Retropubic radical prostatectomy: Clinicopathological observations and outcome analysis of 428 consecutive patients

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ABSTRACT

Aim: We report the outcome analysis of retropubic radical prostatectomy (RRP) performed in 428 patients in terms of pathological findings, complications, and survival.

Materials and Methods: Systematically recorded case reports forms of consecutive 428 RRPs done over a 14-year period were analyzed using the SPSS 14 software. Secondary analysis was done to evaluate era specific (pre and post 2002) changes in clinical features and survivals.

Results: Seven-year overall survival (OAS), cancer-specific survival (CSS), and event-free survival (EFS) was 83.2%, 82.8%, and 69.8% respectively in our series. Era-specific survival showed higher CSS post 2002, and there was an increase in presentation with organ-confined disease. Univariate and multivariate analysis showed statistically significant impact on era specific outcome. With the improvement in techniques decrease in complications rate and increase in quality of life was noted.

Conclusions: Our series spanning over decade demonstrates that RRP is viable option to offer cure to organ-confined carcinoma prostate. Further, there is evidence of stage migration and improvements in outcome in post 2002 patients. Although our series is modest in number, the success rates and outcome data matches those reported in the literature.

Key words: Complications, era-specific outcome, Gleason score, multivariate analysis, nerve sparing, outcome, pathology, retropubic radical prostatectomy, survival

INTRODUCTION

Retropubic radical prostatectomy (RRP) is the standard treatment for localised prostate cancer and is highly effective in producing long-term survival in majority of patients.[1] However, this surgery remains one of the most challenging surgery in urology as it has to provide the best possible oncological outcome in terms of negative surgical margins and relapse-free survival.[2] Further, it should also provide best functional results with regard to urinary continence and erectile function.[3,4] Therefore, it is logical to shift the focus to the improvement in quality of life (QOL) having achieved reasonable success in attaining cancer control across the world. Literature is full of the several advances in surgical techniques aiming at better QOL and reduction of morbidity. Of interest is the development of minimal invasive (lap and robotic) approaches, which are currently in vogue with comparable outcomes. Here we report our experience of RRP performed in the last 14 years.

MATERIALS AND METHODS

From January 1996 through December 2009, a total of 588 open radical prostatectomies (ORP) were performed by the first author. Of them, only 428 patients with minimum follow-up of 6 months were included in this review. Further, the data were censored after maximum follow-up of 84 month to compare the two eras before and after 2002. The accrual of the data was from case report forms, which

were filled at regular intervals at the time of admission and during subsequent follow-ups. SPSS software (Version 14) was used for analysis. The case reports forms cataloged the demographic parameters like age, co morbidities, history of previous transurethral resection of prostate (TURP), clinical variables including prostate-specific antigen (PSA) studies, biopsy gleason score, clinical stage, pre and post operative continence and potency. Pathological specimens were classified as per TNM staging. Operative events such as blood loss, time of catheter removal, early and late complications were recorded meticulously. A standard RRP was performed in 383 while nerve sparing RRP was done in 45 patients. Postoperative pathway included early ambulation without assistance, early resumption of oral diet and good pain control. The urethral catheter was removed on the 7 to 21 postoperative days. Patients were followed up at 6 weeks first, then 3 monthly for 2 year, and 6 monthly till 5 years and annually thereafter. Information on potency and continence was obtained from history. Potency was defined as the ability to have penetrating sexual intercourse with or without phosphodiesterase (PDE 5) inhibitors. Men who were not using pads at one year were considered continent. Adjuvant radiotherapy was given in cases with positive margins as reported on histopathological report. Adjuvant hormone therapy was given to patients with lymph node involvement and to patients who developed metastasis. The patient and prostate cancer characteristics were evaluated by student's test, chi-square analysis, and analysis of variance, as appropriate. Survival was analyzed using Kaplan–Meier method and compared using log-rank test. Event-free survival (EFS) was defined as patients alive without disease and increasing PSA levels or radiological evidence of progressive disease or death due to any cause was taken as an event. Prostate cancer-specific survival (CSS) was defined as survival from death attributed to complications of prostate cancer. Further over all survival (OAS) meant as survival from death due to any cause. Univariate (Kaplan–Meier and log-rank test) and multivariate (Cox regression models) proportional hazards were created to evaluate the predictors of cancer-specific survival. A secondary analysis was designed to investigate the era specific (pre and post 2002) clinical and pathological characteristics and outcomes of radical prostatectomy in consideration to the improvement in diagnostic procedures, improved awareness among general population leading to presentation at early stages, and impact of PSA levels. Hence, the cohort was split into two groups, i.e., before 2002 era and post 2002 era depending on the year of surgery. The specific changes in the clinical, pathological stage, and difference in the outcome of CSS in the two eras was evaluated.

RESULTS

The clinical data of all 428 patients are given in Table 1. Mean age in our study was 63.3 years (range 42.4–82.6 years) with 156 (36.4%) patients having had prior TURP

Table 1: Clinical characteristics of patients with prostate cancer and their comparison in two eras

	All patients	Two Eras		P value
		<2002	>2002	
All	N = 428	N = 137	N = 291	
Age (median)	63 years	62	64	
Range	44-84 years	44-74	44-83	NS
Comorbidities	181	72	109	
Hypertension	121	58	63	
Diabetes	40	18	22	
IHD	25	5	25	
Previous TURP				
Yes	156 (36.4)	62 (45.3)	94 (32.3)	
No	272 (63.2)	75 (54.3)	197 (67.7)	0.010
Clinical stage				
T1 a + T1b+ T1c	177 (41)	53 (38.6)	124 (42.6)	
T2a +T2b	136 (32)	33 (24)	103 (35)	
T2c	105 (25)	46 (33.7)	59 (20.2)	
T3a + T3b	10 (2.3)	5 (3.6)	5 (1.7)	0.006
Biopsy Gleason score				
4	30 (7)	18(13)	12 (4)	
5-6	231 (54)	67(49)	164 (56)	
7	107 (25)	36(26)	71 (24)	
8-10	60 (14)	16(11.6)	44 (15)	0.005
Pathological Gleason score				
<4	17 (4)	8 (5.8)	9 (3.0)	
5-6	157 (37)	62 (45)	95 (32)	
7	163 (38)	40 (29)	123 (42)	
8-10	91 (21)	27 (20)	64 (20)	0.017
PSA levels				
<4	39 (9.1)	16 (11.7)	23 (7.9)	
4-10	138 (32)	39 (28.5)	98 (33.8)	
10-20	144 (33.4)	45 (32.8)	108 (37.2)	
>20	107 (25)	37 (27)	61 (21)	0.241
Pathological stage				
Organ confined PT0-PT2a+b+c/LN-	161(37.6)	50 (36.4)	111(38.4)	
PT3a (LN-)	76 (17.7)	20 (14.6)	56 (19.2)	
PT3b (LN-)	100 (23.6)	35 (25.5)	65 (22.3)	
LN+	91 (21.2)	32 (23.4)	59 (20.3)	0.055
PSM	98 (23)	45 (32)	43 (14)	0.001

LN - Lymph node, psm - Positive surgical margins, Figures in parenthesis represents percentage

and 227 patients were in the high risk (d'Amico) category. Standard radical prostatectomy was done in 383 (89.5%) patients and 45 (10.5%) had nerve-sparing operations. Pelvic lymph node dissection was done in all patients. The mean operative time was 160 minutes (range 130–200 minutes) and median blood loss of 500 ml (range 300–2000 ml). The catheter was removed on the 10th day in 181 (42.3%)

patients, and on the 14th day in 106 (24.7%) patients. The median hospital stay was 6 days. Early and late complication occurred in 45 and 28 patients, respectively [Table 2a]. Urine leak was seen in 8 (1.9%) patients, which was managed conservatively with placement of the urethral catheter for 2 weeks and none of whom required surgery. Spontaneous expulsion of catheter occurred in 6 (1.4%) patients requiring reanastomosis in 3 (0.7%) and endoscopic reinsertion in other 3 (0.7%). Further, 4 (0.93%) and 10 (2.3%) patients had major and minor wound infection, respectively. Prolonged lymphorrhea was a sequel in 6 (1.4%) patients, which settled with conservative therapy; however, of the 8 (1.9%) patients

who had lymphocoele, only 2 (0.47%) required aspiration. Ten patients (2.3%) had anastamotic stricture that required bladder neck incision, 2 (0.47%) patients underwent visual internal urethrotomy VIU for urethral stricture. Continence was assessed at 6, 12, 24, and 52 weeks (1 year). At 12 weeks, total 145 (33.9%) patients and at one year total 420 (98.3%) patients were continent. Review of potency in those who had nerve sparing RRP and completed 1-year follow-up demonstrated that 59% patients achieved good erection suitable for intercourse with or without PDE-5 inhibitors.

Pathological findings

On histopathology of the radical prostatectomy specimen gleason score was <4, 5-6, 7, 8-10 in 17 (4.%), 157 (37%), 163 (38%), and 91 (21%) patients, respectively [Table 1]. Further, organ-confined (pT0-T2) disease, invasion of capsule (pT3a), and seminal vesicle (pT3b) without positive lymph nodes was seen in 161(37.6%), 76 (17.1%), and 100 (23.5%) patients. Lymph node metastasis (LN+) was seen in 91(21.2%) patients. Positive surgical margins (PSM) were noted in 98 (23.2%) patients; of them 42 (27%) had previous TURP. Correlation between clinical variables and pathological stage, positive LN and (PSM) status was analyzed [Table 2b].

Seven-year survival analysis

In our series, median follow-up was 66.5 months (3–84 months). In them, (*N* = 428) seven year OAS, prostate CSS, and EFS rate was 83.2%, 82.8% and 69.9%, respectively. [Table 3, Figure 1a-f] Further, seven year prostate CSS was calculated in 418 patients (10 died due to other causes) in relation to PSA value, biopsy and pathology gleason score, clinical and pathological stages using Kaplan–Meier method and log-rank test [Figure 2a-e, Table 4]. In patients with PSA <4 ng/ml, 4.1-10 ng/ml, 10.1-20 ng/ml and >20.1

Table 2a: Complications and review of literature

Complications	Present study (%)	(References) literature
Early complications (*n* = 45)		
Urinoma/urine leak	8 (1.9)	0.2-17.3[18-24]
Urinary retention	3 (0.7)	0.6-3.6[18,19,20,21,23,25]
Major wound complications	4 (0.93)	0.6-2.9[18,20,21]
Minor wound infection	10 (2.3)	
Dehiscence	2 (0.047)	0-1.4[18,20,23,26]
Urinary retention	3 (0.7)	0.6-3.6[18,19,21,23,25]
Catheter expulsion	6 (1.4)	
Re V-U anastomosis after catheter expulsion	3 (0.7)	
Lymphorrea	6 (1.4)	
Late complications (*n* = 28)		
Bladder neck contracture	10 (2.3)	1.0-17.9[18,23,22,25,27]
Urethral stricture	2 (0.047)	0.4-4.1[18,22,23,25]
Inguinal hernia	4 (0.93)	1.5-17.0[18,28]
Bladder calculus	4 (0.93)	0.6[18]
Lymphocele	8 (1.9)	0.1-6.9[18,19,22,23,26]

Table 2b: Clinical variables vs pathological stage

| Variable	Total patients (%)	Organ confined PT0-PT2 (%)	PT3a (%)	PT3b (%)	LN positive (%)	*P value*
Clinical stage						
T1 a + t1b+ T1c	177 (41)	74 (42.4)	31 (17.5)	33 (19.2)	37 (20.9)	
T2a +T2b	136 (32)	47 (39)	23 (16.9)	30 (22)	30 (22)	
T2c	105 (25)	31 (30.5)	21 (20)	31 (30.5)	20 (19)	
T3a + T3b	10 (2.3)	1 (10)	1 (10)	4 (40)	4 (40)	*P* = 0.20
PSA						
<4	39 (9.1)	15 (38.5)	5 (12.8)	13 (33.3)	6 (15.4)	
4-10	138 (32)	70 (51.1)	21 (15.3)	20 (14.6)	26 (19)	
10-20	144 (33.4)	59 (38.6)	36 (23.5)	34 (22.2)	24 (15.7)	
>20	107 (25)	16 (16.3)	14 (14.3)	33 (33.7)	35 (35.7)	*P* = 0.001
Biopsy Gleason						
<4	30 (7)	17 (56.7)	7 (23.3)	3 (10)	3 (10)	
5-6	231 (54)	126 (54.5)	37 (16)	35 (15.2)	33 (14.3)	
7	107 (25)	11 (10.3)	22 (20.6)	40 (37.4)	34 (31.8)	
8-10	60 (14)	7 (11.7)	10 (16.7)	22 (36.7)	21 (35.0)	*P* = 0.001
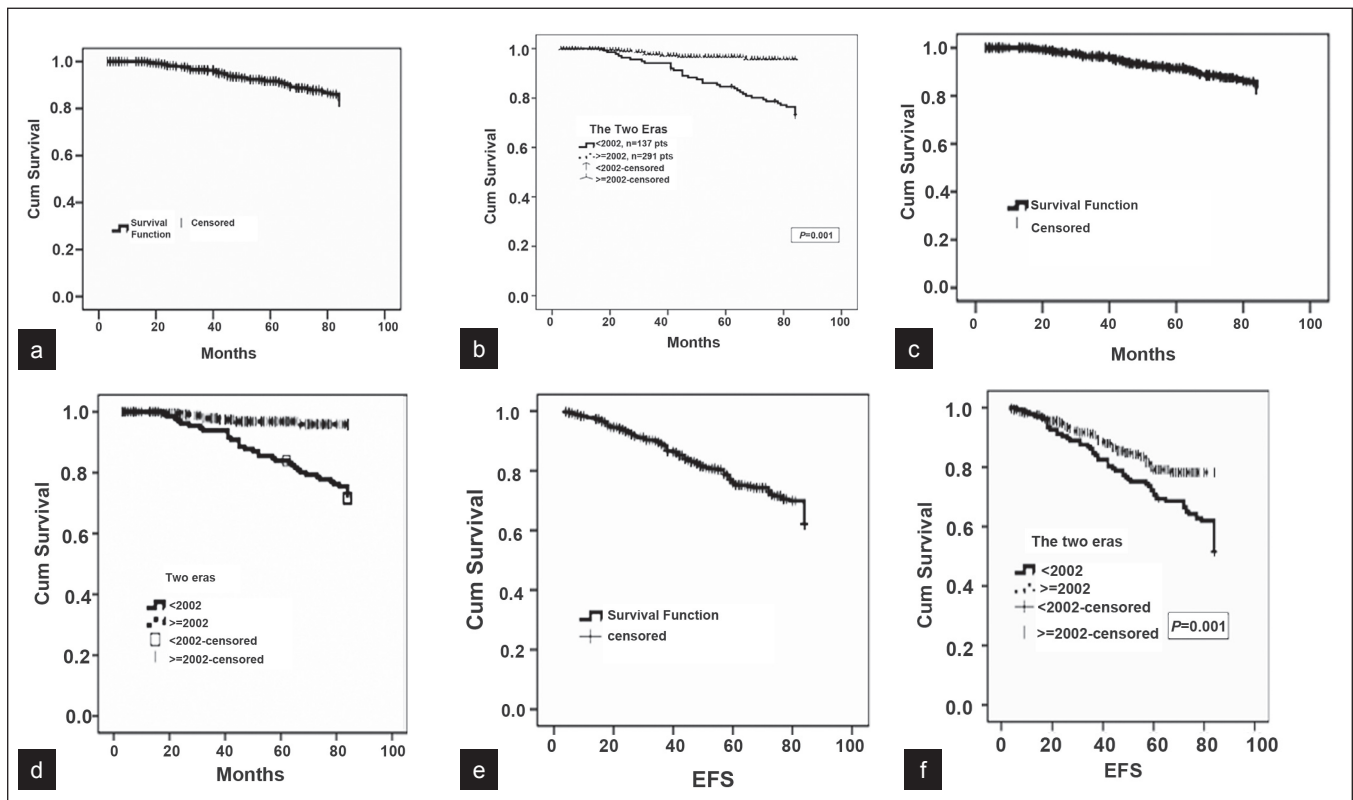
Figure 1: Survival KM curves of the whole population and the two eras. (a) OAS of whole Population *n* = 428 pts, (b) OAS of two different eras, (c) Prostate CSS of whole population *n* = 418 pts, (d) Prostate CSS of two different eras, (e) EFS of whole population *n* = 428 pts, (f) EFS of two different eras

ng/ml seven year survival was 78.6%, 85.5%, 84.3%, and 82%, respectively. Similarly in patients with biopsy gleason score of < 4, 5-6, 7, and 8-10 it was 95.8%, 89%, 75.9%, and 56%, respectively. Clinical T stage wise, seven year survival was 83.4%, 89%,76%, and 71% in T1, T2a+T2b, T2c, and T3, respectively, while pathological stage wise it was 96.9%, 79%, 73%, and 72%, in organ confined (PT0-2), PT3a, PT3b, and LN+ve patients, respectively. Log-rank analysis of all the above variables showed that only biopsy gleason sore and pathological stage had an impact on survivals.

Predictors of CSS

In the univariate analysis using the Kaplan–Meier method, the previous TURP, Clinical stage (T), PSA, margin positivity were not significant; however, biopsy gleason score, pathological stage, and gleason score, LN+ve, and two eras of surgery were significant. Multivariate analysis (Cox regression model) showed significant difference in survival in two eras, higher clinical (T2C and T3) and higher pathological stage, biopsy gleason score >8 and LN +ve patients [Table 5].

Era-specific (<2002 and >2002) analysis

The secondary analysis revealed 137 and 291 patients in the pre and post 2002 era [Table 1]. Era-specific analysis showed significant impact in all clinical stages at presentation, biopsy and pathology gleason score, and in LN and margin

PSM) patients in post 2002 era. Further, there was distinct increase in number of organ confined (T1-2a+b) disease in post 2002 era [86 (62%) vs. 227 (77%), *P* = 0.006] indicating stage migration. Pathologically, there was increase in organ-confined disease and reduction in LN +ve and PSM numbers. Kaplan–Meier analysis of seven year survival showed all 3 survivals (OAS, CSS, and EFS) had improvement in post 2002 era (*P* = 0.001) (Table 3, Figure 1a-c). Similarly, when survivals were calculated as per PSA values there was no impact on the survival in both eras, however, there was some improvement in survivals in early clinical stages T1-2 and biopsy gleason scores (5-6 and 7-10) [Table 4 and Figure 2a-e]. Similar trend was noted in pT3 with LN negative and all path gleason scores (except score of <4) in post 2002 era. In univariate and multivariate analyses, era-specific outcome showed statistical significance (*P* < 0.0001) [Table 5].

DISCUSSION

We first reported our initial experience of retropubic radical prostatectomy a decade and half ago.[5] Up to year 2002 the accrual of patients was slow due lack routine diagnostic studies like PSA and biopsies. However in the later years there has been steady rise in patients with organ-confined prostate cancer. Paucity of speedy accrual of patients in the early part of the study (till 2002) we used our extra peritoneal radical cystectomy approach to master the technique of the handling of DVC and urethral sectioning.[6] We believe that this part of
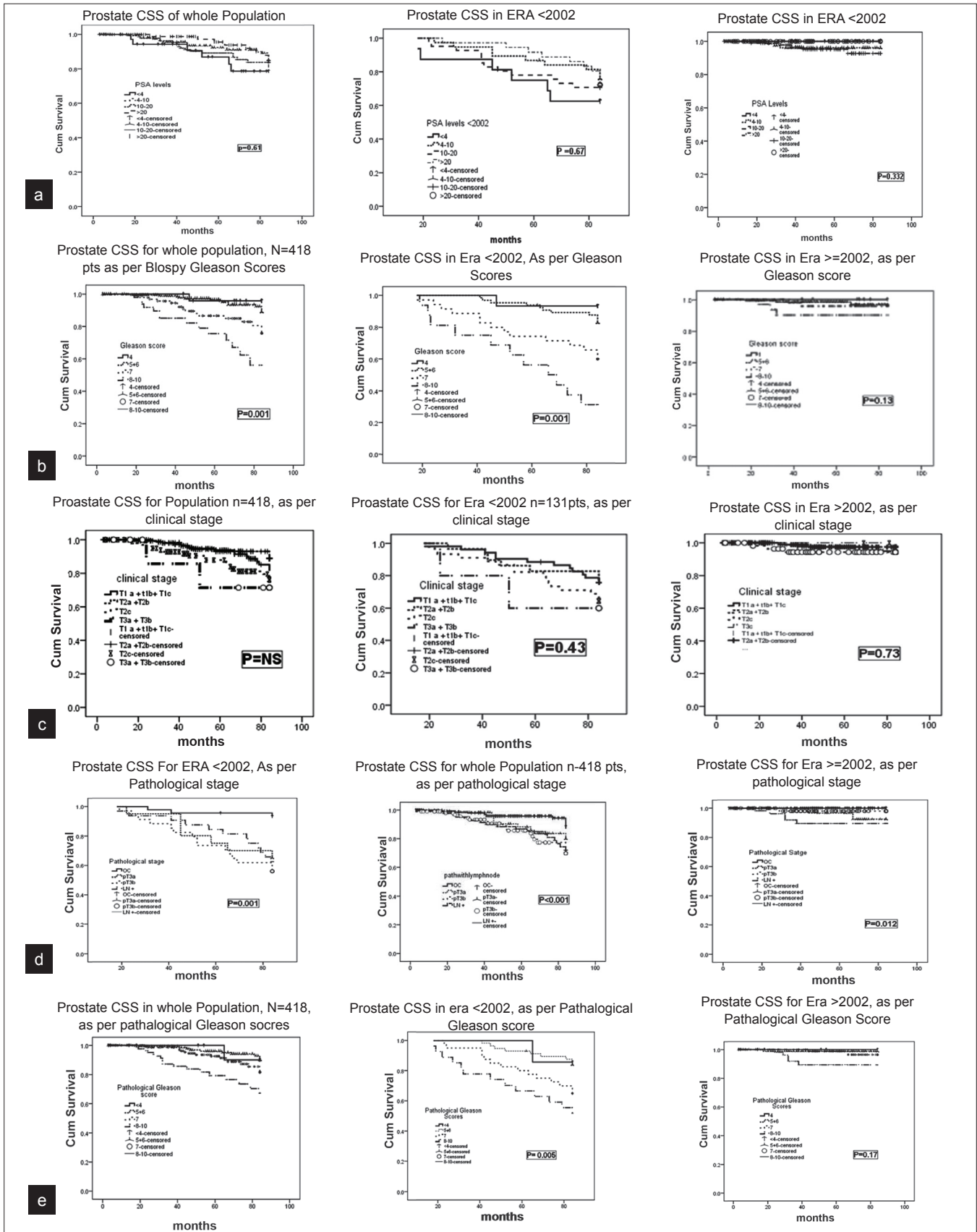
Figure 2: Prostate cancer specific survival in relation to all variables. (a) Prostate CSS of whole population and the two eras with PSA levels, (b) Prostate CSS of whole Population and the two eras with Biopsy GS, (c) Prostate CSS of whole population and the two eras with clinical stage, (d) Prostate CSS of whole population and the two eras with pathological stage, (e) Prostate CSS of whole population and the two eras with pathology gleason scores

Table 3: Survival analysis results of whole population and the two eras using KM method

Overall survival	5 years	7 years	
428 pts	91.6%	83.2%	
137 pts <2002	84.6%	72.7%	
291 pts >2002	96.8%	95.9%	*P* = 0.001
Prostate cancer specific survival (PCSS)	5 years	7 years	
418 pts	91.5%	82.8%	
131 pts <2002	84%	71.6%	
287 pts >2002	96.8%	95.9%	*P* = 0.001
Event free survival (EFS)			
All population	75.9%	69.9%	
137 pts <2002	72.3%	51.6%	
291 pts >2002	79.1%	78.2%	*P* = 0.001

the radical prostatectomy is not only important for continence and reduction in morbidity but also for oncological outcome in terms of margin status, relapse free survival. Refinements in the operative technique of radical prostatectomy, including nerve-sparing, in the last 20 years has led to low perioperative morbidity and mortality and a high probability of complete tumor eradication.[1,7] However we have performed nerve sparing procedure in only 11.2% patients in our series. Further bilateral pelvic node dissection was performed in all, although in 177 patients (PSA < 10) only radical prostatectomy could have been adequate as per literature.[8] We were unsure of low PSA due to previous TURP and PSA standardization technique. Operative time and blood loss was comparable in our series to the literature and higher blood loss was in the initial period occurred while we were standardizing the operation. Early complications [Table 2a] in our series mainly revolved around prolonged drainage, lymphoceles, wound seroma, and dehiscence. Further, vesicourethral reanastamosis in first 24 hrs was done in 3 (0.7%) patients due to spontaneous expulsion of the urethral catheter in early part of series while endoscopic insertion was done in later. Late urinary complications such as anastomotic stricture and stress urinary incontinence considerably affect patient's quality of life and are reported in the range of 0.48% to 11.6%.[9,10] In our series, both early and late complications were comparable to the literature [Table 2a]. We had no operative mortality although in larger series it is reported to be about 0.4%.[11] Continence result reporting after RRP has been variable due to lack of uniformity in defining, assessing, and reporting.[12] However, the impact of these factors on the variability of results is uncertain. Most of the series have reported complete recovery of continence by 6-12 months. In catalona study,[7] 96% of men younger than 70 years of age and 87% older than 70 years recovered urinary continence within 18 months of radical prostatectomy. In our series, 33% patients and 98% patients achieved continence at 12 weeks and at one year. In the later half, i.e., after 2002, we modified our technique by meticulously everting the bladder neck edges and repairing the post wall of bladder by few interrupted vicril sutures

with the aim to reduce the anastamotic stenosis. However, 8 (1.8%) patients in our series remained incontinent, in 3 of them catheter had come out requiring reanastamosis while others had advanced disease at the apex. The second important aspect of outcome of radical prostatectomy is return of erectile function which usually takes longer than recovery of continence. In most patients, erections begin to return in three to six months after prostatectomy and continue to improve for 18 to 24 months or longer. Presumably, the delay in recovery is due to the time required for the cavernosal neurovascular bundles to recover from the surgical trauma (traction, sutures, etc.) sustained during removal of the prostate. We evaluated potency in those who had nerve sparing RRP (*n* = 45) in our series and completed 1-year follow-up and found that only 59% patients achieved good erection suitable for intercourse with or without PDE-5 inhibitors. Several authors have[1,13] reported lower percentage of return of sexual potency in their series and argued that potency depends on the age and pathological stage of the disease in spite of the best technique. In our series, pathological findings correlated poorly to clinical parameters like PSA levels, biopsy gleason score and clinical stage of the disease [Table 2b]. Broadly speaking, long duration of the series and the diagnostic (PSA and biopsy) and staging techniques were still evolving in the earlier part of the series (<2002) must have contributed to the discrepancy resulting in upstaging the disease at pathology specimen to pT3 and LN+ve in majority of our patients (60%). Moreover, in our series a third of patients (149) had prior formal TURP resulting in higher margin positivity (42/156, i.e, 27%) in comparison to (56/272, i.e., 20%) in non-TURP patients [Table 1]. Jaffe[15] reported similar higher positive margin rates of 21.8% in patients with a history of TURP. All above factors showed impact by reducing the seven year OAS, CSS, and EFS in our series when compared to the literature.[7-11,16] Further, lower CSS survival in relation to PSA, biposy gleason, and clinical stage in our series may be due to the upstaging of disease and upgrading of gleason score at pathology in significant number of patients. Additionally, CSS in patients with pathological (pT0-3) stages and positive nodes was comparable to the literature.[7,17] However, when the secondary analysis of the data was done in two eras, i.e, pre and post 2002 there was significant improvement in number of organ confined disease on clinical staging, and pathological staging, reduction margin and node positivity in post 2002 era. Similarly, there was similar improvement in survival in post 2002 era in terms OAS, CSS, and EFS. Further, clinical and pathological stage wise there was positive impact in CSS in post 2002 era. We have seen marked improvements in CSS in post 2002 era, which can be due to increased awareness, standardization of PSA and biopsy techniques, imaging and staging methods, and improved surgical techniques and timing of additional therapies in follow-up resulting in stage migration. Secondly, the median follow-up in post 2002 era was 66 months, while in pre 2002 era was censored at 84 months, hence the difference in 2 era needs to be updated further.

Table 4: Cancer-specific survival in whole population and two eras vs clinical and pathological variables using KM method

	All patients N = 418			Era <2002			Era ≥2002			Pair wise comparison b/w two eras P value
	N = pts	5 yrs (%)	7 yrs (%)	*N* = pt	5 yrs (%)	7 yrs(%)	*N* = pt	5 yrs (%)	7yrs (%)	
PSA levels										
<4	39	87	78.6	16	75	62	23	100	100	NS
4–10	137	92.5	85.5	38	87	76	96	96	96	NS
10–20	153	89.6	84.3	41	78	71	107	95.2	92	NS
>20	98	95.7	82	36	91.7	72	61	100	100	NS
Total pts	418	*P* = 0.61		137 pts	*P* = 0.67		287	*P* = 0.332		
Biopsy gleason score										
<4	27	95.8	95.8	15	93	93	12	100	100	0.439
5-6	225	96.6	89	65	83	83	160	98	97	0.019
7	106	86.6	75.9	35	74	60	71	96	96	0.001
8-10	60	75.6	56	16	56	31	44	90	90	0.002
Total Pts	418	*P* = 0.001		131	*P* = 0.001		287	*P* = 0.012		
Clinical stage										
T1 a + T1b + T1c	175	93.7	83.4	52	88	77	123	97.7	94.9	0.03
T2a + T2b	130	93	89	29	82	76	101	97.2	97.2	0.005
T2c	103	87	76	45	82	64	58	94.3	94.3	0.011
T3a + T3b	10	71	71	5	60	60	5	100	100	0.343
Total pts	418	*P* = 0.08		131	*P* = 0.43		287	*P* = 0.73		
Pathological stage										
Organ confined (PT0-T2) +LN -ve	161	98.5	96.9	45	96	93	106	100	100	0.059
PT3a +LN-ve	76	88	79	20	75	65	56	92	92.5	0.020
PT3b +LN-ve	100	86	73	34	73	60	64	98	98	0.001
LN +ve	91	86	72	32	84	62	69	89	89.5	0.085
Total pts	418	*P* = 0.001		131	*P* = 0.001		287	*P* = 0.012		
Pathology Gleason score										
<4	16	90	90	7	86	86	9	100	100	.513
5-6	150	96	90	57	93	84	93	98.8	98.8	.019
7	161	92.5	81.5	40	80	65	121	98.8	96.3	.000
8-10	91	79	67	27	66.7	52	64	89.4	89.4	.009
Total pts	418	*P* = 0.001		131	*P* = 0.005		287	*P* = 0.017		

Table 5: Multivariate Cox regression models predicting CSS in whole population

Variable	HR (95%CI)	*P value*
Age	0.99 (0.94-1.04)	0.81
PSA levels	0.86 (0.66-1.12)	0.27
Two eras (<2002,>2002)	0.28 (0.09-0.46)	<0.001
All clinical stages	0.95 (0.63-1.28)	0.56
Clinical stage T2c and T3	1.45 (1.12-1.89)	0.004
Biopsy Gleason score >8	1.76 (1.09-2.8)	0.02
Path Gleason score	1.02 (0.618-1.71)	0.923
Pathological stage	1.89 (1.23-2.92)	0.004
Lymphnode positivity	0.58 (0.35-0.94)	0.030
Cut margins	0.94 (0.61-1.70)	0.63
TURP	0.95 (0.50-1.80)	0.89

CONCLUSIONS

Our series spanning over a decade demonstrates that RRP achieves comparable results as published in western literature in organ confine prostate cancer. Post 2002 sub-analysis showed improved survival which can be attributed to improved awareness, stage migration due to increasing use of PSA and TRUS guided biopsies and better surgical techniques.

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