

# Comparison of Perioperative Outcomes in Open and Laparoscopic Radical Cystectomy with Modified Ureterosigmoidostomy (MainzII): A Retrospective Analysis

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#### **Research Article**

Keywords: Radical cystectomy, Urinary diversion, Mainz pouch II, Laparoscopic, Open, Bladder cancer

Posted Date: August 30th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-805660/v1

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# Abstract

**Background:** To analyze perioperative conditions and long-term efficacy of open modified ureterosigmoidostomy urinary diversion (OMUUD) in patients with bladder cancer who underwent open radical cystectomy (ORC) and laparoscopic radical cystectomy (LRC).

**Methods:** In this retrospective study, the clinical data of patients who underwent open and laparoscopic radical cystectomy plus open modified ureterosigmoidostomy urinary diversion in our hospital were collected from January 2011 to December 2019. In addition, perioperative data of 56 patients who underwent ORC and OMUUD were compared with those of 118 patients who underwent laparoscopic radical cystectomy (LRC) plus OMUUD. A long-term follow-up was performed to compare the overall survival (OS) and progression-free survival (PFS) rate between the two groups.

**Results:** Results showed that there was no significant difference between ORC+OMUUD group and LRC+OMUUD group in terms of gender, age, body index, pre-operative ASA grade, history of transurethral resection of bladder tumor (TURBT) before surgery, tumor T stage, lymph node dissection range, pathological grade, and positive postoperative surgical margin. The mean operation time in the open group was shorter than that in the <u>laparoscopic group</u> P<0.001<sup>®</sup>. Moreover, the estimated intraoperative blood loss P<0.001<sup>®</sup> and postoperative hospital stay P=0.023<sup>®</sup> were better in the laparoscopic group than in the open group. The incidence of complications between 30 days (P=0.665) and 90 days (P=0.211) time-points after surgery was not significantly different. Similarly, the OS (P=0.237) and PFS (P=0.307) between the two groups were comparable.

**Conclusion:** This study shows that the LRC group has long operation time, but less estimated intraoperative blood loss, short postoperative hospital stay, small trauma, and fast postoperative recovery compared to open surgery. Moreover, the incidence of complications at 30 - and 90-days postoperation, as well as the OS and PFS is not different between laparoscopy and open surgery.

# Introduction

Bladder cancer (BC) is one of the most common malignant tumors of the urinary system, and its incidence has been increasing annually in recent years. <sup>[1]</sup>. Although non-muscle-invasive bladder cancer type is the most prevalent type of BC, 20–30% of patients with BC have muscle-invasive bladder cancer which is more aggressive and likely to metastasize. Radical cystectomy with pelvic lymph node dissection is the gold standard treatment for muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer. <sup>[2–3]</sup> Before invention of laparoscopic techniques, open radical cystectomy (ORC) was the most common method of radical cystectomy.<sup>[4]</sup> However, ORC is associated with high perioperative complications and mortality due to complexity of the operation and significant surgical trauma. <sup>[5–6]</sup> For these reasons, medical centers around the world have adopted laparoscopic radical cystectomy (LRC) because it is minimally invasive for bladder cancer treatment. <sup>[7–10]</sup> Application of LRC has been shown to accelerate postoperative recovery, shorten postoperative hospital stay, and faster

return to daily activities. <sup>[7, 8, 10, 11]</sup> However, few studies have investigated the long-term outcomes and efficacy of LRC and ORC in terms of tumor control. <sup>[7–9, 12]</sup>

Currently, there are many types of urinary diversion operations following radical cystectomy, each with its own advantages and disadvantages. Ureteral sigmoid anastomosis urinary diversion is one of the commonly used urinary diversion methods after total cystectomy. It has been performed in our center for more than 20 years. Modified ureteral sigmoidostomy (Mainz II) is a simple and easily repeatable surgical procedure with good safety and efficacy. <sup>[13]</sup> In our center, it is used as an alternative to urinary diversion. Since 2011, hundreds of patients have undergone OMUUD after LRC. In this study, we will review the use of LRC with OMUUD in a single-center. In addition, the safety and efficacy of this approach was compared to that of ORC + OMUUD.

# **Patients And Methods**

A total of 174 patients with bladder cancer who underwent radical total bladder resection plus Mainz Pouch II from January 2011 to December 2019. Among them, 56 patients received ORC and OMUUD, whereas 118 patients received LRC and OMUUD.

Patients were prescribed to undergo surgery if they had: (1) muscular infiltrating bladder cancer with stages of PT2-T4A, N0-NX, and M0;and (2) T1G3 stage, transurethral resection or enucleation of bladder tumor, and recurrence of non-muscular invasive bladder cancer after bladder perfusion chemotherapy. On the other hand, patients were contraindicated for the surgery if they had: (1) fecal incontinence, (2) history of radiotherapy in the pelvic cavity, (3) sigmoid diverticulum, (4) intestinal polyps, (5) chronic diarrhea, and (6) history of rectum and sigmoid colon surgery. The Clavien-Dindo scale was used to evaluate the incidence of postoperative complications at 30 and 90 days after surgery. <sup>[14]</sup>

# **Surgical Methods**

The two groups of patients underwent standard pelvic lymph node dissection and total cystectomy. For men, surgery was performed on bladder, prostate, and seminal vesicle. For women, operation was carried out on the bladder, uterus, and bilateral ovaries. In the laparoscopic group, an incision of about 6–8 cm was made in the middle of lower abdomen for urinary diversion. In the open group, urinary diversion was performed after lymph dissection and radical cystectomy. The surgical approach adopted for OMUUD was previously described.<sup>[15]</sup>

# Follow-up

All patients were followed up every six months in the first three years and annually thereafter. Follow-up was done through outpatient reexamination and telephone conversations. The most recent follow-up was done on 28th February 2021. At each follow up, we recorded perioperative clinical information, incidence

of complications within 30 days and between 30 to 90 days after surgery, postoperative urine control (satisfactory urine control was defined as a patient requiring less than or equal to 1 pad), postoperative overall survival and progression-free survival.

# Statistical analysis

All data were analyzed using SPSS22.0 statistical software, and GraphPad Prism 8 was used to draw the survival curve for survival analysis. Enumeration data were expressed as percentage. A Chi-square test (X2) was used to compare the enumeration data, whereas an iron sum test was used to compare nonnormal distribution data. Measurement data that were normally distributed were expressed as mean ± standard deviation, whereas non-normal measurement data were combined with the median quant M (P25, P75). The independent sample t test was used to compare differences between groups when the variance was homogeneous, and the Mann-Whitney U test was used when the variance was not homogeneous. The Kaplan-Meier survival analysis was used to analyze overall survival rate and tumor progression-free survival, and the survival curves were compared using the Log-rank test. P < 0.05 was considered statistically significant.

# Results

Initial analysis revealed no significant differences in age, gender, body mass index (BMI), score of American Society of Anesthesiologists (ASA), history of TURBT, and basic clinical information between the two groups (P > 0.05) (Table 1). Similarly, no significant difference was found in PT staging, PN staging, number of dissected lymph nodes, pathological grade, positive rate of surgical margin, and postoperative pathology between the two groups (P > 0.05) (Table 2). The mean operation time in the ORC + OMUUD group was shorter than in LRC + OMUUD group [331.95  $\pm$  63.94 min vs 472.12  $\pm$  103.72 min, P < 0.001], whereas the estimated intraoperative blood loss [600 (400–1000) ml vs 400 (300–600) ml, P < 0.001] and the postoperative hospital stay [22.20  $\pm$  7.08 days vs 19.33  $\pm$  7.98days, P < 0.05] were better in the LRC + OMUUD group than in the ORC + OMUUD group (Table 2).

Baseline characteristics of patients who received ORC + OMUUD or LRC + OMUUD					
ltems	ORC + OMUUD(n = 56)	LRC + OMUUD(n = 118)	P value		
Age/years	61.00 ± 11.59	61.11 ± 9.57	0.947 <sup>a</sup>		
Gender,n(%)			0.992 <sup>b</sup>		
Male	46(82.14)	97(82.20)			
Female	10(17.86)	21(17.80)			
BMI(kg/m <sup>2</sup> )	22.94 ± 2.76	22.83 ± 3.29	0.841 <sup>a</sup>		
ASA score,n(%)			0.130 <sup>b</sup>		
1-11	41(73.21)	98(83.05)			
111	15(26.79)	20(16.95)			
Previous TURBT, n (%)			0.171 <sup>b</sup>		
Yes	27(48.21)	44(37.29)			
No	29(51.79)	74(62.71)			
<sup>a</sup> Independent sample t test					
<sup>b</sup> Pearson's χ2 test (or continuous correction χ2 test)					

ltems	ORC + OMUUD(n = 56)	LRC + OMUUD(n = 118)	P value
PT stage,n(%)			0.053 <sup>b</sup>
Ta/T1	5(8.93)	32(27.12)	
Τ2	31(55.35)	52(44.07)	
Т3	15(26.79)	24(20.34)	
Τ4	5(8.93)	10(8.47)	
PN stage,n(%)			0.916 <sup>b</sup>
Negative	55(98.21)	114(96.61)	
Positive	1(1.78)	4(3.39)	
Lymph node yield	8.48 ± 2.92	9.25±5.11	0.300 <sup>a</sup>
Pathological gread,n(%)			0.523 <sup>b</sup>
Low grade	14(25.00)	35(29.66)	
High grade	42(75.00)	83(70.34)	
Surgical margin,n(%)			0.916 <sup>b</sup>
Negative	55(98.21)	114(96.61)	
Positive	1(1.79)	4(3.39)	
Time of operation	331.95 ± 63.94	472.12 ± 103.72	0.000 <sup>b</sup>
Estimated blood loss	600(400-1000)	400(300-600)	0.000 <sup>c</sup>
Postoperative length of stay	22.20 ± 7.08	19.33 ± 7.98	0.023 <sup>b</sup>
<sup>a</sup> Pearson's χ2 test (or continu	ous correction $\chi 2$ test)		
<sup>b</sup> Independent sample t test			
<sup>c</sup> Mann-Whitney U test			

Table 2 The perioperative and pathological characteristics of patients who received ORC + OMUUD or LRC + OMUUD

Analysis of complications based on the Clavien-Dindo complication grading system showed that the incidence of postoperative complications in at 30 days (23.21% vs. 26.27%, P = 0.665) and 90 days (25% vs. 16.95%, P = 0.211) (Table 3) after operation was comparable between ORC + OMUUD and LRC +

OMUUD groups. The rate of complete urine control was 89.28% (50/56) in the ORC + OMUUD group and 90.68% (107/118) in the LRC + OMUUD group.

Table 3

Items	ORC + OMUUD	LRC+OMUUD	P value
	(n = 56)	(n = 118)	
30-day complication rate,n(%)			
Clavien I	8(14.29)	21(17.80)	
Clavien II	4(7.14)	7(5.93)	
Clavien III	1(1.79)	1(0.85)	
Clavien IV	0	2(1.69)	
Clavien V	0	0	
Overall complication rate, n (%)	13(23.21)	31(26.27)	P=0.665 <sup>a</sup>
90-day complication rate,n(%)			
Clavien I	7(12.50)	13(11.02)	
Clavien II	3(5.36)	4(3.39)	
Clavien III	4(7.14)	2(1.69)	
Clavien IV	0	1(0.85)	
Clavien V	0	0	
Overall complication rate, n (%)	14(25.00)	20(16.95)	P=0.211 <sup>a</sup>
Ureteric implantation site stricture, n (%)	3(5.36)	8(6.78)	P = 0.979 <sup>a</sup>

The median follow-up time in this study was 30.5 months (IQR 18-62.25 months). The 1-year, 3-year, and 5-year overall survival rates (Fig. 1) were not significantly different between ORC group and LRC group (78.6% vs. 83.8%, 53.5% vs. 66.9%, 49.5% vs. 59.9%, log-rank test  $\chi^2$  = 1.400, P = 0.237). Similar observations were made for the 1-year, 3-year and 5-year progression-free survival rates (Fig. 2) (82.9% vs 84.8%, 60.9% vs 74.7%, 55.7% vs 69.4%, respectively). In addition, results of the Kaplan-Meier curve analysis revealed no survival difference between ORC and LRC groups (log-rank test x2 = 1.428, P = 0.307).

# Discussion

Currently, radical total cystectomy is the main treatment for muscular-invasive bladder cancer and highrisk non-musculo-invasive bladder cancer. In recent years, laparoscopic radical surgery has been widely to treat bladder cancer because it is minimally invasive technology due to application of Da Vinci robot.Wu *et al.* <sup>[16]</sup> reported that laparoscopic radical bladder cancer surgery has less blood loss and short postoperative hospital stay compared with open radical bladder cancer surgery, but there was no difference in lymph node dissection.Moreover, laparoscopy provides a clear operation field, large operation space, and can therefore identify pelvic anatomical structures, hence reduce the risk of damaging blood vessels, nerves, and urethral sphincter during operation.<sup>[17]</sup> Given that it causes less trauma and bleeding, it results in faster recovery after operation.

In this study, the comparison of perioperative data between the two groups showed that the laparoscopic group showed advantages in less intraoperative blood loss and shorter postoperative hospital stay, which indicates that laparoscopy causes less trauma and results in quick recovery. The results showed that operation time in the laparoscopic group was longer than in the open group. This may be attributed to the lack of mastery of laparoscopy technique in the treatment of bladder cancer. However, the recently developed surgical instruments such as ultrasonic knife and energy platform have shortened the operation time during laparoscopic radical treatment of bladder cancer.

After radical resection of bladder cancer, there are many options for reconstructing the urinary tract. The most common is the orthotopic neobladder surgery. In our center, sigmoid rectobladder surgery is the preferred option for urinary tract reconstruction. Fisch *et al.* <sup>[18]</sup> proposed a modified controlled urinary flow diversion based on ureteral sigmoid anastomosis in 1993, i.e., sigmoid rectocystectomy (Mainz®). The procedure meets the requirements of low-pressure controllable bladder volume, low pressure, antireflux, and controlled urination by leveraging on ureteral sigmoid anastomosis. It, therefore, overcomes major complications caused by the lack of anti-reflux effect of ureteral anastomosis and the high pressure caused by intestinal contraction. <sup>[19]</sup> Compared to other controllable neobladder procedures, Mainz® is relatively simple to perform, takes shorter operation time, cause less trauma, and does not lead to complications such as urinary incontinence and intestinal leakage. <sup>[20]</sup> In this study, no significant differences were found between the two groups in the incidence of complications at 30 days (P = 0.665) and at 90 days after surgery (P = 0.211). Collectively, these results prove the safety and efficacy of laparoscopy for radical resection of prostatic cancer plus sigmoid rectocystectomy.

Despite the important findings presented, this study also had some limitations. First, this is a retrospective study conducted in a single center, with a small sample size. Second, although there was no significant difference in baseline data between groups, there may be some selection bias which may affect the results. Therefore, future multi-center prospective randomized controlled studies with large sizes should be conducted to validate the present results.

## Conclusion

In conclusion, this study shows that patients undergoing LRC + OMUUD experience less intraoperative trauma and have better postoperative recovery compared to those receiving ORC + OMUUD. However, urine control rate and postoperative survival are comparable between the two groups. These findings demonstrate that LRC + OMUUD is safe and effective for the treatment of bladder cancer. However, this conclusion should be further validated in large clinical studies.

## Declarations

### Acknowledgements

None

### Author's Contribution

Bin Zhang, Data Collection, Data analysis, Manuscript writing

Yang He\*, Data Collection, Data analysis, Manuscript writing

Duo Zheng, Data Collection, Follow-up of all patients

Junyao Liu,Follow-up of all patients

Peng Qi, Follow-up of all patients

Dali Han, Follow-up of all patients

Zhongjin Yue, Performed OMUUD with ORC, also performed OMUUD with LRC

Panfeng Shang<sup>#</sup>, Project development, Performed OMUUD with ORC, also performed OMUUD with LRC

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### Competing interests:

All authors have no conflicts of interest or financial ties to disclose.

### Funding:

This work was supported by the key research and development (R&D) projects of Gansu Province (Grant No. 17YF1FA126). Special fund project for doctoral training program of Lanzhou University Second Hospital (Grant No.YJS-BD-14), Special fund project for doctoral training program of Lanzhou University Second Hospital (Grant No.YJS-BD-25),CuiYing Science and Technology Innovation plan project of Lanzhou University Second Hospital (Grant No. CY2017-BJ05)).

### Ethical information:

This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study received the Lanzhou University Second Hospital Ethical Committee approval(2017A-053).

### Availability of data and materials

Raw data may be requested from the authors with the permission of the institution.

### Competing interests:

All authors have no conflicts of interest or financial ties to disclose.

### Consent for publication

Not applicable

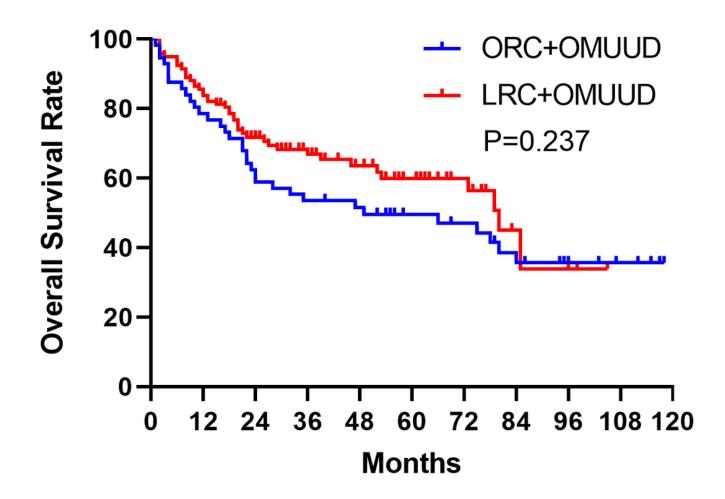
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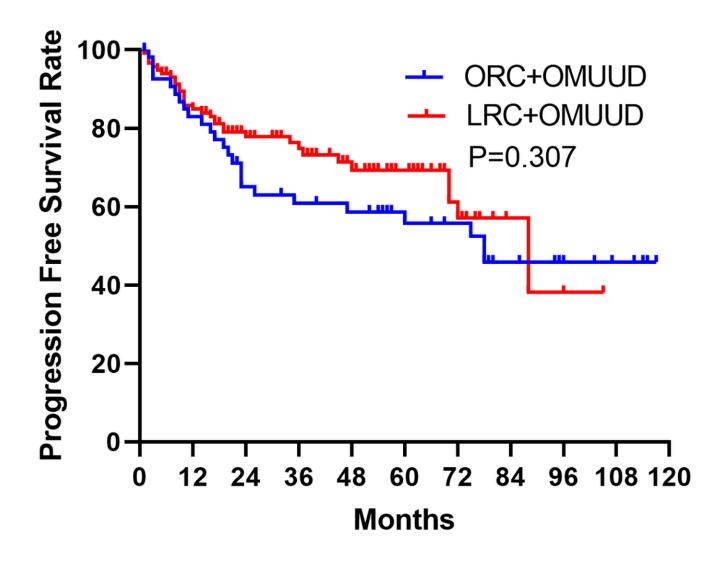
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### **Figures**



### Figure 1

Kaplan-Meier curves of overall survival probability in patients who received ORC+OMUUD and LRC+IMUUD



#### Figure 2

Kaplan-Meier curves of progression-free survival probability in patients who received ORC+OMUUD andLRC+ IMUUD