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ORIGINAL ARTICLE

Fifteen-year single-centre experience with three different surgical procedures of nerve-sparing cystectomy in selected organ-confined bladder cancer patients

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Abstract
Objectives To evaluate technical feasibility and oncologic and functional outcomes of three different surgical procedures of nerve-sparing radical cystectomy (NS-RC) for the treatment of organ-confined bladder cancer at a single referral centre.
Materials and methods All consecutive cases of NS-RC carried out between 1997 and 2012 were retrospectively analysed. NS-RC included nerve-sparing cysto-vesicleprostatectomy (NS-CVP), capsule-sparing cystectomy (CS-C) and seminal-sparing cysto-prostatectomy (SS-CP). Peri-operative parameters and post-operative outcomes were analysed.
Results Overall, 90 patients underwent NS-RC, 35 (38.9 %) of whom received a NS-CVP, while 36 (40 %) and 19 (21.1 %) underwent capsule CS-C and SS-CP, respectively. No difference was registered comparing oncologic outcomes of the three different techniques; however, two local recurrences after CS-C were attributed to the surgical technique. Complete post-operative daytime and night-time urinary continence (UC) at 24 and 48 months was achieved in 94.4 and 74.4 % and in 88.8 and 84.4 % of cases, respectively. CS-C showed both the best UC and sexual function preservation rate at early follow-up (24 months). Overall, a satisfactory post-operative erectile function (IIEF-5 $\geq$ 22) was proved in 57 (68.6 %) and 54 (65.0 %) patients at 24 and 48 months, respectively. Significant difference was found when comparing sexual function preservation rate of NS-CVP (28.5 %) to that of CS-C (91.6 %) and SS-CP (84.2 %).
Conclusion NS-RC for male patients accounted for 7.4 % of overall radical cystectomy. To a limited extent of the selected organ-confined bladder cancers treated, the three different procedures analysed showed comparable results in terms of local recurrence and cancer-specific survival. Both CS-C and SS-CP procedures provided excellent functional outcomes when compared to original NS-CVP.

Keywords Radical cystectomy · Nerve sparing · Capsule sparing · Intrafascial prostatectomy · Urinary incontinence · Sexual function · Cancer-specific survival

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Introduction

Nerve-sparing radical cystectomy (NS-RC) configures one of the most exciting issues of modern surgery for both patient's high post-operative expectations and innovative surgical context.

Looking at prostate cancer treatment, the nerve-sparing surgery has widely been applied for more than 20 years achieving a consolidate position in the routine clinical practice of every urologic unit. When bladder cancer is in question, the expectations of NS-RC appear even more attractive. In spite of the unquestionable improvement of patient's post-operative quality of life (QoL) related to the introduction of orthotopic bladder substitution (OBS), the frequent disturbances of the urinary continence (UC) [1, 2] and the loss of the erectile function subsequent to conventional radical cysto-prostatectomy [3, 4] may explain the

reluctance of both the surgeon to propose and the patient to accept radical surgery for bladder cancer. This is even more true when patients are young, potent and suffering from an organ-confined disease. During the mid-1980s, the nerve-sparing approach was seen as the possible key to overcome these limitations. However, the use of this procedure actually remained limited over the years. Urothelial carcinoma must be considered as a potential lethal disease and the risk that privileging post-operative QoL could compromise the oncological safety deserves to be carefully taken into account in decision-making. Additional limiting factors to NS-RC diffusion may be represented by the need of both to respect an appropriate patient selection and to complete an adequate surgical learning curve. Moreover, the different surgical procedures introduced in clinical practice over the last 20 years, with the valuable intent to improve safety and results, have probably appeared to be as a confounding factor. In this retrospective study, 90 selected patients suffering from non-muscle invasive or organ-confined bladder cancer submitted to NS-RC at a single reference centre were critically revised in order to assess safety, efficacy and the future potential of this surgery in routine practice.

Materials and methods

Clinical and pathologic data concerning all consecutive cases of NS-RCs performed at our Institution between January 1997 and January 2012 were analysed for the assessment of the incidence, distribution over time, surgical technique characteristics and post-operative oncologic and functional outcomes. During the interval of time considered, three different surgical procedures were adopted in clinical practice.

Nerve-sparing cysto-vesicleprostatectomy (NS-CVP)

This technique, adopted according to that initially described by Walsh et al. [5, 6] and Pricktett et al. [7] in 1988, includes the "en bloc" removal of bladder, prostate and seminal vesicles only leaving the neurovascular bundles intact. This procedure was mainly carried out by a transperitoneal approach, using a combined ante-retrograde bladder dissection in combination with an interfascial prostatectomy.

Capsule-sparing cystectomy (CS-C)

This technique, described by our group in 2001 [8], includes as preliminary step a transurethral resection of prostate (TURP) and the entire removal of the bladder while leaving the prostate capsule, vas deferens, seminal vesicles and neurovascular bundles intact. The extirpative time was completed via extraperitoneal approach except for three patients for whom a laparoscopic transperitoneal technique was preferred [9].

The pre-operative assessment included both transrectal US-guided prostate biopsies (12–18 cores) irrespective of the PSA value and biopsies of bladder neck and prostatic urethra. Prostate biopsies were taken at least 14 days before RC, while biopsies of bladder neck and prostatic urethra were obtained at the time of previous transurethral resection for bladder cancer. Between 1997 and 2001, TURP was completed consensually to RC (15 patients). Subsequently, TURP was carried out together with systematic prostate biopsies about 14 days before RC in order to obtain definitive pathology from prostate specimens at the time of radical surgery.

Intrafascial seminal-sparing cysto-prostatectomy (SS-CP)

This procedure was completed similarly to that firstly described by Puppo et al. [10] in 2008 and subsequently referred in different series by Ong et al. [11] and Hautmann et al. [12]. The main steps include a blunt extraperitoneal antegrade dissection between the posterior bladder wall and the seminal vesicles up to the ejaculatory ducts and a retrograde intrafascial prostatectomy. With this procedure, seminal vesicles, vas deferens and neurovascular bundles were left intact into the pelvis. Regardless of the kind of technique for NS-RC, a preliminary pelvic lymph node dissection (PLND) including iliac, obturatory, hypogastric and common nodes up to the ureter cross was bilaterally performed. In all patients, after cystectomy, an OBS according to the Hautmann technique [13] was accomplished.

Criteria for patient selection included age of $\leq$65 years, high-risk non-muscle invasive bladder cancer (NMIBC) or clinical tumour stage T $\leq$ 2 without evidence of disease at bladder neck and total PSA <4.0 ng/ml with normal DRE. In accordance with the policy at our department for T1/T2 stage patients, no case received a neo-adjuvant chemotherapy. As mentioned, for capsule-sparing cystectomy (CS-C) approach, negative prostate biopsies and the absence of urothelial carcinoma at prostate urethra were also requested. Additional pre-operative criteria included a Charlson index (CCI) [14] of <2 in all cases and a satisfactory sexual function documented by the 5-item International Index of Erectile Function questionnaire (IIEF-5) [15].

Data concerning both comprehensive clinical and pathological characteristics as well as oncological outcomes including overall survival (OS) and disease-specific survival (CSS), retrospectively (from 1997 to 2001) or prospectively (from 2002) collected in a dedicate institutional database, have been revised for the purpose of this study, in accordance with the ethical guidelines of the institute.

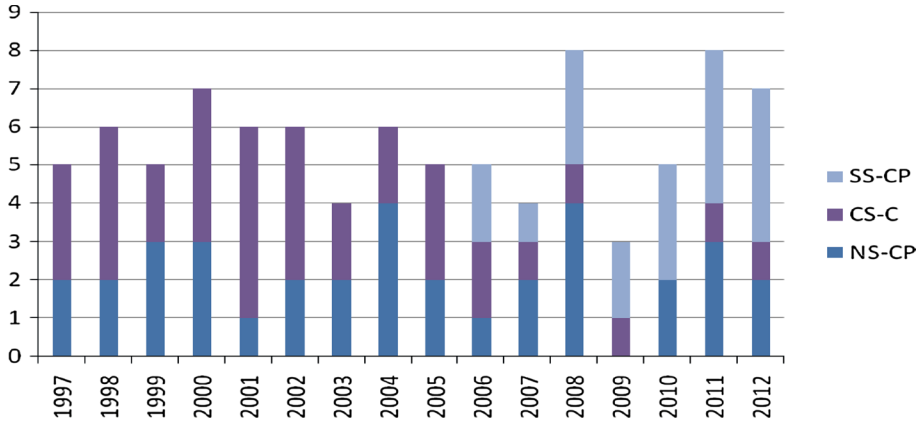

Fig. 1 Distribution of the different nerve-sparing cystectomy surgical techniques with time. *NS-CVP* nerve-sparing cystovesicleprostatectomy , *CS-C* capsule-sparing cystectomy, *SS-CP* seminal-sparing cystoprostatectomy

Local recurrence (LR) was defined as any recurrence of urothelial carcinoma within the pelvic soft and/or ureteral or urethral tissue. Complete UC was defined for patients totally pad-free, while a satisfactory sexual function was assumed for IIEF-5 $\geq$ 22 irrespective of the use of PDE5-I drugs. Use of PDE5-I after surgery was suggested to patients with IIEF-5 $\leq$ 21 at 3-month post-operative visit. In all cases, the follow-up was carried out by MR or CT chest, abdomen and pelvis without and with contrast every 6 months for 5 years. In addition, at 24 and 48 months, international validated tools and questionnaires for UC (ICIQ-SF, voiding diary and pad test) and for sexual function assessment (IIEF-5) were systematically administered. Descriptive statistics of categorical variables focused on frequencies and proportions. Means, medians and ranges were reported for continuously coded variables. Chi-square test and *t* test were used to compare proportions and means, respectively.

Statistical significance was considered at $p < 0.05$. Statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA).

Results

A total of 1,412 consecutive patients underwent radical cystectomy for bladder cancer at our institute during the analysed period of time, and for 1,217 of them, both comprehensive clinical and pathologic data were available. The median age was 67.8 years (mean 69; range 32–93) with 262 (21.5 %) of these patients being female and 955 (78.5 %) male, respectively. Overall, 102 (8.8 %) patients underwent a kind of nerve-sparing procedure at the time of radical cystectomy. Of them, 12 (11.8 %) were female and 90 (88.2 %) male, respectively. Of the 90 NS-RC male patients, 35 (38.9 %) received a nerve-sparing radical NS-CVP, while 36 (40 %) and 19 (21.1 %) received a capsule CS-C and an seminal-sparing cysto-prostatectomy (SS-CP), respectively. All surgical procedures were completed by the same surgeon (RC). About 85 % of CS-C were carried out between 1997 and 2007, while all SS-CP were completed between 2006 and 2012. Conversely, NS-CVP were almost homogeneously distributed along the entire period of time. Figure 1 shows the distribution of different kinds of NS-RC during the interval of time investigated. Mean age was 58.1 (range 48–67), 48.3 (range 41–58) and 53.2 (range 36–64) years for NS-CVP, CS-C and SS-CP, respectively. In all cases, the pre-operative Charlson index was <2, while IIEF-5 was ≥26 in 80 (88.8 %) patients and between 22 and 25 in the remaining. Bladder cancer was clinically organ-confined (≤T2) in all patients with prevalence of T1,G3/high grade, recurrent and failure after BCG therapy (68.8 %). Four patients proposed for CS-C were excluded at the time of pre-operative assessment, of them two due to prostate cancer on biopsies and two due to extended CIS at prostate urethra. Table 1 shows pre-operative patient characteristics and peri-operative parameters including mean operative time, mean blood loss, re-operation rate and post-operative hospital stay of different surgical techniques. As expected, due to the additional TURP, CS-C was documented to be the most time-consuming technique compared to NS-CVP and SS-CP ($p < 0.01$) that had similar duration. No difference from a statistical point of view could be documented in terms of blood loss and re-operation rate comparing different procedures.

Oncologic outcomes

Comparing clinical and pathological tumour stages, a 7.7 % rate of understaging was registered (six pT3, one pT4) and two patients were found with positive pelvic nodes. On the other hand, 20 patients (22.2 %) were found without residual tumour (pT0) at definitive pathology. Overall, nine (10 %) patients were diagnosed with low-risk prostate cancer on definitive pathology (six after NS-CVP and three after SS-CP, respectively), but none of them required additional treatment. Post-operative total PSA value was <0.1 ng/ml in all cases of NS-CVP and SS-CP patients, and no case of post-operative prostate

Table 1 Pre-operative patient characteristics and peri-operative parameters

	NS-CVP	CS-C	SS-CP	*p* value
Age at surgery (*years*)				
Mean	58.1	48.3	53.2	0.01
Range	48–67	41–58	36–64	
SD	5.34	5.11	6.41	
Pre-operative T stage distribution				
Ta recurrent	6	9	3	0.8
T1, HG/BCG failure	24	24	14	
T2 single	5	3	2	
Concomitant Cis	6	5	2	0.7
Charlson comorbidity score				
0	31	33	15	0.4
1	4	3	4	
Pre-operative IIEF-5 index				
≥26	28	35	17	0.06
22–25	7	1	2	
Overall operative time (*minutes*)				
Mean	310	420	340	0.01
Range	4.2–5.8	4.8–7.5	4.2–6.6	
Blood loss (*cc*)				
Mean	550	600	650	0.3
Range	280–1,800	350–2,200	350–2,600	
Re-operations	2	2	1	0.9
Mean hospital stay (days)	16	17	15	0.3

NS-CVP cysto-vesicleprostatectomy, *CS-C* capsule-sparing cystectomy, *SS-CP* seminal-sparing cysto-prostatectomy

Table 2 Definitive pathologic features and oncologic outcomes of different NS-RC procedures

	NS-CVP	CS-C	SS-CP	*p* value
Pathology stage				
pT0	4	11	5	0.5
pTa	7	4	5	
pT1	17	15	6	
pT2	3	2	2	
pT3	2	3	1	
pT4	1	0	0	
LNI	1	1	0	0.4
Follow-up				
Mean	111.71	133.69	43.15	0.0001
Median	113	141	36	
Local recurrences (%)	2 (5.7 %)	2 (5.5 %)	0	0.5
Cancer-specific mortality (%)	3/35 (8.6 %)	4/36 (11.1 %)	0	0.3

NS-CVP cysto-vesicleprostatectomy, *CS-C* capsule-sparing cystectomy, *SS-CP* seminal-sparing cysto-prostatectomy, *LNI* lymph node invasion

cancer could be detected in the CS-C series. The minimum follow-up was of 24 months for all patients. At a median follow-up of 58 months (mean 66, range 16–174), the overall local recurrence rate was documented to be 4.4 % (four patients: two after NS-CVP and two after CS-C). The two local recurrences met after CS-C were initially described at the remnant prostate capsule. Both of them progressed with distant metastasis within 48 months in spite of salvage chemotherapy regimen. Both local recurrences after NS-CVP were documented in clinically understaged patients (1 pT4 and 1 pT2b, pN1 at definitive pathology).

The overall cancer-related mortality was 7.7 % (seven patients: three after NS-CVP and four after CS-C), without statistical difference comparing different kinds of techniques. Table 2 describes the oncologic outcomes of different kinds of NS-RC.

Functional outcomes

Functional outcomes at means of 24- and 48-month follow-ups are detailed in Table 3. Post-operative UC rate at both intervals of time was obtained in a total of 79 (87.7 %) cases. According to our criteria, overall complete post-operative daytime and night-time UC at 24 and 48 months was achieved in 93.3 and 67.8 % and in 88.8 and 68.1 %, respectively. Compared to other techniques, a significant advantage from a statistical point of view was documented after CS-C in terms of complete night-time UC at early follow-up. Due to consistent post-voiding urinary residual volume (≥70 ml), 17 (19 %), patients were instructed to use the clean intermittent catheterization (ICC). Comparing different surgical techniques, CS-C patients were more inclined to develop an outlet obstruction at longer follow-up (>48 months) compared to NS-CVP patients. Five of the 12 patients requiring ICC after CS-C also underwent transurethral resection of the prostate to treat their urinary obstruction. Considering erectile function recovery, data concerning sexual performance by IIEF-5 questionnaire were obtained in all and in 54 (60 %) cases at 24- and 48-month follow-up, respectively. Post-operative PDE5-I was taken for a minimum of 3 months in 19 (54, 2 %), seven (19.4 %) and six (31.0 %) of NS-CVP, CS-C and SS-CP, respectively. According to our criteria, an overall satisfactory erectile function was documented in 59 (65.5 %) patients at 24-month follow-up. Looking at the distribution of the satisfactory erectile function rate, a significant difference($p < 0.001$) was found when comparing NS-CVP (28.6 %) to CS-C (91.6 %) and SS-CP (84.2 %) at 24 months, regardless the use of PDE5-I. This trend was confirmed at 48-month F-U (20 and 86 % for NS-CVP and CS-C, respectively).

Table 3 Functional outcomes of different surgical NS-RC procedures

	NS-CVP	CS-C	SS-CP	*p* value
Complete daytime UC (%)				
24 months	88.6	97.2	94.7	0.3
48 months	82.9	94.4	89.5	0.3
Complete night-time UC				
24 months	57.1	83.3	63.2	0.05
48 months	62.9	77.8	63.2	0.3
CIC	4	12	1	0.02
IIEF-5 $\geq$ *22*				
At 24-month F-U	10/35 (28.6 %)	33/36 (91.6 %)	16/19 (84.2 %)	<0.001
At 48-month F-U	6/29 (20.0 %)	25/29 (86.0 %)		
PDE5-I (at least 3 months)	19 (54.2 %)	7 (19.4 %)	6 (31.0 %)	0.001

NS-CVP cysto-vesicleprostatectomy, *CS-C* capsule-sparing cystectomy, *SS-CP* seminal-sparing cysto-prostatectomy, *UC* urinary continence, *CIC* clean intermittent catheterization

Discussion

The nerve-sparing approach has been advocated as the new frontier of urologic surgery during the last 20 years [16–18]. Its ambitious target is the improvement in the patient's post-operative quality of life (QoL) while respecting oncological radicality. In uro-oncology, this aim substantially coincides with the preservation of both post-operative perfect UC and satisfactory sexual performance. In spite of preliminary reports concerning this approach dating back to the mid-1980s, only recently the amount of the patients treated and the length of the follow-up have allowed for some definitive considerations. This retrospective study was mainly aimed to define the current impact of the nerve-sparing surgery for the treatment of selected bladder cancer patients at a tertiary urologic centre. In addition, the peri-operative aspects and the post-operative outcomes of three different surgical techniques adopted during a 15-year period of time were described and critically analysed. The authors are aware that due to the retrospective design of the study and the reduced number of patients per group, definitive comparative analyses of the different techniques cannot be drawn. Interestingly, the overall rate of NS-RC was less than 9 %, and this rate has not changed during the time, showing that the growth of this surgery, in addition to the reasonable oncologic concerns [19, 20], suffers from intrinsic limitations mainly related to the restricted clinical indications and the surgical complexity. Up to now, only a few referral centres [21–23] declared the rate of their NS-RCs, while there is no mention at all in the literature about the weight of this surgery in peripheral urologic centres making any comparison unsuitable. Over the time, the distribution of the different techniques used at our centre reflects the knowledge progressively acquired in the neuroanatomy field and in the refinement of the surgical technique that allowed for a remodelling of the original surgical approach. Oncologic criteria for NS-RC patient selection at our centre were the same for all the different procedures and remained unchanged over the time. All patients were less than 65 years and proved sexually potent before surgery. More than 85 % of patients were high-risk NMIBC failure after BCG with only few selected T2 stage less than 3 cm far from the bladder neck. However, a non-negligible understaging (8 %) was registered at definitive pathology, and this ascertainment deserves to be taken in adequate consideration whenever a nerve-sparing technique is proposed. The nerve-sparing cysto-prostatectomy as originally described was undertaken from mid-1990s and has never been totally abandoned. The related cancer-specific mortality of this procedure adjusted for pathology tumour stage appears in agreement with the literature [24, 25] supporting the oncologic safety of this technique. The two cases of local recurrence registered in this series (one pT4 and one pT2b, pN1 at definitive pathology) could be attributed to the pre-operative understaging rather than to the NS procedure. On the other hand, the weak point of the standard nerve-sparing cysto-prostatectomy was the reduced sexual function preservation rate (<35 % even in skilled hands) that gives this procedure not reliable for patients extremely keen to preserve their sexual function. Mainly in order to overcome this limitation, different original procedures based on part [22, 26–28] or the whole prostate [29] preservation together with vas deferens and seminal vesicles were introduced into clinical practice. We described our capsule-sparing technique in 2001, and preliminary functional results were communicated in 2004 [8]. To date, 36 patients received this procedure and have been followed up for at least 36 months. Post-operative outcomes were surprisingly favourable with both overall immediate and complete UC and sexual function preservation rates exceeding 90 %. However, in spite of the described rigorous pre-operative assessment, two patients experienced an urothelial carcinoma recurrence at prostate capsule and died after progression in spite of salvage treatment. These failures were interpreted as originating from undetected foci of CIS of the remnant urothelium left at the level of verumontanum at the time of preliminary TURP. As a consequence, in order to improve the pre-operative detection of both prostate urothelial carcinoma and occult prostate carcinoma, from 2002, the TURP was planned together with prostate biopsies at least 2 weeks before RC. Although no additional cases of local recurrence were registered, the surgical flow chart became elaborate and time-consuming,

requiring three sequential operative times (staging TURB, TURP with prostate biopsies and RC). In addition, in spite of the excellent daytime and night-time UC obtained at both early and midterm follow-up, a consistent rate of late outlet obstruction requiring CIC or second TURP was registered. These reasons explain the progressive abandonment of this procedure during the last years. From 2006, on gaining familiarity with radical intrafascial prostatectomy, a procedure based on the removal of the bladder and the whole prostate leaving the neurovascular bundles and seminal vesicles was adopted. The target was to achieve the best compromise between oncologic safety and post-operative functional results. To January 2012, 19 patients have undergone this procedure and were valuable for results at a minimum 24-month follow-up. Early and midterm complete UC and potency rate, although slightly lower than after capsule-sparing cystectomy, were highly satisfactory (>80 %) without detrimental oncologic safety. Out of 1,115 patients who underwent non-nerve-sparing radical cystectomy at our institution in the same period of time, a total of 502 received an orthotopic bladder substitution. Based on the institutional database, the rate of complete daytime and night-time UC, adjusted for age (288 patients ≤65 years) at 24-month follow-up, was 78 and 55 %, respectively. These rates appear slightly inferior to those registered after the NS-CVP but definitely lower when compared to those obtained after CS-C and SS-CP techniques. However, due to the difference in the number of patients included in nerve and non-nerve-sparing series, statistical comparison could not be obtained. In patients who underwent non-nerve-sparing surgery, both the pre-operative and post-operative IIEF-5 were only occasionally collected precluding the chance to investigate their possible preservation of sexual function. On the other hand, this information is extremely difficult to find in the literature.

The overall rate of both local recurrence and cancer-specific mortality of NS-RC, after adjustment for the pathology stage, did not significantly differ from those of conventional radical cysto-prostatectomy. Likewise, no statistical difference could be documented comparing oncologic results of the three different techniques showing that, when respecting the mentioned criteria of selection, all of them are equally safe. Except for the longer operative time of CS-Cs, the remaining intraoperative parameters as well as the hospitalization time and the post-operative complication rate were documented to be similar for the different NS surgical solutions.

These results are in line with those recently published by Jacobs et al. [30] coming from a randomised study including similar NS techniques and similar criteria for patient selection. However, any comparison of our results to those referred in the literature may be misleading due to the reduced number of cases included in all different series, the different follow-up length and the technical details. It should be also admitted that being the majority of patients included in our investigation at a rather low recurrence risk, the oncologic outcome of the three procedures can be expected to be comparable due to the limited number of adverse events. This choice, based on the oncological caution, to propose the novel NS procedures only to selected low stage ($p \leq$ pT2) gave the authors the chance of analysing a very homogeneous series of patients from the pathological point of view. On the other hand, a recent, wide, long-term experience by Martens et al. [21] showed that saving the entire prostate can be considered safe from the oncological point of view, irrespective of pT stage when a rigorous pre-operative patient's assessment was respected. In this direction, our criteria of patient selection appear as excessively restricted and probably deserve to be revised. As far as functional results are concerned, both capsule-sparing and intrafascial seminal-sparing cysto-prostatectomy obtained very satisfactory results ensuring for both excellent daytime UC and potency when compared to the reduced outcomes of the original procedure. On these basis, the current policy of the authors is to adopt NS-CVP for patients at relatively older age (55–70 years) irrespective of the tumour location at the bladder and for whom the preservation of sexual function, although appreciated, is not referred as an essential condition for the RC acceptance. On the other hand, younger patients, extremely keen to preserve sexual function and tumour far from the trigone, are recommended for intrafascial seminal-sparing cysto-prostatectomy. This study suffers from the limitations of any retrospective investigation. The authors are aware that in spite of the consistent overall amount of patients, the number of patients in each group is limited hampering the statistical analysis. The choice of the different surgical procedure was not randomized; the mean age of NS-CVP patients was slightly higher, while the follow-up of SS-CP patients, although exceeding 24 months, was definitively shorter compared to the other subgroups. In addition, the health-related quality of life was not included in this investigation. Nevertheless, this experience may reflect the impact of this attractive surgery during a long period of time in clinical practice and, probably, represents the first study that analyses different NS-RC techniques, all of them performed at a single institution. According to this experience, the nerve-sparing cystectomy deserves to be assumed as a consolidate, safe and effective surgery for selected patients. However, due to the expected reduced patient's recruitment and the need of a well-refined surgical technique, this surgery seems to configure a specific field of competence of limited reference centres.

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standard All participants gave their informed consent to use their data for this retrospective study.

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