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REVIEW

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Categorisation of complications of endoscopic extraperitoneal and laparoscopic transperitoneal radical prostatectomy

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Abstract The aim of the present review is to focus on the various attempts of categorisation of complications after endoscopic extraperitoneal and laparoscopic transperitoneal radical prostatectomy. Several classifications of complications and adverse events have been proposed in the literature but none is widely accepted or applied so far. We thus present a review of the existing literature and the complications of our series of 900 patients treated with endoscopic extraperitoneal radical prostatectomy (EERPE). We applied the recently revised Clavien classification system to grade EERPE complications.

Keywords Laparoscopy · Endoscopic radical prostatectomy · Complications · Clavien system · Prostate cancer

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Introduction

Transperitoneal and extraperitoneal laparoscopic radical prostatectomies have both been recognised as standard techniques for management of localized prostate cancer at specialized centres [1–7]. In 2003, we reported our own initial experience with endoscopic extraperitoneal radical prostatectomy (EERPE) and our initial results showed functional and oncological results similar to those of laparoscopic radical prostatectomy, but also a complete avoidance of intraperitoneal complications. Since then the technique has been continuously ameliorated, and has been established as a first line therapy for localized prostate cancer. In addition, a nerve-sparing, potency-preserving approach has matured [6, 8–12].

Endoscopic extraperitoneal radical prostatectomy has many advantages but is not without complications. The complexity of the surgery and the adequate training of the laparoscopist significantly influence the complication rate. Surgeons ought to be aware of possible complications and their prevention, recognized without delay, and finally managed safely and efficiently.

The aim of the present review is to focus on the various attempts of categorisation of complications after endoscopic extraperitoneal and laparoscopic intraperitoneal radical prostatectomy. A review of the current literature will be provided even though a comparison among series is subjective due to inconsistency of complication categorisation. The eventual aim should be to obtain a complete and standardised way of reporting all negative outcomes for operative and nonoperative procedures. We reviewed the available literature and applied the recently revised Clavien classification as a classification system for grading complications after radical prostatectomy. An analysis of our data from 900 EERPE procedures is presented to show the applicability of the proposed classification system.

Literature review

There have been numerous attempts in the literature attempting to categorise complications and their severity and create a common objective basis of comparison among the different studies [13]. Thus, various classifications of complications and adverse events have been proposed in the literature but none is widely accepted or applied so far. The absence of consensus among laparoscopists and surgeons in general on a common method to report complications has hampered proper evaluation and comparison between different studies.

The Clavien classification system was introduced in 1992 to define and classify negative surgical outcomes by differentiating their complications, sequelae, and failures. This system was initially used for complications associated with cholecystectomy and was recently updated and validated in a large cohort of general surgical cases (Table 1). Modifications of the previous classification consisted in an increase of numbers of grades from 5 to 7, including 2 subgroups for grades 3 and 4. The Clavien classification system focuses mainly on the therapeutic consequences of a complication, emphasising on the risk and invasiveness of the therapy used to correct a complication. Intraoperative complications that are promptly identified and corrected intraoperatively without any deviation from the normal postoperative course of the patient are not graded, for example, epigastric vessel injury and prompt intraoperative correction. Grade I complications are classified as deviation from the normal postoperative course without the need for pharmacololgical treatment or surgical, endoscopic, and radiological interventions. Grade II complications are minor and may require pharmacological intervention with drugs not administered for grade I complications. Blood transfusions and total parenteral nutrition are also included. Grade III complications require surgical, endoscopic or radiological intervention but they are self-limited. They are stratified into grades IIIa—intervention not using general anaesthesia and IIIb—intervention requiring general anaesthesia. Life threatening complications (including central nervous system complications) requiring intensive care unit management are classified as grade IVa—single organ dysfunction or IVb—multi-organ dysfunction. Deaths resulting from complications are classified as grade V. Finally, the suffix "d" is assigned to the respective grade of event, when the patient suffers from a disability at the time of discharge (Table 1) [14, 15].

Grades I and IIa complications in the initial classification correspond to grades I and II complications of the revised version. Prior grade IIb complications are now ranked as grade III complications. The length of hospital stay is no longer included in this revised ranking system, because there is a discrepancy among the various countries with different medical systems. In addition, life-threatening complications, i.e. acute respiratory distress syndrome with the need for mechanical ventilation, prior ranked as grade IIb are currently included in the grade IV complications. Finally, any impairment of body function at the time of discharge is no longer ranked as grade III, but is referred to with the suffix "d" in the revised classification. In the same manuscript Dindo defined complications as any deviation from the normal postoperative course, taking into account asymptomatic complications such as arrhythmia and atelectases. They also defined sequelae as "after effects" of surgery that are inherent to the procedure. They finally stated that sequelae and failure to cure should not be included in the proposed classification of complications. The main drawback of this classification is the fact that the treatment regimes for a given complication may vary among different institutions or countries, thus influencing the subjectivity of the ranking system [15].

Gonzalgo retrospectively reviewed the records of 250 patients with clinically localized prostate cancer who underwent transperitoneal laparoscopic radical prostatectomy. They used the updated Clavien grading classification system. A total of 34 morbidities (13.8%) and

Table 1 Clavien classification of surgical complications (according to Dindo) [15]

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic or radiological intervention.
Grade IIIa	Intervention not under general anaesthesia.
Grade IIIb	Intervention under general anaesthesia.
Grade IV	Life-threatening complication (including central nervous system complications) requiring intensive care management.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Death of patient.
Suffix "d"	If the patients suffer from a complication at the time of discharge, the suffix "d" (for disability) is added to the respective grade of complication. This label indicates the need for a follow up to fully evaluate the complication.

zero mortality were noted. A wide spectrum of complications was observed, although the majority (94.1%) were self-limited and classified as grade II or III. There were only two grade IV complications (5.9%) and no grade V complications. Postoperative ileus and bleeding requiring transfusion were the most frequent complications with an incidence of 3.3 and 2.8%, respectively. 0.8% had rectal injuries, which were recognized and repaired intraoperatively without further sequelae [16].

Guillonneau prospectively evaluated the morbidity and minor and major complications of laparoscopic radical prostatectomy. They used the initial complication grade proposed by Clavien for laparoscopic surgery. The amount of patients who presented with at least 1 complication in their series was 17.1% with a major complication rate of 5.3%, comparable to that in other contemporary series. A total of 105 complications were observed in 97 patients (17.1%), including 21 major (3.7%) and 83 minor (14.6%) complications. Twenty-one patients (3.7%) underwent reoperation for a postoperative complication, including ten (1.76%) who required an intensive care unit stay. 1.2% of patients required conversion to conventional retropubic radical prostatectomy. Mean blood loss was 380 ± 195 ml and the overall transfusion rate was 4.9%. In two patients (0.3%) deep vein thrombosis was associated with another surgical complication but not with pulmonary embolism. Urological, bowel, and hemorrhagic complications represented 66.6, 16.2 and 7.6% (total 89.4%) of all complications, and 20, 33.3 and 33.3% of all repeat interventions, respectively [13].

Veen used the definition of a complication developed by the Association of Surgeons of the Netherlands. According to this classification a complication is a condition or event, unfavourable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy, including prolonged hospital stay. If an event resulted in prolonged hospital stay, which was judged by the responsible physician at that moment, it was registered as a complication. They did not use a mean duration of prolonged hospital stay as a reference [17].

Bhandari reported complications of 300 robotic laparoscopic prostatectomies based on the classification of Clavien, but admitted that these criteria are flexible and different surgeons may report complications differently. There were 17 complications, of which 16 (5.3%) were related to surgery and 1 was related to anaesthesia. A total of 11 complications (3.7%) were minor (grade I) and 5 (1.7%) were major (grade II). Three patients (1%) required reoperation. There were no grade III or IV complications [18].

Arai reported their experience with the retrospective evaluation of early complications (within 30 days postoperatively) and postoperative convalescence after laparoscopic radical prostatectomy. A total of 66 complications were reported in 55 patients (37.2%). Intraoperative complications were noted in 25 of 148 patients (16.9%): ten rectal injuries (6.8%), five bladder injuries (3.4%), five cases of subcutaneous emphysema (3.4%), two intestinal injuries (1.4%), one major vessel injury (0.7%), one ureteral injury (0.7%), and one obturator nerve injury (0.7%). Overall, 16 of 148 patients (10.8%) required open conversion or postoperative open surgical repair. The most common postoperative complications were anastomotic leakage (6.8%), wound infection (4.7%), and perineal pain (4.7%) [19].

When reviewing the literature on endoscopic (laparoscopic) extraperitoneal radical prostatectomy (LERPE) we found the following reports. Bollens reported his initial experience with LERPE. Major complications were found in 4% of the operated patients. One developed an immediate postoperative transient acute renal failure due to a tubular necrosis of a solitary kidney. This patient underwent haemodialysis for 10 days and recovered a normal renal function. The second developed an urethrorectal fistula on day 20, probably due to a rectal wall necrosis after coagulation. The fistula was closed by a perineal surgical approach. Minor complications included three epigastric vessels injuries treated laparoscopically during the procedure, two urinary tract infections, one prolonged ileus (transperitoneal approach), two urinary leakages (treated by 10 additional days of catheterisation), four transient urinary retentions probably due to early removal of the catheter and treated by 2 days of further catheterisation, one laparoscopic drain removal (transperitoneal approach), one thrombophlebitis and one late hernia on a 10-mm port site (before systematic closure of 10-mm port sites). No death or intraperitoneal organ injury occurred [1].

Rozet from the Montsouris group recently reported their experience with LERPE. No mortality and no cardiac complications were reported. Major postoperative complications occurred in 2%, including pulmonary embolism, pulmonary edema, peritonitis, and rectourethral fistula secondary to nondiagnosed rectal tears, vesicocutaneous fistula, symptomatic lymphocele, urinary retention, and anastomotic stenosis in one each, and infected pelvic haematomas and prolonged ileus due to urine diffusion into the peritoneum in two cases each. In 1.7% of these cases reoperations were necessary, including colostomy, vesicocutaneous fistula treated with open re-anastomosis, vesicourethral stenosis treated with endoscopic incision, laparoscopic lymphocele marsupialization and acute urinary retention treated with endoscopic vesical clots evacuation in one each, and infected pelvic haematoma evacuation and endoscopic bilateral ureteral stent placement in two each. Minor complications were observed in 55 cases (9.2%). A total of 30 anastomotic leaks were revealed. Twenty cases of urinary retention following bladder catheter removal, requiring new catheter placement for 1 week, three cases of lymphoceles and two of an umbilical port site abscess, while seven blood transfusions (1.2%) with an average of 3 U of packed cells (range 2–6) were also necessary [7].

Martina presented the experience with EERPE of a "laparoscopy naive" urologist in a community hospital. A total of 16 complications occurred in 14% of patients (16/114). Eight of these complications were early and eight were late. The early complications were pelvic haematoma in one patient, epigastric vessel haemorrhage in one, transitory anuria in one, urinary retention in four, and gross haematuria in one patient. The epigastric vessel injury was diagnosed in the immediate postoperative period and was treated surgically. No other early complication required reoperation. Thus, the overall early reoperation rate was 0.9% (1 of 114). No intraoperative or perioperative deaths occurred. Late complications were seven cases of bladder neck stenosis and one case of bladder calculus. These were all treated endoscopically with success [20].

When reporting our complications we have categorised them as early and late, using the 1-month period as the cut off point. This makes referral to complications easy for all physicians and eliminates eventual discrepancies due to the various health system policies. Currently, we do not refer to major or minor complications. There is no concurrence among physicians regarding the correct interpretation of minor and major complications, thus resulting in overestimating or underestimating the untoward postoperative events. This emphasises the need of a unanimously accepted and standardised grading system to report complications. The Clavien grading system, even though with its own flaws, satisfies the need of standardisation and objectiveness, and thus in the present manuscript we propose its use for reporting complications after radical prostatectomy.

Our experience

Endoscopic extraperitoneal radical prostatectomy has become a standardised endoscopic procedure in various international urologic institutions. An increasing number of laparoscopists is embarking upon this treatment modality around the world. Therefore, it is of great importance to understand the evolving spectrum of perioperative morbidity associated with EERPE. Various groups performing laparoscopic radical prostatectomy have documented their perioperative complications but only few have used a standardised classification system [13, 16, 18, 21–26]. Comparing intraoperative and postoperative morbidity among the available surgical techniques is cumbersome, if not impossible, due to the lack of a common definition and categorization of complications among physicians.

Today our experience is based on a large series of 900 patients, who underwent minimally invasive radical prostatectomy using this entirely extraperitoneal retropubic approach. We present the complications of our 900 EERPE cases and categorise them according to the revised Clavien classification system (Table 2) [15].

The incidence of intraoperative complications was 0.8%. Six patients (0.7%) sustained intraoperative rectal injuries, which were repaired endoscopically with a two-layer suture. In one case (0.1%) injury of the interureteric crest was performed intraoperatively. Double pigtail stents were inserted bilaterally to ascertain ureteral viability, and the bladder neck was reconstructed at the six o'clock position. Intraoperative epigastric vessel injuries caused by trocar placement promptly identified and treated were documented in nine patients (1%), and were managed by coagulation, clipping or suturing. The later intraoperative events in these patients did not influence the postoperative patient's course and did not require any further treatment. They were thus not included in the Clavien grading categorisation, even though we have always reported them as complications in all our previous publications.

Exactly 3.4% of the patients required early postoperative reinterventions, 9 patients due to bleeding (open revision × 3, endoscopic revision × 5), 2 patients due to postoperative anuria (bilateral double J catheter insertion × 1, percutaneous nephrostomy × 1), 14 patients due to symptomatic lymphoceles (percutaneous drainage × 5, laparoscopic fenestrations × 9), 1 patient with a rectourethral fistula (colostomy–secondary repair), and 6 patients due to major anastomotic leakage (mono J catheter placement × 5, endoscopic performance of a neo-anastomosis during second postoperative day × 1).

Nineteen patients developed urinary retention after catheter removal on day 3–5 after the operation (12 × day 3, 4 × day 4, 3 × day 5). All cases of urinary retention were treated with one-four days of catheterisation. It is noteworthy that some surgeons that remove the catheter later on day 7–8, or even after 14 days or more in open surgery at some hospitals, do not report such complications. The catheterisation for additional 2–3 days could easily not be considered a complication, when the overall catheterisation time is indeed shorter than other reported series in the literature. Nevertheless, the Clavien system suggests grading of such untoward events, and thus fails to differentiate and evaluate such differences in medical practice. A very interesting study by Guillonneau showed that when removing the catheter on the second, third or fourth day the risk of acute urinary retention was 25, 4.9, and 3.2%, respectively [13]. Based on this intriguing study, we routinely remove the catheter on the fifth postoperative day if the anastomosis is watertight, and very seldom have problem pertaining to retention.

Sixteen patients required prolonged catheterisation due to minor anastomotic leakage. In general there is no standardised definition for "prolonged" catheterisation. We have arbitrarily considered the 14 days as a cut-off point for defining this term. Two patients presented temporary obturator nerve apraxia treated with neurotrope drugs, two developed deep vein thrombosis treated conservatively, two developed perineal haematoma and were treated with percutaenous drainage, one developed preperitoneal haematoma, and one osteitis pubis and

Table 2 EERPE complications

Clavien grade		*n* (%)	Management
Intraoperative complications			
I	Rectal injury	6 (0.7%)	2-layer suture
IIIa	Injury to interureteric crest	1 (0.1%)	DJ catheter placement and suture
Early complications (< 1 month postoperatively)			
I	Urinary retention	19 (2.1%)	1–4 extra catheterisation days
I "d"	Anastomotic leakage	16 (1.8%)	Prolonged catheterisation (> 14 days)
II	Preperitoneal haematoma	1 (0.1%)	Conservative
II	Deep vein thrombosis	6 (0.7%)	Conservative
II	Urinary tract infection	8 (0.9%)	Conservative (antibiotics)
II "d"	Temporary obturator nerve apraxia	2 (0.2%)	Conservative
II "d"	Pubic osteitis	1 (0.1%)	Antibiotic treatment
IIIa	Perineal haematoma	2 (0.2%)	Percutaneous drainage
IIIa IIIa	Anuria	2 (0.2%)	DJ catheter placement × 1 Nephrostromy placement × 1
IIIa IIIb	Symptomatic lymphocele	14 (3.6%)[a]	Percutaneous puncture × 5 Laparoscopic fenestration × 9
IIIa IIIb	Anastomotic leakage	6 (0.7%)	Mono J catheter placement × 5 Re-anastomosis (second postop. day) × 1
IIIb	Rectourethral fistula	1 (0.1%)	Colostomy, secondary repair
IIIb IIIb	Bleeding/haematoma	9 (1%)	Endoscopic revision × 4 Open revision × 5
IVa	Uro-sepsis	1 (0.1%)	Conservative (Intensive care for 5 days)
Late complications (> 1 month postoperatively)			
IIIa	Anastomotic stricture	2 (0.2%)	Endoscopic bladder neck incision
IIIb	Port site hernia	2 (0.2%)	Open repair
IVa	Myocardial infarction	1 (0.1%)	Surgical treatment
IVa	Cerebrovascular event	1 (0.1%)	Conservative

One hundred and one complications in 98 patients out of 900 EERPEs
[a]The occurrence of symptomatic lymphoceles (3.6%) refers to the 389 patients in whom a lymphadenectomy was deemed necessary

both were treated conservatively; eight presented with urinary tract infection and were treated conservatively, and one developed sepsis and was admitted in the intensive care unit for 5 days. Fourteen patients developed minor penile haematomas requiring no intervention. They were also not included in the Clavien grading system, because they did not alter the normal patient's postoperative course. Nineteen patients were detected with asymptomatic lymphocele and were only observed. The later patients were not included in the Clavien classification, even though reported in all our previous publications, because they did not influence the postoperative patient's outcome.

Exactly 0.7% of the patients required late postoperative reinterventions, two patients due to anastomotic stricture treated by endoscopic bladder neck incision, and two patients due to a port site hernia treated by open hernia repair. One patient suffered from a myocardial infarction 2 months postoperatively. Another patient had a cerebrovascular accident 3 months postoperatively and recovered without any sequelae.

In addition, we should emphasise that some patients presented more than one complication. One patient presented with postoperative bleeding requiring endoscopic revision and anastomotic leakage requiring mono J insertion. In another patient rectal injury was experienced intraoperatively, and postoperatively there was a need for a colostomy due to a rectourethral fistula formation. One patient presented with preperitoneal haematoma and urinary retention.

We applied the Clavien recently revised classification system to rank our EERPE complications. We encountered 55, 18, 15, 21, and 3, group I, II, IIIa, IIIb, and IVa complications, respectively (Table 2).

Conclusions

Our experience with 900 cases has proved that EERPE is a well established technique for the management of prostate cancer in centers of excellence. The herein presented review aims to emphasize on the need for unanimously accepted complication nomenclature and rating. Attempts to categorise complications and adverse events in general have not been accepted with great enthusiasm by the medical community. The importance of reporting complications tends to be underestimated by the medical community. In addition, there is always the burden of further legal and financial aspects of complication registration. The ideal classification for reporting complications of any therapeutic regime must meet many requirements and serve many needs. Web based platforms, developing a document-based global complication database could be of particular interest. Further effort should be made based on the collaboration of many international centres to establish a well accepted and efficient method for reporting and categorising complication, assisting the physician in understanding and resolving clinical problems.

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