COMPARISON OF 30-DAY COMPLICATIONS BETWEEN ILEAL CONDUIT AND NEO BLADDER SURGICAL METHODS AFTER RADICAL CYSTECTOMY, A COHORT STUDY IN IRAN

Ehsan Nourbakhsh¹*

¹Medical Doctor, Faculty of medicine, Shahid Beheshti university of medical sciences, Tehran, Iran. Email: ehsannourbakhsh.md@gmail.com, Orcid: 0000-0003-0000-8240

Kimia Ahmadi²

²Medical Doctor, Faculty of medicine, Tehran University of medical sciences, Tehran, Iran. Email: <u>Kimia.ahmadi.md90@gmail.com</u> Orcid: 0000-0002-2402-7668

Abstract

Objective: This study aimed to evaluate and compare 30-day postoperative complications between the ileal conduit and neo bladder methods after radical cystectomy.

Methods: The data of 94 patients with bladder cancer, undergoing radical cystectomy withtwo surgical methods of ileal conduit (n=32) and neo bladder (n=62) by the same surgeon, were collected. Thirty-day postoperative complications were collected, and the severity of complications in these two different methods was evaluated and compared according to the Clavien-Dindo standard system.

Results: According to the results of the current study, the chance of major complications in patients undergoing IC surgery is 1.81 times higher than those receiving the NB intervention. Therefore, the NB surgical approach is associated with fewer major complications than IC (27.5% vs. 40.6%, p-value=0.0196). The incidence of urinary tract infections (UTI) was slightly higher in NB than IC (6.4% vs. 6.2% p-value = 0.053). Besides, IC had a higher incidence of wound complications at the superficial surgical site (12% vs. 7%, p-value = 0.0327). The incidence of ileus was higher in NB compared to the IC group (38% vs. 28%, p-value = 0.510).

Conclusion: According to the observations of this study, the incidence of 30-day postoperative major complications was lower in the NB surgical approach compared to IC. Also, the incidence of surgical site infection was higher in the IC method.

Keywords: Radical Cystectomy, Ileal Conduit, NeoBladder, Postoperative Complications.

1. INTRODUCTION

Bladder cancer is the 11th most common cancer in terms of incidence and 14th cancer leading to death worldwide [1,2, 3]. More than 12 million new cases of bladder cancer are diagnosed across the world each year, with approximately 145000 annual mortalities [4, 5]. Research has also shown that the global burden of bladder cancer will have an increasing trend in the future [6]. The gold standard of treatment for high-grade bladder cancer includes radical cystectomy (RC) surgery, extensive lymphadenectomy, and urinary diversion, among which ileal conduit and orthotopic neo bladder can be mentioned

[6-8]. The procedure used for urinary diversion depends on several factors, including the patients' clinical conditions and the patient and the surgeon's desire for a particular method to find an appropriate surgical procedure with the least disturbance in patients' quality of life regarding postoperative complications [8]. Neo bladder surgery has recently become a common technique for urinary diversion in radical cystectomy. Yet, the ileal conduit is considered a standard method for urinary diversion [9]. No studies have so far compared the early (30-day) complications after radical cystectomy [9, 10]. also so far as our knowledge, there are a few studies in this field

¹ Corresponding Author: Ehsan Nourbakhsh, Email: ehsannourbakhsh.md@gmail.com

which all patients had underwent surgery by one surgeon.

This study aimed to evaluate and compare 30-day complications of the IC and NB procedures after radical cystectomy by one surgeon and to evaluate the strengths and weaknesses of each method.

2. Materials and Methods

The medical records of 94 patients with muscle invasive bladder cancer were reviewed in this retrospective study from January 2016 to April 2019 after ethical baord approval to review the patients' records. All patients received radical cystectomy, pelvic lymphadenectomy, and urinary diversion in three medical centers of Labbafinezhad, Erfan Saadat Abad, and Ghiassi in Tehran, Iran. Neobladder and ileal conduit approaches were applied on 62 and 32 patients, respectively. Information on the patients' clinical characteristics and diseases, pre- and post-operative outcomes, complications within 30 days after surgery was collected to compare the two surgical techniques. The 30-day postoperative period is generally the standard for assessing early postoperative complications [11]. Then, the postoperative complications experienced by all patients in the IC and NB groups were classified into 5 grades and evaluated according to the Clavien-Dindo standard classification (Table 2). As shown in Table 2, grades 1 and 2 represented minor, and grades 3-5 reflected major surgical complications [10-121.

2.1. Statistical Methods

As shown in **Table 1**, study variables included age (continuous), sex (male, female), weight (continuous), body mass index (continuous), duration of disease (<1 year, 1-3 years, >3 years), type of invasive cancer and its stage, history of comorbidity (yes, no) and smoking (yes, no), pre- and post-operative hemoglobin (continuous), duration of surgery (continuous), length of postoperative hospitalization (continuous), duration of Foley catheter application (continuous), and the drain (continuous). Variables related postoperative complications were also listed in Table 2 according to the Clavien-Dindo standard classification system to compare the two groups. Table 3 shows the frequency of complications for the two study groups. SPSS 22 software was used to perform the calculations of all the collected data. Descriptive statistical tests including Chie square, Independent T-Test, and related nonparametric tests were used for analyses. Correlation tests were also used to evaluate quantitative variables. P-values <0.05 were considered significant.

3. Results

3.1. Patients' characteristics

Table 1 summarizes the patients' characteristics according to the type of urinary diversion performed. Males made up 83% and 81% of patients in the NB and IC groups, respectively (P-value <0.1). The body mass index of 31.3% of patients undergoing IC was in the range of overweight and obese, while only 24.2% of patients in the NB group were in this range (P-Value < 0.383). Overall, 28% and 22.5% of patients who suffered from their disease for more than three years underwent IC and NB, respectively (P-value<0.492). The mean duration of surgery was 191 minutes in the IC group and 232 minutes in the NB group (P-value <0.001). The mean length of hospitalization in the IC and NB groups was 6 and 7 days, respectively (P-value <0.03). The mean preoperative hemoglobin of patients was 12.2 in both IC and NB groups, reaching 9 and 9.3 ml in the IC and NB groups, respectively, after surgery (P-values <0.320 postoperative, respectively).

3.2. Postoperative Complications

Table 2 shows the most common 30-day postoperative complication in patients according to the Clavien-Dindo classification. At least one complication was observed in all patients in both groups. Therefore, there was no difference in the occurrence of overall complications in both groups. Grade 1 complications, including all complications that did not require therapeutic intervention, were observed in 12.5% of patients in the IC group (4/62), and 16.6% of patients in the NB group (10/62). Grade 2 complications, including complications that needed therapeutic interventions with drugs, were observed in 46.9% of patients in the IC group (15/32) and 53.1% of patients in the NB group (34/62). Overall, minor complications were more common in the NB procedure (72.5% vs. 59.4%, p-value= 0.0029).

In contrast, major complications (grades 3-5) were observed in 40.6% and 27.5% of patients in the IC and NB groups, respectively (p-value = 0.0196). Grade 3 complications, which required reoperation or any surgical or radiological interventions, were observed in 31% of patients in the IC group (10/32) and 22.5% of patients in the NB group (14/62). Grade 4 complications, which were lifethreatening complications, were observed in 2 patients in the IC group (6.25%) and 4 patients in the NB group (6.15%). There was only one death in the IC group due to cardiac arrest during postoperative hospitalization, regarded as grade 5. There were no deaths observed in the NB group.

3.3. Frequency of any Complication Related to Clavien -Dindo Classification:

Table 3 summarizes the complications with Clavien-Dindo associated each classification grade. In both groups, gastrointestinal complications such as ileus, infections, surgical wound-related complications, and anemia were the most recurrent complications [6, 10, 15, 16]. There were more wound infections requiring treatment in the patients of the IC group (25% vs. 16%, p-value=0.0430 respectively). The need for blood transfusion due to anemia was also higher in the patients undergoing IC surgery than those in the NB group (32% vs. p-value=0.0319). Hernia requiring 21% reoperation was observed in 6% of IC patients and only 1% of NB patients. As mentioned, unfortunately, there was one death in the IC group due to cardiac arrest.

In contrast, 38% and 28% of patients in the NB and IC groups experienced gastrointestinal complications such as ileus, respectively (p-value = 0.510). Urinary tract infection was reported in 6.4% of NB and 6.2% of IC patients (p-value = 0.053). One patient from the NB group suffered sepsis.

4. Discussion

Recently, Abe et al. studied and compared 90-day postoperative complications of the IC and NB approaches using the Clavien-Dindo classification system at the Memorial-Sloan Kettering Cancer Center. Using this

classification system in the cohort performed in the present study, there were no significant differences in the incidence of overall postoperative complications between the IC and NB groups compared to the study, as well as other studies [9, 11, 17]. It seems that the present study is the only research in which all patients underwent surgery by one surgeon who also performed all postoperative followups. Therefore, the likelihood of bias in examining and comparing the complications of the two approaches minimizes, while it is also possible to obtain more reliable results. In the present study, the NB surgical method showed fewer major complications (grades 3-5) in multivariate analyses (p-value = 0.0196). Unfortunately, there was one death during the 30-day study of postoperative complications in the IC group. There were no deaths recorded in the NB group. According to the results of logistic regression, the chance of major complications in patients undergoing IC surgery was 1.81 times higher than those receiving the NB intervention. Therefore, it seems that if proper preoperative care, good surgical conditions, and skilled surgeons are available, Neo bladder surgical approach leads to fewer comorbidities in comparison with ileal conduit.

According to the comparison of each complication in the two groups, patients undergoing IC surgery experienced a higher incidence of wound complications at the superficial surgical site (12% vs. 7%, p-value = 0.0327). Also, more complications of the major surgical site, which generally require treatment, were observed in the IC compared to the NB group (25% vs. 16% p-value = 0.0430) [10][18]. In general, the incidence of urinary tract infections (UTI) was slightly higher in the NB and IC approaches (6.4% vs. 6.2% p-value = 0.053), However, there was sufficient information available on the number of patients having pre-operative bacteriuria (Table 1) and prophylactic treatments were performed for patients in the first postoperative days to reduce the incidence of UTI in both groups. The incidence of ileus was higher in the NB compared to the IC group (38% vs. 28%, p-value = 0.510). The duration of surgery was longer in NB than the IC method (3.7 ± 0.8) hrs vs. 3.09 ± 0.7 hrs, P-value <00.1). The length of hospitalization was also slightly higher in NB than the IC group (7.0 ± 2.4 days vs. 6.1 ± 2.1 days, P-value= 0.030), which is obviously due to the longer duration of NB surgery compared to IC.

As previously mentioned, the incidence of major complications was lower in the NB approach (27.5% vs. 40.6%, p-value = 0.0196) in the present study. However, this group had a higher incidence of minor complications (72.5% vs. 59.0%), which is similar to the results obtained by Abe et al. [9] Also, the incidence of postoperative wound infection was higher in patients undergoing IC surgery compared to the NB method. Abe et al. and Erber et al. also reported similar results [9, 10]. The incidence of postoperative ileus was higher in NB than the IC approach. Erber et al. and Nieuwnhuijzen et al. also reported similar results. The incidence of ileus in patients of the NB group may be particularly due to the possibility of urine leakage from the unfilled Neobladder in the early postoperative hours According to the results of logistic regression, there was a significant relationship between the patients' BMI and the incidence of surgical site infection. According to these assessments, the chance of surgical site infections in patients with a BMI at the level of overweight is 1.99 times higher than those with a normal BMI (p-value = 0.006). Therefore, BMI can be an independent risk factor for surgical wound infections [19-22].

This cohort study had several limitations. First, it could not report some minor postoperative complications due to limitations in reviewing the patients' records in retrospective studies, along with the lack of access to complications in all patients. Also, this study did not investigate various factors such as the type of NB surgery and the anastomosis technique that affect the postoperative recovery process and the severity of complications because of insufficient information. Future studies can explore these issues. However, this study reflects the incidence of 30-day postoperative complications and the recovery process in patients with bladder cancer in Iran.

5. Conclusion

According to the results of this study on 94 patients with bladder cancer in three medical centers, there was no significant difference between the IC and NB approaches regarding the overall postoperative complications after radical cystectomy. Moreover, the NB surgical approach had fewer major complications than IC.

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Conflict of interest Financial support Ethics statement.

REFERENCE

- [1] Almehmadi M, Alzahrani K, Salih MM, Alsharif A, Alsiwiehri N, Shafie A, Almalki AA, Dahlawi H, Al-hazmi A, Alkhalidi A, Al-ghoraibi N. Assessment of thyroid gland function by evaluating of TSH, FT3 and FT4 hormones in untreated cancer patients. J Adv Pharm Edu Res. 2020;10(4):37-42.
- [2] Alhashmi M, Alshaikhi R. Hepatotoxicity in Cancer Patients Receiving Anthracyclin at KAUH: A Retrospective Study. Int. J. Pharm. Phytopharmacol. Res. 2020;10(2):82-7
 [3] Chavan S, Bray F, Lortet-Tieulent J,
- Goodman M, Jemal A. International variations in bladder cancer incidence and mortality. Eur Urol. 2014;66. https://doi.org/10.1016/j.eururo.2013.10.0 01.
- [4] Ploeg M, Aben KKH, Kiemeney LA. The present and future burden of urinary bladder cancer in the world. World J Urol. 2009;27. https://doi.org/10.1007/s00345-009-0383-3.
- [5] Ferlay J, Bray F, Pisani P et al. Cancer Incidence, Mortality and Prevalence Worldwide. GLOBOCAN 2002.
- [6] Shabsigh A, Korets R, Vora KC, Brooks CM, Cronin AM, Savage C, et al. Defining Early Morbidity of Radical Cystectomy for Patients with Bladder Cancer Using a Standardized Reporting

Methodology. Eur Urol. 2009;55. https://doi.org/10.1016/j.eururo.2008.07.0 31.

[7] Kim SH, Yu A, Jung JH, Lee YJ, Lee ES. Incidence and risk factors of 30-day early and 90-day late morbidity and mortality of radical cystectomy during a 13-year follow-up: A comparative propensity-score matched analysis of complications between neobladder and ileal Conduit. Jpn J Clin Oncol. 2014;44. https://doi.org/10.1093/jjco/hyu051.

[8]Lawrentschuk, Nathan and DSC. No Title. Urol. Ann. 2015;7:1–7. https://doi.org/10.4103/0974-7796.148553.

[9] Abe T, Takada N, Shinohara N, Matsumoto R, Murai S, Sazawa A, et al. Comparison of 90-day complications between ileal conduit and neobladder reconstruction after radical cystectomy: A retrospective multi-institutional study in Japan. Int J Urol. 2014;21. https://doi.org/10.1111/iju.12357.

[10] Erber B, Schrader M, Miller K, Schostak M, Baumunk D, Lingnau A, et al. Morbidity and Quality of Life in Bladder Cancer Patients following Cystectomy and Urinary Diversion: A Single-Institution Comparison of Ileal Conduit versus Orthotopic Neobladder. ISRN Urol. 2012;2012.

https://doi.org/10.5402/2012/342796.

[11] Sogni F, Brausi M, Frea B, Martinengo C, Faggiano F, Tizzani A, et al. Morbidity and Quality of Life in Elderly Patients Receiving Ileal Conduit or Orthotopic Neobladder After Radical Cystectomy for Invasive Bladder Cancer. Urology. 2008;71. https://doi.org/10.1016/j.urology.2007.11. 125.

[12] Stimson CJ, Chang SS, Barocas DA, Humphrey JE, Patel SG, Clark PE, et al. Early and late perioperative outcomes following radical cystectomy: 90-day readmissions, morbidity and mortality in a contemporary series. J Urol. 2010;184. https://doi.org/10.1016/j.juro.2010.06.007

[13] Khalil E-SA. Long term complications following ileal conduit

urinary diversion after radical cystectomy. J Egypt Natl Canc Inst. 2010;22.

[14] Atduev V, Ledyaev D, Gasrataliev V, Lyubarskaya Y, Amoev Z, Shevelev I. Predictors for development 30-day complications after radical cystectomy (RC). Eur Urol Suppl. 2018;17. https://doi.org/10.1016/s1569-9056(18)33831-4.

[15] Fearon KCH, Ljungqvist O, Von Meyenfeldt M, Revhaug A, Dejong CHC, Lassen K, et al. Enhanced recovery after surgery: A consensus review of clinical care for patients undergoing colonic resection. Clin Nutr. 2005;24. https://doi.org/10.1016/j.clnu.2005.02.002

16] Svatek RS, Fisher MB, Matin SF, Kamat AM, Grossman HB, Nogueras-González GM, et al. Risk Factor Analysis in a Contemporary Cystectomy Cohort Using Standardized Reporting Methodology and Adverse Event Criteria. J Urol. 2010;183. https://doi.org/10.1016/j.juro.2009.11.038

[17] Parekh DJ, Gilbert WB, Koch MO, Smith JA. Continent urinary reconstruction versus ileal conduit: A contemporary single-institution comparison of perioperative morbidity and mortality. Urology. 2000;55. https://doi.org/10.1016/S0090-4295(99)00619-6.

[18] Nieuwenhuijzen JA, de Vries RR, Bex A, van der Poel HG, Meinhardt W, Antonini N, et al. Urinary Diversions after Cystectomy: The Association of Clinical Factors, Complications and Functional Results of Four Different Diversions. Eur Urol. 2008;53. https://doi.org/10.1016/j.eururo.2007.09.0 08.

[19] Gendall KA, Raniga S, Kennedy R, Frizelle FA. The impact of obesity on outcome after major colorectal surgery. Dis Colon Rectum. 2007;50. https://doi.org/10.1007/s10350-007-9051-0.

[20] Smith RL, Bohl JK, McElearney ST, Friel CM, Barclay MM, Sawyer RG, et al. Wound Infection after Elective Colorectal Resection. Ann Surg. 2004;239. https://doi.org/10.1097/01.sla.000012429 2.21605.99.

[21] Benoist S, Panis Y, Alves A, Valleur P. Impact of obesity on surgical outcomes

after colorectal resection. Am J Surg. 2000;179. https://doi.org/10.1016/S0002-9610(00)00337-8.

[22] Dindo D, Muller MK, Weber M, Clavien PA. Obesity in general elective surgery. Lancet. 2003;361. https://doi.org/10.1016/S0140-6736(03)13640-9