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## Research Article

# Outcome Changes after Diverse Radical Prostatectomy among Prostate Cancer Patients: Comparison of One and Five Years of Follow-Up

## Introduction

Prostate cancer develops slowly and is frequently diagnosed in elderly men, and its treatments are associated with adverse effects on the urinary and sexual function of patients [1]. Radical prostatectomy (RP) may reduce the disease-specific mortality of patients with prostate cancer, although this approach has been shown to have long-term negative complications with no improvement in overall patient survival [2]. Chen et al. [3], recommended that longitudinal measurement of patients' reported outcomes is crucial because of the time-dependent nature of symptom development after treatment.

Urinary incontinence and sexual dysfunction are common long-term consequences of RP [4]. Bill-Axelson et al. [5], conducted a longitudinal survey in Sweden and found that men with prostate cancer reported more leakage, impaired erections, and greater distress after the RP procedure. Moreover, five years after RP, patients continued to experience urinary incontinence and sexual dysfunction [2].

## Urinary incontinence

Urinary incontinence (defined as frequent urinary leakage or no control) is one of the major immediate complications that may occur after RP [1,6]. Although the severity of urinary incontinence often decreases with time after RP [6-8], previous studies have demonstrated that 8% to 87% of patients still experience urinary incontinence at six months and 5% to 44.5% remain incontinent at one to two years after surgery [7-12]. Moreover, up to 50% of patients report some degree of incontinence two years after RP [3], even after pelvic floor muscle exercise intervention.

Lin et al. [13], used a one-hour pad test to examine urinary incontinence after RP. These authors found that even when patients were given pelvic muscular floor exercise for three

months, there was still an average of 9.27 cc of urinary leakage in the exercise group, as compared to 27.11 cc of urine leakage in the group without exercise. Moreover, five years after RP, 15.3% of the patients who were treated with RP still experienced urinary incontinence [2].

## Sexual dysfunction

Another complication of RP is impotence (defined as insufficient erections for intercourse) [2]. Impotence occurs in 25% to 100% of patients after prostatectomy [14-18]. In fact, 80% to 90% of patients reported difficulty with erections after prostatectomy [10,19], and previous studies have indicated that the recovery of sexual function may take up to two years after RP [20-23], with 60% of men still reporting sexual dysfunction two years after RP [19,24,25]. However, another study conducted by Zielinski [2], showed that five years after a prostate cancer diagnosis and the RP procedure, 79.3% of men continued to experience sexual dysfunction. A study conducted by Soares et al., showed that the five years long term potent rate was 76.6% of previously potent, non-diabetic, and aged <70 years after RP with bilateral nerve preservation [26].

Cancer-related treatments may cause acute or delayed side effects and long-term complications [27]. Although urinary incontinence and sexual dysfunction after RP treatment have been well documented, information about long-term follow-up remains sparse in Taiwan. According to the literatures, prostate cancer patients with local disease have a five-year survival rate of nearly 100% [21,28]. Longitudinal measurements are therefore important to understand the long-term changes that can occur as a consequence of surgical procedures for prostate cancer.

In addition, one study reported that men who received RP were likely to experience profound long-term symptoms of distress [5]. One previous study estimated that 30% of prostate cancer patients experience clinically relevant general distress, and limited evidence suggests that this distress decreases

within five years after treatment [29]. To clarify whether these findings are applicable to Taiwanese patients, we also explored patients' perceived physical symptoms of distress and their changes over time in this study.

## The study

### Aims

The purpose of this study was to explore the changes in complication outcomes after two types of RP procedures among prostate cancer patients and to assess the perceived symptoms of distress following RP.

### Methods

#### Design

This study applied a comparison design with pre- and post-tests. All participants were assessed for urinary function, sexual function and perceived symptoms of distress at one year post-treatment. These variables were assessed again at five years after treatment to determine whether the adverse outcomes had changed and whether there were significant improvements over time. We also compared the results for different RP procedures (open vs. laparoscopic).

#### Setting and samples

There were two stages for the recruitment and assessment of participants. The first stage was conducted one year after treatment, and the data were collected from November 2007 to July 2010. Seventy-two patients were recruited from hospitals in Taiwan. All participants were performed the RP procedure by three senior surgeons with over 20 years in urological experiences. The inclusion criteria for the participants included the following: (a) diagnosed prostate cancer and RP surgery and (b) the ability to communicate in Mandarin or Taiwanese. Exclusion criteria included patients aged over 80 years, and previous pelvic surgery. Nine patients were excluded due to personal privacy concerns (7 patients), family refusal (1 patient), or dissatisfaction with the medical treatment (2 patients). A total of 62 participants completed the one-year assessment.

The second stage of the assessment followed the same group of participants five years after treatment, and data were collected from November 2012 to December 2015. Thirteen patients were lost due to death (3 patients), personal privacy concerns (3 patients), or lost connections (7 patient). Forty-nine participants completed both the one- and five-year assessments, and the analyses in this study were based on the findings of these 49 participants.

#### Instrument

**Urinary incontinence scale:** This scale was developed by the first author to assess the urinary incontinence of prostate cancer patients after the RP procedure [30]. The scale includes eight items and indicates the severity of each item using a five-point Likert scale, with 1 corresponding to "never occurs" and 5 to "always occurs". The possible scores ranged from 8

to 40, with higher scores indicating more severe incontinence. The construct validity of this scale was determined using an explorative factor analysis, and the results were found to account for 60.28% of the variance. The scale validity was also demonstrated by criterion-related validity, and the results showed a good correlation with the University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) urinary function subscale and the one-hour pad test. The internal consistency was examined with Cronbach's alpha, and a previous study reported a coefficient value of 0.90 [30]. In this study, the alpha coefficient was 0.90 at one year and 0.91 at five years after RP.

**Sexual function questionnaire:** The five-item International Index of Erectile Function (IIEF-5) was used to assess the patients' erectile dysfunction (ED) in this study. The IIEF-5 was developed by Rosen et al. to examine the presence and severity of ED, and the index items focus on erectile function and intercourse satisfaction. The scores range from 5 to 25 [31]. In this index, ED is categorized into five types based on the following scores: severe (5-7), moderate (8-11), mild to moderate (12-16), mild (17-21), and no ED (22-25) [31,32]. Previous studies demonstrated the good validity and reliability of this questionnaire when it was used in RP recipients [20]. The Cronbach's  $\alpha$  in this study was 0.87 at the one-year examination and 0.85 at five years after RP.

**Personal features and disease-related variables:** Several demographic items were added to the questionnaire, including age, marital status, education level, employment status, and exercise habits. The following disease-related variables were also included: operation type, nerve-sparing surgery, comorbidities (such as diabetics, hypertension, and myocardial ischemia), and the patient's history of use of erectile aids (such as phosphodiesterase inhibitors, e.g., sildenafil (Viagra) and tadalafil (Cialis)). One self-reported 0-10 numeric scale was used to assess the participants' perceived physical symptoms of distress, with 1=no distress and 10=extreme distress. Higher scores indicated that more physical symptoms of distress were perceived. We also used a questionnaire to ask patients whether they were experiencing urinary incontinence (defined as Yes/No) at the five-year follow-up examination.

#### Ethical considerations

This study was approved by the study participants' hospital's institutional review board (No. EMRP-096-084). A written consent form informed the participants that participation was voluntary and that there were no physical, social, or legal risks involved in the research.

#### Statistical analysis

Statistical analysis was performed using the IBM SPSS Statistical Package version 20.0. The values were expressed as frequencies, percentages, means, and standard deviations (SDs). A Chi-squared test was used to examine the differences in demographic variables and disease-related variables and the similarities between the open surgery and the laparoscopy surgery groups at one year after surgical procedure. We used the three variables' sum scores (urinary incontinence scale,

IIEF-5, and perceived physical symptoms of distress) as the outcome variables. A mixed model for generalized estimation equations (GEEs) was used in the repeated measurement analysis of patients' outcome changes at each time point. The differences between the surgical groups at each time point were identified.

## Results

### Characteristics of the participants

A summary of the personal characteristics of the study participants is presented in Table 1. A total of 49 participants completed both stages of the study: 27 from the open surgery procedure group and 22 from the laparoscopic procedure group. The mean age of the participants was 65.4 years (SD = 6.7 years), with a range from 47 to 79 years. The majority of the patients were married (95.9%), with a similar distribution of patients with more or less than 9 years of education. Most of the participants (65.3%) exercised regularly. The majority of participants had not received nerve-sparing surgery (57.1%) or alternative therapy (85.7%). Many of the participants (59.2%) had other diseases (hypertension, diabetes, and heart disease). To improve their sexual function, 77.6% of patients received erectile aids.

Nearly all personal and disease-related characteristics of the participants were similar between the groups treated by open and laparoscopic RP (test by Pearson  $X^2$ , all  $p > 0.05$ ), except for the rate of nerve-sparing surgery ( $X^2 = 4.30$ ,  $p < 0.05$ ), which was treated as a covariate in the GEE model.

### Outcome changes over time

**Urinary incontinence:** As shown in Table 2, 46.9% of the participants reported experiencing urinary incontinence, including 44.4% in the open surgery group and 50.0% in the laparoscopy group, at five years after RP. As shown in Table 3, the average urinary incontinence mean score in the open surgery group at one year post-RP was 20.4 (SD=8.4), and the mean score decreased to 12.9 (SD=11.7) at five years post-RP. In the laparoscopy group, the one-year urinary incontinence mean score was 9.7 (SD=6.1), which decreased to 5.5 (4.8) at five years after the procedure. Both the RP group (all  $p < 0.01$ ) and the number of years after RP (all  $p < 0.05$ ) were associated with significant differences in urinary incontinence, indicating that all RP patients experienced significant improvements in their urinary function over time.

**Sexual dysfunction:** In this study, 59.1% of the participants reported experiencing severe sexual dysfunction at five years after surgery, including 66.7% in the open surgery group and 50% in the laparoscopy group (Table 2). The mean score for the IIEF in the open surgery group at one year post-RP was 7.51 (SD=4.06) compared with 8.0 (2.7) at five years after the procedure. In the laparoscopy group, the mean one-year IIEF score was 8.1 (SD=4.3) compared with 10.9 (6.1) at five years post-RP. Neither the RP group (all  $p > 0.05$ ) nor the number of years after RP (all  $p > 0.05$ ) was associated with a significant difference in sexual dysfunction (Table 3), indicating that even though the mean scores for the IIEF increased, the patients who

underwent RP did not experience a significant improvement in their erectile function.

**Table 1:** Baseline Characteristics of the Participants (N=49).

Variables (n, %)	n (%) Open surgery (n=27)	n (%) Laparoscopy (n=22)	$\chi^2$	P value
Age (at surgery)	Range: 47 - 79	Mean=65.4 yrs (SD=6.7)	0.97	0.378
< 65 yrs (17, 34.7)	11(40.7)	6(27.3)		
≥65 yrs (32, 65.3)	16(59.3)	16(72.7)		
Marital status				0.702
Single (2, 4.1)	1(3.7)	1(4.5)		
Married (47, 95.9)	26(96.3)	21(95.5)		
Educational years			1.04	0.308
≤ 9 years (25, 51.0)	12(44.4)	13(59.1)		
> 9 years(24, 49.0)	15(55.6)	9(40.9)		
Exercise			2.04	0.153
Regular (32, 65.3)	20(74.1)	12(54.5)		
Irregular (17, 34.7)	7(25.9)	10(45.5)		
Nerve-sparing surgery			4.30	0.038
None (28, 57.1)	19(70.4)	9(40.9)		
Yes (19, 42.9)	8(29.6)	13(59.1)		
Alternative therapy				0.503
No (42, 85.7)	24(88.9)	18(81.8)		
RT (1, 2.0)	0	1(4.5)		
ADT (5, 10.2)	3(11.1)	2(9.1)		
RT+ADT (1, 2.0)	0	1(4.5)		
Comorbidities			1.39	0.238
Yes (29, 59.2)	18(66.7)	11(50.0)		
No (20, 40.8)	9(33.3)	11(50.0)		
Erectile aids			0.53	0.465
Yes (38, 77.6)	22(81.5)	16(72.7)		
No (11, 22.4)	5(18.5)	6(27.3)		

**Note:** Cell count less than 5 used Fisher's Exact Test. Exercise regularly: 3-4 days of exercise per week; Irregular: seldom exercise or exercise 1-2 days per week.

**Abbreviations:** RT: Radiotherapy; ADT: Androgen Deprivation Therapy; UI: Urinary Incontinence.

**Table 2:** The Outcomes at Five Years Post-RP for the Two Groups (N=49).

Variables n (%)	Open surgery group n (%)	Laparoscopy group n (%)
<b>UI</b>		
<b>No (26, 53.1)</b>	<b>15(55.6)</b>	<b>11(50.0)</b>
<b>Yes (23, 46.9)</b>	<b>12(44.4)</b>	<b>11(50.0)</b>
<b>IIEF</b>		
<b>No ED (22-25) (1, 2.0)</b>	<b>0(0)</b>	<b>1(4.5)</b>
<b>Mild (17-21) (5, 10.2)</b>	<b>2(7.4)</b>	<b>3(13.6)</b>
<b>Mild to moderate (12-16) (3, 6.1)</b>	<b>2(7.4)</b>	<b>1(4.5)</b>
<b>Moderate (8-11) (11, 22.4)</b>	<b>5(18.5)</b>	<b>6(27.3)</b>
<b>Severe (5-7) (29, 59.1)</b>	<b>18(66.7)</b>	<b>11(50.0)</b>

**Note:** Abbreviations: UI: Urinary incontinence; IIEF: International Index of Erectile Function. Groups with an n < 5 used Fisher's Exact Test.

**Perceived physical symptoms of distress:** The average mean score for perceived physical symptoms of distress in the open surgery group at one year post-RP was 6.1 (SD=2.7), which decreased to 3.9 (SD=2.5) at five years post-RP. In the laparoscopy group, the one-year mean score for perceived physical symptoms of distress was 4.2 (SD=2.1), which decreased to 2.9 (SD=1.6) at five years post-RP. There were significant differences in the perceived physical symptoms of distress between the RP groups (all  $p < 0.05$ ) and at one-year compared with the baseline ( $p < 0.05$ ), but no difference was found compared with the baseline at five years post-RP (Table 3). These results indicate that all of the patients who underwent an RP procedure experienced a reduction in their perceived physical symptoms of distress. In addition, at five years post-RP, the mean level of perceived physical symptoms of distress was similar between the groups, with a decrease in the level of distress observed over time.

**Effects of the RP procedure on patient outcome:** Table 4 shows the changes in patient outcomes based on the RP group. After controlling for nerve-sparing surgery, the GEE tests indicated that there was no interaction between the RP group and the number of years after surgery ( $Z = 1.47$ ,  $p = 0.226$ ). However, a significant difference in urinary incontinence was observed for both the RP group ( $Z = 22.73$ ,  $p < 0.001$ ) and the number of years after the procedure ( $Z = 11.93$ ,  $p < 0.001$ ). These results showed that the decrease in the urinary incontinence score in the open surgery group was significantly greater than that in the laparoscopy group, with a significant decrease observed at five years post-RP (the regression coefficients were negative). With regard to the outcome change for the IIEF, significant differences were observed for the number of years after the procedure ( $Z = 6.01$ ,  $p = 0.014$ ) but not for the RP group ( $Z = 0.04$ ,  $p = 0.852$ ). These results indicate that the increase in the IIEF score at five years post-RP was significantly greater than that at one year post-RP (the regression coefficients were negative). For the outcome change related to physical

**Table 4:** The Outcome Scores Over Time for the Two Surgical Procedure Groups (N=49).

Parameter	Regression coefficient	SE	Z	P Value	95% CI
<b>UI score</b>					
Intercept	20.12	2.25	80.21	<0.001	15.71~24.52
Difference between groups (Laparoscopy/open surgery*)	-10.52	2.21	22.73	<0.001	-14.84~-6.19
Difference between years (5-year/1-year*)	-7.34	2.12	11.93	<0.001	-11.49~-3.17
Interaction of year and group	3.10	2.56	1.47	0.226	-1.92~8.12
<b>IIEF score</b>					
Intercept	8.53	1.03	68.59	<0.001	6.51~10.55
Difference between groups (Laparoscopy/open surgery*)	0.19	1.04	0.04	0.852	-1.84~2.22
Difference between years (5-year/1-year*)	-2.73	1.09	6.01	0.014	0.39~4.81
Interaction of year and group	2.21	1.33	2.78	0.096	-0.39~4.81
<b>Perceived symptoms of distress score</b>					
Intercept	2.96	0.33	82.06	<0.001	2.32~3.60
Difference between groups (Laparoscopy/open surgery*)	-0.90	0.35	6.71	0.010	-1.59~-0.22
Difference between years (5-year/1-year*)	-1.06	0.23	21.85	<0.001	-1.50~-0.62
Interaction of year and group	0.42	0.35	1.49	0.755	-0.26~1.10

**Note:** Dependent variables: UI: Urinary Incontinence score, IIEF: International Index of Erectile Function score; PSD: Perceived Symptoms of Distress score. Controlled for nerve-sparing surgery, all  $p > 0.05$ .

\*as a reference

**Interaction of year and group:** differences between the open surgery group and laparoscopy group at all year points.

UI, Equation used:  $Y = 20.12 - 10.52 \times \text{group} - 7.33 \times (\text{year}) + 3.10 \times (\text{interaction of year and group})$ .

IIEF, Equation used:  $Y = 8.53 + 0.19 \times \text{group} - 2.73 \times (\text{year}) + 2.21 \times (\text{interaction of year and group})$ .

Perceived symptoms of distress, Equation used:  $Y = 2.96 - 0.90 \times \text{group} - 1.06 \times (\text{year}) + 0.42 \times (\text{interaction of year and group})$ .

**Table 3:** Mean Outcome Scores at the One-year and Five-year Follow-ups for the Two Groups (N=49).

Time	Open surgery group Mean (SD)	Laparoscopy group Mean (SD)	Test (Z)	P value
<b>UI scores</b>				
1-year	20.4(8.4)	9.7(6.1)	-4.03	<0.001
5-year	12.9(11.7)	5.5(4.8)	-2.20	0.028
Test (p value)	Z=-3.10(0.002)	Z=-2.60(0.009)		
<b>IIEF</b>				
1-year	7.5(4.1)	8.1(4.3)	1.01	.312
5-year	8.0(2.7)	10.9(6.1)	0.45	.651
Test (p value)	Z=1.88(0.060)	Z=1.92(0.054)		
<b>PSD</b>				
1-year	6.1(2.7)	4.2(2.1)	-2.55	.011
5-year	3.9(2.5)	2.9(1.6)	-1.52	.128
Test (p value)	Z=-3.24(0.001)	Z=-2.06(0.039)		

Abbreviations: UI: Urinary incontinence; IIEF: International Index of Erectile Function; PSD: Perceived Symptoms of Distress.

Note: tested using the Mann-Whitney U test (Z).

symptoms of distress, significant differences were observed for both the RP group ( $Z = 6.71$ ,  $p = 0.010$ ) and number of years post-RP ( $Z = 21.85$ ,  $p < 0.001$ ). These results indicate that the decrease in the physical distress score in the open surgery group was significantly greater than that in the laparoscopy group, with a significant decrease observed at five years post-RP (the regression coefficients were negative).

## Discussion

This study was performed to examine the changes in the complications and perceived physical symptoms of distress after two types of RP procedures among prostate cancer patients. We will discuss the complication-related outcomes (urinary incontinence and sexual dysfunction) and perceived physical symptoms of distress sequentially below.

This study found that the study participants' urinary incontinence showed significant changes after both open and laparoscopic RP. These results indicated that the RP recipients' urinary incontinence decreased over time. However, 44.4%

and 50.0% of the study participants still reported suffering from urinary incontinence at five years post-RP. These results are similar to those reported in a study by Bill-Axelsson et al. [5], which found that patients consistently reported urinary leakage, impaired erections, and distress after eight years of follow-up. However, the urinary incontinence rates for both groups are higher than those reported by Zielinski et al. [2], Potosky et al. [33], and Soares et al. [26], (15%, 14-16%, and 6.2% respectively). These differences in the rates of incontinence may be related to the use of diverse measurement tools, different definitions of urinary incontinence, and the fact that the present study used a single question to ask participants whether they experienced urine leakage [2,33].

As shown in Table 1, we found that nerve-sparing surgery was a confounding variable ( $p < 0.5$ ), and after controlling for this variable, the results (Table 3) revealed a significant improvement in urinary incontinence after one year ( $p < 0.001$ ), indicating that urinary incontinence decreased over time in both groups. Urinary incontinence decreased significantly in all patients, regardless of the RP procedure. However, urinary incontinence persisted in many patients at five years after RP, and these results are consistent with the findings of a previous study [33].

As shown in Table 2, the sexual dysfunction rates showed that 7.4% of the participants had mild and mild to moderate dysfunction, 18.5% had moderate dysfunction, and 66.7% had severe dysfunction at five years after open surgery. In the laparoscopy group, the sexual dysfunction rates showed that 4.5% of the participants had no erectile dysfunction, 13.6% had mild dysfunction, 4.5% had mild to moderate dysfunction, 27.3% had moderate dysfunction, and 50.5% had severe dysfunction at five years after the procedure. A study by Bill-Axelsson et al. [5], found that patients who underwent an RP procedure consistently reported impaired erections after eight years. These results indicate that although sexual function may improve over time, there are long-term adverse outcomes for many patients, with participants who received open RP showing more severe dysfunction than those who received laparoscopic RP. These results are consistent with the previous literature and indicate that laparoscopic RP appears to provide better outcomes in comparison with open RP [34]. However, this study found that the participants' mean sexual dysfunction scores did not show significant changes, although the  $p$  values of both groups at five years were nearly significant.

Because nerve-sparing surgery was found to be a confounding variable, we performed an analysis that controlled for this factor, and we found significant differences based on the number of years post-RP, but not for the RP group. These results showed that the sexual function of both groups of participants improved over time. Our findings are consistent with those reported in a study by Zielinski [2] which showed that patients' overall sexual function improved over time, with the impotence rate improving from 82.1% at two years after RP treatment to 79.3% at five years.

Sexual dysfunction is often more complex than the biology of ED [35]. Some patients in this study reported penile

shortening and never regained erectile function after RP. These complications dominated their daily life and decreased their quality of life. These results support those described by Resnick et al. [36], who found that at 15 years after surgical treatment, 87% of prostate cancer patients were still experiencing sexual side effects.

A study by Bill-Axelsson et al. [5], indicated that patients who underwent an RP procedure still suffered from distress eight years later. These authors found that the mean average perceived physical symptoms of distress showed significant decreases over time in two groups of RP patients with significant differences observed at 5 years, but not 1 year, post-surgery. After controlling for nerve-sparing surgery as a confounding variable, the participants' perceived physical symptoms of distress showed significant changes in both groups in our present study. In particular, our results showed that the RP recipients' perceived physical symptoms of distress decreased over time. These results support a previous study showing that nearly one-third of prostate cancer patients experienced clinically relevant distress, but that these symptoms of distress decreased within five years after treatment [28].

We used the mean score for urinary incontinence and the IIEF at five years post-RP for the two surgical groups to conduct a power analysis to test this study's effect sizes. The results showed that when the power was set to 0.80 and the alpha was 0.05 (two-tailed), the effect sizes were 0.80 and 0.64, respectively (moderate effect sizes) [37]. Our findings with regard to the sample size calculation provide a basis for further research.

### Limitations of this study and recommendations for future research

The present study has some limitations. First, our participants were only recruited from one hospital in southern Taiwan, which may have limited the ability to generalize the results of this study to other populations. Second, there was a four-year interval between the two time points of follow-up; therefore, we lost contact with some patients, which led to a decrease in the study sample size at five years. In addition, the perceived physical symptoms of distress may have been related to psychological problems, such as anxiety or depression, which we did not take into account in our study. Thus, further studies are recommended. Additionally, this study only examined the changes in complications for five years, and further studies should be performed to assess the longer-term outcomes after RP.

### Conclusion

The results of this study demonstrate that prostate cancer patients who have undergone RP experience long-term adverse complications. These results provide new information about the long-term complications of two different RP approaches for clinically localized prostate cancer that will help guide treatment decisions. Oncological and urological nurses should be aware of the complications experienced, should recognize the changes in adverse outcomes, and should consider early intervention to decrease the adverse effects in cancer survivors.

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