

# A retrospective overview on the health-related quality of life of patients after RALP

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## **Abstract**

**Introduction and objectives:** We made a retrospective evaluation of the patients who underwent robot-assisted laparoscopic radical prostatectomy (RALP) for prostate cancer in order to assess the impact of minimal invasive surgery on the health-related quality of life (HRQoL).

**Material and methods:** From December 2009 to February 2013, 112 robotic-assisted radical prostatectomies were performed at the Cluj-Napoca Clinical City Hospital.

Among the patients, 54 postoperatively responded to the EPIC, SF-12 and AUA-Si health related quality of life evaluation forms. Perioperative data concerning oncological disease, sexual and urinary function were also collected. We compared the oncological status of the urinary, bowel, sexual and hormonal functions among responders with provided normative values and we looked for relevant correlations with the nerve sparing technique and the quality of life.

**Results:** Median time from intervention was 18.5 months with a median age of 64 years at the time of RALP. Nerve-sparing was performed in 28 of the cases among which 50% of the patients reported spontaneous erections. Of the patients, 23 reported no urinary pad use, and 19 used one safety pad on a daily basis. The urinary and sexual functions were significantly affected by the robotic-assisted procedure ( $p < 0.00001$  and  $p < 0.000001$ , respectively), the former with impact on HRQoL. Comorbidities proved to have a negative impact on both physical and mental SF-12 components ( $p < 0.05$  and  $p < 0.01$ , respectively).

**Conclusions:** The HRQoL is mainly affected by incontinence and comorbidities also account for a non-negligible part. Nerve sparing has an impact on both urinary and sexual outcome and accounts for a better preservation of sexual functioning after RALP.

**Key words:** EPIC, nerve sparing, prostate cancer, quality of life, RALP

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## Introduction and objectives

The da Vinci® Si™ Surgical System is being increasingly used in many urology centers with promising oncological and functional outcomes for patients [1]. Given its heightened accuracy and reliability robot-assisted laparoscopic radical prostatectomy (RALP) has become the technique of choice for patients undergoing surgical treatment for prostate cancer in our clinic.

Previous studies [2-4] have shown that, in spite of the advantages provided by minimally invasive surgery, patients still have to face two main issues after RALP, namely deficitary continence and sexual dysfunction. These drawbacks are mostly procedure-related and may be encountered in patients who underwent radical prostatectomy [5] by various techniques. However, it seems that surgeon experience and skill are factors in favor of better postoperative outcomes concerning continence and potency [6].

Having started our robotics program a little more than three years ago with the introduction of the da Vinci® Si™ robot to our clinic and the consecutive migration from classic laparoscopy for a number of procedures gave us the opportunity to analyze the outcomes, as related by our patients, and to assess our work expertise during and after the learning curve.

The aim of the present study was to assess the health-related quality of life (HRQoL) among the patients who underwent RALP for prostate cancer in the Cluj-Napoca Clinical City Hospital urology center. The reason was to achieve a better understanding of the postoperative life of our patients in order to improve our practice, to ameliorate preoperative counselling to future patients and gain the ability to alleviate issues that sometimes are being felt difficult to bring up to our attention during the follow-up.

## Material and methods

In order to build a comprehensive data collection with detailed information from each of our patients we opted for the „Extended Prostate Cancer Index” (EPIC) which is an instrument designed on top of the “UCLA-Prostate Cancer Index” to evaluate prostate cancer treatment outcomes from a patient based perspective. We decided that the best way to obtain data was by sending mails containing the EPIC survey, including the AUA Symptom Index and the SF-12 and Demographic add-ons [7-9] to selected patients. In order to increase the response rate, we also included pre-stamped return envelopes and a letter explaining the

purpose and the ethical aspects of this survey along with the documents mentioned above.

All collected data were inserted into an electronic database using a spreadsheet application. Domain scales scores were computed using a special spreadsheet form created for this purpose. Additional data were obtained from the patient management software used on the in-hospital computers, including histopathology examination results and procedure related data.

We selected 112 consecutive patients that underwent RALP in our robotics urology center since December 2009 when our robotics program was initiated, until February 2013. All patients were first screened for prostate adenocarcinoma by the means of prostate specific antigen blood levels (PSA) and digital rectal examination [10]. TRUS guided prostate biopsy was used for disease confirmation and staging in concordance with the EAU guidelines on prostate cancer. The Sloan-Kettering prostate cancer nomograms were used to evaluate the likelihood of lymph node involvement and extracapsular extension establishing the indication for pelvic lymph node dissection and nerve sparing.

Transperitoneal RALP was performed in all 112 cases. After discharge patients entered a follow-up program with visits at one, three, six, and 12 months in the first year continued with two visits per year hereinafter. Patients also underwent oncology evaluation with additional oncology treatment in the case of positive resection margins or biochemical recurrence.

We had a total of 54 responders, which accounts for a 48.21% response rate after a three month interval from the day the envelopes were dispatched in April 2013. Exclusion criteria were based on the failure to fill the survey forms in a manner both apprehensible and complete. Two response forms were deemed to have not met the inclusion minimum and were therefore excluded. The study was built using response from 52 patients.

The EPIC form mainly focuses on four domain scales measuring the urinary, bowel, sexual and hormonal function after treatment. For each of these scales means were calculated and compared with provided normative control values from a healthy (prostate cancer free) lot, available for use along with the survey forms [11]. For statistical analysis, IBM SPSS Statistics software has been used. One Sample T-Test was applied in order to observe the presence of statistically significant differences. We also looked for signif-

ificant correlations between domain scales means and both postoperative and demographic data, using Pearson's correlation coefficient.

Median age at the time of intervention was 64 years and the median follow-up time measured in months from the intervention date to survey completion, was 18.5 months. There were eight patients that received additional oncology treatment after RALP for locally advanced disease (stage pT<sub>3a-b</sub>) or oncologically pN+. However, a separate analysis of their results was not performed considering the small number of cases.

## Results

From the histopathology examination results we found that 48.1% of the patients were staged pT<sub>2a-c</sub> and 51.9% pT<sub>3a-b</sub> which accounts for locally advanced prostate-cancer (Table 1). Bilateral pelvic lymph node dissection was performed in 55.8% of all cases. There was only one case of lymph node involvement among the studied patients.

**Table 1 - TNM Staging**

	Frequency	Percent	Cumulative Percent
pT <sub>2a</sub>	8	15.4	15.4
pT <sub>2c</sub>	17	32.7	48.1
Valid pT <sub>3a</sub>	19	36.5	84.6
pT <sub>3b</sub>	8	15.4	100.0
Total	52	100.0	

In 28 cases a form of nerve sparing was performed, one bundle being preserved in 17.3% of all patients, respectively, both bundles in 36.5% of the patients (Table 2).

**Table 2 - Nerve Sparing Approach**

	Frequency	Percent	Cumulative Percent
None	24	46.2	46.2
One sided	9	17.3	63.5
Valid Bilateral	19	36.5	100.0
Total	52	100.0	

When we assessed the difference between evaluated domain scales scores and provided data, we found statistically significant lower urinary and sexual function scores compared to normative values from the healthy control group (*Sig.* =*p*<0.00001 and *Sig.*=*p*<0.000001, respectively – Table 3&4).

**Table 3 - Sexual Summary (Evaluated vs. Controls)**

Sexual Summary (Mean Value = 27.6 / Test Value = 61.4)					
t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
				Lower	Upper
-13.169	51	.000000	-33.80250	-38.9555	-28.6495

**Table 4 - Urinary Summary (Evaluated vs. Controls)**

Urinary Summary (Mean=76.44 / Test Value = 89.5)					
t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
				Lower	Upper
-5.390	51	.000002	-13.06269	-17.9279	-8.1975

The impact of nerve sparing on functional outcomes, continence and sexual function is presented in tables 5 and 6. There can be seen that 19 patients in 24 had no spontaneous erections where a non nerve sparing resection was performed versus eight patients in 19 in the case of bilateral nerve sparing. Concerning continence (Table 6), 20 patients in 28 are continents, where a form of nerve sparing was performed. Among all 52 RALP patients 80.76% are continent (no pad use or one safety pad) and 44.23% are fully continent (no urinary pads whatsoever).

**Table 5 – Potency stratified by Nerve Sparing**

		Spontaneous Erections		Total
		None	Yes	
Nerve Sparing	None	19	5	24
	One sided	6	3	9
	Bilateral	8	11	19
Total		33	19	52

**Table 6 – Continence stratified by Nerve Sparing**

		Number of Pads Used				Total
		None	1/day	2/day	3+/day	
Nerve Sparing	None	13	9	1	1	24
	One sided	4	5	0	0	9
	Bilateral	6	5	6	2	19
Total		23	19	7	3	52

We found  $R^2=0.010$  and  $B=0.307$  considering a linear relationship between nerve sparing and the number of pads used per day and  $R^2=0.120$  and  $B=0.184$  for nerve sparing vs. spontaneous erections, respectively, where  $B$  is  $X$ 's coefficient in the regression equation. These results account in both cases for a positive relationship between observed variables. We also found statistically significant correlations in both cases

(Sig.= $p<0.05$ ) with  $r=0.346$  for potency and  $r=0.316$  for the number of pads used per day (Table 7).

**Table 7 – Correlations: Nerve Sparing vs. Potency / Continence**

	Nerve Sparing	Spontaneous Erections	Number of Pads Used
Pearson Correlation	1	.346*	.316*
Sig. (2-tailed)		.012	.023
N	52	52	52
R <sup>2</sup>		.120	.010
B		.184	.307

\* Correlation is significant at the 0.05 level (2-tailed).

Both SF-12 Mental Component Scale (MCS) and Physical Component Scale (PCS) scores were influenced by the urinary function summary, but not the sexual function summary ( $p<0.01$  and respectively  $p<0.01$  – Table 8&9).

**Table 8 – Correlations: Urinary Summary vs. HRQoL**

	Urinary Summary	SF-12 PCS	SF-12 MCS
Pearson Correlation	1	.477**	.361**
Sig. (2-tailed)		.000	.008
N	52	52	52
R <sup>2</sup>		.227	.131
B		.315	.243

\*\* Correlation is significant at the 0.01 level (2-tailed).

**Table 9 – Correlations: Sexual Summary vs. HRQoL**

	Sexual Summary	SF-12 PCS	SF-12 MCS
Pearson Correlation	1	.208	.197
Sig. (2-tailed)		.139	.162
N	52	52	52
R <sup>2</sup>		.043	.039
B		.146	.140

The total number of comorbidities negatively correlated with both the physical and mental domain scores of the SF-12 survey add-on ( $p<0.05$  and respectively  $p<0.01$  – Table 10). The negative relationship can also be observed when observing  $B<0$  in both cases.

**Table 10 – Correlations: Number of Comorbidities vs. HRQoL**

	Number of Comorbidities	SF-12 PCS	SF-12 MCS
Pearson Correlation	1	-.299*	-.430**
Sig. (2-tailed)		.031	.001
N	52	52	52
R <sup>2</sup>		.090	.015
B		-.185	-.022

\* Correlation is significant at the 0.05 level (2-tailed).

\*\* Correlation is significant at the 0.01 level (2-tailed).

## Discussion

Kaye et al. reported good urinary function outcomes in both laparoscopic and robotic radical prostatectomy patients where at least one neurovascular bundle has been preserved [12]. Similar findings were reported by Choi et al. concerning both urinary function and continence at four months after RALP in a group of 602 consecutive patients [13]. However, at 12 and 24 months, respectively they reported significant improvements in urinary function scores only. Srivastava et al. also reported in 2013 a 71.8% early return of continence at 12 weeks time in the case of bilateral nerve sparing and a general continence rate of 55.8% [14]. Parker et al. reported a urinary function score of 55.8% at one year after prostatectomy [15].

When health related quality of life was considered, Liss et al. reported that HRQoL score were highest in patients that did not require the use of urinary pads compared to those who needed a security pad [16]. Incontinence was associated with lower HRQoL as well in a study published by Buckley et al. in 2012 for a group of patients who underwent either RALP or transurethral resection of the prostate (TURP) [17].

Among our patients we found that urinary functioning scores were strongly correlated with both mental and physical components of the SF-12 measured HRQoL score ( $R^2=0.131$ ,  $r=0.361$ ,  $p<0.01$  and  $R^2=0.227$ ,  $r=0.477$ ,  $p<0.01$  respectively – Table 8). This is consistent with other studies which show that urinary functioning impairments are bothersome and responsible for lower HRQoL scores.

When the postoperative sexual functioning was assessed stratification by the nerve sparing approach was performed knowing that the lack of bundle preservation is the main cause of sexual dysfunction. As expected, there were better outcomes in the subgroup where both bundles were spared compared to lower potency where only one bundle was spared, and even

lower where a wide non nerve-sparing resection was required. These findings are consistent with other reports in the literature [18]. Gralnek et al. reported, in 2000, higher sexual domain scores for patients who underwent radical prostatectomy and a form of nerve sparing was performed compared to those where no neurovascular bundle has been preserved [19]. Burnett et al. performed a meta-analysis of 31 studies that had groups of at least 50 patients, and found that the potency rate after radical prostatectomy, measured by the presence of erections, was varying between 9% and 86% [20].

However, when evaluating potency in prostatectomy patients other data must be taken into account. The median group age at the time of intervention was 64 years and a median of 18.5 months have passed until the form submission. When we correlate this with a more in-depth analysis of the responses given to the questions related to sexual functioning we realize that some of the patients simply are not interested to engage in sexual activities for various reasons, but it is fair to admit that there is another part that is highly bothered by the decrement in potency. It is also interesting that only five of all patients reported using any form of erection improvement therapy considering that a PDE5 inhibitor prescription is given upon patient discharge and other methods are presented on request.

We observed a statistically significant difference when comparing the obtained values for sexual functioning with the provided normative ones from a healthy, cancer-free lot (27.6 vs. 61.4,  $p < 0.000001$  – Table 3). This means that in our group of patients there is a high enough decrease in potency that may be considered significant. However, a shortcoming of a retrospective study, this included, is the inability to use the same group of patients for control considering that sexual functioning may be altered at baseline, in untreated prostate cancer patients [21]. Also, we found an acceptable correlation level between nerve sparing and potency ( $R^2 = 0.12$ ,  $r = 0.346$ ,  $p < 0.05$  – Table 7).

When we looked for correlations between the SF-12 scales, which measure both mental and physical aspects of the quality of life, and the sexual functioning, no statistical significance was found (Table 9). This result shows that even if patients present with both impaired urinary and sexual functioning, in our group, their HRQoL is affected by the decrease in continence but not potency.

Also the total number of comorbidities was nega-

tively correlated with both SF-12 MCS ( $R^2 = 0.015$ ,  $r = -0.430$ ,  $p < 0.01$  – Table 10) and SF-12 PCS ( $R^2 = 0.09$ ,  $r = -0.299$ ,  $p < 0.05$  – Table 10) quality of life components. This finding is consistent with those reported by Daskivich et al. who observed poorer long-term HRQoL outcomes in patients with baseline comorbidities [22]. Similar findings were also reported by Arredondo et al. [23] and Xuan et al. [24]. In other words comorbidities account for a decrease in HRQoL that is not directly linked to prostate disease.

## Conclusions

The urinary and sexual functioning is diminished in patients who underwent RALP compared to healthy controls, but the HRQoL is mainly affected by urinary function related issues. Nerve sparing has an impact on both urinary and sexual functions and both one sided and bilateral approaches, accounts for a better preservation of sexual functioning after RALP. The number of comorbidities contributes to a decrease in HRQoL that is not linked to prostate disease.

## References:

1. Crișan N, Petruț B, Nechita F, Feciche B, Mihaly Z, Stanca D, Coman I: *The Closer Programme - Initial Experience with Laparoscopic Versus Open Radical Prostatectomy*. TMJ, 2010;60(2-3):232-5
2. Anderson CB, Kaufman MR, Dietrich MS, Barocas DA, Chang SS, Cookson MS, Smith JA Jr, Clark PE, Herrell SD: *Recovery of urinary function after radical prostatectomy: identification of trajectory cluster groups*. J Urol 2012;187(4):1346-51
3. Ambert V, Braticevici B, Damian D, Chira I, Iconaru V, Radu T, Constantin T: *Radical prostatectomy in the treatment of prostate cancer. The experience of the Urology Clinic of Prof. Dr. Th. Burgele Clinical Hospital*. J Med Life 2009;2(3):279-87
4. Litwin MS, Melmed GY, Nakazon T: *Life after Radical Prostatectomy: A Longitudinal Study*. J Urol. 2001;166(2):587-92
5. Stanford JL, Feng Z, Hamilton AS, et al.: *Urinary and Sexual Function After Radical Prostatectomy for Clinically Localized Prostate Cancer: The Prostate Cancer Outcomes Study*. JAMA 2000;283(3):354-360.
6. Walsh PC, Marschke P, Ricker D, Burnett AL: *Patient-reported urinary continence and sexual function after anatomic radical prostatectomy*. Urology 2000;55(1):58-61
7. Wei J, Dunn R, Litwin M, Sandler H, Sanda M: *Development and Validation of the Expanded Prostate Cancer Index Composite (EPIC) for Comprehensive Assessment of Health-Related Quality of Life in Men with Prostate Cancer*. Urology 2000;56:899-905
8. EPIC + SF12 and AUASI Instrument – Available: <http://www.med.umich.edu/urology/research/EPIC/EPIC-AUASI-SF12-2.2002.pdf>

9. EPIC - Demographics add-on – Available: <http://www.med.umich.edu/urology/research/EPIC/EPIC-Demog-2.2002.pdf>
10. Crișan N, Feciche BO, Porav Hodade D, Mihaly Z, Meteș O, Petruț B, Stanca D, Nechita F, Petcu V, Coța R, Sârb D I, Jalalizadeh B, Bungărdean C, Spârchez Z, Lăpușan C, Giurgiu CR, Coman I.: *Experiența „Centrului de Screening în Cancerul de Prostată” Cluj-Napoca în primul an de activitate.* Revista Română de Urologie, 2006; 5(1):42-7
11. *Characteristics of EPIC domain-specific summary and subscale scores for 112 controls without prostate cancer* – Available: <http://www.med.umich.edu/urology/research/EPIC/norms.pdf>
12. Kaye DR, Hyndman ME, Segal RL, Mettee LZ, Trock BJ, et al.: *Urinary Outcomes Are Significantly Affected by Nerve Sparing Quality During Radical Prostatectomy.* Urology 2013;82(6): 1348-54
13. Choi WW, Freire MP, Soukup JR, Yin L, Lipsitz SR, Carvas F, Williams SB, Hu JC: *Nerve-sparing technique and urinary control after robot-assisted laparoscopic prostatectomy.* World J Urol 2011;29(1):21-27
14. Srivastava A, Chopra S, Pham A et al.: *Effect of a Risk-stratified Grade of Nerve-sparing Technique on Early Return of Continence After Robot-assisted Laparoscopic Radical Prostatectomy.* E Urol. 2013;63(3):438-44
15. Parker WR, Wang R, He C, Wood DP: *Five year Expanded Prostate cancer Index Composite-based quality of life outcomes after prostatectomy for localized prostate cancer.* BJU Int. 2011;107(4):585-90
16. Liss MA, Osann K, Canvasser N, et al.: *Continence Definition After Radical Prostatectomy Using Urinary Quality of Life: Evaluation of Patient Reported Validated Questionnaires.* J Urol. 2010;183(4):1464-8
17. Buckley BS, Lapitan MCM, Glazener CM and for the MAPS Trial Group: *The effect of urinary incontinence on health utility and health-related quality of life in men following prostate surgery.* Neurol. Urodyn. 2012;31(4):465-9
18. Kundu SD, Roehl AK, Eggener SE, et al.: *Potency, continence and complications in 3,477 consecutive radical retropubic prostatectomies.* J Urol. 2004;72(6.1):2227-31
19. Gralnek D, Wessells H, Cui H, Dalkin BL.: *Differences in sexual function and quality of life after nerve sparing and nonnerve sparing radical retropubic prostatectomy.* J Urol. 2000;163(4): 1166-70
20. Burnett AL, Aus G, Canby-Hagino ED, et al.: *Erectile Function Outcome Reporting After Clinically Localized Prostate Cancer Treatment.* J Urol. 2007;178(2):597-601
21. Talcott JA, Rieker P, Propert KJ, et al.: *Patient-Reported Impotence and Incontinence After Nerve-Sparing Radical Prostatectomy.* J Natl Cancer Inst. 1997;89: 1117-23
22. Daskivich TJ, van de Poll-Franse LV, Kwan L, Sadetsky N, Stein DM, Litwin MS: *Comorbidity Severity and Quality of Life After Treatment for Early-stage Prostate Cancer.* Prostate Cancer Prostatic Dis. 2010;13(4):320-7
23. Arredondo SA, Elkin EP, Marr PL, et al.: *Impact of comorbidity on health-related quality of life in men undergoing radical prostatectomy: data from CaPSURE.* Urology 2006;67(3):559-65
24. Xuan J, Kirchdoerfer LJ, Boyer JG, Norwood GJ: *Effects of comorbidity on health-related quality-of-life scores: an analysis of clinical trial data.* Clin Ther. 1999;21(2):383-403