ADDIS ABABA UNIVERSITY

COLLAGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE DEPARTMENT OF SURGERY

THIRTY DAYS POSTOPERATIVE OUTCOME OF RADICAL CYSTECTOMY AND ASSOCIATED FACTORS AT TASH, ETHIOPIA

Investigator: Anmut Woretaw(MD, Urology fellow)

Advisors: Seyefe Bekele (MD, Assistant professor of Urology)

Admasu Melaku (MD, Assistant professor of Urology)

July, 2025

ADDIS ABABA, ETHIOPIA

PI	Anmut Woretaw(MD, Urology fellow)
Advisors	Seyefe Bekele (MD, Assistant professor of Urology) Admasu Melaku(MD, Assistant professor of Urology)
TITLE	**THIRTY DAYS POSOPERATIVE OUTCOME AFTER RADICAL CYSTECTOMY AND ASSOCIATED FACTORS** AT TASH, ETHIOPIA.
Study area	Addis Ababa, Ethiopia
Study period	April 2025-June 2025
Total cost	60,753 Birr
PI Address	Email: aworetaw0@gmail.com Phone number: 0911126182
Advisors	Dr.Admasu Melaku and Dr.Seyefe Bekele

ACKNOWLEDGMENTS

My appreciation goes to Addis Ababa University for giving me the chance to conduct this study. I thank the administrators of TASH for their permission to conduct project in the hospital.

I would like to express my deepest gratitude to my advisors; Dr Seyefe Bekele and Dr. Admasu Melaku who helped me in all aspect of development of the research paper to its final form including topic selection and research proposal development.

I am profoundly grateful to Dr.Hailemariam Shiferaw (HPB surgeon) and Dr.Mequanint Tariku(Fetomaternal subspecialist) for their consultancy and help.

I am also deeply grateful to data collectors, especially sister Tsigereda Mulugeta whose help was instrumental.

Finally my sincere thanks go to those who participate in the management of studied patients.

ABBREVIATIONS /ACRONYMS

BCG	bacille Calmette-Guerin
BMI	body mass index
CDC	Clavien Dindo classification
EBL	estimated blood loss
ECOG	Eastern Cooperative Oncology Group
FNAC	fine needle aspiration
GA	general anesthesia
GFR	glomerular filtration rate
Hct	hematocrit
LN	lymph node
LUTS	lower urinary tract symptoms
MIBC	muscle invasive bladder cancer
MOH	Ministry Of Health
MR	mortality rate
POD	post-operative day
SSI	surgical site infection
TASH	Tikur Anibesa Hospital
TMT	tri-modal therapy

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGUERS

ABSTRACT

Background: radical cystectomy is one of the complex and technically demanding urologic surgeries. It is done usually for non-metastatic muscle invasive bladder cancer. Globally the morbidity and mortality rate is significantly high, even the advancement of operative techniques doesn't change the outcome significantly. And, the outcome of RC is not well studied in Ethiopia including in the study area.

Objectives: The objective of this study was to assess the thirty days postoperative outcome of open radical cystectomy and associated factors among patients who were operated at Tikur Anbesa Specialized Hospital.

Method: Institution based cross sectional retrospective study was conducted on consequently selected patients who were operated in Tikur Anbesa Specialized Hospital from September 2020 to May 2025. Data was collected using Kobotoolbox from the patients' medical records. Then exported to Excel and exported to SPSS version 25 after cleaned. Subsequently descriptive analysis and binary logistic regression was done. Association between independent and outcome variables studied using multivariable logistic regression. Variable with p –value <0.05 was used to declare the level of significance.

Result: A total of 35 cases were analyzed the average age was 55.54 years. Male sex accounts for 74.3%. ONB was done in 25.7% whereas the rest was IC. 45.7% of the operated patients were with smooth post-operative course others developed minor and major complications. Pre and post-operative biopsy showed 32 cases were urothelial cancer whereas 3 cases were non-urothelial cancer.in 22 cases post-operative biopsy was found and marginal status define. Of these 22 cases 68.2% was margin positive. There were about 4 deaths early post operatively due to surgical causes.

Multivariable regression analysis showed serum albumin level <3g/dl was associated with post-operative complication with p-value of 0.019 and adjusted odds ratio of 14.54.

Conclusion: The 30 day mortality and morbidity rate were 11.4% and 54.3% respectively. Serum albumin <3g/dl was associated with post-operative complication.

Keywords: RC, post-operative outcome, serum albumin level

1. INTRODUCTION

1.1. Background

Radical cystectomy is one of the most technically demanding and invasive surgical procedure in urology [1]. RC describes removal of the bladder, adjacent organs, and regional LNs. In males, it involves surgical removal of bladder, seminal vesicles and prostate. Whereas in females it is just anterior pelvic exenteration [2]. Historically, the first open cystectomy was performed by Bernhard Bardenheuer in January, 1887 in Koln, Germany. In 1949, Marshall and Whitmore gave the first detailed description of radical cystectomy. Progressively, the technique was improved and made safer. In 1993, Sanchez de Badajoz reported the first laparoscopic radical cystectomy [3]. Radical cystectomy with pelvic LN dissection is done for non-metastatic MIBC and high risk non muscle invasive bladder tumors like BCG resistant and high grade tumors which are not responsive for less invasive treatment modalities [4].

The surgery involves both gastrointestinal and urinary systems during reconstructive phase of radical cystectomy. So, radical cystectomy has high morbidity and mortality. The reported perioperative morbidity and mortality is 19-99% [1]. The 30 day mortality rate is 2.1% whereas 90 day mortality rate is around 4.7%[4]. The preoperative factors including age, gender, comorbidities, preoperative hemoglobin, creatinine, and albumin level while the intraoperative blood loss, operative time, type of urinary diversion, and need of additional procedures along with the histopathological stage were studied as a part of intraoperative and postoperative variables as a whole determine surgical outcome [5].

1.2. Statement of the problem

The 30 days mortality rate after RC was 5.1% as stated in paper published in India in 2021.there was 10 deaths in the first 30 days among 195 patients under went RC. And 350 complications in 96 (49.3%)patients occurred. of these 46 patients(23.5%) developed major complications as classified with CDC [5]. Whereas in retrospective study done by Sophia Liff Maibom and colleagues and published in 2021 30 day MR was found to be 2.1% [4]. And a single centered retrospective study done from 2017-2022 in Croatia, South Eastern Europe 30 day MR was found to be 0.9% .There were 2 deaths among 215 patients and 55patient (25.6%) developed early complications [6]. Whereas study done in Egypt in 2013,of 31 patients who underwent RC two of them dead with in the first 30 postop days [7]. With time, surgical technique and perioperative optimization increased but RC doesn't show parallel improvement in surgical outcome [8].

Radical cystectomy (RC) and urinary diversion are the gold standard treatments for muscle-invasive urinary bladder cancer, as well as for some non-muscle invasive disease [3].

RC may be associated with significantly improved overall survival and cancer specific survival as opposed to those who received TMT. In addition, it was shown that patients who received TMT exhibited a higher risk of all-cause mortality when compared with those who underwent RC [9].

In this study; important socio demographic variables, preoperative and postoperative determinants will be included using cross sectional study design. In spite of searching effort, there is no information in the study area. Therefore, the aim of the study is to assess the thirty days postoperative outcome and associated variables of RC in TASH, Ethiopia where there is no prior accessible study in this area.

1.3. Significance of the study

Surgeons, Urologic surgeons in particular may use the result of this study as a reference to their work measure and improve outcome. Oncologists, anesthesiologist and pathologists may use the result for improving the care for these patients. Policy makers, health system administrators and primary health care workers can use the result as an input to give an attention for the diagnosis of bladder tumor and proved their patients need intervention from Urologists. The study may be the reference for subsequent studies.

2. LITERATURE REVIEW

Retrospective analysis of 195 patients who underwent RC in India and published in 2021 showed 30 day mortality rate was 5.1% [10].In other retrospective study done in California,USA on 2047 patients for whom RC was done from 2003-2019,the 30 day mortality rate was 1.3% [11]. and study done by Sophia Liff Moibom and published in 2021, 30 day mortality rate was 2.1%[4].Early post op death reported was 0.9% from sample size 215 in study done in Croatia ,Southeast Europe [6]. Retrospective study done on 2778 patients who underwent RC from 2000-2009 in 48 hospitals in Canada, early mortality rate was reported to be 2.8% [12]. whereas retrospective study done in Egypt on 31 patients who underwent radical cystectomy, there was 2 deaths within 30 days of the operation(6.5%) [7].

RC is associated with high risk of complications. particularly, RC candidates tend to be aged and have multiple comorbidities [1].Retrospective analysis done by Naci Burak Cinar and colleagues ,out of 211 patients who underwent open RC 467 complications were occurred within 30 days. Of these 33 patients(15.6%) faced sever complication which demands reoperation with GA. 20 patients(9.4%) re-operated due to postop ileus and 35 patients readmitted within 30 days [1]. In another study done in Zagreb University, of 215 patients operated with open RC 55 patients (25.6%) developed early postop complications. Of these 42.3% was urinary complication, 21.2% was wound related, 18.5% was intestinal complications and the rest were; stoma, cardiopulmonary vascular and neurogenic [6].

In another retrospective study done in India on 195 patients for whom open RC was done; 350 complications in 96 patients (49.3%) developed. Of these 46 patients (23.5%) developed major complications which are CDC>III. Fascial dehiscence accounts 13.3 % and ureteroileal leak accounts for 2.6%. One patient re-operated for fecal fistula who sustains rectal injury during the initial surgery. Another patient was also re-operated for removal of packs which were put during the initial surgery as a result of intraoperative bleeding during the first surgery [10].

Another Indian retrospective study done over 2006-2011 on 70 patients who underwent open RC; wound site infection, pyelonephritis, acidosis, urine leak, wound dehiscence, fecal leak and bowel obstruction occurred in 14,12,8,3,3,2 and 2 patients respectively [13].

Study done by Mahish Kalloli, the mean age at diagnosis was 58.6 years and most of the patients were in the age group of 50-70 year [13]. In another study on RC; there is no significant difference between patients aged >75 years and younger patients for preoperative comorbidity, perioperative complications, blood transfusion rates, and postoperative mortality. Age should not be an absolute contraindication to RC in elderly patients [14]. Among those patients with muscle invasion, those age 75 years and older were less likely to undergo radical cystectomy (14%) compared with patients ages 55– 64 years (48%) and those ages 65–74 years (43%). Patient age may contribute to treatment decisions in patients with muscle-invasive disease, even when comorbidity is taken into account [15].

In retrospective study done on 70 patients who underwent RC,9 of them were female and 61 were male [13].there was no cancer related outcome difference after RC b/n male and female after controlling other factors [16].

Study done on 212 patients, the mean BMI was 25.1% and BMI >25% was associated with increased morbidity and mortality [17].

Subjects with low preoperative serum albumin had a significantly higher complication rate than those with normal albumin levels. Neurologic and wound complications occurred with significantly greater frequency among patients with low albumin levels. Rates for other major complications, including cardiac, gastrointestinal, genitourinary, infectious, bleeding, pulmonary, and thromboembolic, were similar for the two groups [14]. Perioperative albumin level <3.5mg/dl is associated with increased morbidity and mortality [7].in another study done on 1097 patients who underwent RC mortality and morbidity was found to be high for albumin level <4mg/dl and specially when level drops<3mg/dl death rate will be raised markedly [14].

In retrospective study done on 251 patients for whom RC was done, EBL was 1100ml [1].

In another prospective study which was done from 2008-2011 on 80 patients who underwent RC mean blood loss was analyzed in two groups. On 40 patients stapling device was used whereas, in another half of patients electrosurgical unit and suture ligation was used, then EBL in each group was compared. In stapling group EBL was 708ml whereas in electrosurgical group it was 687ml, so there was no significant difference in EBL b/n the groups [18].

In previous study done on 251 patients mean operative time was 420 minutes(7hrs) [1]. In another study mean operative time was 375minutes [19].

Retrospective study done in Netherland states hospital volume beyond 30 RC annually could decrease postoperative mortality [20].

high volume centers showing a reduction in mortality by as much as 37% at 30 days [21].

Resent study done in Netherland showed rate of positive surgical margin after RC for MIBC was 9.3%.[22] In another study done in China, potential risk factors for positive surgical margin were advanced cancer, mixed histology, surgeon dependent factors and availability of intraoperative frozen section biopsy.[23]

Conceptual framework

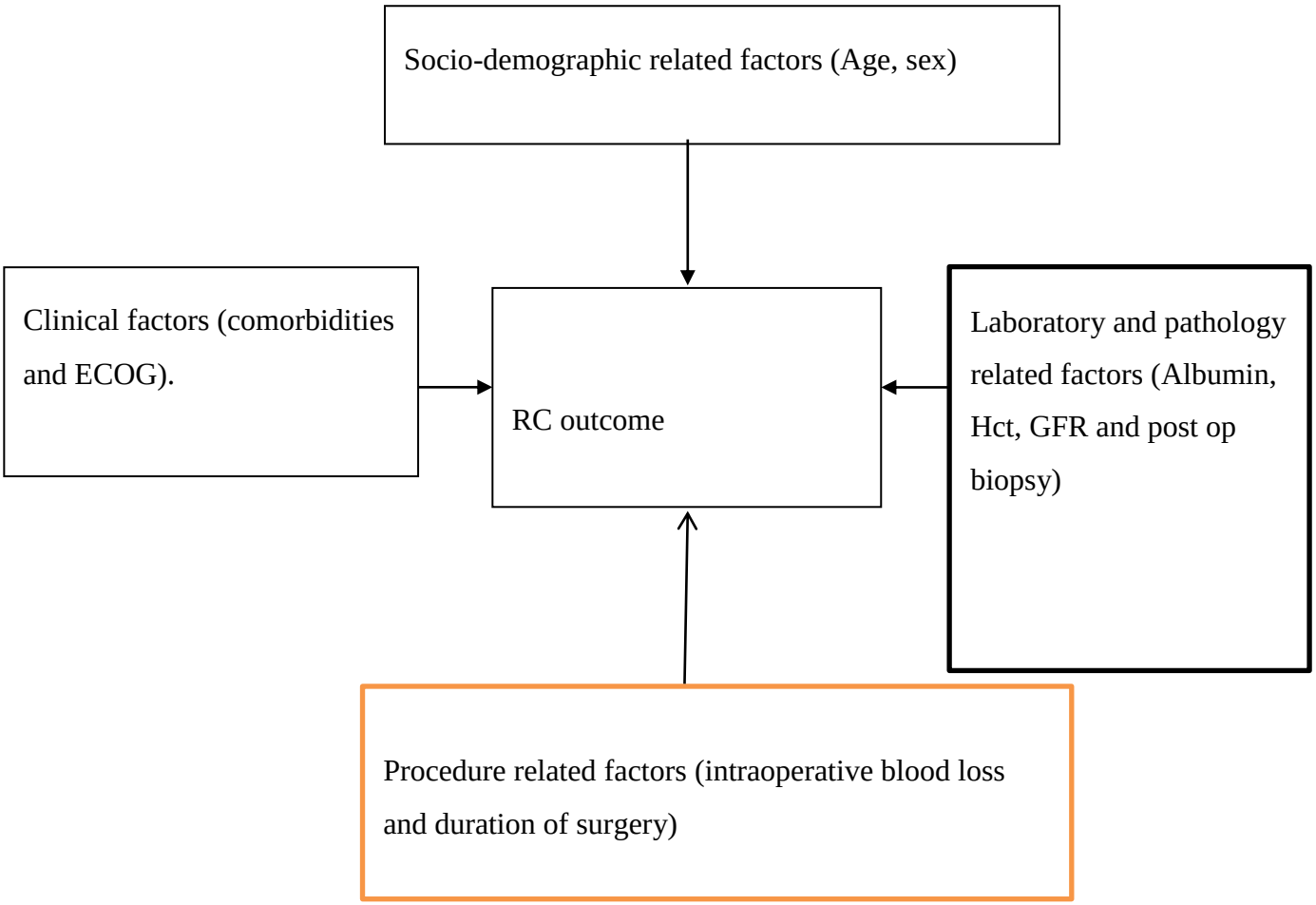

Figure 1: Conceptual framework adapted from literature

3. OBJECTIVE

3.1. General objective

- To assess the thirty days postoperative outcome of radical cystectomy and associated factors among patients who were operated at TASH, Addis Ababa Ethiopia.

3.2. Specific objective

- To know thirty days postoperative outcome of RC in the study period.
- To assess variables associated with RC outcomes

4. METHODS AND MATERIALS

4.1. Study area

The study was conducted in TASH which is located in Addis Ababa, the capital city of Ethiopia, serving as national referral hospital. It is the country's biggest tertiary hospital with around 700 hospital bed capacity. It has a Urology unit under which RC procedure was done. The hospital has oncology, pathology, endoscopic, diagnostic services.

4. 2. Study period

- The study was conducted from May-July 2025.

4.3. Study design

- Institution based cross sectional retrospective study was done.

4.4. Source population

- All patients for whom RC was done at TASH.

4.5. Study population

- All patients for whom RC was done at TASH and whose medical documents found.

4.6. Study variables

4.6.1. Dependent variables

- Treatment out come

3.6.2. Independent variables

- Socio-demographic related factors (Age, sex)
- Clinical factors (comorbidities)
- Laboratory imaging and pathology related factors (albumin, HCT, GFR, preoperative imaging, histologic type)
- Procedure related factors (EBL, duration of procedure time and procedure type)

4.7. Sample size and sampling technique

4.7.1 Sample size

The assumptions of single population formula was used for sample size calculation at 95% confidence interval (two sided), 5% margin of error. Since there was no study done in Ethiopia with related topic, proportion of 50% was considered. So sample size was calculated as follows:-

$$n_o = \frac{(Z\alpha/2)^2 p\,(1-p)}{d^2}$$

$$n_o = \frac{(1.96)^2 0.5\,(1-0.5)}{0.05^2} = 384(aproximated)$$

Where: n_o is the maximum possible sample size

$Z_{\alpha/2}$ is standard score value for 95 % confidence level for two sides normal distribution

p = is the proportion of population (The magnitude of thirty day postoperative mortality and morbidity of RC. p = 0.5)

d = is margin of error tolerated

Za/2 = the standard and normal variable at (1-a) % with 95% (1.96) confidence level

Patient data base in TASH showed that there were about 44 RC done over the past years of these for only 35 cases relatively good documentation was found. As the source population is less than the calculated sample size, all cases with good data documentation was taken without using correction formula.

4.7.2. Sampling technique /procedure

- Consecutive enumerative sampling of all patients for whom radical cystectomy was done.

4.8. Inclusion and exclusion criteria

4.8.1. Inclusion criteria

- All patients for whom radical cystectomy was done and whose medical record was found.

4.8.2. Exclusion criteria

- Patients with incomplete clinical data were excluded from the study.

4.9. Data collection procedure

Data was collected by one general practitioner and one nurse. All important socio demographic data, laboratory values, pathologic and other necessary variables were revised and filled from hard and soft copy of patients' medical records.

4.10. Quality control

Pretest was conducted at TASH, in 5% of the sample to check the completeness and consistency of the questionnaire. The data was collected by trained general practitioner and a nurse using a structure and pre tested questionnaire in close supervision by the PI. The filled data was checked by investigator for completeness and consistency visually.

4.11. Data analysis

Data cleaning was done. Accuracy, consistency and missing values and variables were checked. Data collected using Kobo toolbox then exported to Excel. After cleaned it was exported to SPSS version 25 for analysis. Descriptive statistics in terms of frequency tables and percentages was done. Binary logistic regression analysis was conducted and association between independent and outcome variables assessed. Variables with P-value of $\leq$ 0.2 were considered for multivariable logistic regression analysis. The degree of association between the dependent and independent variables assessed by adjusted Odds ratio along with 95% CI. Level of statistical significance declared at P-value less than 0.05.

4.12. Data dissemination

- The result of the study will be disseminated to concerned bodies of Addis Ababa University, TASH, MOH and other concerned bodies. Hard copy will be left will be given to the university library periodical. It can be presented no seminars and national research conferences, published in local or international journal.

4.13. Operational definition

- Thirty days morbidity/mortality = defined as complication/death within 30 days after surgery.
- Clavien Dindo classification=it is a classification used to rank severity of postoperative complications.
- Minor complications defined as Clavien – Dindo class 2 and 3a complications.
- Major complications defined as Clavien – Dindo class 3b or 4 complications

4.14. Ethical considerations

Ethical clearance was obtained from research ethics committee of college of health sciences, Addis Ababa University. Then formal letter of cooperation was obtained from the department of surgery. The obtained data was used only for study purpose and its anonymity and confidentiality were ensured.

5. RESULTS

5.1. Socio-demographic characteristics of study participants

Thirty five radical cystectomy cases were analyzed. Age ranged from 25-78 years with mean age of 55.54 years. Only 3 patients were having comorbidities. (See table 1)

Table 1: Socio demographic characteristics

Variable	Category	Number	Percent
Gender	Male	26	74.3
	Female	9	25.7
Age at presentation	<65	26	74.3
	≥65	9	25.7
Comorbidity	Yes	3	8.6
	No	32	91.4
ECOG	0	6	17.1
	1	24	68.6
	2	5	14.3

5.2. Radiologic and laboratory variables

Mean serum albumin was 3.2g/dl and minimum and maximum values were 1.5 and 4.4g/dl respectively

See table 2

Table 2: Laboratory and Imaging variables

Variable	Category	Number	Percent
Immediate preoperative Hct	30-45%	30	85.7
	<30%	5	14.3
Immediate preoperative GFR	>60ml/min	25	71.4
	30-59ml/min	8	22.9
	<30ml/min	2	5.7
Immediate preoperative serum albumin	≥3g/dl	24	68.6
	<3g/dl	11	31.4
preoperative CT/MRI based staging	Not found	18	51.4
	T1	0	0
	T2	6	17.1
	T3	8	22.9
	T4	3	8.6

5.3. Procedure related variables

Mean, minimum and maximum duration of procedure time were 399.7, 300 and 450 minutes respectively. Whereas, mean, minimum and maximum EBL were 1007ml, 200ml and 3000ml respectively.

Table 3: Procedure related variables

Variable	Category	Number	Percent
Type of Procedure done	IC	26	74.3
	ONB	9	25.7
Estimated blood loss in ml	<500	5	14.3
	500-1000	16	45.7
	>1000	14	40.0
Duration of surgery in minutes	≤ 360	6	17.1
	>360	29	82.9

IC : Ileal conduit, ONB: Orthotopic Neobladder

5.4. Histopathologic variables

Greater than 90% of the tumors were urothelial cancer and 68.6% was high grade tumor. From the total subjects, about 16 post op biopsy either not found or didn't describe marginal status. From the remaining 19 cases 63.2% was margin positive.

Table 4: Histopathologic variables

Variable	Category	Number	Percent
TURBT biopsy	Ta	3	8.6
	T1	13	37.1
	T2	19	54.3
Post op biopsy	Not found	8	22.9
	T1	1	2.9
	T2	20	57.1
	T3	3	8.6
	T4	3	8.6
Grade	Low	11	31.4
	High	24	68.6
Histologic type	Urothelial	32	91.4
	Non-urothelial	3	8.6
Post-op marginal status	Negative	7	36.8
	Positive	12	63.2

5.5. Postoperative variables

Descriptive statistic showed 5 major complications of which 4 died due to MOF sec to septic shock sec to anastomosis leak

From the total 35 cases 19(54.3%) of then developed post-operative complication whereas 16 (45.7%) patients were having smooth post-operative course. Death rate was 11.4%. (See table 5)

Table 5: Postoperative variables

Variable	Category	Number	Percent
30 day surgical outcome	No complication	16	45.7
	Minor complication	14	40
	Major complication	5	14.3
Post- operative complication	No	16	45.7
	Yes	19	54.3
Management of complications	Conservative	5	26.3
	With LA	10	52.6
	With GA	4	21.1
Death within first 30 post op days	Yes	4	11.4
	No	31	88.6

.LA=local anesthesia

.GA=general anesthesia

5.6. Association between independent and dependent variables

The association between independent and dependent variable was assessed by Binary logistic regression model. Serum albumin and procedure type showed p-values of 0.013 and 0.153 respectively. Other variables as shown in table 6 their respective p- value was >0.2

(See table 6)

Table 6: result of binary logistic regression

Variable	Category	Number (Percent)	Crude odds ratio	p-value	95% CI
Sex	Male	26(74.3)	1.0		
	Female	9(25.7)	2.00	0.391	0.306-13.062
Age group	<65years	26(74.3)	1.0		
	≥65years	9(25.7)	1.705	0.494	0.370-7.854
ECOG	0	6(17.1)	1.0	0.769	
	1	24(68.6)	2	0.469	0.306-13.062
	2	5(14.3		0.999	
GFR	>60	25(71.4)	1.0	0.339	
	30-59	8(22.9)	2	0.241	0.641-22.744
	<30	2(5.7)	0.000	0.999	
ALBUMIN	≥3	24(68.6)	1.0		
	<3	11(31.4)	16.67	0.013	1.818-152.770
Grade	Low	11(31.4)	1.0		
	High	24(68.6)	1.015	0.983	0.242-4.255
Procedure type	IC	26(74.3)	1.0		
	ONB	9(25.7)	3.2	0.153	0.649-15.775
Procedure duration group	≤360min	6(17.1)	1.0		
	>360min	29(82.9)	0.817	0.817	0.14-4.721
Blood loss group	<500ml	5(14.3)	1.0	0.790	
	500-1000ml	16(45.7)	1.929	0.529	0.250-14.887
	>1000ml	14(40)	2.00	0.513	0.250-15.991

5.7. Association between independent and dependent variables, multivariable logistic regression

After controlling confounders on multivariable logistic regression, serum albumin <3g/dl was associated with post-operative complication with P- value of 0.019 and adjusted odds ratio of 14.54. (See table 7)

Table 7**:** Association between independent and dependent variables, multivariable logistic regression

Variable	Category	Number (Percent)	AOR	P-value	95% CI
ALBUMIN	≥3g/dl	24(68.6)	1.0		
	<3g/dl	11(31.4)	14.54	0.019	1.551-136.286
Procedure type	IC	26(74.3)	1.0		
	ONB	9(25.7)	2.024	0.433	0.347-11.796

aOR =adjusted odds ratio

6. DISCUSSION

The target of the study was to assess the thirty days mortality and morbidity after RC and what are contributing factors in patients who were operated at TASH, Addis Ababa, Ethiopia. The mortality rate was found to be 11.4%. This result was higher than reports from USA [11], India [10], Canada [12], and Egypt [7] which were reported 1.3%, 5.1%, 2.8%, and 6.5% respectively.

The overall complication rate or morbidity rate of this study was found to be 54.3%. Of which 40% was minor complication and 14.3% was major surgical complication managed with reoperation with GA. The result was higher than that of Nuci Burak cinar study [1] and Indian study [10] which were 15.6% and 23.5% major complications respectively. From the Indian study the overall complication rate was 49.3%.

This variation can be due to late presentation of our patients and related nutritional status with associated low serum albumin level. Logistic regression analysis was done to determine how immediate preoperative serum albumin and other independent variables affect surgical outcome after RC. A total of 35 patients were studied. Of the independent variables immediate pre-operative serum albumin was associated with immediate post-operative complications with (p-value of 0.019) and adjusted odds ratio of 14.54. When the serum albumin <3g/dl, post op complication will increase by 14.54 fold. Our above association showed similar association between serum albumin and surgical complications when serum level is <3.5g/dl [7] and especially when serum albumin level is <3g/dl [14].

Other independent variables in our study as shown in the result section didn't show significant impact on surgical outcome.

The mean age in this study was 55.54 years ranging from 25 years up to 78 years. Study done by Mahish Kalloli, the mean age at diagnosis was 58.6 years and most of the patients were in the age group of 50-70 year [13]. In another study on RC; there is no significant difference between patients aged >75 years and younger patients for preoperative comorbidity, perioperative complications, blood transfusion rates, and postoperative mortality [14]. Almost similar with our study finding. Age should not be an absolute contraindication to RC in elderly patients as far as no other contraindications.

Males account about 74.3% of cases in this analysis which is less than the retrospective study results done on 70 patients who underwent RC, of which 61 were male [13].Similar with study done in Switzerland, there is no association noted between sex difference among subjects and surgical outcome [16].

The minimum, maximum and mean procedure times in this study were 300, 450 and 399.7 minutes respectively which is comparable with other study findings [1, 19]. In the current study, Operation duration didn't show significant correlation with surgical outcome.

In our analysis the mean intraoperative blood loss was 1007 ml which is comparable with retrospective study findings done on 250 subjects (1100ml) [1]. Estimated blood loss didn't show significant correlation with post RC complication.

In our study from 35 cases post-operative biopsy was not found in 16 cases. So free margin status was analyzed for the rest 19 cases, free margin was achieved for only 7 cases (36.8%) which is lower than Netherland study result showed rate of negative surgical margin after RC for MIBC was 90.7% [22]. In another study done in China, potential risk factors for positive surgical margin were advanced cancer, mixed histology, surgeon dependent factors and availability of intraoperative frozen section biopsy [23]. Study done in Netherland stated that hospital volume greater than 30 RC annually could decrease postoperative mortality [20].

The possible causes for low rate of achieving free margin in our analysis are, possibly late presentation of our patients, not doing intraoperative frozen section biopsy, small sample size, relatively low volume center and other factors which need further study.

7. CONCLUSION AND RECOMMENDATION

Conclusion

Overall retrospective single institution based cross sectional study with binary logistic regression analytical tool was used and the thirty days postoperative morbidity and mortality were analyzed and found to be 54.4 and 11.4% respectively. Serum albumin level <3g/dl showed significant association with post-operative complication.

Strength of the study

-This study includes wide spectrum of variables. It is the first study on the procedure outcome.

-The results have practical real world application

-The scope of the research was manageable and achievable

Limitation of the study

- It was a retrospective cross sectional single institution study with small sample size, so inferring to the general population may be limited.
- Poor documentation of patients' data

RECOMMENDATION

- Patients with serum albumin with <3g/dl should be optimized before surgery
- Physicians involved in all courses of management of subjects can use the result of this study as a reference to measure their effort and improve outcome in subsequent practices.
- Study focusing on long term surgical outcome by strict follow-up of patients should be done
- Further study focusing on how to improve surgical outcome should be done
- Strict patient data handling and meticulous documentation
- possibly frozen section biopsy should be started

10. REFERENCES

[1] N. B. Cinar, H. Yilmaz, I. E. Avci, K. Cakmak, K. Teke, and O. Dillioglugil, “Reporting perioperative complications of radical cystectomy: the influence of using standard methodology based on ICARUS and EAU quality criteria,” *World J. Surg. Oncol.*, vol. 21, no. 1, pp. 1–12, 2023, doi: 10.1186/s12957-023-02943-9.

[2] K. Aminoltejari and P. C. Black, “Radical cystectomy: A review of techniques, developments and controversies,” *Transl. Androl. Urol.*, vol. 9, no. 6, pp. 3073–3081, 2021, doi: 10.21037/tau.2020.03.23.

[3] W. Zheng *et al.*, “Comparison of laparoscopic and open cystectomy for bladder cancer: A single center of 110 cases report,” *Transl. Androl. Urol.*, vol. 1, no. 1, pp. 4–8, 2012, doi: 10.3978/j.issn.2223-4683.2012.02.01.

[4] S. L. Maibom, U. N. Joensen, A. M. Poulsen, H. Kehlet, K. Brasso, and M. A. Røder, “Short-term morbidity and mortality following radical cystectomy: A systematic review,” *BMJ Open*, vol. 11, no. 4, 2021, doi: 10.1136/bmjopen-2020-043266.

[5] B. Nayak *et al.*, “Contemporary Outcomes of Open Radical Cystectomy: a 5-Year Experience from a Tertiary Care Center,” *Indian J. Surg. Oncol.*, vol. 12, no. 1, pp. 86–93, 2021, doi: 10.1007/s13193-020-01226-z.

[6] B. Čikić *et al.*, “OPEN RADICAL CYSTECTOMY : SINGLE CENTER RESULTS AND OUTCOMES IN THE LAST FIVE YEARS,” pp. 21–27, 2023, doi: 10.20471/acc.2023.62.s2.3.

[7] K. Mursi, H. Elfayoumy, I. Saad, A. Tawakol, and H. Badawy, “The effect of preoperative clinical variables on the 30- and 90-day morbidity and mortality after radical cystectomy: A single-centre study,” *Arab J. Urol.*, vol. 11, no. 2, pp. 152–158, 2013, doi: 10.1016/j.aju.2013.03.006.

[8] N. Patidar, P. Yadav, S. K. Sureka, V. Mittal, R. Kapoor, and A. Mandhani, “An audit of early complications of radical cystectomy using Clavien-Dindo classification,” *Indian J. Urol.*, vol. 32, no. 4, pp. 282–287, 2016, doi: 10.4103/0970-1591.191244.

[9] A. R. Al-Qudimat *et al.*, “Comparing trimodal therapy with radical cystectomy in muscle-invasive bladder cancer: an updated meta-analysis,” *Front. Surg.*, vol. 10, no. December, pp. 1–12, 2023, doi: 10.3389/fsurg.2023.1276746.

[10] B. Nayak *et al.*, “Contemporary Outcomes of Open Radical Cystectomy: a 5-Year Experience from a Tertiary Care Center,” *Indian J. Surg. Oncol.*, vol. 12, no. 1, pp. 86–93, 2021, doi: 10.1007/s13193-020-01226-z.

[11] S. Sobhani *et al.*, “Perioperative mortality for radical cystectomy in the modern Era: experience from a tertiary referral center,” *Int. Braz J Urol*, vol. 49, no. 3, pp. 351–358, 2023, doi: 10.1590/S1677-5538.IBJU.2022.0405.

[12] A. S. Zakaria, F. Santos, A. Dragomir, S. Tanguay, W. Kassouf, and A. G. Aprikian, “Postoperative mortality and complications after radical cystectomy for bladder cancer in Quebec: A population-based analysis during the years 2000-2009,” *Can. Urol. Assoc. J.*, vol. 8, no. 7–8, pp. 259–267, 2014, doi: 10.5489/cuaj.1997.

[13] M. Kalloli, “International Journal of Health Sciences and Research Outcome of Open Radical Cystectomy and Ileal Conduit : A Single Center Experience,” no. October 2012, 2020.

[14] I. Y. H. Ng, X. Shen, H. Sim, R. C. Sarri, E. Stoffregen, and J. J. Shook, “基因的改变 NIH Public Access,” *J Neurochem*, vol. 4, no. 1, pp. 1–15, 2015, doi: 10.1111/bju.12405.Preoperative.

[15] G. R. Prout, M. N. Wesley, R. Yancik, L. A. G. Ries, R. J. Havlik, and B. K. Edwards, “Age and comorbidity impact surgical therapy in older bladder carcinoma patients: A population-based study,” *Cancer*, vol. 104, no. 8, pp. 1638–1647, 2005, doi: 10.1002/cncr.21354.

[16] F. P. Stangl, O. D. Buehler, P. Y. Wuethrich, M. A. Furrer, and F. C. Burkhard, “Sex Does

Not Affect Survival: A Propensity Score-Matched Comparison in a Homogenous Contemporary Radical Cystectomy Cohort," *Clin. Genitourin. Cancer*, pp. 1–10, 2023, doi: 10.1016/j.clgc.2023.10.009.

[17] M. Hirobe *et al.*, "Complications within 90 days after radical cystectomy for bladder cancer: results of a multicenter prospective study in Japan," *Int. J. Clin. Oncol.*, vol. 23, no. 4, pp. 734–741, 2018, doi: 10.1007/s10147-018-1245-z.

[18] M.-V. K. and M. M. Friese C, Yang J, "乳鼠心肌提取 HHS Public Access," *Physiol. Behav.*, vol. 46, no. 2, pp. 248–256, 2019, doi: 10.1016/j.urolonc.2013.06.006.Blood.

[19] Z. G. Gul, A. B. Katims, J. S. Winoker, P. Wiklund, N. Waingankar, and R. Mehrazin, "Robotic assisted radical cystectomy versus open radical cystectomy: A review of what we do and don't know," *Transl. Androl. Urol.*, vol. 10, no. 5, pp. 2209–2215, 2021, doi: 10.21037/tau.2019.11.32.

[20] A. Richters *et al.*, "Hospital volume is associated with postoperative mortality after radical cystectomy for treatment of bladder cancer," *BJU Int.*, vol. 128, no. 4, pp. 511–518, 2021, doi: 10.1111/bju.15334.

[21] W. S. Tan, B. W. Lamb, and J. D. Kelly, "Complications of Radical Cystectomy and Orthotopic Reconstruction," *Adv. Urol.*, vol. 2015, 2015, doi: 10.1155/2015/323157.

[22] J. Bosveld *et al.*, "The impact of positive surgical margins after cystectomy on oncological outcomes: a nationwide study," *BJU Int.*, pp. 766–774, 2024, doi: 10.1111/bju.16611.

[23] X. Hong *et al.*, "Impact of surgical margin status on the outcome of bladder cancer treated by radical cystectomy: A meta-analysis," *Oncotarget*, vol. 8, no. 10, pp. 17258–17269, 2017, doi: 10.18632/oncotarget.12907.

11. APPENDIX

Annex I: Assurance form

I, the undersigned agreed to accept responsibility for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the research and publications office of Addis Ababa University.

PI:

Dr. Anmut Woretaw (MD, Urology fellow)

Signature _____Date _____

Advisor:

Dr. **Seyefe Bekele**(MD, Assistant professor of Urology)

Dr. Admasu Melaku(MD, Assistant professor of Urology)

Signature _____ Date_____

Annex II: Questionnaire

Part1. Socio demographic data

S. No	Socio-demographic factors		Remark
1	Age in complete years	_____	
2	Sex	1. Male 2. Female	
3	Physical status of patient (ECOG)	1.ECOG 0 2. ECOG 1 3. ECOG 2	
4	Other known medical illness	1. No known comorbidity 2. Hypertension 3. DM 4. if other specify_____	

Part 2. Radiologic and Laboratory features (CT- Scan or MRI)

S. No	Imaging and laboratory variables		
1.1	Location of tumor	1. away from bladder neck/trigon 2. adjacent to bladder neck	
1.2	Stage of tumor based on the imaging used :	----------	
2	Immediate Preoperative Serum Albumin	_____g/dl	
3	Immediate Preoperative HCT in %	---	
4	Immediate Preoperative GFR in ml/min	1 >60 2 30-60 3< 30	
5	preoperative TURBT biopsy result	----------	

Part 3. Intra operative events and pathology results

1	Duration of surgery in minutes	_____	
2	Intra operative blood loss in ml	----------	
3	Post op biopsy pathology result	----------	
4	Margin status	1. Negative 2. Positive 0. Not stated	
5	Grade	1. Low grade 2. High grade	

6	Histologic type	1. urothelial ca 2. nonurothelial	

Part 4. Postoperative variables

S. No	Variables		Remark
1	Postoperative outcome within first 30 postoperative days	1. Smooth and minor complication 2. Major complication/death	
1.1	Was the outcome death?	1. Yes 2. No	
1.2	If yes, cause of death	----------	
2	What Surgical complication the patient developed?	0.no complications 1. minor complication managed conservatively/Local anesthesia 2.major complication managed with general anesthesia	
3	How was the Surgical complications managed	----------	
4	Type of procedure done	1 ileal conduit 2 neobladder	