ORIGINAL ARTICLE

A comparative study between open and laparoscopic approach in radical cystectomy with orthotopic ileal neobladder

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KEYWORDS
Bladder cancer; Neobladder; Laparoscopy; Complications; Incontinence

Abstract
Objective: Probably, laparoscopic radical cystectomy with ileal neobladder and neovesicourethral anastomosis is one of the most complex procedures in minimally invasive surgery.

Materials and methods: Prospective study carried out in 72 patients surgically treated for invasive bladder neoplasia between January 2008 and October 2013. Patients underwent radical cystectomy with ileal neobladder (open approach in 33 patients and laparoscopic approach in 39). The study assessed comparatively surgical outcomes, continence rate and postoperative complications.

Results: Mean age was 63.5 ± 9 years (64.3 open vs. 62.7 laparoscopic, \( p = 0.46 \)), mean surgery time 323.6 ± 78.7 minutes (321.3 vs. 326.5, \( p = 0.77 \)), average hospital stay 14.8 days ± 8.1 (16.2 vs. 13.6, \( p = 0.2 \)), transfusion rate 40.3% (66.7% vs. 17.9%, \( p < 0.001 \)) and complications rate 47.2% (63.6% vs. 33.3%, \( p = 0.01 \)). Major complications were reported in 29.1% of cases (39.4% open vs. 20.5 laparoscopic, \( p = 0.07 \)). With a mean follow-up rate of 42.5 ± 19.2 months (range 15–70), 50 (69.4%) patients remained alive and free of disease. Continence was evaluated in these patients: total continence rate was 38% (50% vs. 27%, \( p = 0.09 \)) and diurnal continence rate 58% (70.8% vs. 46.1%, \( p = 0.07 \)). Self-catheterization rate was 8% (4.2% vs. 11.5%, \( p = 0.67 \)). Total incontinence rate was 34% (25% vs. 42.3%, \( p = 0.19 \)).

Conclusion: According to our experience, transfusion rate, number and severity of complications are lower in laparoscopic cystectomy with ileal neobladder. No statistically significant impact on operative time and on hospital stay was observed. In patients undergoing laparoscopic approach, continence rate is lower but not statistically significant.

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PALABRAS CLAVE
Cáncer vesical; Neovejiga; Laparoscopia; Complicaciones; Incontinencia

Estudio comparativo entre abordaje abierto y laparoscópico en la cistectomía radical con reservorio ortotópico ileal continente

Resumen

Objetivo: La cistectomía radical laparoscópica con neovejiga ileal y anastomosis neovescicourethreal realizada por laparoscopia posiblemente sea uno de los procedimientos más complejos de la cirugía mínimamente invasiva.

Material y métodos: Estudio prospectivo realizado entre enero de 2008 y octubre de 2013 con 72 pacientes afectos de neoplasia vesical infiltrante, intervenidos mediante cistectomía radical con neovejiga ileal (33 mediante técnica abierta y 39 laparoscópica). Evaluamos de forma comparativa los resultados quirúrgicos, la tasa de continencia y las complicaciones postoperatorias.

Resultados: La edad media fue 63,5 ± 9 años (64,3 abierta vs. 62,7 laparoscópica, p = 0,46), el tiempo medio quirúrgico 323,6 ± 78,7 min (321,3 vs. 326,5, p = 0,77), la estancia media 14,8 ± 8,1 días (16,2 ± 13,6, p = 0,2), la tasa de transfusión 40,3% (66,7% vs. 17,9%, p < 0,0001), la tasa de complicaciones 47,2% (63,6% vs. 33,3%, p = 0,01). Sucedieron complicaciones mayores en 29,1% (39,4% abierta vs. 20,5% laparoscópica, p = 0,07). La media de seguimiento fue 42,5 ± 19,2 meses (rango 15-70); 50 pacientes (69,4%) estaban vivos y libres de enfermedad y pudieron ser evaluados con respecto al estado de continencia. La tasa de continencia total fue 38% (50% vs. 27%, p = 0,09) y la tasa de continencia diurna 58% (70,8% vs. 46,1%, p = 0,07). La proporción de pacientes con autocateterismo fue 8% (4,2% vs. 11,5, p = 0,67). La tasa de incontinencia total fue 34% (25% vs. 42,3%, p = 0,19).

Conclusión: En nuestra experiencia la tasa de transfusión, el número y severidad de complicaciones es menor en la cistectomía radical con neovejiga realizada mediante abordaje laparoscópico, sin claro impacto en el tiempo quirúrgico y en la estancia hospitalaria. La tasa de continencia de los pacientes intervenidos mediante abordaje laparoscópico es inferior, aunque sin alcanzar significación estadística.

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Introduction

Radical cystectomy with pelvic lymphadenectomy is the treatment of choice for muscle-invasive bladder cancer. Laparoscopic radical cystectomy and robot assisted cystectomy with different urinary diversions have proven to be safe and reliable techniques, and they have advantages in terms of operative and postoperative outcomes. The use of orthotopic ileal reservoirs has become the standard method of urinary diversion after radical cystectomy in both sexes, in selected patients and whenever possible.

Laparoscopic radical cystectomy with extracorporeal reconstruction of the ileal reservoir, followed by neovesicourethreal anastomosis through laparoscopy is performed at institutions with expertise in this approach, but it remains one of the most complex minimally invasive urological techniques. Given the limited studies on this technique, it is unknown whether the laparoscopic approach has advantages over the open approach of orthotopic reservoirs in terms of surgical and oncological outcomes.

We present a prospective comparative study of patients with bladder cancer operated by means of open radical or laparoscopic cystectomy, and have undergone orthotopic ileal reservoir. Surgical outcomes, complications, and functional outcomes focused on urinary continence are described.

Materials and methods

Non-randomized prospective and comparative study was conducted between January 2008 and October 2013 with 72 consecutive patients treated at the University Hospital of Getafe undergoing radical cystectomy with orthotopic ileal reservoir, either by open (n = 33) or laparoscopic approach (n = 39). Table 1 shows the characteristics of the patients studied. Demographic data include age, sex, and body mass index (BMI). None of the patients received neoadjuvant treatment and in all extended pelvic lymphadenectomy was performed including the lymph nodes belonging to external, internal, and common iliac vessels.

The open technique is performed through medium infraumbilical approach. For the laparoscopic approach, the patient is placed in Trendelenburg position and 4

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Demographic data of the series evaluated.</th>
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<tbody>
<tr>
<td>Mean age (range)</td>
<td>63.5 ± 9 (44–83)</td>
</tr>
<tr>
<td>Distribution by sexes (%)</td>
<td>Male 67 (93)  Female 5 (7)</td>
</tr>
<tr>
<td>Mean body mass index (range)</td>
<td>28 ± 4 (20–40)</td>
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</tbody>
</table>
Incision, less damage of the abdominal wall, and less scarring (Fig. 2).

In both approaches, intraoperative biopsy of ureters and urethra is sent to rule out tumor involvement and decrease the risk of recurrence. The type of neobladder and the way to perform uretero-intestinal anastomosis varies according to the preferences of the surgeon, regardless of the approach, Studer (n = 50, 69.4%) and Hautman (n = 18, 25%) reservoirs being the most used, as well as the direct reimplantation technique (n = 42, 58.4%) or the Wallace II plate (n = 30, 41.6%).

The study focuses on the assessment of the surgical outcomes: operative time, transfusion rate, and complications according to the Clavien-Dindo classification. We also evaluated functional results concerning the postoperative continence status: total continence (dry and completely satisfied patient), daytime continence (dry patient during the day who needs sanitary napkin or night collector) and incontinence (patient using napkins or diapers and has frequent urine leakage). The complications were analyzed in all cases during the first postoperative year. This classification system, accepted and widely used, allows for a better comparative analysis of surgical complications.

Postoperative follow-up of patients during their stay in ward included early withdrawal of nasogastric probe, start of early tolerance according to the evolution of each patient, use of non-opioid analgesics and early ambulation. All patients were managed with epidural catheter with bupivacaine perfusion (0.125%) and fentanyl (2 mcg/ml), according to the unit protocol of acute postoperative pain conducted by the anesthesia service of our institution. In this series of patients, we did not carry out any fast-track program of multimodal rehabilitation in a strict sense, although the aim of the postoperative follow-up during hospitalization was in all cases to reduce the perioperative stress and the organ damage caused by surgical trauma, accelerating the overall recovery of the patient. Ureteral catheters were removed between days 11 and 13 postoperatively in all cases that showed no postoperative complications, and bladder catheterization between days 15 and 21 of the surgery. The anatomo-pathological features of the specimen defined the use of adjuvant therapy, individualized for each patient.

Patients were evaluated monthly and every 3 months during the first year and every 6 months thereafter. The mean follow-up of patients at the time of study closure was 42.5 ± 19.2 months. The complete continence was defined as day and night control without the use of absorbents. The nocturnal continence is assumed when the patient voluntarily stands up at night to perform maneuvers of bladder evacuation without urinary leaks. The functional results were based on quantifying the involuntary leakage of urine and the number of absorbents used.

Results

The mean age of the patients was 63.5 ± 9 (range 44–83) years. A total of 67 (93%) patients were male and 5 (7%) female. The demographic data between the 2
groups were similar in age and BMI. The mean surgical time was 323.6 ± 78.7 min (321.3 ± 90.5 open and 326.5 ± 63.5 laparoscopic; p = 0.77). The mean hospital stay was 14.5 ± 8.1 days (16.2 ± 9.5 open and 13.6 ± 6.6 laparoscopic; p = 0.2). The rate of overall, intra-, and postoperative transfusion was 40.3%. A significant decrease was observed in the rate of transfusion in the laparoscopic approach, in which 17.9% (7/39) of the cases were transfused vs. 66.7% (22/33) of those undergoing open surgery (Chi-square, p < 0.0001).

A total of 34 patients of the total (47.2%) had complications. The number of complications was higher in 63.6% (21/33) of patients undergoing open surgery and in 33.3% (13/39) of patients treated by laparoscopy, with statistically significant difference (Chi-square, p = 0.01). 21 cases (29.1%) had major complications (grade > III) that occurred more frequently in open surgery (39.4% [13/33] vs. 20.5% [8/39]), although this difference was not statistically significant (Chi-square, p = 0.07). Endoscopic resolution was possible in 61.9% (13/21) of patients with major complications.

Major postoperative complications included acute pyelonephritis, ureteral stenosis, surgical wound infection, bladder lithiasis, vesicourethral anastomosis stenosis, intestinal fistula, and evisceration. Table 2 shows the relative frequency of these complications, both in the overall series and in each of the approaches. Although no significant differences were observed between the two approaches and the type of complications, evisceration and surgical wound infection were more frequent in open surgery. In contrast, intestinal fistula was greater in laparoscopic surgery. The number of cases of stenosis of the ureterointestinal anastomosis was similar in both groups. Logically, the unnoticed lesion in the anterior wall of the rectum during laparoscopic surgery was more frequent.

The mean follow-up was 42.5 ± 19.2 (range 15–70) months. 13 patients received adjuvant treatment with cisplatin and gemcitabine (18%). A total of 50 patients (69.4%) were alive and free of disease at the end of the study and they could be evaluated on the functional results achieved. The complete continence rate was 38% (19/50), 50% (12/24) being in open surgery, and 27% (7/26) in laparoscopy. This difference did not reach statistical significance (Chi-square, p = 0.09). The total daytime continence rate was 58% (29/50), reaching 70.8% (17/24) in open surgery and 46.1% (12/26) in laparoscopy. Similarly, although it is a noticeable difference, it did not reach statistical significance (Chi-square, p = 0.07). The proportion of patients requiring self-catheterization was 8% (4/50), 4.2% (1/24) resulting in open surgery, and 11.5% (3/26) in laparoscopy (Fisher, p = 0.67). The overall rate of incontinence recorded was 34% (17/50), 25% (6/24) being in open surgery and 42.3% (11/26) in laparoscopy (Chi-square, p = 0.19).

### Discussion

Radical cystectomy with orthotopic urinary diversion is a good treatment option for muscle-invasive bladder cancer in selected patients. The completion of an ileal reservoir is a complex technique that increases the risk of complications and perioperative morbidity. Most existing studies on this procedure are retrospective and comparative studies in patients undergoing open radical cystectomy with different types of intestinal reservoirs. In these studies, no significant differences are observed in the incidence of complications and functional results, regardless of the type of reservoir used. Other series use the same type of ileal reservoir (Hautmann or Kock) for all patients, with similar results. Stenzl et al. review the main series of the literature on patients undergoing open radical cystectomy and orthotopic diversion, and they highlight excellent functional and surgical results without compromising the oncological outcomes.

In recent years, minimally invasive techniques, such as laparoscopy and robot-assisted laparoscopy, have been developed as a viable surgical option in many urological diseases, with the advantage of reducing morbidity and hospital stay, thanks to the early onset of tolerance and a decrease in analgesic use. There are numerous studies comparing open radical cystectomy and robot-assisted laparoscopy. Kaiven Li et al. present a systematic review of 962 cases and conclude that robot-assisted radical cystectomy produces lower blood loss, complication rate, and hospital stay. However, there are few prospective studies comparing open radical cystectomy and conventional laparoscopy. If we also try to compare the two approaches in patients who have undergone intestinal neobladder, the studies are even scarcer. The study by Basilotte et al. compares 13 patients who underwent laparoscopic radical cystectomy and 11 who underwent open...
radical cystectomy, both with Studer ileal neobladder.\textsuperscript{17} No statistically significant differences were observed in operative time, blood loss, or complications between both approaches. However, the laparoscopic approach showed lower use of analgesics in the postoperative period, with earlier onset of tolerance and shorter hospital stay.\textsuperscript{17}

In our study, there is an obvious improvement in the transfusion rate and the number and severity of complications for the laparoscopic approach. The blood loss and overall transfusion rate in our series are similar to others of radical cystectomy using minimally invasive techniques.\textsuperscript{1-5,18} With regard to the surgical time, no differences between the two approaches are detected, the time in laparoscopy being very similar to open surgery. This is mainly because the surgeons performing this procedure already had prior experience in laparoscopic surgery and, therefore, there was no learning curve.

The overall complication rate in our series is similar to those described in other studies that conduct a systematic collection of complications, both minor and major.\textsuperscript{18,19} The overall reduction in the number and severity of complications due to the laparoscopic approach is evident. The decrease in the likelihood of having complications in patients undergoing laparoscopic approach is statistically significant, and the reduction of major complications in these same patients is very close to statistical significance. Basillette et al.\textsuperscript{17} also describe more complications in open surgery, although in their experience, major complications were more frequent in patients undergoing laparoscopy, without actually observing differences between both groups due to the small number of patients with complications. Regarding the type of surgical complications, in our experience, those related to the surgical wound (infection and evisceration) occurred almost exclusively in patients undergoing open surgery. Stenosis of the ureteroileal anastomosis was equivalent in both groups.

Regarding functional outcomes in this study, although in open surgery the daytime continence rate is very similar to that described in other series, the overall continence rate is lower than in other works of the literature.\textsuperscript{9,10,20} The technical difficulties and accuracy in performing the intracorporeal neovesico-urethral anastomoses may explain this fact. However, other factors such as prior continence and patient age should be taken into account and can greatly influence the results in one sense or another.

Therefore, in this study we can conclude that laparoscopic radical cystectomy with neobladder is a safe and effective procedure, with fewer complications than open surgery, with a lower rate of transfusion and with seemingly worse continence rate. This last point should be specifically studied in prospective randomized studies to control the uncontrolled factors in this experience.

**Conflict of interest**

The authors declare that they have no conflict of interest.

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