surgery.<sup>6-9</sup>

On the contrary, the same studies showed several concerns about the higher risk of positive surgical margins (PSMs), especially in locally advanced diseases, but the data on this topic remain inconclusive.<sup>7</sup> However, the major drawback of the current Literature is that most studies compare cases from expert standard RARP surgeons to cases coming from unexperienced RSP surgeons.

The aim of our study was to report the results of RSP in high-risk prostate cancers managed in a multicentric setting of expert surgeons and to analyze the predictors of positive surgical margins (PSMs) and urinary continence.

## Materials and methods

### Data source

We invited surgeons from centers with internationally renowned experience in RSP to participate in the study. Surgeons were invited to send an electronic database of prospectively collected data of their consecutive RSPs performed in high-risk prostate cancer out of their learning curve (after having performed at least 100 RSP).

All surgeries were performed as described by Galfano *et al.*,<sup>10</sup> with minor variations based on individual surgeon preferences.<sup>5</sup>

### Definition of variables

For each patient, the following clinical and pathological data were analyzed: age at surgery, previous prostatic surgery, preoperative total PSA (ng/

mL), biopsy Gleason score and ISUP group, clinical stage (cTNM, 2017), prostatectomy Gleason score and ISUP group, pathological prostate weight, pathological stage (pTNM, 2017), and PSMs. Surgical specimens were evaluated at each center, and no central pathological review was performed. Nevertheless, the specimens were managed and reports were compiled according to internationally recognized standards.<sup>11</sup>

Perioperative variables included console time for prostatectomy, operative time, nerve-sparing status, bladder neck-sparing status, blood loss, perioperative transfusion rate, intraoperative and early postoperative complications (within the first 90 days after surgery) classified according to Clavien Dindo,<sup>12</sup> time to catheter removal, and in-hospital stay. Continence recovery was defined as the use of no pads or one safety pad. Immediate continence recovery was defined as the ability to use no pads or one safety pad within one week after catheter removal. Potency recovery was defined as the ability to achieve penetrative intercourse with or without the use of PDE5 inhibitors. Biochemical recurrence was defined as 2 postoperative PSA samples of 0.2 ng/mL or above. Adjuvant treatment was defined as a treatment initiated within 3 months from surgery because of adverse pathological features; salvage treatment was defined as a subsequent therapy performed after more than 3 months because of a biochemical or clinical relapse. Follow-up was collected during regular outpatient visits or during phone calls through institutional questionnaires.

### Statistical analysis

Median and interquartile ranges (IQR), as well as frequencies and proportions, were reported for continuous and categorical variables, respectively. The Mann-Whitney U test and  $\chi^2$  Test were used to compare the statistical significance of differences in the distribution of continuous and categorical variables, respectively. Logistic regression analysis was used to identify the independent predictive values of the prognostic variables.

The Kaplan-Meier method was used to estimate continence and potency recovery, and the log-rank test was used to test differences be-

tween curves. All statistical analyses were performed using the Statistical Package for Social Sciences software, version 20 (SPSS Inc., Chicago, IL, USA). All tests were two-sided with a significance level set at  $P < 0.05$ .

### Results

We included 579 patients operated by 9 expert surgeons in 7 centers between January 2014 and June 2019. Table I, II, III show the details of the

TABLE I.—*Perioperative features.*

Feature	% or median value (IQR)
Age	66 (60-70)
BMI	26.8 (24.5-29.4)
Previous abdominal surgery	
No	69%
Yes	31%
Previous BPH surgery	
No	94.5%
Yes	5.5%
PSA	9.6 (6.3-20)
cT	
cT1a-b	0.8%
cT1c	20.4%
cT2a-b	29.3%
cT2c	18.5%
cT3-4	31%
Biopsy ISUP group	
1	7.3%
2	13.6%
3	16.6%
4	45.1%
5	17.4%
Neoadjuvant hormonal therapy	
No	76%
Yes	24%
ASA Classification	
1	24.3%
2	60.6%
3	15.2%
Surgical time	195 (160-230)
Pelvic LND	
No	4.7%
Yes	95.3%
Bladder neck	
Spared	86.2%
Dissected	13.8%
Nerve-sparing	
Full bilateral	23%
Partial or unilateral	29.5%
Non nerve-sparing	47.5%
Urine drain	
Transurethral catheter	40.2%
Suprapubic tube	59.8%
Catheter removal (POD)	7 (7-9)
Discharge (POD)	3 (2-4)

TABLE II.—*Complications.*

Clavien Dindo	%	Description
1-2	2.9%	2% postoperative transfusion 0.9% deep venous thrombosis
3a	4.8%	4.2% lymphocele (percutaneous drainage) 0.6% acute urinary retention
3b	1%	0.2% compartment syndrome 0.2% ureteral reimplantation for ureteral injury 0.6% reintervention for bleeding
4	0	
5	0	

perioperative features, complications, and post-operative features. One week after catheter removal, no pad urinary continence was achieved in 47,3% of cases; 66,8% of cases used no pad or 1 safety pad. At 1 year follow-up, 84,5% of patients were continent, 72% wearing no pad and the others 1 safety pad, and BCR occurred in 16,5% of cases. After a median follow-up of 22 months, 89% of patients were continent (75% wearing no pad), and BCR occurred in 27,5% of cases.

### Predictors of PSMs

At univariate analysis, PSA, ASA score, pathological ISUP group, pT, and pN, were significant predictors of PSMs (Table IV). At multivariate analysis, only PSA, prostate volume, and surgical time remained independent predictors of PSMs (Table V).

### Predictors of urinary continence

At univariate analysis, PSA, ASA Score, biopsy ISUP group, bladder neck sparing and nerve-sparing status, prostate volume, pT, and pN were significant predictors of postoperative urinary continence (Table VI). At multivariate analysis, only ASA score and PSMs remained significant predictors of urinary continence recovery (with ASA Score trend but not significant) (Table VII).

Figure 1 and Figure 2 show the Kaplan-Meier curves for BCR-free survival and urinary continence recovery.

### Discussion

The present study reports the largest multicentric contemporary series of patients undergoing RSP

TABLE III.—Pathological features and functional outcomes.

Feature	% or median value (IQR)
<b>pT</b>	
pT2	40.1%
pT3a	35.9%
pT3b	23%
pT4	1%
<b>Pathological ISUP group</b>	
1	3.8%
2	23%
3	32.6%
4	19.9%
5	20.7%
Prostate weight	40 (30-50)
Number of lymphnodes	20 (16-26)
<b>pN</b>	
0	80.8%
1	14.6%
Nx	4.6%
<b>Overall surgical margins</b>	
Negative	68.7%
Focal	9.2%
Positive	22.1%
<b>Surgical margins in pT2</b>	
Negative	85.9%
Focal	6.2%
Positive	7.9%
<b>Surgical margins in pT3-4</b>	
Negative	57.2%
Focal	11.2%
Positive	31.6%
Median follow-up	22 (14-47)
<b>Status</b>	
Free from disease after surgery	61.8%
Free from disease after adjuvant/salvage treatments	32.4%
In progression	3.4%
Death from disease	0.6%
Death from other causes	1.7%
<b>Adjuvant treatments</b>	
Radiotherapy	6%
Hormonal therapy	5%
RT+HT	10.6%
<b>Salvage treatments</b>	
Radiotherapy	7.9%
Hormonal therapy	4.6%
RT+HT	6.6%
Chemotherapy	0.8%
<b>1-year continence (0-1)</b>	
Yes	84.5%
No	15.5%
<b>1-year Erectile function</b>	
Spontaneous	25.2%
PDE5i	17.5%
Alprostadil	2.5%
Penile prothesis	0.2%
No erections	54.6%

TABLE IV.—Predictors of positive surgical margins at univariate analysis.

Feature	Negative Surgical Margins	Positive Surgical Margins	p
Age	66 (61-70)	66 (59-70)	0.167
PSA	8.31 (6-16)	13 (8.1-23.1)	<0.001
<b>ASA Score</b>			
1	72.5%	27.5%	0.011
2	71%	29%	
3	54.9%	45.1%	
<b>Previous BPH surgery</b>			
No	71.1%	28.9%	0.657
Yes	76.9%	23.1%	
<b>Neoadjuvant therapy</b>			
No	68.4%	31.6%	0.975
Yes	69.4%	30.6%	
<b>Biopsy ISUP group</b>			
1	76.2%	23.8%	0.081
2	57.9%	42.1%	
3	65.6%	34.4%	
4	73%	27%	
5	65.7%	34.3%	
<b>cT stage</b>			
T1a-c	68.1%	31.9%	0.558
T2a	67.6%	32.4%	
T2b	76.2%	23.8%	
T2c	63.8%	36.2%	
T3-4	68%	32%	
<b>Bladder Neck</b>			
Preserved	70.3%	29.7%	0.350
Partially spared	60.4%	39.6%	
Wide resection	60%	40%	
<b>Nerve-sparing</b>			
Full	74.6%	25.4%	0.08
Partial	71.3%	28.7%	
Non nerve-sparing	64.3%	35.7%	
Surgical Time	195 (150-230)	195 (165-238)	0.356
Discharge	3 (2-4)	3 (2-4)	0.265
Catheter removal	7 (7-9)	7 (7-9)	0.249
Prostate volume	40 (30-55)	40 (30-50)	0.085
<b>pT</b>			
2	85.9%	14.1%	<0.001
3a	60.3%	39.7%	
3b-4	52.5%	47.5%	
<b>pN</b>			
Nx	73.1%	26.9%	0.003
N0	71.3%	28.7%	
N1	52.4%	47.6%	
<b>Pathological ISUP</b>			
1	81%	19%	0.006
2	72.4%	27.6%	
3	68.3%	31.7%	
4	75.5%	24.5%	
5	54.9%	45.1%	

TABLE V.—Multivariate logistic regression model for prediction of PSMs ( $P < 0.001$ ).

Feature	Exp (B)	P
Age	0.994	0.809
PSA	1.014	0.040*
ASA Score	1.146	0.587
Previous BPH surgery	0.831	0.791
Neoadjuvant therapy	0.777	0.248
cT	1.155	0.222
Biopsy ISUP	0.854	0.221
Prostate volume	0.976	0.005*
Bladder neck	1.653	0.226
Nerve-sparing	1.436	0.066
Surgical Time	1.005	0.038*
Urine drain (SPT vs. catheter)	0.879	0.696
Catheter removal	0.914	0.215

\*Statistically significant.

performed by expert surgeons for high-risk prostate cancer. The results showed that RSP is also feasible in this setting, with oncological results similar to standard RARP and with improved results on urinary continence recovery.

To date, only a few data are available for RSP in high-risk cases,<sup>13</sup> coming from a small single-center series including the beginning of their Retzius-sparing experience. In that study, 50 patients operated by 3 different surgeons were evaluated: PSMs were present in 42% of cases, urinary continence was reached by 38% of patients 1 week after catheter removal and by 82% 3 months after surgery. These figures are quite far from our 31% PSMs (mainly present in locally advanced cases) and from 66% of patients with early continence recovery. These differences could be mainly explained by the fact that the patients in our study were operated by surgeons outside their learning curve.

Comparing our data to those from standard robotic radical prostatectomy performed in high-risk prostate cancer cases, the largest literature series coming from high-volume centers are those coming from Detroit<sup>14</sup> and Celebration.<sup>15</sup> In those studies, PSMs ranged between 29% and 33%, perfectly comparable to our 31%; concerning with BCR, one study did not report the data<sup>14</sup> and the second one<sup>16</sup> reported up to 19% of patients experiencing BCR at a mean follow-up of 24 months; in our experience, BCR was apparently more frequent (27%); this could be due to

TABLE VI.—Predictors of urinary continence recovery at univariate analysis.

Feature	Continent patients	Incontinent patients	P
Age	66 (60-70)	68 (63-71)	0.095
PSA	9.4 (6.2-20)	13.9 (8.4-26.5)	0.005
ASA Score			
1	80.8%	19.2%	0.002
2	92.5%	7.5%	
3	87.7%	12.3%	
Previous BPH surgery			
No	90.2%	9.8%	0.126
Yes	80.8%	19.2%	
Neoadjuvant therapy			
No	88.9%	11.1%	0.069
Yes	88.9%	11.1%	
Biopsy ISUP group			
1	82.9%	17.1%	0.048
2	86.7%	13.3%	
3	82.4%	17.6%	
4	92.6%	7.4%	
5	90.7%	9.3%	
cT stage			
T1a-c	93.4%	6.6%	0.098
T2a	96.9%	3.1%	
T2b	83.3%	16.7%	
T2c	87%	13%	
T3-4	87.3%	12.7%	
Bladder Neck			
Preserved	87.2%	12.8%	0.02
Partially spared	74.5%	25.5%	
Wide resection	60%	40%	
Nerve-sparing			
Full	93%	7%	0.000
Partial	96.2%	3.8%	
Non nerve-sparing	82.8%	17.2%	
Urine drain			
Transurethral	90%	10%	0.581
Suprapubic	88.3%	11.7%	
Surgical time	195 (160-230)	195 (150-240)	0.438
Discharge	3 (2-4)	3 (3-4)	0.490
Catheter removal	7 (7-9)	7 (7-9)	0.296
Prostate volume	40 (30-50)	48 (40-59)	0.003
pT			
2	92.3%	7.7%	0.000
3a	92.3%	7.7%	
3b-4	78.9%	21.1%	
pN			
Nx	100%	0%	0.017
N0	89.8%	10.2%	
N1	81.5%	18.5	
Pathological ISUP			
1	100%	0%	0.169
2	89.7%	10.3%	
3	87.9%	12.1%	
4	92%	8%	
5	84.1%	15.9%	
Surgical margins			
Negative	92.3%	7.7%	0.001
Positive	81.9%	18.1%	
Radiotherapy			
No	90.7%	9.3%	0.063
Yes	85.1%	14.9%	

TABLE VII.—Multivariate logistic regression model (Urinary continence) ( $P<0.001$ ).

Feature	Exp (B)	p
Age	1.051	0.139
PSA	0.998	0.821
ASA Score	0.478	0.043*
Previous BPH surgery	0.902	0.913
cT	1.240	0.224
Neoadjuvant therapy	0.816	0.559
Bladder neck	2.217	0.121
Nerve-sparing	1.506	0.157
Prostate volume	1.006	0.512
pT	1.166	0.614
pN	1.232	0.686
ISUP group	0.799	0.432
PSMs	4.099	0.001*

\*Statistically significant.

worse pathological features in our series (50% vs. 60% of locally advanced disease, no pathological ISUP group, or Gleason score reported

in the study). Unfortunately, data concerning the location of PSMs are not available; we have the perception that anterior margins are not really different from the standard approach; in fact, knowing the topography of the tumor through the MRI, the surgeon can conduct the surgery farther or closer to the prostate also in the anterior surface of the organ.

With regard to immediate urinary continence recovery, Kumar *et al.* reported 3 months urinary continence ranging between 71% and 91%, while Abdollah did not report early continence data. Long-term urinary continence results in the standard approach ranging between 82% and 94%, with higher values obtained in selected patients undergoing a full nerve-sparing surgery.

Our 66% of continent patients 1 week and 89% 1 year after surgery are not directly comparable to the figures obtained with the standard

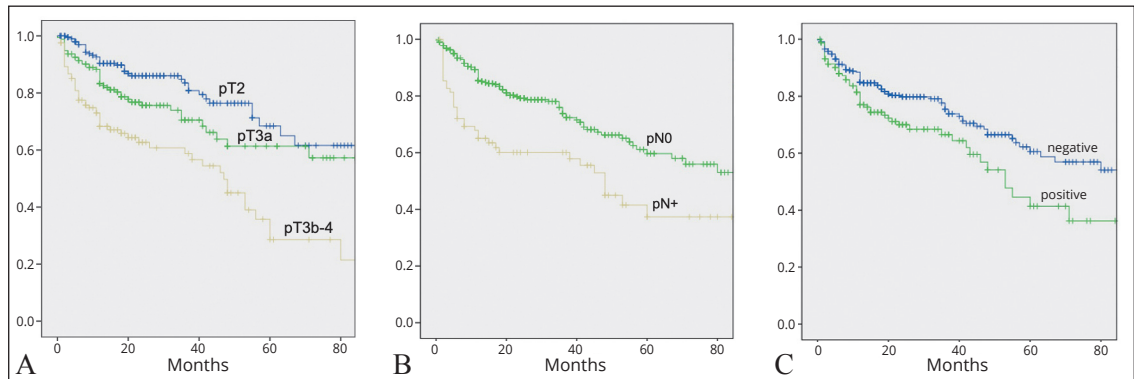


Figure 1.—Kaplan Meier curve of biochemical relapse-free survival according to A) pT stage ( $P=0.000$ ); B) pN stage ( $P=0.001$ ); C) positive surgical margins ( $P=0.004$ ).

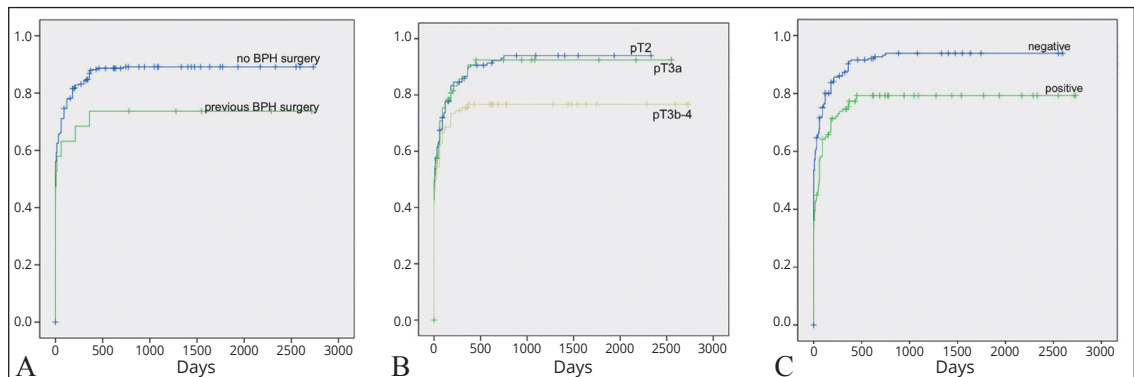


Figure 2.—Kaplan Meier curve of urinary continence recovery according to A) history of previous BPH surgery ( $P=0.119$ ); B) pT stage ( $P=0.040$ ); C) positive surgical margins ( $P=0.000$ ).

approach, but it can be thought that RSP can overcome the results obtained with the standard approach only by the best surgeons in the world.

Unfortunately, in this setting sexual function is not a primary issue. Nevertheless, we found about 40% of patients having erections sufficient for intercourse; this figure is similar to what described by the most recent literature.<sup>17</sup>

The median in-hospital length of stay of our study is 3 days, that reflects the different postoperative patterns in 3 different continents; while in USA usually patients are discharged the day after surgery, in China typically the patient is discharged a few days after catheter removal, while in Europe we have intermediate situations

Among the predictors of PSMs, high PSA, high prostate volume and high surgical time resulted statistically significant. Those 3 features are related with an increased surgical difficulty; as such, they represent quite well the increased risk of having PSMs.

Among the predictors of urinary continence, only ASA score and PSMs turned out to be statistically significant. While ASA score can be related to the physical performance of the patient and consequently with the muscular tone, PSMs are mainly related to the extension of the disease (and of the anatomical damage) and to the need of consequent therapies.

### Strengths and limitations of the study

The strength of our study is its multicentric nature and the fact that the surgeons are skilled surgeons outside their learning curve; in this way, we have real life mature data confirming the feasibility and usefulness of RSP in this setting of patients.

However, the study is not devoid of limitations: it is a multicentric series, with different pathologists evaluating the specimens without a central revision; it is a retrospective study, and the analysis of the results has not been conducted by a third party and no control group is present. Still, these limitations make it a real-life study.

### Conclusions

We report the first multi-center experience of Retzius-Sparing Prostatectomy in high-risk pros-

tate cancer patients. Considering that this setting of patients generally has the worst functional results, 89% of continent patients confirm that this approach helps achieve good functional results. Predictors of PSM and urinary continence were identified.

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