

1 **The narrow vesicourethral angle measured on postoperative cystography can**
2 **predict urinary incontinence after robot-assisted laparoscopic radical**
3 **prostatectomy**

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8

9 Running title: cystgram predicting incontinence after RALP

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73 ABSTRACT

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75 OBJECTIVE

76 Radical prostatectomy is associated with complications including urinary incontinence.

77 A significant association between specific features of the vesico-urethral

78 anastomosis and urinary incontinence after radical prostatectomy has been

79 demonstrated. The aim of this study was to identify the most useful predictor of

80 postoperative urinary incontinence after robot-assisted laparoscopic radical

81 prostatectomy (RALP) according to the features of the vesico-urethral anastomosis as

82 determined by postoperative cystography.

83

84 MATERIALS AND METHODS

85 The final study cohort consisted of 150 patients. Postoperative cystography was

86 performed within 1 week after RALP. The ratio between the longitudinal and

87 horizontal lengths (L/H) of the bladder, the position of the urethrovesical

88 junction (UVJ), and the bladder neck angle as seen on the cystogram were

89 evaluated. Post-operative continence status was evaluated by 1-hour pad

90 test 1 day after the catheter removal and safety pad retrospectively from

91 patient records. The association between these variables and urinary
92 incontinence was then analyzed. All patients were followed for at least 1 year
93 postoperatively.

94

95 RESULTS

96 The continence rate of the pad test and 1 month and 1 year after RALP were
97 31.3%, 56%, and 93.3%, respectively. In multivariate analyses, urinary
98 incontinence was significantly associated with nerve sparing, L/H, and the vesical angle
99 as determined on the 1-hr pad test, but only the vesical angle at 1 month and 1 year
100 postoperatively.

101

102 CONCLUSION

103 A narrow vesical angle measured on cystography is a useful predictor of postoperative
104 urinary incontinence after RALP.

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107 Keywords

108 Vesicourethral angle, postoperative, urinary incontinence,

109 robot-assisted laparoscopic radical prostatectomy, cystography

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127 Abbreviations & acronyms

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129 RALP=robot-assisted laparoscopic radical prostatectomy

130 L/H=The ratio between the longitudinal and horizontal lengths of the

131 bladder

132 UVJ=urethrovesical junction

133 PVUA=the posterior vesicourethral angle

134 BMI=body mass index

135 PSA=prostate-specific antigen

136 NS=nerve sparing

137 OR=odds ratio

138 CI=confidence interval

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145 Introduction

146 Radical prostatectomy is one of the definitive treatments for localized
147 prostate cancer. However, radical prostatectomy has been associated with
148 complications and sequelae, including erectile dysfunction and urinary
149 incontinence; these complications markedly decrease patient quality of life.
150 Factors contributing to urinary incontinence are surgical experience, nerve
151 sparing technique, bladder neck preservation, periurethral suspension,
152 posterior reconstruction, total reconstruction, functional-length urethral
153 sphincter preservation, and athermal dorsal vein complex dividing [1-7].
154 Perioperative images may facilitate prediction of urinary incontinence after
155 RALP. Coakley et al. reported that membranous urethral length determined
156 on magnetic resonance imaging (MRI) was related to the time taken to
157 achieve stable postoperative urinary continence [8]. However, MRI is
158 excessively expensive for use as a routine follow-up survey. In contrast,
159 cystography is a convenient method for evaluating anastomotic leakage in
160 daily practice. Parameters measured on postoperative cystography that are
161 reportedly significantly associated with urinary incontinence after
162 laparoscopic radical prostatectomy or robot-assisted laparoscopic radical

163 prostatectomy (RALP) include postoperative shorter membranous urethral
164 length, a more downward-directed bladder neck and a sharper bladder neck
165 angle, a more downward-directed position of the urethrovesical junction
166 (UVJ), hypo urethral movement, the narrow posterior vesicourethral angle
167 (PVUA), and the higher ratio between the longitudinal and horizontal length
168 of the bladder (L/H ratio) [9-14].

169 In the present study, we aimed to determine the most useful predictor of
170 postoperative urinary incontinence after RALP according to the
171 vesicourethral anastomotic features as measured on postoperative
172 cystography.

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174 Methods

175 Patients

176 The Institutional Review Board of our hospital approved this study. RALP
177 was introduced in our hospital in August 2013, and 112 RALP operations had
178 been performed by the end of September 2014. We retrospectively collected
179 data from patients who underwent RALP between October 2014 and
180 January 2016. In total, 187 patients were assessed for study inclusion; nine

181 refused to undergo the pad test, seven could not perform the pad test due to
182 pain, desire for defecation, marked incontinence, hematuria, or restricted
183 fluids, two did not have the catheter removed due to leakage of the
184 anastomosis, and 19 had insufficient cystography results. The final study
185 cohort included 150 patients. All patients were followed up for at least 1 year
186 postoperatively. Postoperative cystography was performed within 1 week
187 after RALP. The study was presented to the institutional review board and
188 approved as a retrospective cohort study based on the available evidence.
189 The research conformed to the Declaration of Helsinki and local legislation.

190

191 Surgical procedure

192 Nerve sparing technique, anterior and posterior reconstruction, and bladder
193 neck preservation were selected as required. Obturator lymph node
194 dissection was performed in selected patients who had > 10% incidence of
195 lymph node metastasis according to the Partin nomogram. The nerve
196 sparing technique was performed in selected patients, most of whom
197 underwent unilateral intrafascial dissection. After the prostate was removed
198 from the rectal bed, Rocco's suture was performed. The vesicourethral

199 anastomosis was performed using continuous suturing with 4-0
200 monofilament double needle using the Van Velthoven technique, and was
201 confirmed to be watertight. Anterior fixation was performed between the
202 bladder wall and the sutured dorsal vein complex. A pelvic drainage tube
203 was passed through the da Vinci port on the right side.

204

205 Postoperative cystography

206 Cystography was performed on postoperative day 6 or 7. A total of 100 ml of
207 saline solution containing contrast media was infused into the bladder, and
208 front-view images were obtained. The 45°-semilateral-view images were not
209 included in the current study, as they were inaccurate and unstable due to
210 unstable patient positioning. Provided there was no leakage at the
211 anastomosis, the balloon catheter was removed. If leakage was detected,
212 cystography was repeated 7 days later. Anatomical features were evaluated
213 using the following methods.

214

215 Cystography parameters

216 The following parameters were measured on front-view cystography: the L/H

217 ratio, and the craniocaudal distance from the most proximal margin of the
218 symphysis pubis to the position of the UVJ (Fig. 1). The bladder neck angle
219 was measured as the angle of the bladder neck relative to the bilateral
220 margin over the pelvic inlet (Fig. 2). The measurements were done blinded to
221 the continence results.

222

223 Urinary incontinence definition

224 The continence status was assessed by the 1-hour pad test conducted the day
225 after catheter withdrawal, and the patient-reported pad usage over the 1
226 month and 1 year interval after RALP.

227 The 1-hour pad test was performed according to the International Continence
228 Society recommendations. The patient was instructed not to void, and to
229 then drink 500 ml of sodium-free liquid. After sitting or resting for 30
230 minutes, the patient performed the recommended activities. The continence
231 group consisted of patients with a pad weighing ≤ 2 g after the test, while the
232 incontinence group consisted of patients with a pad weighing > 2 g [15].

233 Regarding the patient-reported pad usage, recovery of urinary continence
234 was defined as wearing no pads or wearing an occasional pad for security.

235 Statistical analysis

236 The Mann-Whitney U test was used to determine significant differences in
237 parameters. Univariate logistic regression analysis was carried out to
238 determine the predictive factors for urinary incontinence. The independent
239 predictive factors were then confirmed using multivariate logistic
240 regression analysis with a stepwise procedure. Finally only remaining
241 factor listed in table. Cutoff values for independent predictive factors of
242 urinary continence were determined using receiver operating
243 characteristics (ROC) analysis. All analyses were performed with the SPSS
244 statistical package, version 21 (SPSS, Chicago, IL, USA). A p value of < 0.05 was
245 considered significant.

246

247 Results

248 The patient characteristics are shown in Table 1. The respective urinary
249 continence rates at the 1-hour pad test, and 1 month and 1 year after RALP
250 were 31.3%, 56%, and 93.3%.

251 Univariate analysis revealed four significant predictors of urinary incontinence at the
252 1-hour pad test (Table 2). Multivariate analysis revealed that nerve sparing technique,

253 L/H ratio, and vesical angle were significantly associated with urinary incontinence at
254 the 1-hour pad test; vesical angle was also significantly associated with urinary
255 incontinence at 1 month and 1 year after RALP (Table 3, 4). There were no
256 significant differences in vesical angle between the patients who underwent
257 nerve sparing ($100.2^{\circ} \pm 13.9$) and those who did not ($98.3^{\circ} \pm 11.2$), respectively,
258 $p= 0.8288$.

259 We performed ROC analysis to elucidate the optimal cutoff value for vesical angle.
260 Respective cutoff values of 100.47° , 100.47° , and 86.5° yielded the best accuracy
261 in ROC analysis at the 1-hour pad test, and at 1 month and 1 year post-RALP.
262 The bigger angle is better. According to the area under the ROC curve, the
263 respective sensitivities at the 1-hour pad test, and at 1 month and 1 year
264 post-RALP were 0.6705, 0.6567, and 0.7726 (Fig. 3).

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266 Discussion

267 Among a variety of factors, including cystography parameters, the vesical
268 angle was the strongest predictor of both very early and late urinary
269 continence after RALP. ROC analysis showed that a vesical angle $100^{\circ} <$ was
270 associated with poor urinary continence in the early postoperative period.

271 The early recovery of urinary incontinence after radical prostatectomy is
272 reportedly related to various demographic and anatomical factors, as well as
273 surgical techniques. Many investigators have reported that modified surgical
274 techniques improve the time to recovery of urinary incontinence [1-7].

275 However, none of these technical efforts completely enabled the prediction
276 of early recovery of urinary incontinence, and it might be difficult to validate
277 the surgical techniques carried out by each individual surgeon.

278 Perioperative images may facilitate prediction of urinary incontinence.
279 Studies have investigated whether postoperative cystography can assist with
280 the prediction of urinary incontinence by evaluating postoperative
281 membranous urethral length, vesical angle, UVJ position, urethral
282 movement, PVUA, and L/H ratio. Ito et al. reported that the L/H ratio and
283 PVUA are significantly associated with urinary incontinence in univariate
284 analysis, but the evaluated point was not reported [14]. Shao et al. reported
285 that a more downward-directed bladder neck and a sharper bladder neck
286 angle are associated with urinary incontinence at 1, 6, 12, and 24 months
287 post-RALP in univariate analysis; however, they evaluated the bladder neck
288 angle and the level of the bladder neck on postoperative cystography, and did

289 not include the L/H ratio [12].

290 One of the unique aspects of our study is that the 1-hour pad test was used
291 to define very early urinary continence after RALP. The pad test was
292 performed the day after catheter removal, and 30% of the patients were
293 continent (≤ 2 g urine leakage). Haga et al. also used the pad test to define
294 continence after RALP, and reported that the postoperative degree of
295 external urethral sphincter atony was significantly associated with urinary
296 continence at the 1-hour pad test [9] ; however, the evaluated point was not
297 provided.

298 To determine why a narrow vesical angle was associated with urinary
299 incontinence, we need to consider the normal male voiding mechanism.
300 Nishio et al. reported that striated urethral sphincter relaxation and
301 anterior fibromuscular stroma contraction occurred at initiation of voiding to
302 open the bladder neck and urethra, and change the posterior vesical urethral
303 angle (narrow the bladder neck angle) on real-time MRI [16] ; this situation
304 resembled urethral incontinence. We also considered the effect of urethral
305 stress. To prevent postoperative incontinence, it is reportedly important to
306 avoid tension on the final anastomosis by releasing the bladder from the

307 peritoneum [17]. The vesical angle could be related to the stress applied to
308 the urethra, which is an important factor affecting urinary incontinence.
309 When the urethra was stressed along the longitudinal axis, the urethral
310 lumen was tensioned and opened. The stronger the urethral stress along the
311 longitudinal axis, the longer the longitudinal length of the bladder, which
312 pulled the UVJ position down caudally, and consequently increased the L/H
313 ratio and narrowed the vesical angle. Therefore, urinary incontinence
314 occurred. Among the various factors affecting urinary incontinence, the
315 vesical angle was one of the most important.

316 Although not demonstrated *in vivo*, an oblate bladder may have better
317 compliance than a prolate bladder, and higher storage pressure may work
318 against urinary continence [18]. That is, the wider the vesical angle, the
319 more compliant the bladder. These anatomic features may cause these effects
320 by sparing the functional urethral length, bladder neck preservation, and
321 posterior and anterior reconstruction. Tewari et al. described a reproducible
322 technique for supporting the urethral continence mechanism by anterior and
323 posterior reconstruction, referred to as the 'total anatomic reconstruction'
324 technique ; cystography showed that patients that underwent total

325 reconstruction had minimal descent of the UVJ compared with a control
326 group and an anterior reconstruction group [19]. However, in the current study,
327 the position of the UVJ was not significantly associated with urinary incontinence at the
328 1-hour pad test in multivariate analysis; we considered that a wide vesical angle
329 revealed the same condition in the current study. Our results indicate that
330 support of the lateral side of the vesicourethral anastomosis to the pelvic
331 floor, such as the iliopubic tract, may be good for maintaining urinary
332 continence.

333 The recovery of urinary incontinence is not only positively affected by nerve
334 sparing, but also by preserving as much as possible of the anatomical cradle
335 of the prostate, its associated investing fascia, its anterolateral tissues, and
336 its posterolateral neurovascular bundles. However, the present study found
337 no significant differences in vesical angle between the nerve sparing group
338 and the non-nerve sparing group. Hence, the most useful predictor of urinary
339 incontinence is controversial.

340 For patients with urinary continence, physical therapy with pelvic floor
341 rehabilitation is the most common first-line treatment. If the vesical angle
342 measured on cystography was less than 100° and urinary incontinence was

343 remarkable, patients may require medical therapy or pelvic floor
344 rehabilitation in the early postoperative period.

345 To the best of our knowledge, the present study is the first to perform
346 multivariate analysis of a variety of cystography parameters and report that the
347 vesical angle is significantly associated with both short- and long-term urinary
348 incontinence.

349 The present study included the following limitations. First, most of the surgeries were
350 carried out by a total of six surgeons. However, three experienced surgeons supervised
351 all operations performed by the other three surgeons. Second, this was a
352 non-randomized retrospective study conducted in a single institute. Third, there was a
353 small number of patients. Fourth, 1hr pad test was not performed 1 months and 12
354 months after RALP. Fourth, The continence status by safety pad was evaluated
355 interview by physician, not the validated questionnaire. Further prospective,
356 randomized, multicenter studies are required to confirm our findings.

357 In conclusion, the vesicourethral anastomosis features measured on
358 postoperative cystography could facilitate prediction of postoperative urinary
359 incontinence after RALP. Narrow vesical angle is significantly associated with
360 urinary incontinence at the 1-hour pad test performed the day after catheter removal,

361 and at 1 month and 1 year after RALP. The vesical angle on cystography is a useful

362 predictor of urinary incontinence after RALP.

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379 Disclosure statement

380 One of our author, Tadashi Matsuda received a research grant from Intuitive Surgical

381 Co., Ltd.

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458 Figure legends

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460 Fig. 1 Front view. The figure shows the measurement of the longitudinal (a) and
461 horizontal (b) (L/H) length ratio. (c) Craniocaudal distance from the most proximal
462 margin of the symphysis pubis to the position of the urethrovesical junction.

463

464 Fig. 2 The bladder neck angle was measured as the angle between the bladder neck
465 and the bilateral margin over the pelvic inlet.

466

467 Fig. 3 The ROC curve of the vesical angle to predict urinary incontinence at (a)
468 1hr-pad test, (b) 1 month and (c) 1 year was shown with AUC of the parameters. The
469 most accurate cut off values at 1hr-pad test, 1 month, and 1 year were 100.47, 100.47,
470 and 86.5 degree, respectively.

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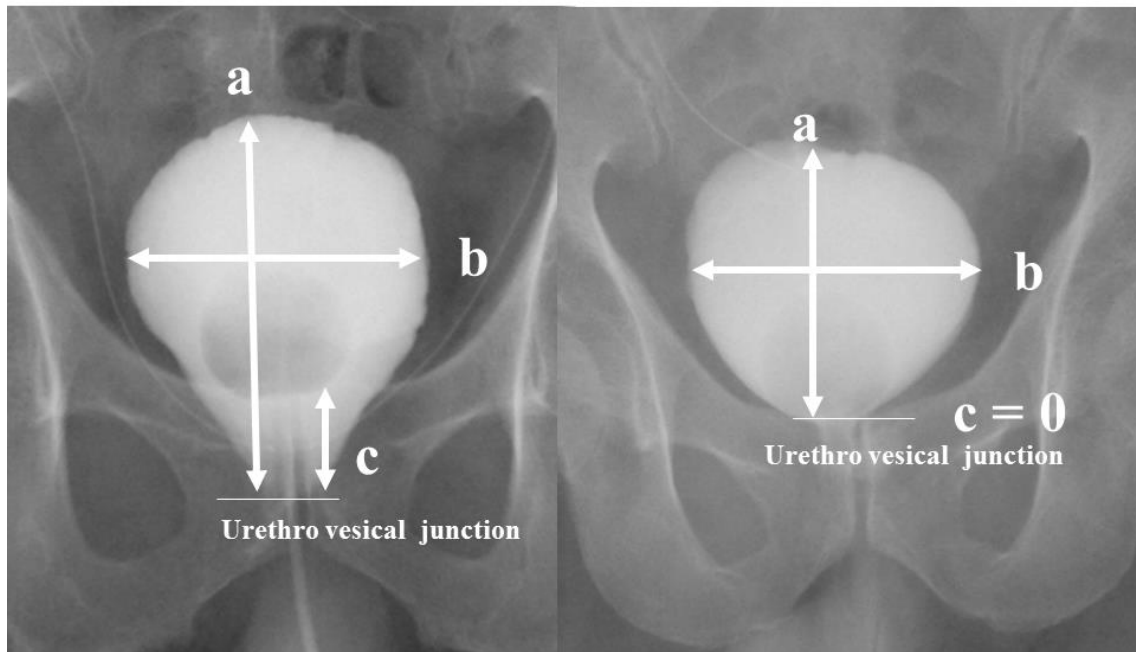
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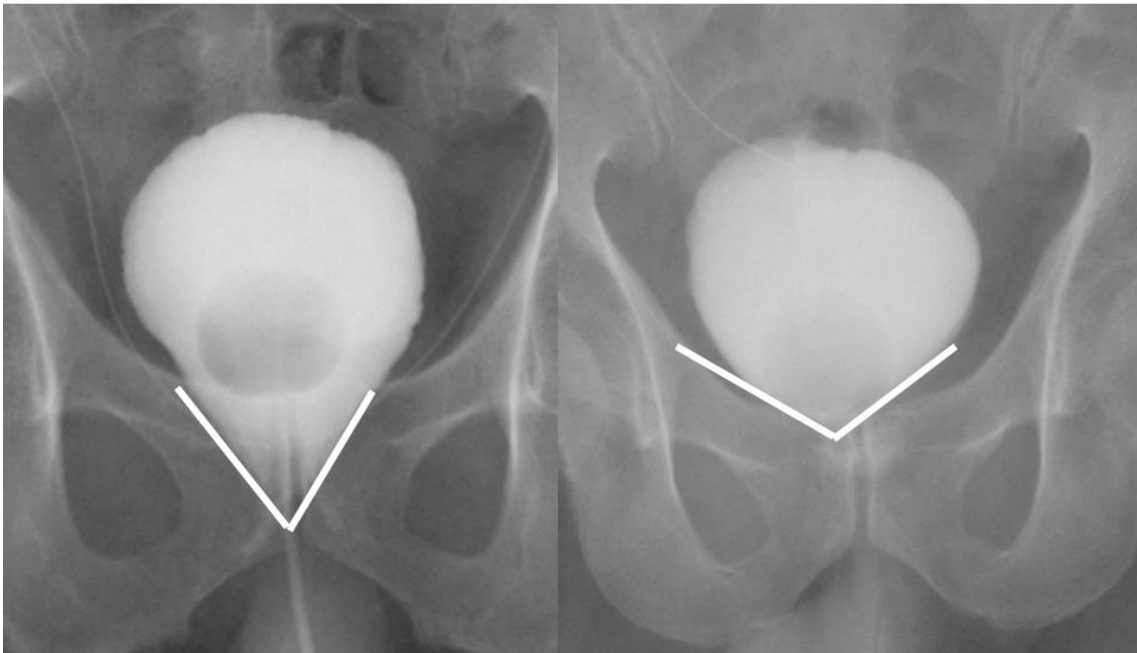
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476 Fig. 1



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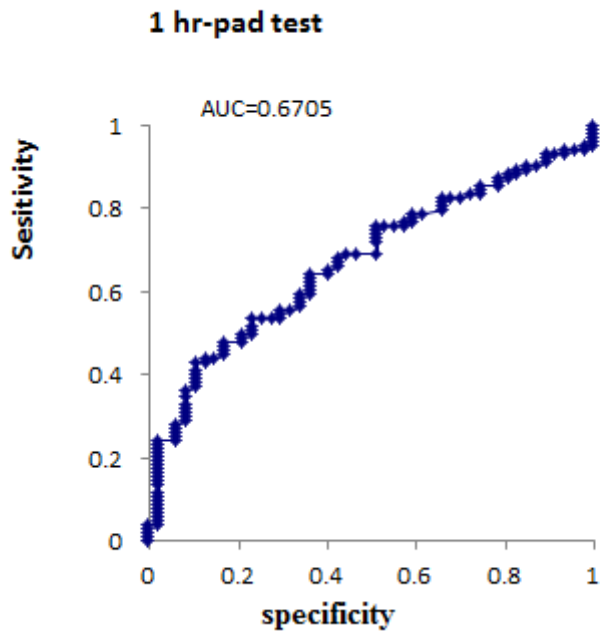
495 Fig. 2



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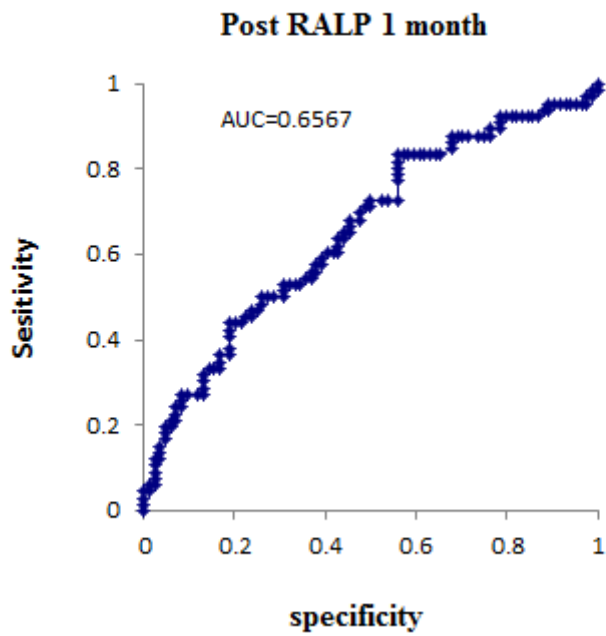
514 Fig. 3

515 (a)



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517 (b)



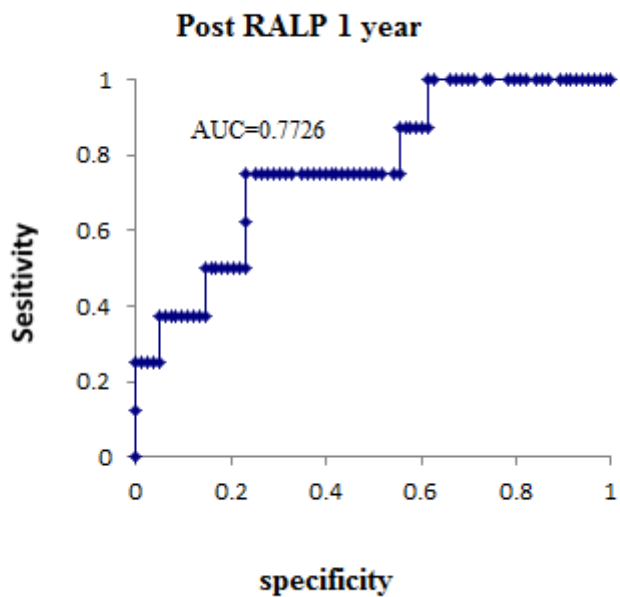
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522 (c)



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524 Table 1 Patients characteristics

525

526 Valuable

527	N	150
528	Age(year)	69 ± 4.8
529	BMI	24 ± 2.8
530	PSA(ng/ml)	6.8 ± 8.6
531	Clinical stage	
532	T1c	115
533	T2a	26
534	T2b	4
535	T2c	2
536	T3a	3
537	NS(%)	72(48)
538	Specimen weight(g)	43 ± 18.1
539	L/H(%)	109 ± 19
540	Vesical angle(°)	98 ± 12.6
541	Position of UVJ(mm)	11.2 ± 6.9

542

543 Continuous variables were reported as median (± standard deviation)

544

545

546

547

548 Table 2 Univariate and multivariate analysis for incontinence at 1 hr-pad test on the
 549 next day of the catheter removal

550

551	552 Valuable	551 Pad test		551 P value univariate	551 P value multivariate
		552 $\leq 2g$	552 $2g <$		
553	N	47	103		
554	Age(year)	68.0 \pm 5.0	69.0 \pm 4.7	0.1702	
555	BMI	23.4 \pm 3.1	24.1 \pm 2.7	0.3369	
556	NS(%)	30(63.8)	42(40.8)	0.0103	0.0055
557	Specimen weight(g)	42.0 \pm 14.7	44.0 \pm 22.3	0.2731	
558	L/H(%)	105.2 \pm 13.3	112.9 \pm 20.5	0.0033	0.00354
559	Vesical angle($^{\circ}$)	103 \pm 9.4	95.4 \pm 13.2	0.0008	0.0059
560	Position of UVJ(mm)	9.9 \pm 6.2	11.5 \pm 7.1	0.0129	

561 Continuous various were reported as median (\pm standard deviation)

562

563

564

565 Table 3 Univariate and multivariate analysis for incontinence at 1M after RALP

566

567	568 Valuable	567 Safety pad(1M)		567 p value univariate	567 p value multivariate
		568 0-1	568 $2 \leq$		
569	N	84	66		
570	Age(year)	69.0 \pm 5.2	68.0 \pm 4.2	0.8350	
571	BMI	24.3 \pm 3.1	23.9 \pm 2.5	0.4156	
572	NS(%)	45(53.6)	27(40.9)	0.1839	0.127
573	Specimen weight(g)	41.5 \pm 23.9	44.5 \pm 14.7	0.1304	
574	L/H(%)	107.5 \pm 17.9	112.5 \pm 20.0	0.0745	
575	Vesical angle($^{\circ}$)	101.5 \pm 11.1	93.4 \pm 13.4	0.0010	0.006
576	Position of UVJ(mm)	10.4 \pm 5.8	12.5 \pm 7.8	0.0069	0.1184

577 Continuous various were reported as median (\pm standard deviation)

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581 Table 4 Univariate and multivariate analysis for incontinence at 1year

582

583		Safety pad(1year)		p value	p value
584	Valuable	0-1	2 \leq	univariate	multivariate
585	N	125	9		
586	Age(year)	69 \pm 5.5	69 \pm 3.6	0.6957	
587	BMI	23.8 \pm 2.8	26.2 \pm 2.9	0.1219	
588	NS(%)	68(54.4)	3(33.3)	0.3109	0.858
589	Specimen weight(g)	42 \pm 16	50 \pm 11.1	0.1505	
590	L/H(%)	107 \pm 19.5	113.6 \pm 20.1	0.2059	
591	Vesical angle($^{\circ}$)	98.4 \pm 12.1	86.1 \pm 14.5	0.0088	0.0103
592	Position of UVJ(mm)	11.0 \pm 7.2	20.1 \pm 8.2	0.0110	

593 Continuous various were reported as median (\pm standard deviation)

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