Original Article

Surgical and oncological short-term outcomes of prone extralevator abdominoperineal excision for low rectal cancer

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ABSTRACT

Introduction: In recent years, a standardized surgical approach for low rectal cancer was proposed and adopted in many centres. The extralevator abdominoperineal excision introduce an extensive resection of the pelvic floor and demonstrated superiority if the procedure is done in the prone jack-knife position, especially regarding intraoperative perforation and circumferential resections margins. The aim of this study is to evaluate the surgical and oncological short-term outcomes of prone extralevator abdominoperineal excision.

Methods: All patients registered in our institution from January 2003 to January 2015 who underwent abdominoperinal excision or prone extralevator abdominoperineal excision for low rectal cancer after preoperative chemoradiation were retrospectively included from prospective maintained data base and were compared regarding surgical and oncological outcomes.

Results: Eighty-nine patients underwent curative intent resections. Abdominoperineal resection was performed in 67 patients and prone extralevator abdominoperineal excision in 22 patients. There were no statistical significant differences between groups regarding pathological stage, median number of harvested lymph node, intraoperative perforation, circumferential resections margins involvement and recurrence rates. Surgical outcomes were statistically different between groups. Twenty-six patients (29%) developed perineal complications, 21% of the abdominoperineal resection patients and 55% of the prone extralevator abdominoperineal excision (p < 0.001). Most of these complications were due to delayed perineal wound healing (12.4%), and wound abscesses (4.5%). However, the readmission rate and median length of hospital stay was higher in the abdominoperineal resection group (p < 0.001).

Conclusion: Prone extralevator abdominoperineal excision is comparable to standard abdominoperineal resection. It was associated to a decrease in length of hospital stay and readmission rate, although more perineal complications occurred. We cannot recommend...
Introduction

Since 1908, when Milles published his paper about better oncological results achieved with his new technique of abdominopereineal resection (APR) for low rectal cancer (LRC), a great effort has been made to improve treatments outcomes of this ravishing disease.  

The introduction of total mesorectal excision (TME), autonomic nerve preservation and preoperative chemoradiotherapy (CRT) was essential to improve surgical outcomes and decrease local recurrence rate while preserving urinary and sexual functions. Standardized surgery seems to enhance the overall survival of patients with RC. However, those improvements observed in TME for low anterior resection (LAR) did not benefit the TME for APR at the same extent, despite the increased morbidity of this technique. Patients submitted to APR often had higher local recurrence rate, increased positive circumferential resection margin (CRM) and poorer survival compared to LAR.

When the tumour is located further down in the pelvis, closer to the anorectal ring, the surgical margins are at special risk during conventional APR. Moreover, tumours located at the anterior rectal wall, where the mesorectal fat is narrow, are also at great risk of positive CRM. For these reasons, tumours located in these critical areas have higher rate of positive CRM. The increased rate of positive CRM for APR compared to LAR is still a matter of debate, although it can be justified by the lack of clear standardized surgical technique.
and failure to identify the anatomical landmarks of the pelvic floor. These surgical obstacles often make the surgeon to enter in the wrong surgical planes, compromising surgical margins and leading to tumour perforation.

In recent years, a standardized surgical approach for LRC was proposed by the Karolinska Institute, in Sweden.9 Later, other centres in Europe adopted it as a standard of care. The so-called extralevator abdominoperineal excision (ELAPE) introduces an extensive resection of the pelvic floor including the entire anal sphincter complex, the levator muscles and part of the coccyx. Usually APR surgical specimens show a typical narrowing at the anorectal ring level, called “waist”. In the ELAPE, the levator muscles and the mesorectum are removed en bloc with the anal canal. By doing so, a cylindrical specimen is created. This might improve the rate of negative CRM without a significant increase in morbidity.10

The aim of this study is to compare the surgical and oncological short-term outcomes of ELAPE, with the patient in a prone jack-knife position (pELAPE) during the perineal dissection, to standard APR.

Methods

This study is a retrospective analysis of the database from a tertiary referral centre in surgical oncology in Brazil comprising biopsy proven rectal adenocarcinoma patients who received neoadjuvant CRT and submitted to conventional APR or pELAPE. During this period, our standard of care for locally advanced rectal adenocarcinoma within 10 cm from the anal verge was preoperative CRT followed by surgical resection. The neoadjuvant treatment plan included external beam pelvic radiation (dose ranging from 45.0 Gy to 50.4 Gy) combined with fluoropyrimidine-based chemotherapy (bolus 5-fluorouracil or oral capecitabine).

Patients population and group definition

All patients registered in INCA from January 2003 to January 2015 who underwent APR (group 1) or pELAPE (group 2) for LRC after preoperative CRT were included in the present study.4 Exclusion criteria were: synchronous distant metastases determined by computer tomography (CT) scans or magnetic resonance imaging (MRI), squamous cell carcinoma histology, recurrent tumours, and previous transanal excision. LRC was defined as any lesion located 5 cm or less from the dentate line (DL) detected by digital rectal examination or rigid proctoscopy.

The two groups were compared using the following variables: preoperative and postoperative tumour-node-metastasis (TNM)-classification,11 level of tumour from dentate line patient demographics, neoadjuvant and adjuvant treatment, abdominal access (open, laparoscopic or robotic surgery), periooperative complications (unexpected bleeding, damage to adjacent organs or structures, IOP, pathological stage, CRM status, distal margin, harvest lymph node (LN)), postoperative complications, reoperations, readmission rates and deaths.

APR technique

APR in lithotomy position was the standard surgical procedure in our Institution for low rectal cancer not suitable to sphincter preserving techniques until 2012. This procedure begins with the abdominal approach (open, laparoscopic or robotic) to perform the high ligation of inferior mesenteric vessels, mobilization of left colon and dissection along the mesorectal fascia usually to the level of pelvic floor until completion of TME. Then, leg elevation and Trendelenburg tilt in a lithotomy position is set for the perineal phase of the operation. At the discretion of the attending surgeon, a variable amount of perianal skin and fat tissue from ischiorectal fossa around the anal canal is removed during cephalad dissection. Then, the pelvic floor is reached, communicating the pelvic and the perineal spaces. A circumferential dissection of the anorectal ring is completed in order to release the surgical specimen. Pelvic closure technique is at the surgeon’s preference, including primary closure, use of local and distant flaps, or left open until delayed healing or closure.

pELAPE technique

The surgical steps are well described in previous publications.10,12 The abdominal dissection begins essentially as in APR except that dissection along the mesorectal fascia in the “holy plane” stops at the level of the seminal vesicles anteriorly and at the level of coccyx posteriorly. This is meticulously done even by open, laparoscopic or robotic technique. Prior to turning the patient to ventral decubitus, the terminal stoma is usually attached to skin at its definite location in the left lower quadrant and the trocars incisions are closed. Then, the patient is placed on a prone jack-knife position and an extended perineal dissection is performed. The resection includes the perineal and anal skin, the sphincter muscles and all the levator muscles laterally to their insertion at the pelvic sidewall. The coccyx is routinely removed en bloc with the specimen. For anterior tumours, in which the anterior margin is presumed to be involved, a portion of prostate or the posterior vaginal wall is excised en bloc to assure a negative CRM. Aiming to reduce the pelvic floor defect, the uterus, bladder or great omentum is mobilized and anchored posteriorly to the Waldeyers fascia. A prosthetic double-sided mesh (Proceed™, Ethicon, Somerville, NJ, USA) is inserted and sutured to the pelvic sidewall whenever the surgeon assumed that the defect were at risk for perineal hernia. Dermal closure is usually made in multiple layers to avoid wound dehiscence.

Pathological analysis

Pathological examinations were performed by INCA Pathology Department following a strict protocol which included fixation in 10% formalin, paint of the CRM, and serial slicing from the distal margin at 3-5 mm interval.13 The minimum distance from tumour deposits to CRM was recorded using whole-mount sections.14 CRM with less than 1 mm was considered positive involvement, according to previous evidence.15,16 Intraoperative perforation (IOP) was the occurrence of an
iatrogenic communication of the rectal lumen to external resection margin, and this information was retrieved from the surgical notes, specimen photographs or pathology reports.

**Follow-up**

After discharge, patients were evaluated in 2 weeks and then regular visits were scheduled at 1, 2 and 3 months. Nonetheless, our nurse team, up to three times a week, took care of complicated or open perineal wounds with the support of the attending surgeon. Delayed wound closure was mainly treated with saline irrigation and calcium alginate dressing. Follow-up continued in a three-month interval during the first two years and then in a six-month interval basis. Carcinembryonic antigen (CEA) levels were taken at each medical visit and abdominal and pelvic CT scans were performed twice a year during the first two years and then yearly for the next three years. MRI was used to confirm pelvic recurrence if suspected. Surveillance colonoscopy was performed at 3-year intervals. Local recurrence was suspected by imaging of growing pelvic mass that could be accompanied by elevation in CEA levels or positive emission tomography scans (PET-TC) evidence. Biopsy was indicated in doubtful cases.

**Statistical analysis**

All data were collected in a prospective maintained database. Statistical analysis was performed using SPSS 17.1 (IBM SPSS Inc., Armonk, NY, USA). Null hypotheses of no difference were rejected if p-values were less than 0.05 or, equivalently, if the 95% confidence intervals of risk point estimates excluded 1.

**Results**

From January 2003 to February 2015, 89 patients with low rectal cancer were treated with neoadjuvant CRT and underwent curative intent resections. APR was performed in 67 patients and pELAPE in 22 patients. Median patient age was 58 years and 60% were male. Clinical and pathologic characteristics of the patient population are shown in Table 1. There was

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**Table 1 – Comparison of APR vs pELAPE for low rectal cancer.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall</th>
<th>APR</th>
<th>pELAPE</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients (%)</td>
<td>89</td>
<td>67</td>
<td>22</td>
<td>0.685</td>
</tr>
<tr>
<td>Age (mean)</td>
<td>58</td>
<td>57</td>
<td>58</td>
<td>0.581</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>53 (60%)/36 (40%)</td>
<td>41 (61%)/26 (39%)</td>
<td>12 (55%)/10 (45%)</td>
<td>0.058</td>
</tr>
<tr>
<td>Median tumour height (cm)</td>
<td>0.5</td>
<td>1</td>
<td>0</td>
<td>0.907</td>
</tr>
<tr>
<td>Preoperative CRT (%)</td>
<td>89 (100%)</td>
<td>67</td>
<td>22</td>
<td>0.007</td>
</tr>
<tr>
<td>Median RT interval (weeks)</td>
<td>15</td>
<td>14</td>
<td>24</td>
<td>0.234</td>
</tr>
<tr>
<td>Median CRM width (cm)</td>
<td>0.4</td>
<td>0.4</td>
<td>0.3</td>
<td>0.642</td>
</tr>
<tr>
<td>CRM involvement overall (%)</td>
<td>32 (37%)</td>
<td>23</td>
<td>9</td>
<td>0.007</td>
</tr>
<tr>
<td>DL involvement overall (%)</td>
<td>40 (46%)</td>
<td>27</td>
<td>13</td>
<td>0.006</td>
</tr>
<tr>
<td>IOP (%)</td>
<td>10 (11%)</td>
<td>6</td>
<td>4</td>
<td>0.209</td>
</tr>
<tr>
<td>pT stage (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>5 (5.6%)</td>
<td>3</td>
<td>2</td>
<td>0.91</td>
</tr>
<tr>
<td>1</td>
<td>1 (1.1%)</td>
<td>1</td>
<td>0</td>
<td>0.63</td>
</tr>
<tr>
<td>2</td>
<td>15 (16.9%)</td>
<td>13</td>
<td>2</td>
<td>0.17</td>
</tr>
<tr>
<td>3</td>
<td>58 (65.2%)</td>
<td>44</td>
<td>14</td>
<td>0.17</td>
</tr>
<tr>
<td>4</td>
<td>10 (11.2%)</td>
<td>6</td>
<td>4</td>
<td>0.17</td>
</tr>
<tr>
<td>Median harvest LN</td>
<td>12</td>
<td>11</td>
<td>16</td>
<td>0.329</td>
</tr>
<tr>
<td>Positive LN (%)</td>
<td>30 (33.7%)</td>
<td>25</td>
<td>5</td>
<td>0.209</td>
</tr>
<tr>
<td>Abdominal approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open</td>
<td>58 (65.2%)</td>
<td>56</td>
<td>2</td>
<td>0.91</td>
</tr>
<tr>
<td>VLP</td>
<td>25 (28.1%)</td>
<td>10</td>
<td>15</td>
<td>0.68</td>
</tr>
<tr>
<td>Robotic</td>
<td>6 (6.7%)</td>
<td>1</td>
<td>5</td>
<td>0.22</td>
</tr>
<tr>
<td>Perineal mesh</td>
<td>21 (27%)</td>
<td>1</td>
<td>20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Perineal complication (%)</td>
<td>26 (29%)</td>
<td>14</td>
<td>12</td>
<td>0.003</td>
</tr>
<tr>
<td>Recurrence (%)</td>
<td>31 (35%)</td>
<td>26</td>
<td>5</td>
<td>0.17</td>
</tr>
<tr>
<td>Local (%)</td>
<td>10 (31%)</td>
<td>8</td>
<td>2</td>
<td>0.33</td>
</tr>
<tr>
<td>Distant (%)</td>
<td>16 (50%)</td>
<td>13</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Local and distant (%)</td>
<td>6 (19%)</td>
<td>5</td>
<td>1</td>
<td>0.17</td>
</tr>
<tr>
<td>Median LOS (days)</td>
<td>6</td>
<td>7</td>
<td>5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Readmission rate</td>
<td>7</td>
<td>7</td>
<td>0</td>
<td>0.126</td>
</tr>
<tr>
<td>Median follow up (months)</td>
<td>87</td>
<td>94</td>
<td>22</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

APR, abdominoperineal resection; pELAPE, prone extralevator abdominoperineal excision; CRT, chemoradiotherapy; CRM, circumferential resection margin; DL, dentate line; IOP, intraoperative perforation; LN, lymph node; LOS, length of hospital stay.

a Student t-test.

b Chi-square test.

c Mann-Whitney test.

d Fisher's exact test.
no difference in age or gender distribution between groups. All patients had preoperative CRT; however, the median time interval between CRT and surgery was significantly longer in pELAPE group (p = 0.007).

Regarding anatomical localization, tumours in pELAPE group more frequently invaded the dentate line (p = 0.006). Regarding surgical technique, there was a great imbalance in minimally invasive abdominal access between groups. Most of APR was done by laparotomy and most of pELAPE was performed by laparoscopy or robotic surgery. The main reason for it is that pELAPE patients were operated in most recent years when the minimally invasive technique was broadly used. There were also more perineal mesh reconstructions in PELAPE group (p < 0.001).

There were no statistically significant differences between groups concerning pathological stage, median number of harvested LN, IOP and CRM involvement (Table 1). Complete pathological response was observed in 5 (5.6%) of patients, 3 (4.5%) in APR group and 2 (9.1%) in pELAPE group. There was also no difference in overall recurrence rates, however median follow-up was shorter in pELAPE group (p < 0.001).

Surgical outcomes were statistically different between groups (Table 2). Among all 89 resected patients, 26 (29%) developed perineal complications after surgery that required prolonged wound care, 21% of the APR and 55% of the pELAPE group (p < 0.003). Most of these complications were due to delayed perineal wound healing (12.4%), and wound abscesses (4.5%). Nonetheless, the readmission rate and median LOS (<0.001) were higher in the APR group. It is important to note that minimally invasive surgery was performed in 90.9% of the pELAPE patients; on the other hand, only 16.4% of the patients in the APR had laparoscopic or robotic surgeries.

### Discussion

The ELAPE resection emerged in the last decade as a promising technical evolution of APR. Since then it was mostly adopted in Europe and China, and the advantages regarding reduction of IOP and CRM positivity could be reproduced by other centres, although, this favourable result was brought into question when a meta-analysis, published in 2012, failed to demonstrate these oncological advantages. Moreover, two other meta-analyses, published in 2015, found discrepant results regarding the superiority of the ELAPE.

pELAPE procedure was firstly performed at our institute in 2012, and since then a great proportion of LRC were treated by this technique and most of them (90.9%) by minimally invasive surgery. Therefore, it is important to report that in the present study we are comparing surgical and short-term oncological results from our most recent series of patients with an historical cohort of patients. At a first glance, one could state that our results did not reproduce the same favourable results published by other centres and that we could not improve our negative CRM rate changing from APR to pELAPE, even with the addition of minimally invasive technique. Nonetheless, a critical analysis of our data is warranted before hasty conclusion.

In our study, the APR and pELAPE groups were not exactly balanced despite they were treated for the same disease at the same institute. We identified at least three unmatched variables. Firstly, patients in the APR group had less involvement of the DL (42% versus 81%). We reserve pELAPE procedure for the very low and locally advanced tumours. In recent years, we indeed increased sphincter preservation surgery for LRC, including intersphincteric resection and transanal excision using transanal endoscopic microsurgery (TEM), relying in more accurate preoperative staging modalities (MRI and endorectal ultrasound) and more moderns’ neoadjuvant treatments. The second great imbalance between the two groups was the use of minimally invasive procedures (laparoscopy or robotic surgery) for the abdominal approach. The third major heterogeneity between groups was the increased interval between CRT and surgery, 14 weeks in the APR group and 24 weeks in the pELAPE group. It is known that there is a trend for delay the surgical treatment after
Habr-Gama et al. in a recent publication support these initial findings, showing that patients who underwent consolidation chemotherapy during the neoadjuvant treatment should have the assessment of tumour within 12 weeks to achieve higher rates of complete regression. However, the 24 weeks interval seen in pELAPE group probably reflects more reliance on “watch and wait” nonoperative treatment.

Analysing all data we can infer that pELAPE patients had more advanced and lower tumours with more involvement of the sphincter complex, all this with more late fibrosis radiotherapy effects due to longer interval between CRT and surgery. Even so, the overall CRM involvement, mean CRM width and IOP rate were not different between groups. Therefore, pELAPE did not compromise the surgical radicality but did not improve surgical outcomes. Two recent published data corroborate the hypothesis that ELAPE and pELAPE may not affect oncologic outcomes, including CRM involvement, IOP, local recurrence or mortality and are in correlation with our findings.

Our great concern related to the adoption of pELAPE as a standard procedure for LRC is the increased surgical morbidity observed in this technique. We had a real increase in perineal surgical complications from 21% to 55% (p < 0.003) changing from APR to pELAPE. The ideal wound closure and how to fulfill the pelvic defect after removing all the pelvic floor muscles needs to be tailored. We mostly use Proceed™ mesh, a double layered mesh of polypropylene-polydioxanone composite with oxidized cellulose with primary skin closure. Our study is the first one reporting the use of this material for primary closure of perineal defect after pELAPE. The use of this mesh has been largely studied for ventral hernia repairs. In a series of 100 consecutive laparoscopic ventral hernia surgeries, no bowel complications were reported with the use of Proceed™ mesh after a 50 months follow-up.

Other study with 210 patients showed favourable results in laparoscopic ventral and incisional hernia repair using Proceed™ mesh. In rectal cancer patients, the use of this mesh is restricted to a small series of 12 patients with perineal hernias after APR treated laparoscopically.

It is believed that the cellulose layer prevent bowel adhesions meanwhile the polypropylene mattress prevent herniation throughout perineal defect. Despite all these potential advantages of Proceed™ mesh, we observed an increase in the rate of perineal complications compared to our previous experience in conventional APR, in which only one patient had mesh use. One patient in pELAPE had late wound complications related to mesh displacement, delayed wound closure, urinary fistula and bowel obstruction due to adhesions and failure to incorporate the mesh in subcutaneous tissue. In one case of dehiscence, the mesh remained exposed for more than a year and was removed to allow perineal healing.

Our results are in consensus with a recent publication regarding perineal complications after ELAPE that reported an alarming 44% of perineal wound complication including dehiscence and perineal hernia. In the literature, there are plenty of options for perineal wound closure after ELAPE. The Swedish ELAPE original paper proposes glutur flap for the perineal wound closure, but this technique has the disadvantage of prolonged hospitalization and restriction of early mobilization.

A meta-analysis, published in 2013, comparing outcomes of biomesh insertion, flap reconstruction and primary closure, found no evidence to support any of these techniques. A recent single centre study about perineal wound closure using biomesh also revealed an increase morbidity of this technique. In this study 53 patients underwent ELAPE, of them, 3 (6%) patients developed perineal hernia, 11 had fistulae, 4 had perineal abscess and 4 had superficial wound infections. Chronic pain was also present in one-third of the patients evaluated. A recently published systematic review focused on the results of ELAPE and the use of mesh, flaps or both to closure the perineal defect. The review found 17 studies meeting their inclusion criteria and only one was a Randomized Clinical Trial. The biological meshes used in these revised studies were cross-linked porcine dermal collagen (Permacol™), porcine intestinal submucosa (Surgisis®) and human acellular dermal matrix meshes (Surgical Mesh©). In the 436 cases identified, there were 41 perineal hernias (9.4%) and 93 wound infections (21.3%). The overall rate of perineal complications was higher ranging from 11.3% to 25%, and the most common complication was infection and perineal sinus. Compared to myocutaneous flaps, biological mesh insertions had the same rate of complications but were associated to shorter operative time and early mobilization, which was more cost-effective in the author’s conclusion. It is of some importance to report that there are very few studies comparing biological mesh for perineal reconstruction and all of them are low-level evidence.

Our surgical outcomes for APR and pELAPE are comparable to the literature. We postulate that there is no proof of superiority of any specific mesh over the others so far, even if the perineal mesh insertion is routinely needed. Nonetheless, we still use mesh insertion in our routine. However, since our study, closed we started to use more local tissue interposition (uterus, omental flaps and bladder) between mesh and bowels. We are now also performing more myofascial mobilization for skin closure over the mesh in order to decrease tension and prevent dehiscence. We believe that with these technical modifications, our perineal wound complication rates can be overcome. Finally, a randomized multicentre clinical trial is being conducted in Europe aiming to compare the results of perineal mesh closure (acellular biological mesh – Strattice™) with primary perineal wound closure. The endpoints are perineal hernia, wound healing and cost-effectiveness. Those results are awaited.

In our case series, the pELAPE technique combined to minimally invasive surgery achieved a reduction in postoperative LOS and reduced the readmission rate compared to APR. Although there were more perineal wound complications, they were not life threatening and could be managed in an outpatient basis in most cases. Our study could not define if the main factor associated to reduction observed in the LOS was the perineal approach, the minimally invasive surgery or both.

We believe that our retrospective study has limitations. One of the drawbacks is the long period of the study analysis. The study period spanned twelve years during which the skills of surgeons and the surgical techniques could have improved. In addition, the evolution of minimally invasive surgery was
incorporated in our surgical approach. It means that patients treated after 2012 were more prone to receive laparoscopy or robotic surgery and therefore bias regarding surgical complications and LOS may have occurred. Another potential limitation is the discrepancy between the number of patients included in each group. The number of patients in the pELAPE group was three times smaller than APR group and therefore our findings should be corroborated with larger series of patients treated with pELAPE.

Conclusion

pELAPE is comparable in terms of radicality to standard APR and was associated to a decrease in LOS and in readmission rate, although more perineal complications occurred. We cannot recommend it as a standard technique for all rectal tumours. Notwithstanding, pELAPE can be considered a more radical approach when there is sphincter complex or levators muscles invasion.

Conflicts of interest

The authors declare no conflicts of interest.

REFERENCES