

Cutaneous ureterostomy with definitive ureteral stent as urinary diversion option in unfit patients after radical cystectomy¹

Ureterostomia cutânea como opção de derivação urinária em pacientes em condições clínicas após cistectomia radical

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ABSTRACT

PURPOSE: Simple diversions are underutilized, mostly for unfit, bedridden, and very self-limited patients requiring palliative surgical management due to life-threatening conditions. Experience with cutaneous ureterostomy (CU) as palliative urinary diversion option for unfit bladder cancer patients is reported.

METHODS: We retrospectively reviewed clinical and operative parameters of 41 patients who underwent CU following RC in three specialized Cancer Centers from July/2005 to July/2010. Muscle-invasive disease (clinical Stage T2/worse), multifocal high-grade tumor, and carcinoma in situ refractory to intravesical immunotherapy were the main indications for RC. Double-J ureteral stents were used in all patients and replaced every 6 months indefinitely. Peri-operative morbidity and mortality were evaluated.

RESULTS: Median age was 69 years (interquartile range - IQR 62, 76); 30 (73%) patients were men. Surgery in urgency setting was performed in 25 (61%) of patients, most due to severe bleeding associated with hemodynamic instability; 14 patients (34%) showed an American Society of Anesthesiologists score 4. Median operative time was 180 minutes (IQR 120, 180). Peri-operative complications occurred in 30 (73%) patients, most Clavien grade I and II (66.6 %). There was no per-operative death. Re-intervention was necessary in 7 (17%) patients. Overall survival was 24% after 9.4 months follow-up.

CONCLUSIONS: CU with definitive ureteral stenting represents a simplified alternative for urinary diversion after palliative cystectomy in unfit patients. It can be performed quickly, with few early and late postoperative complications allowing RC in a group of patients otherwise limited to suboptimal alternatives. Future studies regarding the quality of life are warranted.

Key words: Postoperative Complication. Survival. ASA Score. Morbidity. Aged. Bladder Cancer Neoplasms.

RESUMO

OBJETIVO: Relatar a experiência do emprego da ureterostomia cutânea (UC) como forma de derivação urinária definitiva em pacientes portadores de neoplasia vesical avançada, em más condições clínicas e que necessitam de tratamento paliativo.

MÉTODOS: Foram analisados retrospectivamente os parâmetros clínicos e operatórios de 41 pacientes submetidos a cistectomia radical e UC em três centros oncológicos especializados. A UC foi a derivação urinária escolhida quando os pacientes não apresentavam

condições clínicas de serem submetidos a outro tipo de derivação. Foram avaliados a morbidade peri-operatória e a sobrevida global. **RESULTADOS:** A idade média dos pacientes foi de 69 anos (intervalo interquartil - IQR 62, 76); 30 (73%) pacientes eram do sexo masculino. Vinte e cinco pacientes (61%) foram submetidos a cirurgia de urgência sendo a maioria devido a hemorragia grave associada a instabilidade hemodinâmica. O tempo cirúrgico médio foi de 180 minutos (IQR 120, 180). As complicações peri-operatórias ocorreram em 30 (73%) pacientes sendo a maioria classificadas como “Clavien” graus I e II (66,6%). Não houve óbito per-operatório. A reabordagem cirúrgica foi necessária em 7 (17%) dos pacientes e a sobrevida global foi de 24% após 9,4 meses de seguimento. **CONCLUSÕES:** A UC com implante de “stent” ureteral é uma alternativa simples de derivação urinária, após cistectomia paliativa, em pacientes sem condições clínicas de serem submetidos a procedimentos cirúrgicos mais complexos. A UC é um procedimento rápido e apresenta taxas de complicações aceitáveis. Essa alternativa cirúrgica permite melhorar a qualidade de vida dos pacientes portadores de tumores vesicais localmente avançados.

Descritores: Complicação Pós-Operatória. Sobrevida. Risco Anestésico. Morbidade. Câncer de Bexiga.

Introduction

In 2010, an estimated 70,530 Americans were diagnosed with bladder cancer (BC) and 14,680 died from their disease. BC represents the fourth most common cancer and is the ninth leading cause of death from cancer in the United States¹.

Muscle invasive bladder cancer (MIBC) accounts for approximately 20-30% of the newly diagnosed cases. Moreover, 10% to 30% of the initially non-muscle invasive cancer will progress to muscle-invasive disease^{2,3}. Radical cystectomy (RC) with urinary diversion is considered the standard treatment for MIBC.⁴

Age is an independent risk factor for developing bladder cancer. As result of the continuous improvement in life expectancy, more elder patients are expected to harbor the disease⁴. Bladder cancer is the fourth leading cause of cancer related mortality in men 80 years old or older⁵.

Management of MIBC in the elderly is becoming an important issue in urological practice for the continuous ageing of the population; additionally, the demands for palliative handling and/or treating unfit patients are considerable in support of aged. These patients usually have an increased probability of harboring severe co-morbidities (as diabetic, chronic renal failure, hypertension cardiac disease), with increased treatment related morbidity. Moreover, life-threatening conditions (i.e. bleeding and renal insufficiency) related to advanced disease are more prone to occur, adding an even higher risk of peri-operative complications and mortality.

While several centers have concluded that RC may be performed with a higher but acceptable morbidity rate⁶⁻⁸, its role in elderly patients is still in debate due to the associate morbidity. Complication rates following RC have been reported in the range of 24% to 64% with some authors identifying age as a significant risk factor for peri-operative complications, mostly related to urinary diversion⁹.

Cutaneous ureterostomy (CU) represents an alternative

to ileal conduct in highly ill patients, reducing surgical trauma and risk of complications. It avoids surgical and metabolic complications such as small bowel obstruction, paralytic ileum, delirium and delayed restart of deambulation¹⁰. We report on our experience with cutaneous ureterostomy with definitive ureteral stenting as urinary diversion option after radical cystectomy in unfit patients and after palliative handling.

Methods

Detailed review was conducted from all 41 consecutive radical cystectomies followed by CU performed at 3 specialized cancer centers, from July 2005 to July 2010 after institutional review board's approval.

Muscle-invasive disease (clinical Stage T2 or worse), multifocal high-grade tumor, and carcinoma in situ refractory to intravesical immunotherapy were the main indications for RC. Orthotopic neobladder and ileal conducts are the standard urinary diversion options after RC at the institutions. Unfit patients or palliative cystectomies were selected for CU: - American Society of Anesthesiologists (ASA) score¹¹ 4, - urgent basis because of intractable bleeding, and/or - low serum albumin levels.

Ureterostomy was performed through a direct, spatulated end-to-side uretero-cutaneous anastomosis. A double-J ureteral stent was used in all patients and replaced every 6 months. Antibiotic prophylaxis is maintained for life.

Collected data included clinical and surgical parameters, and co-morbidities. Complication and hospitalization information was obtained from a prospectively maintained database, and was verified or augmented retrospectively for every patient in the series by detailed review of patient records, including outpatient visits. All intra-operative and postoperative complications were tabulated from the date of surgery until last follow-up visit.

Complications were graded using the modified Clavien classification system¹² establishing as grade I—oral medication or bedside care; grade II—intravenous therapy or thoracostomy

tube; grade III—intubation, interventional radiology, endoscopy, or reoperation; grade IV—major organ resection or chronic disability; and grade V—death.

Statistical analyses were conducted using Stata 10.0 (StataCorp LP, College Station, TX).

Results

Radical cystectomy followed by cutaneous ureterostomy was performed successfully in all patients. Demographics data are shown in Table 1. The median age was 69 years (interquartile range - IQR 62, 76); 30 (73%) patients were men. Four patients had synchronous prostate cancer diagnosed before the procedure. The medians serum hemoglobin and albumin levels were 10 mg/dL (IQR 8, 11) and 2.8 mg/dL (IQR 2.5, 3.4), respectively. 14 patients (34%) showed an ASA score 4.

TABLE 1 – Patient preoperative clinical data. All values are median (interquartile range -IQR) or frequency (proportion, %)

Variable	Total (n)
Number of patients	41
Median age (IQR)	69 (62,76)
Male (%)	30 (70)
ASA Score \geq 3 (%)	25 (61)
Median hemoglobin (IQR)	10 mg/dL (8, 11)
Median albumin (IQR)	2.8 mg/dL (2.5, 3.4)
Clinical Stage (%)	
I	3 (5)
II	10 (17.7)
III	18 (31.6)
IV	26 (45.7)

Surgery in urgency setting was performed in 25 (61%) of patients, most due to severe bleeding associated with hemodynamic instability. The median operative time was 180 minutes (IQR 120,180). Blood transfusion was necessary in all patients. Seventeen patients (42%) received blood transfusion before the procedure, and 15 (37%) patients had it during the procedure. The median blood packs needed were 4 (IQR 3, 5). No per-operative death occurred.

One or more postoperative early complications occurred in 30 patients (73%). Graded events included 6 (20%) grade I, 14 (46.6%) grade II, 6 (20%) grade III, 2 (0.7%) as grade IV, and 2 (0.7%) as grade V. Re-intervention was necessary in 7 (17%)

patients. Wound dehiscence, intestinal obstruction, and bleeding were the main reason for re-intervention. The median hospital stay was 8 days (IQR 4, 8 days). Overall survival was 34% after a median of 9.4 months follow-up.

Discussion

Although presented data included unfit patients and does not represent a genuine elderly population (median age 69, 62-76), we envisage a growing central role of CU in bladder cancer treatment as populace ages. A large number of the elderly patients are expected to harbor competing co-morbidity such as diabetes, hypertension, and renal failure. This can be translated in a large number of patients with low performance status requiring treatment for a life threatening invasive bladder cancer¹⁰.

Cancer is an important cause of death and morbidity in the elderly. Muscle-invasive bladder cancer occurs predominantly in an elderly population with a reported mean age of 68 years in contemporary series¹. The continuous increasing in lifespan and the effect of age in bladder cancer development are responsible for an increasing incidence of elderly patients harboring the disease. By 2020 there will be 52 million elderly, representing more than 20% of the United States population¹³.

Bladder cancer incidence in people over 85 years is two-fold higher compared with those younger than 65 years¹⁴. Radical cystectomy followed by urinary diversion is considered standard treatment for MIBC⁴. The indications for cystectomy and the selection of urinary reconstruction are not essentially dependent on the patient's age; however, there is a clear progressive increase in co-morbidities with age.

If left untreated, elder patients with BC are at risk of dying from consequences of tumor growth and spread, i.e. bleeding, instead of associated age-related illness¹⁵. Studies have suggested that co-morbidity and not age is the most important predictor of complications^{15,16}. When the decision for a radical cystectomy is made, not the real but much better the "biological" age of the patient should be taken into consideration.

Whether radical cystectomy for muscle-invasive bladder cancer is justified even in older patients, not only the possible improvement of the long-term survival has to be recognized, but also the impact of the therapeutical approach on the patients' quality of life is at least as important as the latter point. This aspect should be focused on future studies.

Thanks to advances in surgical technique, anesthesia, and intensive care, the mortality and morbidity rates following radical cystectomy in elderly patients have dramatically decreased,

achieving similar results to those reported in younger patients^{8,9}. Nevertheless, several centers specifically evaluating RC in the elderly have concluded that RC may be performed with a higher but acceptable morbidity rate^{7,8,17,18}.

Regardless of age, complications after definitive treatment for invasive bladder cancer can be associated with the radical cystectomy or the urinary diversion. Therefore, choosing a less morbid urinary diversion can decrease the complications rate. Ileal conduit has been successfully used as the urinary diversion option in patients with high risk and more advanced disease. However, complications related to the gastrointestinal tract violation are even frequent, mainly among elder patients.

Cutaneous ureterostomy may represent an alternative to ileal conduit. Deliveliotis et al compared complication rates after modified cutaneous ureterostomy and the ileal conduit in high-risk patients. CU was associated with lower early and late complication rates, as shorter length of hospitalization¹⁰.

Our data showed complications in 73% of patients. Although higher than described in current RC series, our patients represent a selected poorer performance status cohort. Moreover, most of the complications are grade I and II (66.6%). There were two post-operative deaths; they occurred in highly sick patients undergoing surgery in an urgency setting due to severe bleeding, and were probably not related to the procedure, once occurred over 30 days after the procedure.

Our data confirms that in unfit high-risk patients, radical cystectomy can be safely performed, even on an urgent basis. Furthermore, cutaneous ureterostomy might still have a role as a quick and reliable option of urinary diversion. A short operative time associated with reduced bleeding, and avoidance of enteral anastomosis might be associated with reduced morbidity after CU. Enteric fistula would be a devastating complication in such ill population, from who its incidence would be higher due associated malnutrition.

Criticism regarding of CU is based on its higher late complications rates, mainly ureteral-cutaneous stenosis, with consequent urinary tract infection or loss of the renal unit. In our series no stenosis was seen until the last follow-up. Double-j stents are replaced every 6 months and patients were kept under antibiotic prophylaxis for life. Those measures are paramount in reducing late morbidity and stone formation.

Patients who are unable to undergo a curative cystectomy because of advanced stage or poor overall health, may require a palliative intervention because of uncontrollable symptoms (pain) or life threatening conditions like bleeding, and urinary obstruction. Repeated transurethral resections alone or associated

with external beam radiation has been advocated as a treatment option in those situations. Although considered less aggressive, those approaches can be associated with severe hemorrhage, severe irritative symptoms, and high rates of failure in controlling tumor growth.

Multimodal bladder preservation does not appear as an acceptable alternative to a radical surgical treatment if the general health condition of patient allows performing CU. Moreover, those modalities show poor results in situations like uncontrolled bleeding or severe symptoms due to a large tumor burden.

The present study has the limitations of a retrospective analysis and the small number of patients in a clinical series. Furthermore, analyzing complication data in a morbid population undergoing a major procedure for a life threatening disease is not an easy task. There is a lot of confounding overlapping variables. Some morbidity or even death causes can be related to the disease aggressiveness and not the procedure per se. Interpretation of such data has to be done with cautious and future studies are warranted concerning CU.

Conclusions

Although underutilized, cutaneous ureterotomy represents a simplified alternative for urinary diversion after radical cystectomy in unfit patients and/or for palliative management. It can be performed quickly, with reduced morbidity, compared to other urinary diversion options, allowing RC in a group of patients otherwise limited to suboptimal and alternative multimodal bladder preservation. These advantages could be of great significance in high-risk and elderly patients. Future studies regarding the quality of life and including extreme range ages for such procedure are warranted.

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