ORIGINAL ARTICLE

Grading Complication Following Radical Cystectomy and Ileal Conduit for Bladder Cancer Using Clavien Grading System

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ABSTRACT

Objective: To determine the 30-day complication rate of radical cystectomy and urinary diversion using a validated system.

Study Design: An analytical descriptive study.

Place and Duration of Study: The Aga Khan University Hospital, Karachi, from 1990 to 2010.

Methodology: Patients who had undergone ileal conduit (IC) formation, following radical cystectomy (RC) for muscle invasive transitional cell carcinoma, were studied, using a prospectively maintained data base. Basic details were determined, complications were noted and graded according to the modified Clavien grading system (CG). Results were presented using descriptive statistics.

Results: Of all the RC performed at this hospital 89 patients received IC. Of them 75 were male and 14 female. Mean age was 60 years. Mean duration of hospital stay was 14 days. Ten patients each received pre-operative chemotherapy and radiotherapy, respectively. Mean duration of surgery was 8.2 hours, with mean estimated blood loss of 1334 ml. Pre-operative radiotherapy was associated with more complications. No other factor like ASA, co-morbidities, blood loss or duration of stay influenced the complications. Fifty patients (56.2%) did not have any complications. Most common complication of wound infection was seen in 7 patients (CG-2), followed by uretero-ileal leakage in 5, requiring percutaneous intervention under local anaesthesia (GC-3a). Mortality rate was 4.5%, classified as CG-V.

Conclusion: Radical cystectomy with Ileal conduit is a major procedure with a good safety profile at this institute. Long-term follow up is still needed to evaluate delayed complications and quality of life.

Key words: *Bladder cancer. Radical cystectomy. Ileal conduit. Grading. Complications. Modified Clavien grading system.*

INTRODUCTION

Radical cystectomy (RC) with urinary diversion is considered the gold standard treatment for muscle invasive transitional cell carcinoma of the bladder.[1] Previous reported work from our own series indicated that radical cystectomy and bilateral pelvic lymphadenectomy is the standard treatment for muscle invasive and high grade T1 cancers, and as salvage for recurrent cancers. Lymphadenectomy has a potential therapeutic benefit. The pathological stage at cystectomy and nodal status are predictors of 5 years survival.[2] This procedure is described to be associated with various complications,[2] however, the reporting of these complications has not been standardized and is usually divided into major and minor complications.[3] The application of Clavien Grading System (CGS) to urological procedures has made it possible to report urological complications and is much advocated for,[4] however, there is a lack of published literature on complications of RC using this system.[5]

The risks of morbidity and mortality associated with RC are improving particularly the in-hospital outcomes. Using a contemporary population-based cohort, Kim and colleagues noted minimal improvement in postoperative complications and mortality overall or by hospital-volume category from 2001 to 2008.[6] About 29% and 2% of patients undergoing RC will experience a postoperative complication or die during hospitalization, respectively.[6] They suggested identifying the modifiable aspects of postoperative care to improve in-hospital outcomes and safety for patients undergoing RC.[6]

One of the commonest types of diversion following radical cystectomy is the ileal conduit (IC) due to its simplicity, safety and reproducibility in the hands of surgeons with varying degree of expertise.[7] Pycha and colleagues noted that the IC had the highest rate of severe complications as well as surgical re-interventions and late complications in the intestinal tract.[8]

de Vries and colleagues assessed the short-term outcome by using two different nutrition protocols in the perioperative period.[9] They noted that cystectomy and

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urinary diversion is a procedure with considerable risk of complications. Enteral nutrition might be advantageous as compared to parenteral nutrition, showing fewer complications and shorter hospital stay. A high ASA score is associated with more early complications. Selective bowel decontamination may have an additional role in preventing infectious complications after cystectomy.

A standardized reporting system was identified and used in order to rectify confusion that exists in current literature with various definitions of mild, moderate and severe complications, in a series of ileal conduits performed over a long-period of time by 8 different surgeons with varying degree of expertise.

The objective of the study was to determine the 30-day complication rate of a major radical cystectomy and urinary diversion using a validated system.

METHODOLOGY

The medical records of patients undergoing radical cystectomy with ileal conduit were retrieved from a prospectively maintained data base. All patients who had a radical cystectomy followed by ileal conduit of urinary diversion were included. Patients who had orthotopic bladder, continent urinary diversion (Indiana pouch etc.) were excluded. Out of a total of 113 patients, data of 73 patients was used for final analysis, the rest were excluded due to inadequate records and or if any other type of diversion was performed. The study duration was 1990-2010.

The data analyzed was demographic variables like age, gender, body mass index (BMI), pathological stage, Charlson's co-morbidity score, pre-operative haemoglobin, creatinine and albumin, and duration of surgery, transfusions, anastomosis type pre-operative chemotherapy or radiotherapy estimated blood loss (EBL), [Bricker's or Wallace type], American Society of Anaesthesiologists' (ASA) score, duration of hospital stay. All complications within 30 days of surgery were noted and then graded according to Modified Clavien Grading System.[3]

All data are expressed as mean $\pm$ standard deviation or frequency and percentages. Univariate analysis was done, using student's independent t-test for continuous variables and chi-square test for categorical variables. For all statistical tests, p-value < 0.05 was considered statistically significant. The Statistical Package for Social Sciences for Windows, version 17.0, SPSS™, was used for all analysis.

RESULTS

In the study population, there was a male preponderance, 75 males (84%) and 14 females (16%). The mean age was 60 $\pm$ 15.7 years (range 32 - 88). The mean BMI was 26.4 $\pm$ 7.1 (range 16 - 38 kg/m^2). The ASA score was < 2 in 54% (n = 48) patients and > 2 in 46 % (n = 41) patients. Thirty percent patients had no known co-morbidity, 36% (n = 32) had a single co-morbid condition and 33.7% (n = 30) had two or more co-morbidities. Patients were also subjected to pre-operative chemotherapy in 10 (11%) and pre-operative radiotherapy in 10 (11%). Charlson's index co-morbidity score showed that 49% (n = 44) patients with a score of less than 2 and 51% (n = 45) had a score of greater than 2 (Table I).

The mean pre-operative haemoglobin was 11.6 $\pm$ 4.3 (range 7.50 - 15) g/dl with mean pre-operative albumin being 3.2 $\pm$ 1.1 (range 1.60 - 4.20) g/dl. The mean duration of surgery being 8 hours and 40 minutes (range 5 - 13 hours) with estimated blood loss during surgery being less than 1.5 L in 67.5% (n = 60) patients and greater than that in 32.5% (n = 29) patients. Regarding blood transfusions 11.2% (n = 10) did not require any transfusion, 58.4% (n = 52) required 3 or less than 3 units whereas only 29% (n = 26) of patients required greater than 3 units. Fifty two patients (58%) had Brickers' type and 42% (n = 36) had Wallace type of anastomosis done.

The duration of stay analysis showed 62% (n = 55) patients had a stay of less than 14 days and 38% (n = 34) patients had a stay of greater than 14 days.

Table I: Basic data.

Age	60.25 (32-88 years)
Sex	75 M, 14 F
BMI	26.4 (16-38)
Co-morbidities	None (30.3%), Single (36%), 2 or more (33.7%)
Charlson's index	2.4 (0 - 5)
Duration of surgery	8.2 (5 -13 hours)
EBL (avg)	1334 (350 - 3600 mL)
Duration of stay	14.6 (7 - 38 days)
Albumin	3.2 (2.2 - 4.2)
Creatinine	1.38 (0.6 - 9.0)
Haemoglobin	11.6 (7.5 - 15.0)
Complications	29 (40%)

Table II: Complications according to MCGS (n = 39).

Grade 0	No complications	n = 50 (56.2%)
Grade 1	Fever (n=2), prolong ileus (n=4), increase drain output (n=2), TPN (n=1), wound infection (n=1), penile haematoma (n=1)	n = 11 (12.4%)
Grade 2	Wound infection (n=7), DVT (n=1), RTI (n=3), prolong intubation and TPN (n=1)	n = 12 (13.5%)
Grade 3a	Uretero-ileal leakage with percutaneous nephrostomy (n=5), abdominal drain placement for leak (n=1)	n = 6 (6.7%)
Grade 3b	Rectal perforation(n=1), stomal gangrene (n=1), anastamotic leak re-exploration (n=2), ureteric gangrene (n=1)	n = 5 (5.6%)
Grade 4	Acute renal shutdown (n=1)	n = 1 (1.1%)
Grade 5	Death from sepsis (n=2), Death from cardiac arrest (n=1), death from GI bleed (n=1)	n = 4 (4.5%)
Complications	39 (43.8%)	–

n = Number of patients.

Regarding the postoperative complications, 56.2% (n = 50) showed no complications whereas 43.8% (n = 49) had complications. Most commonly grade 2 complications were noted, followed by grade 1, however, a mortality rate of 4.5% was noted as grade 5 complications (Table II).

Multivariate analysis found that only pre-operative radiotherapy was associated with development of postoperative complication, with statistical significance (p = 0.03). None of the other parameters were found related with the postoperative complications.

DISCUSSION

Surgical complication reporting system is of utmost importance not only for standardization of specific procedure related complications, but also as a yardstick for keeping a check on quality control, through auditing the surgeon or the centre where a procedure is performed. Complications following ileal conduit are mostly bowel related, anaesthetic, pulmonary and less frequently metabolic. The reported incidence of peristomal complications following ileal conduit urinary diversion ranges from 15% to 65%.[10] The most commonly reported complications include the stoma or abdominal wall-related changes (parastomal hernia, stoma prolapse, stenosis, and re-traction) and peristomal skin changes. The latter are due to chemical injury (irritant contact dermatitis, pseudoverrucous lesions, and alkaline crustations), mechanical injury (pressure ulcers, skin stripping injuries and muco-cutaneous separation), infection (candidiasis and folliculitis) immunologic disorders such as allergic contact dermatitis; and disease-related lesions (varices, pyoderma gangrenosum and malignancy). Peristomal complications also appear to be under-recognized and underreported.

Recently, Shabsigh and colleagues noted that surgical morbidity following RC is significant and, when strict reporting guidelines are incorporated, higher than previously published.[11] Accurate reporting of post-operative complications after RC is essential for counselling patients, combined modality treatment planning, clinical trial design, and assessment of surgical success. Donat noted that in a review of 109 studies reporting the outcomes for 146,961 patients based on the 10 established criteria for surgical complication reporting, only 2% met 9 - 10, 21% met 7 - 8, 43% met 5 - 6, 30% met 3 - 4, and 4% met 1 - 2 criteria.[12]

Although the Clavien grading system has been in use for some time,[12] it was not until recently that this system was advocated for reporting urological complications.[5] Many urological procedure complications have been reported using this system.[13] This paper studied its effectiveness in reporting post-radical cystectomy complications in a specific type of urinary diversion.

The need for standardized reporting system was highlighted by Donat.[12] In a literature review, he found that the majority of outcome based urological oncology literature used 'major and minor' complications to describe their outcomes, with varying definitions.[12] He reported that one-third of the urological oncology literature used some form of grading system to report complications, of which only 6% used a numerical grading system.[12]

This fact thus highlights the importance of a complication grading system. In this series, most of the complications were of grade 1 and 2 (25.9%). Prolonged ileus (4.5%) and wound infection (7.8%) was the most frequent of the grade 1 and 2 complications seen, respectively. Other studies have reported variable results of ileus and wound infection rates of 0 - 22% and 0 - 15% respectively.[14]

When reviewing higher grades of complications, we encountered much fewer numbers in grade 3 and grade 4, 12.3% and 1.1% respectively. Lastly, the mortality rate of our series is 4.5%, classified as CG 5. The mortality rates for RC have declined over the years,[15] with reports of 30-day mortality rates as low as 0.3% in a series of 296 patients by Cookson and colleagues.[16] However, mortality rate as high as 3.9% have been reported by Bostrom and colleagues in his series of 258 patients.[17]

Shabsigh and his colleagues reported the complications of their radical cystectomy series from Memorial Sloan-Kettering Cancer Centre, using a modified Clavien grading system.[11] They divided the complications into 3 periods, each comprising of 30 days, postoperatively. The complication grades of the present series were comparable to their's. They reported an overall 30-day morbidity of 58%, which was 56.2% in this series. They experienced 48% of grade 1 and grade 2 complications, in comparison with the presently reported rate of 25.9%. In terms of grade 3 and 4 complications, 9.2% were reported by Shabsigh *et al.*,[11] compared to the present overall rate of 13.3%, which is higher. The 30-day mortality rate was 2% in comparison with 4.5% in this series.

In this study, no risk factor could be identified to point towards the development of postoperative complications, except for pre-operative radiotherapy. This could be explained by the fact that an irradiated pelvis may be difficult to dissect, leading to longer duration of surgery resulting in poor concentration ability at more important re-constructive parts of the procedure. This was in contrast to the findings of Ramani and his colleagues, who were unable to identify statistically significant difference in postoperative complications of patient who had received prior radiotherapy.[18] Other factors reported in literature that contributes towards postoperative complications following RC include age, BMI and number of co-morbidities.[19,20] In a recent report

by Poch and colleagues assessing the impact of BMI on complication rate following robotic RC and intra corporeal ileal conduit noted that Robot-assisted intracorporeal ileal conduit can be safely performed in all body mass indices.[21] They, however, emphasized the need for further studies to assess long-term conduit function and stomal complications.[21]

Although this series reported 30-day complication rate alone, better understanding of the procedural outcome can be attained by determining the complications up to 60 or 90 days. This can be considered as one of the limitations of the study along with a smaller sample size in comparison with larger cohorts being reported from other high volume centres.

In terms of the details of the complications, wound infection was found to be the most common complication, followed by uretero-ileal leakage, along with percutaneous intervention. The study by Shabsigh and his colleagues reported ileus to be the most common complication followed by UTI and wound infection.[11] More common uretero-ileal leaks in this study may be reflective of the lesser number of patients undergoing this procedure with subsequently prolonged learning curve. However, the mortality rates still remain close to larger series.

CONCLUSION

The importance of a standardized way of reporting complications in a urological oncological surgery cannot be underrated. The complication rates of radical cystectomy with ileal conduit in our institution are comparable with international literature, with a good safety profile.

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