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Original Article

What are the Significant Prognostic Factors to Predict the Outcome of Conservative (Nondiversion) Treatment in Patents with Cervical Cancer with Radiation Cystitis?

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Abstract

Background: **Hematuria from radiotherapy to treat cervical cancer (CA CX) is a problem and a challenge in patient care for urologists. These patients have continued to suffer from pain, disease chronicity and other side effects of the radiotherapy. From past to present, the algorithm of treatment has focused on outcomes of numerous treatment modalities and described their characteristics, hemostatic mechanisms, advantages and disadvantages.**

Objective: **This study looks back to identify what patient-related factors were important and affected the success prognosis of the treatment, particularly of conservative (nondiversion) treatment.**

Materials and Methods: **It was a retrospective study, using data of patients in the Urology Unit of Lerdsin Hospital over15 years (October 2002 - September 2016). A total of 148 patients had complete data and were divided to 112 patients with conservative (nondiversion) treatment and 36 patients with diversion treatment. Eight patient factors were taken into the study as follows: bladder capacity, grade of telangiectasia, creatinine level, degree of hydronephrosis, urinary tract infection (UTI), severity of bleeding, age and medical illnesses(diabetes mellitus (DM) and/or hypertension (HT)).**

Results: **According to the statistical calculation in the study to compare each of the factors in both groups of the patients, namely with conservative (nondiversion) and diversion treatment, significant differences were found in all factors, except the age. In addition, multiple logistic regression analysis, which controlled the effects of other factors, found that factors that affected the treatment success (to stop bleeding) in patients with CA CX and radiation cystitis were bladder capacity, creatinine level and age. Patients with bladder capacities ≤ 150 ml were 18 times more likely to receive the diversion treatment when compared to those with the capacities > 150 ml. Patients with creatinine levels > 1.50 mg/dl were 61 times likely to receive the diversion treatment when compared to those with the levels ≤ 1.50. Patients aged > 55 years were 0.03 time more likely to receive the diversion treatment when compared to those aged ≤ 55 years.**

Conclusion: **These results may be applied by urologists to predict the success of conservative (nondiversion) treatment and help them make quicker decision in changing the treatment plan to the diversion treatment.**

Keywords: **Hematuria, radiation cystitis, nondiversion, diversion**

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Introduction

In the present day, cervical cancer (CA CX) is the second most common cancer in women. Guidelines and important steps in treatment of this disease in addition to surgery and chemotherapy lie in the radiation therapy.

Radiation-induced hemorrhagic cystitis usually occurs anywhere from 6 months to 10 years after the exposure but may also be delayed for up to 20 years[1]. It was found in 6.5% of pelvic radiation[2]. Treatment of this condition has always been a challenge to urologists because of the pain and suffering of patients from massive loss of blood, urinary tract infection (UTI) or severe septicemia, renal insufficiency, disease chronicity, long-term care, and the need for hospitalization or several admissions and discharges. These eventually result in stress and depression. The patients present with problems of hematuria,dysuria, frequent urination, urinary incontinence, fever, hypogastrium pain, lumbar pain, degenerative kidneys, and some have urinary retention because of clot in bladder, pallor because of blood loss, and considerable pelvic pain.

Mechanism of Radiation-Induced Hemorrhagic Cystitis

The radiation causes endocystitis, followed by telangiectasia, submucosal hemorrhage and interstitial fibrosis[3]. The capacity and flexibility of the bladder, therefore, are decreased. Thus, the patients have frequent urination, micturition painor urinary incontinence. In the end, the radiotherapy results in obliterative endarteritis, mucosal ischemia, ulceration and bleeding (Figure 1).

Another interesting explanation of the pathogenesis is that the radiation causes single- and double-stranded DNA breaks, which lead to activation of DNA damage repair genes and apoptosis. Additionally, DNA penetrates deeper muscles of the urinary bladder, causing endarteritis,compromised blood supply and inadequate supply of nutrients to bladder tissues.

Severity grades of the telangiectasia has been classified by the RadiationTherapy Oncology Group/ European Organization for Research and Treatment of Cancer (RTOG/EORTC). Late radiation morbidity scoring schema is classified as follows[5].

Grade1: Slight epithelial atrophy

Minor telangiectasia (microscopic hematuria)

Grade2: Generalized telangiectasia

Intermittent macroscopic hematuria

Grade3: Severe frequency and dysuria

Severe generalized telangiectasia (often with pethichiae)

Frequent hematuria

Reduction in bladder capacity < 150 cc

Grade4: Necrosis/contracted bladder (capacity (100 ml)

Severe hemorrhagic cystitis

The radiation cystitis is to be managed as per following accepted and gold standard algorithm for hemorrhagic cystitis management (Figure 2). Regarding each treatment modality, mechanisms of the related agents, medications or procedures have

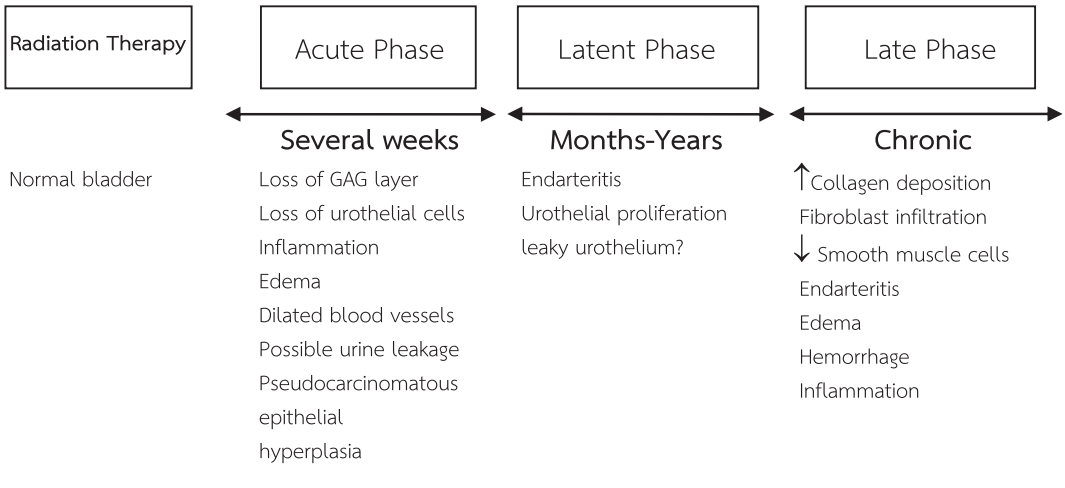

Figure 1 Development state of radiation cystitis[4]

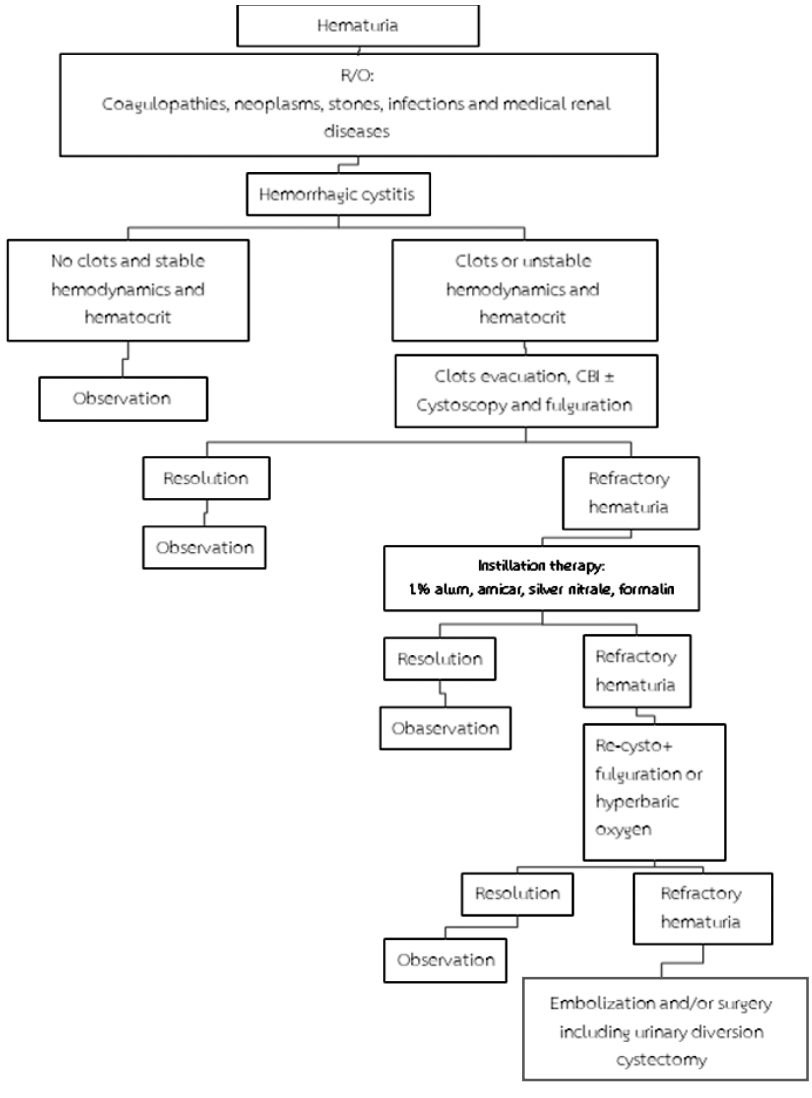

Figure 2 Algorithm for hematuria management[6]

been studied and described, with many conclusions on outcomes, advantages and disadvantages of each modality used[7-23]. On the other hand, based on literature review, the researcher did not find any study that determined patient factors affecting the success of each treatment modality, particularly of the conservative (nondiversion) treatment.

Management of Radiation Cystitis

The treatment providers need to make differential diagnosis for other diseases/conditions with hematuria, such as urinary tract calculi, UTI, inflammation and infection, coagulopathies, nonbladder (renal, ureter, urethra) bleeding and recurrent CA CX with bladder invasion.

Conservative (Nondiversion) Treatment

There are many treatment patterns and different mechanisms to stop the bleeding. The modalities basically include oral and intravenous (IV) medications, endoscopic instillation therapy, endoscopic treatment, using cystoscope with clot evacuation and fulguration, and laser coagulation. There are many medications or agents with several mechanisms used to stop the bleeding, including aminocaproic acid (inhibitor of plasminogen activator, which counteracts effects of urokinase) administered orally, parenterally, intravesically[24]; alum irrigation (astringent at the sites of bleeding, causing protein precipitation at the urothelial surface)[25]; intravesical instillation of silver nitrate solution (0.5 - 1%) for 10-20 min (chemical

coagulation and eschar formation at the bleeding sites)[26]; phenol instillation (100% phenol with 30 ml glycine for 1 min)[27]; and formaldehyde instillation (1-2% concentration for15 min) that cause precipitation of cellular proteins of the bladder mucosa and occluding and fixative action over the telangiectasia tissue and small capillaries[28,29]; IV WF10 (immu-nokine) that counteracts the inflammatory process[11]; and hyperbaric oxygen to make the bleeding subside because of neovascularization, enhanced angiogenesis and granulation tissue formation[19]. In addition, embolization of one or both internal iliac arteries is employed, using blood clot, gel foam or histoacryl[20].

Urinary Diversion Treatment

This treatment is used to decrease exposure of hemorrhagic areas to urokinase to allow hemostasis[21-23]. It includes percutaneous nephrostomy, bilateral cutaneous ureterostomy, ileal conduit, and cystectomy with urinary diversion.

Plenty of other treatment options for the radiation cystitis have also been reported. Examples include conjugated estrogen in oral and IV forms (stabilizing microvasculature)[30], sodium pentosanpolysulfate (uroprotective quality to decrease the inflammatory process)[31], intravesical instillation of prostaglandins (decreasing the inflammatory response and hemorrhage)[32], fibrin hemostatic agent[33], argon plasma coagulation[34], potassium titanyl phosphate (KTP) laser[35], medical antishock trousers and cryotherapy[36].

Materials and Methods

This was a retrospective descriptive study to determine patient factors affecting the success of the conservative (nondiversion) treatment of CA CX patients with the radiation cystitis. Following the hospital ethics approval, data were collected of such patients with the radiation-induced hemorrhagic cystitis at the Urology Unit of Lerdsin Hospital from October 2002 to September 2016, total 15 years. The data used were derived from medical records, IPD and OPD cards that contained complete data until the end of the treatment and allowed for follow-up. The data related to the research were divided into demographic data (such as age, height, weight, body mass index (BMI), underlying diseases, occupation, marital status, time following the radiotherapy for the CA CX until hematuria) and insights into the patients for statistical analyses, study results and answers to the questions of the research. These insights comprised the following eight patient factors:

1. Bladder capacity
2. Grade of telangiectasia
3. Creatinine level (renal function)
4. Degree of hydronephrosis
5. UTI
6. Severity of bleeding
7. Age
8. Medical illnesses(DM, HT)

All patients whose data were studied had to be sorted for other diseases or conditions with hematuria (bladder or non-bladder caused), such as bleeding from inflammation and infection, urinary calculi or tumors, recurrent CA CX with bladder invasion, medical bleeding or coagulopathies.

Medical checkups were performed by checking vital signs; blood chemistry for renal functions (blood urea nitrogen (BUN), creatinine) and other diseases of the patients, such as complete blood count (CBC), electrolytes, liver function test(LFT), fasting blood sugar (FBS), cholesterol (HDL, LDL), triglyceride (TG), uric acid, prothrombin time (PT), partial thromboplastin time (PTT) and bleeding time; chest x-ray(CXR), and electrocardiography(EKG).

Every patient underwent cystoscopy to assess pathological condition of the bladder, to measure the bladder capacity and to record the grade of telangiectasia. The severity of the bleeding was also assessed. Urine exam C/S was conducted in order to assess infection and to determine appropriate antibiotics. Imaging study was conducted to determine the pathological condition of the urinary(KUB) system and degree of hydronephrosis. The differential diagnosis for other diseases/conditions with hematuria was made withthe KUB ultrasonography (U/S), or computed tomography (CT) of the KUB or whole abdomen.

The conservative (nondiversion) treatment used in the patient care in this study (following the cystoscopy) consisted of observation, retained catheter with continuous bladder irrigation (CBI), cystoscopy and clot evacuation, cystoscopy and fulguration, intravesical instillation with 2% formalin, IV WF10, hyperbaric oxygen and embolization of internal iliac artery while the diversion treatment used comprised percutaneous

nephrostomy (PCN), bilateral cutaneous ureterostomy, ileal conduit and cystectomy and diversion.

The patient care procedures were according to the algorithm for radiation cystitis management presented under introduction. The success to stop bleeding at any stage of the conservative (nondiversion) treatment was determined when the patients were free from the gross hematuria for a minimum of six consecutive months (disease free for sixmonths) based on track records of patient care).

Inclusion Criteria

Medical records, and IPD and OPD cards with complete details of the patient demographic data, of the research-related factors as well as of treatment steps, duration, outcomes and follow-up.

Exclusion Criteria

Patients with rebleeding at more than six months after final stage of the nondiversion treatment were not taken as new population (were considered being in successful group). If there was a treatment complication of bladder perforation, the patients had to receive the diversion treatment and were not considered being in unsuccessful group.

Statistical Analyses

Comparison of each of the factors between the patients in the conservative (nondiversion) and diversion treatment groups was made using Chi-square / Fisher's exact test. Factors that affected the success to stop bleeding were determined using multiple logistic regression.

Results

Table 1 contains the demographic data in number and percentage of each factor, the number and percentage of individual diversion and nondiversion treatment.

Table 2 shows a statistical comparison between the groups of patients receiving nondiversion and diversion treatment of the eight factors. The differences between the two groups were found to be significant in all factors, except the age (Chi-square / Fisher's exact test).

Table 3 demonstrates statistical analyses using the multiple logistic regression by controlling impacts

Table 1 The number and percentages of the demographic data of the patients (n = 148)

Variable	Number of patients (%)	Mean ± SD (minimum: maximum)
Age (years)		55.5 ± 4.6 (47:69)
≤ 55	83 (56)	
> 55	65 (44)	
Body weight (kg)		46.9 ± 1.9 (43:52)
Height (m)		1.58 ± 0.25 (1.5:1.67)
Hospital stay (days)		26.9 ± 11.97 (8:52)
BMI (kg/m^2)		18.67 ± 0.78 (17.18:21.64)
After radiation (years)		7.54 ± 3.04 (2:16)
Bladder capacity (ml)		172 ± 6.1 (75:245)
> 150	104 (70.3)	
≤ 150	44 (29.7)	
Grade of telangiectasia		
1	18 (12.2)	
2	83 (56.1)	
3	40 (27.0)	
4	7 (4.7)	
Creatinine level (mg/dl)		1.64 ± 0.45 (1.12:3.6)
≤ 1.5	97 (65.5)	
> 1.5	51 (34.5)	
Hydronephrosis		
No	91 (61.5)	
Mild, moderate, severe	57 (38.5)	
UTI		
Controlled	136 (92)	
Uncontrolled	12 (8.1)	
Severity of bleeding		
Continued/rebleeding	125 (84.5)	
Active bleeding	23 (15.5)	
Medical illness DM, HT		
No	89 (60)	
DM and/or HT	59 (40)	
Procedure of treatment		
Observation	41 (27.7)	
Retained catheter with bladder irrigation	21 (14.2)	
Cystoscopy and clot evacuation	20 (13.5)	
Cystoscopy and fulguration	23 (15.5)	
Intravesical instillation with 2% formalin	5 (3.4)	
IV WF-10	2 (1.4)	
PCN	12 (8.1)	
Bilateral cutaneous ureterostomy	22 (14.9)	
Ileal conduit	2 (1.4)	
Treatment		
Urinary diversion	36 (24.3)	
Nondiversion	112 (75.7)	

Table 2 Comparison between the patients receiving the nondiversion and urinary diversion treatment

Variable	Number of patients (%)		
	Nondiversion	Urinary diversion	*p*-value
Bladder capacity (ml)			< 0.001
> 150	101 (92)	3 (8.3)	
≤ 150	11 (9.8)	33 (91.7)	
Grade of telangiectasia			< 0.001
1, 2	101 (90.2)	0	
3, 4	11 (9.8)	36 (100.0)	
Creatinine level (mg/dl)			< 0.001
≤ 1.5	96 (85.7)	1 (2.8)	
> 1.5	16 (14.3)	35 (97.2)	
Hydronephrosis			< 0.001
No	91 (81.3)	0	
Mild, moderate, severe	21 (18.8)	36 (100.0)	
UTI			0.009*
Controlled	107 (95.5)	29 (80.6)	
Uncontrolled	5 (4.5)	7 (19.4)	
Severity of bleeding			0.004
Continued/rebleeding	100 (89.3)	25 (69.4)	
Active bleeding	12 (10.7)	11 (30.6)	
Age (years)			0.485
≤ 55	61 (54.5)	22 (61.1)	
> 55	51 (45.5)	14 (38.9)	
Medical illnesses (DM, HT)			< 0.001
No	78 (69.6)	11 (30.6)	
DM and/or HT	34 (30.4)	25 (69.4)	

*Fisher's exact test

Table 3 Factors Affecting the Diversion in the Patients

Variable	Urinary diversion Number of patients with successful treatment (%)	OR_{crude}	$OR_{adjusted}$	95% CI	*p*-value
Bladder capacity (ml)					0.003
> 150	3 (8.3)	1	1		
≤ 150	33 (91.7)	101	17.6	2.7-117.8	
Creatinine level (mg/dl)					0.003
≤ 1.5	1 (2.8)	1	1		
> 1.5	35 (97.2)	210	60.8	4.2-883.4	
Age (years)					0.009
≤ 55	22 (61.1)	1	1		
> 55	14 (38.9)	0.8	0.03	0.0-0.4	
Medical illnesses (DM, HT)					0.074
No	11 (30.6)	1	1		
DM and/or HT	25 (69.4)	5.2	10.7	0.8-144.0	

of other factors. The factors that affected the treatment success (to stop bleeding) were bladder capacity, creatinine level and age. The patients with bladder capacities (150 ml were 18 times more likely to receive the diversion treatment as compared to those with bladder capacities > 150 ml (adjusted odds ratio (OR) = 17.6, 95% confidential interval (CI): 2.7-117.8). The patients with creatinine levels >1.5 mg/dl were 61 times more likely to receive the diversion treatment as compared to those with creatinine levels (1.5 mg/dl (adjusted OR=60.8, 95% CI: 4.2-883.4), and the patients over the age of 55 years were 0.03 time more likely to receive such treatment as compared to those (55 years of age (adjusted OR = 0.03, 95% CI: 0.002-0.433).

Discussion

CA CX still is one of the most common cancers in females. Regarding the current treatment in addition to surgery and chemotherapy, radiotherapy is still the main treatment. Side effects of the radiotherapy are dependent on amounts of the radiation used and areas of the radiation exposure[37]. There has been research to find ways to prevent or minimize side effects of the radiotherapy all along, but the radiation cystitis is still substantially found.

The algorithm of treatment involves standard practice guidelines and the hemostatic mechanism of each modality, and has been extensively studied. Most articles focus on effects of each treatment modality. This particular study, therefore, has tried to look back to find patient factors to be used in the success prognosis for the conservative (nondiversion) treatment for this condition so that urologists may use as a guide for assessment of patients during treatment, and these factors may help to change the treatment plan from nondiversion to diversion treatment faster by the urologists relying on information derived from the assessment of various factors that are important to the success in treatment, as displayed by the study results. This seems to be good in overall for clinicians, medical personnel and patients in terms of the disease prognosis, minimization of the prolonged hospitalization of patients, and time, cost and personnel saving. In addition, physical conditions of patients will resume faster with no need to suffer from the pain, blood loss, infection or the disease chronicity anymore.

The decision for the diversion treatment, however, would need to be accompanied by information and explanation of advantages and disadvantages to make patients understand and accept it because the patients will need to have the opening hole for drainage of urine at the waist or abdomen throughout the life in exchange for keeping the blood stopped.

Conclusions

The multiple logistic regression analysis in this study has found that factors that affect the success of the treatment of radiation cystitis in patients with CA CX seem to be bladder capacity, creatinine level and age. Patients with bladder capacities (150 ml were 18 times more likely to receive the diversion treatment as compared to those with the capacities >150 ml. Patients with creatinine levels > 1.5 mg/dl were 61 times more likely to receive the diversion treatment as compared to those with the levels (1.5, and patients aged > 55 years were 0.03 time more likely to receive such treatment as compared to those aged ≤ 55 years.

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บทคัดย่อ **ปัจจัยใดที่มีผลต่อความสำเร็จในการรักษาผู้ป่วยมะเร็งปากมดลูกที่มีปัสสาวะเป็นเลือดจากการฉายแสงโดยวิธี Conservative (Nondiversion) Treatment**

สุรพงษ์ ธนวงศ์วิบูลย์ (พบ., วว.ศัลยศาสตร์ทั่วไป, วว.ศัลยศาสตร์ระบบทางเดินปัสสาวะ)
หน่วยศัลยศาสตร์ระบบทางเดินปัสสาวะ กลุ่มงานศัลยศาสตร์ โรงพยาบาลเลิดสิน กรมการแพทย์

ที่มาและความสำคัญ: ภาวะปัสสาวะเป็นเลือดจากการฉายแสงเพื่อรักษามะเร็งปากมดลูกยังเป็นปัญหาและท้าทายในการดูแลรักษาผู้ป่วยต่อศัลยแพทย์ระบบทางเดินปัสสาวะ ผู้ป่วยเหล่านี้ยังคงต้องทุกข์ทรมานต่อความเจ็บปวด ความเรื้อรังของโรคและผลข้างเคียงอื่น ๆ จากการฉายแสงในอดีตจนถึงปัจจุบัน แนวทางการรักษามีการศึกษาถึงผลของการรักษาในวิธีต่าง ๆ มาอย่างมากมายอธิบายถึงคุณสมบัติกลไกการทำให้เลือดหยุดข้อดีข้อเสียในแต่ละวิธีนั้น ๆ มาโดยตลอด

วัตถุประสงค์: ในการศึกษานี้เป็นเหมือนการมองย้อนกลับเพื่อศึกษาว่ามีปัจจัยใดบ้างในตัวผู้ป่วยที่มีความสำคัญและมีผลต่อการพยากรณ์ถึงผลสำเร็จของการรักษา โดยเฉพาะการรักษาแบบ conservative (nondiversion) treatment

วัสดุและวิธีการ: เป็นการศึกษาแบบ retrospective study ใช้ข้อมูลของผู้ป่วยในหน่วยศัลยกรรมระบบทางเดินปัสสาวะ โรงพยาบาลเลิดสิน (ต.ค. 2545 - ก.ย. 2559) รวม 15 ปี มีคนไข้ที่มีข้อมูลครบถ้วนเพื่อการศึกษาทั้งสิ้น 148 คน แบ่งเป็นการรักษาด้วยวิธี conservative (nondiversion) treatment 112 ราย diversion treatment 36 ราย

ปัจจัยของผู้ป่วยที่นำมาศึกษามี 8 ประการ ดังนี้

Bladder capacity, grade of telangiectasia, creatinine level, degree of hydronephrosis, UTI, severity of bleeding, age, medical illness (DM and/or HT)

ผลการศึกษา: จากผลการศึกษาโดยการคำนวณทางสถิติเพื่อเปรียบเทียบความแตกต่างของแต่ละปัจจัยในผู้ป่วยทั้ง 2 กลุ่ม conservative (nondiversion) และ diversion treatment พบว่ามีความแตกต่างอย่างมีนัยสำคัญทุกปัจจัย ยกเว้น age และจากการวิเคราะห์โดยใช้ multiple logistic regression โดยควบคุมผลกระทบของปัจจัยอื่น ๆ พบว่าปัจจัยที่มีผลต่อความสำเร็จในการรักษา (stop bleeding) ในผู้ป่วย CA cervix with radiation cystitis ได้แก่ bladder capacity, creatinine level และ age คือผู้ป่วยที่มี bladder capacity ≤ 150 cc มีโอกาสต้องทำการรักษาแบบ diversion treatment เป็น 18 เท่า เทียบกับผู้ป่วยที่มี bladder capacity > 150 cc

ผู้ป่วยที่มี creatinine level > 1.50 มีโอกาสต้องทำการรักษาแบบ diversion treatment เป็น 61 เท่าของผู้ป่วยที่มี creatinine level ≤ 1.50

ผู้ป่วยที่มีอายุ > 55 ปี มีโอกาสต้องทำการรักษาแบบ diversion treatment เป็น 0.03 เท่าของผู้ป่วยที่มีอายุ ≤ 55 ปี

สรุป: ผลของการศึกษาทำให้ศัลยแพทย์ระบบทางเดินปัสสาวะสามารถนำมาใช้เพื่อเป็นการพยากรณ์ถึงผลสำเร็จของการรักษาแบบ conservative (nondiversion) treatment และช่วยในการตัดสินใจได้รวดเร็วขึ้นในการเปลี่ยนแผนการรักษาไปเป็นแบบ diversion treatment โดยอาศัยข้อมูลอ้างอิงจากงานวิจัยนี้