

Evaluation of the incidence and types of complications in patients undergoing radical retropubic prostatectomy based on own material

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KEY WORDS

prostate cancer ► radical prostatectomy
► post-operative complications

ABSTRACT

Introduction. Radical retropubic prostatectomy constitutes one of the major methods of treatment for clinically organ-confined prostate cancer. Numerous studies have reported different morbidities associated with this procedure. We assessed postoperative complications connected with radical retropubic prostatectomy in our series and compared them to the data obtained from the literature.

Material and methods. We analyzed a consecutive series of 108 patients undergoing radical retropubic prostatectomy between 01.01.2000 and 30.12.2005 in the Urology Department of the Regional Railway Hospital in Lublin. We evaluated intraoperative complications, early complications (within 1 month postoperatively) and late complications (after 1 month postoperatively.)

Results. There were no deaths in the studied group. Overall, there were 62 intraoperative and early complications observed in 51 (47.2%) patients undergoing the procedure. The main complication was intraoperative hemorrhage requiring blood transfusion observed in 44 (40.7%) patients. As for late complications urinary incontinence and anastomotic stricture was found in 12.1% and 13.7% of patients, respectively. All patients reported erectile dysfunction.

Conclusions. Radical retropubic prostatectomy is a relatively safe procedure. Most patients were not affected by any postoperative complications and urinary continence 12 months after the procedure is consistent with the major referral centers.

in 2003, their number increased to 1,341. In addition to that, the number of patients qualified for radical radiation therapy increased from 547 in 1999 to 1,554 in 2003 [2].

Radical prostatectomy is one of the methods of treatment for clinically organ-confined prostate cancer and, apart from radical radiation therapy, is the main therapeutic method to treat organ-confined prostate cancer. The guidelines of the European Association of Urology (EAU) recommend introducing radical treatment in patients with organ-confined prostate cancer with expected survival of more than 10 years [3]. Gradual developments in operative techniques and postoperative care have significantly reduced mortality and morbidity rates. However, complications decreasing the quality of life of patients are still present. Data regarding intra- and postoperative complications are mainly based on the information from urological centers in the USA, and a relatively low number of data comes from European centers. Due to the fact that own material is relatively extensive, we have decided to analyze data collected in association with operative treatment of patients with locally advanced prostate cancer.

The aim of the study was to determine the incidence and types of post-operative complications in the studied material.

MATERIAL AND METHODS

In the period from 01.01.2000 to 12.30.2005 at the Department of Urology of the Regional Railway Hospital in Lublin, 121 patients underwent radical retropubic prostatectomy due to organ-confined prostate cancer. In 13 cases medical archives were not complete; therefore these patients were excluded from further evaluation. The remaining group of 108 patients was analyzed in detail.

The preoperative diagnosis of cancer was based on a sextant or extended core biopsy, except for one patient, in whom neoplastic tissue was discovered in the TUR-P material. A routine procedure to evaluate the cancer stage included the PSA level determination, digital rectal examination (DRE) and transrectal ultrasound (TRUS). In order to exclude metastases, bone scintigraphy, abdominal ultrasound and AP chest X-ray were performed. An abdominal CT was performed in justified cases.

The pre-operative program included complete blood count, clotting parameters and electrolyte levels, as well as an ECG. All patients received prophylactic antibiotics, namely a single dose of a third-generation cephalosporin one hour prior to the procedure. Antibiotic treatment was then continued with second-generation cephalosporins or fluoroquinolones until the Foley catheter was removed. From one day before the procedure until the day of discharge patients received low-molecular-weight heparin. Compression stockings were used as antithrombotic prophylaxis until patients were mobilized, which usually took place in the first day after the procedure.

All surgical procedures were performed by one operator, according to the Walsh and Donker's technique in order to standardize the studied group. One or two neurovascular bundles were spared in five patients. The vesicourethral anastomosis was performed using a Foley catheter with the diameter of 20-22 F by applying 4-6 sutures. The anastomosis was evaluated

INTRODUCTION

Prostate cancer is a malignancy of increasing clinical significance in the male population. An increased incidence of prostate cancer has been observed in Poland in the last couple of years. In 2000 this malignancy was diagnosed in 4,598 patients, whereas in 2004 it was diagnosed in as many as 6,257 patients, which resulted in the fact that prostate cancer, after lung cancer, became the second most frequently occurring malignancy of men in Poland [1]. At the same time the number of diagnoses of an early stage disease (T_{≤2} N₀ M₀) is increasing; moreover, the disease is diagnosed in younger patients, which correlates with the number of patients, in whom it is possible to introduce radical treatment. In 1990 radical prostatectomy was performed in 395 patients, whereas as early as four years later, namely

Table 1. Clinical characteristics of the studied group of patients.

	Number of patients (%)
Clinical stage of prostate cancer	
T1b	1 (0.9%)
T1c	41 (37.9%)
T2a	51 (47.3%)
T2b	15 (13.9%)
Malignancy stage of prostate cancer according to the Gleason score	
2-4	17 (15.7%)
5-6	63 (58.3%)
7	18 (16.7%)
8-10	10 (9.3%)
Average preoperative PSA level	
< 4 ng/ml	10 (9.3%)
4-10 ng/ml	51 (47.2%)
10-20 ng/ml	39 (36.1%)
> 20 ng/ml	8 (7.4%)

for tightness by administering 100 ml of 0.9% NaCl into the urinary bladder via the Foley catheter. The obturator lymph nodes were routinely resected. After the procedure two safety drains were placed, which were withdrawn when the exudate amount was lower than 50 ml daily. Tissue material (prostate and lymph nodes) collected during the surgery was secured in 10% solution of formaldehyde and sent to the Histopathological Laboratory of the Pathomorphology Institute at the Regional Railway Hospital in Lublin for pathomorphological assessment. Postoperative pain was managed with intravenous or extradural analgesics, the amount of which was controlled by the patients. Patients were discharged when they were fully mobilized and did not require parenteral medications and when safety drains had been removed. The Foley catheter was removed 14 days after the surgery.

Complications were divided into three groups: intraoperative, early (within one month since the procedure) and late (after one month post-operatively). Data regarding intraoperative and early complications were obtained from the analysis of the complete medical documentation of the patients. Patient follow-up after discharge from the Ward of Urology involved follow-up visits at the Urology Center. At the beginning, during the first year of follow-up, visits were scheduled every three months, then every six months in subsequent years. Visits included medical history taking, physical examination, DRE and PSA level determination. Occasionally, an abdominal ultrasound was also performed. Late complications were evaluated based on the questionnaires performed by doctors during patients' visits at the Urology Center not earlier than 12 months since the procedure and after 38 months on average (the longest follow-up period is 77 months). Patients were asked to come for a follow-up visit in order to fill in the questionnaires and 58 patients that participated in that made up 53.7% of the studied group. The degree of urinary incontinence was evaluated based on the daily amount of hygienic pads or inserts used by patients. Urinary continence was defined, when patients did not use at all or used one pad daily as prophylaxis, although they had no problems with urinary incontinence. The effects of erectile dysfunction on the quality of life were evaluated based on subjective patients' feelings on a 4-point grading scale, starting from "it is not a problem for me" up to "it is a great problem for me." Moreover, the incidence of anastomotic stricture as the main late complication was assessed. The evaluation was based on the test of urethral flow and on the assessment of urinary retention after miction in ultrasound examination of the urinary tract.

Table 2. Pathomorphological characteristics of the studied group of patients.

	Number of patients (%)
Clinical stage of prostate cancer	
T2a	56 (51.8%)
T2b	27 (25%)
T3a	16 (14.8%)
T3b	4 (3.7%)
T4	2 (1.9%)
T0	3 (2.8%)
Malignancy grade of prostate cancer according to the Gleason score	
2-4	10 (9.2%)
5-6	61 (56.5%)
7	19 (17.6%)
8-10	15 (13.9%)
0	3 (2.8%)
Positive surgical margins	26 (24.1%)
Negative surgical margins	82 (75.9%)
Lymph node metastases	2 (1.9%)

RESULTS

Characteristics of the studied group of patients

In the studied group of patients qualified for radical retropubic prostatectomy the mean age was 62.8 years (ranged from 49 to 72 years). The mean value of the PSA levels in patients qualified for the surgery was 11.17 ± 8.17 ng/ml. Clinical, organ-confined prostate cancer was diagnosed in all cases. In the majority of the studied material, neoplastic tissue, with the Gleason sum of 5 and 6, was observed, namely in 63 (58.3%) patients. Table 1 presents the distribution of clinical tumor stages, malignancy grades according to the Gleason score, and distribution of pre-operative PSA levels.

In all cases the surgical procedure was performed according to the protocol and surgery time was 248 ± 56 minutes on average (from 150 to 360 minutes). The hospitalization period ranged from 7 to 43 days and on average was 11.4 ± 4.9 days. Pathomorphology assessment of the intra-operative material revealed a locally advanced neoplasm. Positive surgical margins were observed in 26 (24.1%) patients. Lymph node metastases were observed in 2 (1.9%) patients in the post-operative material. Table 2 presents histopathological characteristics of the studied group.

Intraoperative complications

No deaths associated with the procedure of radical retropubic prostatectomy were observed in our material. Massive intraoperative hemorrhage requiring blood transfusion was the predominant intraoperative complication and it occurred in 44 (40.7%) patients. Red blood cell concentrate in the amount of two units (range: 1 to 7 units) was transfused most frequently. Anterior rectal wall damage occurred in 3 (2.8%) patients during prostate preparation. In all cases primary closure of the rectal wall with two layers of sutures without the need for colostomy was performed. Parenteral nutrition was maintained for 3 days, broad-spectrum antibiotic therapy was introduced and then a free-residue diet was initiated. In all three cases the postoperative course was without complications. In one (0.9%) patient, accidental ligation of the right ureter occurred. Transient renal decompression by transcatheter nephrostomy was performed and it was a sufficient treatment as the ligature dissolved and ureter patency was restored. No cases of damage to the obturator nerves or iliac vessels

Table 3. List of intraoperative complications and comparison of their incidence with references.

	Authors' own material n = 108	Diliogluligil et al. [6] n = 472	Augustin et al. [9] n = 1243	Hisasue et al. [10] n = 123
Hemorrhage requiring blood transfusion	44 (40.7%)	137 (29%)	362 (29.1%)	no data
Rectal damage	3 (2.8%)	3 (0.6%)	3 (0.2%)	6 (4.9%)
Ureteral damage	1 (0.9%)	1 (0.2%)	4 (0.3%)	1 (0.8%)
Obturator nerve damage	0	1 (0.2%)	1 (0.1%)	0
Iliac vessel damage	0	5 (1.1%)	0	0

Table 4. List of early complications and comparison of their incidence with references.

	Authors' own material n = 108	Diliogluligil et al. [6] n = 472	Augustin et al. [9] n = 1243	Hisasue et al. [10] n = 123
Lymphorrhea >14 days	5 (4.6%)	2 (0.4%)	16 (1.3%)	6 (4.9%)
Vesicourethral anastomotic stricture	3 (2.8%)	1 (0.2%)	0	4 (3.3%)
Postoperative wound dehiscence	2 (1.9%)	2 (0.4%)	17 (1.4%)	0
Lymphocele formation	2 (1.9%)	10 (2.2%)	37 (2.9%)	1 (0.8%)
Postoperative wound infection	1 (0.9%)	12 (2.5%)	1 (0.1%)	17 (13.8%)
Severe hypotension	2 (1.9%)	3 (0.6%)	1 (0.1%)	0
Pulmonary embolism	1 (0.9%)	5 (1.1%)	2 (0.2%)	1 (0.8%)
Pneumonia	1 (0.9%)	4 (0.8%)	2 (0.2%)	0
Hypertensive crisis	1 (0.9%)	0	3 (0.3%)	0
Paroxysmal atrial fibrillation	1 (0.9%)	4 (0.8%)	6 (0.5%)	1 (0.8%)
Ischemic stroke	1 (0.9%)	1 (0.2%)	2 (0.2%)	0

was observed in the studied group. Table 3 presents intraoperative complications reported in the studied material and their comparison to the literature data.

Early complications

Complications directly connected with the type of surgery performed constituted the main group of early complications. Lymphorrhea lasting for more than 14 days was observed in 5 (4.6%) patients and it was the most common complication. A leaky vesicourethral anastomosis was found in 3 (2.8%) patients. In the above cases it was sufficient to keep safety drains and the Foley catheter for a longer time. In 2 (1.9%) patients post-operative wound dehiscence was observed. In such cases reoperation under general anesthesia was necessary and it involved wound suturing with anti-eventration sutures. The presence of lymphatic cysts was observed in 2 (1.9%) patients. Due to the fact that these cysts were not associated with any complaints, conservative treatment was introduced. In one case a post-operative wound infection developed and it did not require surgical preparation, so conservative treatment was applied. Other early complications, namely pulmonary embolism, pneumonia, cerebral stroke, paroxysmal atrial fibrillation, hypertensive crisis and severe hypotension, occurred in single cases. Table 4 presents an early complication in the studied group and their comparison to data from the literature.

Late complications

Gradual return of complete urinary continence was observed in the studied group of patients who had undergone the surgical procedure. Complete urinary continence was reported after 3 months by 30 (51.7%) patients, after 6 months by 41 (70.7%) patients, and after 12 months by 51 (87.9%) patients. One year after the procedure, mild urinary incontinence was reported by 5 (8.6%) patients and patients had to use 2-3 hygienic

pads daily. In 2 (3.4%) patients severe urinary incontinence was observed and they had to use 4 or more pads daily. Complete urinary incontinence was not observed in any of the patients.

All patients who filled in questionnaires reported complete impotence. According to the subjective evaluation how this complication affected their quality of life only 5 (8.6%) reported that it was not a problem for them. For the vast majority, namely 33 (56.9%) of the patients, this complication was a great problem and significantly decreased their quality of life. Figure 1 presents the effects of erectile dysfunction on the quality of life after radical retropubic prostatectomy according to subjective evaluation by patients.

Vesicourethral anastomotic stenosis stricture was found in 8 (13.7%) patients. In all cases it was sufficient to calibrate the stricture using catheters with increasing diameters.

DISCUSSION

Radical retropubic prostatectomy is a difficult urological procedure requiring great experience and its main aim is to treat an oncological disease. In the past, other methods to treat organ-confined prostate cancer were chosen more often due to high mortality and a great number of post-operative complications. As a result of constant improvements in surgical techniques and post-operative care the number of post-operative complications has significantly decreased. Having analyzed the data from urological centers with many-years of experience in radical retropubic prostatectomy it can be stated that now this procedure is relatively safe for patients. Procedure-related mortality ranged from 0% to 1.2% according to available publications, whereas intraoperative and early complications generally occurred in up to 36.6% of surgically-treated patients [4, 5, 6, 7, 8]. The results obtained in this work do not differ significantly from

the data presented in literature. No deaths due to radical retropublic prostatectomy were observed in the studied group; nevertheless, the number of intraoperative and early complications was slightly higher than in the references, reaching 47.2% of patients in total.

Massive hemorrhage requiring blood transfusion occurred in 44 (40.7%) patients undergoing radical retropublic prostatectomy and was the predominant intraoperative complication. Also, according to other authors, massive intraoperative hemorrhage was the predominant problem associated with the intraoperative damage to pelvic venous plexuses, especially Santorini's plexus. According to available literature, hemorrhage requiring blood transfusion after radical retropublic prostatectomy occurred in 10.6% to 29.1% of surgically-treated patients [6, 8, 9]. Three cases of rectal damage observed in the studied group were primarily managed with two layers of suturing and no other interventions were necessary. Such procedures are most commonly used by other operators in case of this type of complications [8, 9]. Some authors created transient colostomy in such cases [10]. However, this procedure is significantly more troublesome for a patient and it is necessary to delay the surgical procedure. According to the available literature, intraoperative complications, such as damage to the ureter, obturator nerve, or large blood vessels (common, internal and external iliac vein and artery), occurred in single cases and their number was below 1% of the total number of surgically-treated patients [6, 8, 9, 10]. In this work we observed only one (0.9%) case of ureteral damage and no damage to the obturator nerve or to large blood vessels around the operation site was reported.

The analysis of early complications revealed that complications directly connected with the type of performed surgery were more common. Lymphorrhea lasting for more than 14 days was observed in 5 (4.6%) patients and it was the most common complication. In addition, asymptomatic lymphatic cysts were observed in 2 (1.9%) patients. The incidence of the complications mentioned above was not different from that reported in available literature. According to different authors, their incidence ranges from 0.4% to 4.9% of patients with lymphorrhea and from 0.8% to 2.9% of patients with lymphatic cysts [6, 9, 10]. The presence of the complications mentioned above associated with the lymphatic system can be explained by the fact that obturator lymph nodes are routinely resected in all patients. Another early complication associated with radical prostatectomy was the leaky vesicourethral anastomosis found in 3 (2.8%) patients. For comparison, the incidence of this complication reported by other authors and based on large groups of patients ranged from 0.2% to 3.3% of patients [6, 8, 9, 10]. It was sufficient to keep safety drains and the Foley catheter for a longer time. Other early complications were reported in this work only in single cases. Disturbances in the functions of the circulatory and respiratory systems were predominant. In addition to that, thromboembolic complications were also observed. Other authors also observed such complications in patients undergoing radical prostatectomy. The incidence of these complications was below 1% of the total number of surgically-treated patients [6, 8, 9, 10].

Urinary incontinence is a complication that develops after radical retropublic prostatectomy and significantly decreases the quality of life of patients. The definitions of postoperative urinary incontinence available in literature vary; therefore it is difficult to compare these results. According to some authors urinary continence is defined as "no urinary leak", whereas others define it as "using one pad daily or less". In available literature the incidence of urinary incontinence is observed at the level ranging from 0.5% to 14.5% of surgically-treated patients [8, 11, 12]. The authors' data regarding the incidence of this complication are similar to the literature results. One year after the procedure complete urinary continence was reported by 87.9% of the studied patients. A slightly slower return of continence was observed in the studied group, when compared to the results from other urological centers with greater experience in radical retropublic prostatectomy, in which it occurred in 54% to 82% of patients after 3 months, and in 80% to 91% of patients after 6 months [11, 13, 14]. In this study full urinary continence was reported by 51.7%

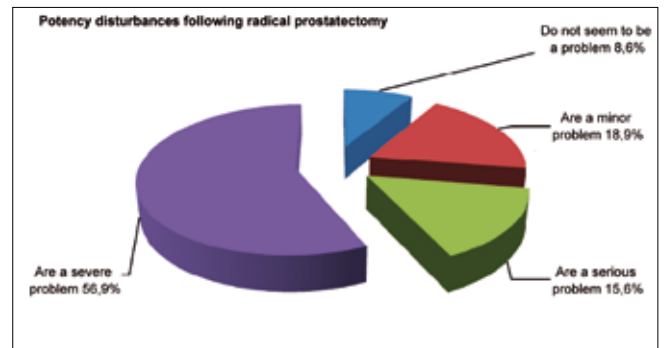


Fig. 1. The effects of potency disturbances on the quality of life following radical retropublic prostatectomy.

of patients after 3 months, and by 70.7% of patients after 6 months. Such differences may be a result of minor modifications to the surgical technique. Deliveliotis et al. demonstrated that return of full urinary continence after 3 months is faster when the bladder neck was spared (69% of patients), than in the case of sparing pubic-prostate ligaments (45% of patients). However, the final number of evaluated patients with complete urinary continence one year after the procedure did not differ between the two groups [15]. Other authors did not demonstrate the effects of bladder mucosa eversion in the incidence of vesicourethral anastomotic stricture and a degree of urinary incontinence [16]. Summing up, due to the fact that the anatomy of the prostate gland, urethra, external urethral sphincter and nerves responsible for urinary continence have been studied more and more thoroughly, the surgical technique applied in this procedure has been improved; consequently, the incidence of urinary incontinence has decreased significantly. In the analysis, 90% of patients reported complete urinary continence one year after the procedure. This rate is thought to be acceptable for patients considering radical retropublic prostatectomy as a method of treatment for organ-confined prostate cancer.

Vesicourethral anastomotic stricture is one of the significant complications after radical retropublic prostatectomy. Surgical technique modifications such as bladder mucosa eversion or the formation of tension-free water-tight mucosa-to-mucosa anastomosis decreased the incidence of anastomotic stricture; however, it may still occur in 0.5% to 32% of patients [17]. In our studied group the incidence of vesicourethral anastomotic stricture was observed in 13.7% of patients. In the case of vesicourethral anastomotic stricture catheters of increasing diameters have been used in literature and in our group [18]. This method was successful in all patients.

Erectile dysfunction is another frequent complication after radical retropublic prostatectomy and results from anatomical damage to the nerves innervating the cavernous bodies. Until Walsh and Donker described surgical anatomical access to the neurovascular bundles (NVB) of the prostate gland and how to spare them during radical retropublic prostatectomy, erectile dysfunction occurred in practically all patients [19]. As a result of the fact that the sparing method mentioned above has become popular, the number of patients with maintained potency after the surgical procedure increased. The main factors affecting the maintenance of penile erection are as follows: the number of spared neurovascular bundles, the patient's age, and the potency quality before the surgical procedure. In the group of 1,843 patients Kundu et al. observed maintained potency in 78% of patients with bilaterally spared neurovascular bundles and in 53% of patients with unilaterally spared NVB [20]. In our studied group all patients reported complete impotence. It was associated with the fact that patients with spared neurovascular bundles did not participate in the analysis of long-term complications. It has to be emphasized that erectile dysfunction significantly affects the quality of life after the surgical procedure. This complication was not a problem for only 8.6% of patients. The remaining men reported significantly decreased quality of life associated with erectile

dysfunction. It is an important argument in the discussion regarding the need to perform NVB-sparing procedures more frequently, especially in young and sexually-active men, for whom survival may be significantly longer than 10 years. On the other hand, the main aim of a surgical procedure is to eliminate the neoplastic disease completely. Sparing neurovascular bundles is associated with a significantly higher risk of positive surgical margins and it may affect as many as 18% of surgically-treated patients [21].

The presence of positive surgical margins (PSM) significantly increases the risk of a biochemical and local relapse [22]. Some authors reported 10-year survival without a biochemical relapse in 81% of patients with negative surgical margins and only in 36% of patients with positive surgical margins [23]. The incidence of PSM in the available literature ranges from 13% to 46% of patients treated with radical retropubic prostatectomy and PSM is most frequently reported in the apex of the prostate and on the posterolateral surface of the prostate gland in the region of the neurovascular bundles [23, 24]. In the studied group the incidence of PSM was not different from the data presented in the literature and was present in 24.1% of surgically-treated patients.

In the studied group, lymph node metastases were observed in 2 [1.9%] cases, which is consistent with the literature data [25]. Currently, there is a discussion regarding the use of extended pelvic lymphadenectomy involving the additional resection of the hypogastric, common iliac, external and internal iliac, and presacral lymph nodes. According to Stone, the use of extended pelvic lymphadenectomy statistically increased the amount of detected lymph node metastases significantly, even three times [26]. The idea of detecting and resecting the sentinel lymph node in prostate cancer is extremely promising, as it seems to be similarly successful to extended pelvic lymphadenectomy, and is associated with a decreased number of lymphatic complications [27].

CONCLUSIONS

Radical retropubic prostatectomy is currently a relatively safe procedure. In the majority of patients the postoperative course is without complications, and the degree of urinary continence is comparable to the data from reference centers. And at the same time, it seems that detailed knowledge of the incidence and types of complications in the studied group is required when patients are qualified for radical treatment.

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