Randomised controlled study of laparoscopic versus open reversal of Hartmann’s procedure

Tarek M. Sehsah*, Osama H. Abd-Raboh, Taha A. Ismail, Soliman M. Soliman

INTRODUCTION

Living with a colostomy has a considerable effect on a patient’s quality of life, satisfaction and self-image. Colostomy has quality of life implications, ranging from skin rashes, sexual dysfunction, parastomal hernia and psychological distress.

A substantial proportion of patients (up to 74%) may be left with a permanent stoma due to impossibility to restore the intestinal continuity.

Open restoration of bowel continuity after a Hartmann procedure is technically challenging and has been associated with significant morbidity (13-50%), including anastomotic leakage (0-15%), incisional hernia and wound infections. The mortality rate for the open approach remains high at 5-10%. Hartmann, a French surgeon, in 1921, published a technique for the treatment of rectal cancer. This technique consisted of sigmoidectomy followed by terminal colostomy in the left iliac fossa and closure of the rectal stump.

While the initial indication has evolved to other pathologies such as perforated diverticular disease and ischaemic colitis, the operation still carries his eponymous name. In 1993, Anderson and Gorey et al described 1st report of a laparoscopically assisted Hartmann’s reversal.
Technical demands of laparoscopic reversal of Hartmann’s (LHR) have limited its universal acceptance. However, the overall rise in experience and confidence in laparoscopic adhesiolysis by surgeons changed this perception.\textsuperscript{14}

A meta-analysis of published literature comparing open vs laparoscopic Hartmann’s reversal in which 8 comparative studies involving 450 patients were analysed showed that LHR has significantly reduced complication rate, intra-operative blood loss and hospital stay, but there was no difference in leak rates.\textsuperscript{15}

LHR procedure is safe, has fewer complications. This approach may be considered for reversal, however, randomized controlled trials are required to strengthen the evidence.\textsuperscript{15}

The aim of this study was to compare LHR versus open reversal of Hartmann’s (OHR) procedure regarding to operative time, postoperative pain, hospital stay, postoperative complications and cost.

**METHODS**

This study was conducted on 40 patients with Hartmann’s colostomy admitted to the general surgery department, Tanta university hospitals, during the period from February 2017 to August 2019. Local ethical committee approval was obtained to enrol patients in this study from faculty of medicine Tanta university. Written consents were obtained from all patients who participated in the study.

Patients were divided into 2 groups, 20 patients each. Randomization was achieved by sealed envelopes to ensure balanced recruitment: LHR group: was subjected to LHR, OHR group: was subjected to OHR.

Statistical analysis was done by SPSS 25 (SPSS Inc., Chicago, IL, USA). Quantitative variables were presented as mean, standard deviation (SD) and range and was compared between the two groups utilizing student’s t-test. Qualitative variables were presented as frequency and percentage (%) and were analysed utilizing the chi-square test or fisher’s exact test when appropriate. P value <0.05 was considered significant.

Inclusion criteria included patients with Hartmann’s colostomy. Exclusion criteria excluded patients with faecal incontinence, patients with non-curable colon and rectal cancer and patients with major comorbidity (cardiac, hepatic or renal failure).

Surgical team positioning was like- surgeon stands at patient’s right side with the dissecting right hand and with his left hand holding a bowel grasper. (Figure 1). The 1\textsuperscript{st} assistant is on the surgeon’s left side, with the camera in his right hand.

The right lower quadrant (RLQ) 5-12 mm, right upper quadrant (RUQ) 5 mm, and midline (ML) 5-12 mm ports are placed as shown (Figure 2). The left lateral (LL) port 5 mm is put as laterally as possible at the level of the ML port these were the port sites.

**Figure 1: Surgical team positioning.**

**Figure 2: Port sites.**

The peritoneum is insufflated to 12 mm of pressure using a 5 mm optical entry port via the RUQ. With adequate Trendelenburg and right side rotated down positioning. Further adhesiolysis (Figure 3) proceeds as required to mobilize small bowel and omentum adherent to the abdominal wall.

**Figure 3: Adhesiolysis of adhesions between small bowel and the abdominal wall.**

Splenic flexure, distal sigmoid stump and rectum are mobilised by energy device as LigaSure® (Figure 4 and 5).
Figure 4: Mobilisation of the sigmoid colon using LigaSure®.

Figure 5: Splenic flexure mobilization.

Division of the upper rectum using stapler using an endoscopic linear stapler via the 12-mm LLQ port. The stoma is mobilized by an elliptical skin incision inclusive of the stoma. The anvil of a 29 F end-to-end anastomosis circular stapling device is inserted into the colonic end and the purse string ligated to ensure closure of the colonic end around the stem of the anvil. The stapler is inserted per anally, either by the surgeon or the assistant, to the proximal limit of the rectal stump under laparoscopic visualization. The stylet of the stapler is advanced through the proximal end of rectal wall. The anvil and colonic end are grasped and the shaft of the anvil is ‘docked’ onto the stylet: The stylet, with anvil attached, is retracted into the head of the stapling device until appropriate tissue compression is achieved (Figure 6).

Figure 6: The stylet with anvil attached.

RESULTS

Pre-procedural work up

Age ranged from 18-72 years with a mean value 36.65±15.73 years in the LHR group and from 17-68 years with a mean value 38.45±12.79 years in the OHR group. The age showed statistically insignificant difference between both groups (p=0.693).

According to the gender, there were 19 male patients (95%) and one female patient (5%) in the LHR group while in the OHR group, there were 14 male patients (70%) and 6 female patients (30%). The gender showed statistically insignificant difference between both groups (p=0.092).

According to the time interval to reversal, in the LHR group it ranged from (2.5-12) months with a mean value 5.225±2.99 months and from 4-13 months with a mean value 5.85±2.28 months in the OHR group. The time interval showed statistically insignificant difference between both groups (p=0.462).

Procedural work up

According to the operative time, in the LHR group it ranged from (145-220) minutes with mean value 274.75±80.65 min and from (114-230) min with mean value 156.75±32.81 min in the OHR group. The operative time showed statistically significant increase in the LHR group (p<0.001).

Post-procedural work up

Time to pass flatus ranged from (1.00-3) days with a mean value 1.78±0.68 days in the LHR group and from (1.50-4) days with a mean value 2.49±0.78 days in the OHR group. The time to pass flatus was statistically significant earlier in LHR group (p=0.004).

Pain score in POD1 ranged from (1-4) NRS with a mean value of 2.1±1.02 NRS in the LHR group and ranged from (1-7) NRS with a mean value of 4.095±2.00 NRS in the OHR group. The pain score showed statistically significant decrease in LHR group (p<0.001).

According to post-operative complications, in the LHR group there was one patient developed bleeding (5%), one developed wound infection (5%), 3 patients developed distension and ileus (15%) and 1 patient developed leak and recolostomy (5%), one patient developed urinoma (5%), 1 patient developed impotence (5%), 1 patient developed incisional hernia (5%) through the RLQ port site while in the OHR group there were 7 patients developed wound infection (35%), one patient developed distension and ileus (5%), no patient developed urinoma (0%), 4 patients developed incisional hernia (20%), no patient developed neither impotence (0%) nor bleeding nor leak (0%). The total post-operative
complication rate showed insignificant difference between both groups (p=0.243) as 6 cases (30%) in the LHR group showed post-operative complications and 10 cases (50%) in the OHR group showed complications in the OHR group.

Table 1: Pre-procedural work up.

<table>
<thead>
<tr>
<th>Variables</th>
<th>LHR group (n=20)</th>
<th>OHR group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Range 18-72</td>
<td>17-68</td>
<td>0.693</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 36.65±15.73</td>
<td>38.45±12.79</td>
<td></td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Male 19 (95)</td>
<td>14 (70)</td>
<td>0.092</td>
</tr>
<tr>
<td></td>
<td>Female 1(5)</td>
<td>6(30)</td>
<td></td>
</tr>
<tr>
<td>Time interval to reversal (months)</td>
<td>Range 2.5-12</td>
<td>4-13</td>
<td>0.462</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 5.225±2.99</td>
<td>5.85±2.28</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Procedural work up.

<table>
<thead>
<tr>
<th>Variables</th>
<th>LHR group (n=20)</th>
<th>OHR group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (min)</td>
<td>Range 145-420</td>
<td>114-230</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 274.75±80.65</td>
<td>156.75±32.81</td>
<td></td>
</tr>
<tr>
<td>Estimated blood Loss (ml)</td>
<td>Range 100-350</td>
<td>50-400</td>
<td>0.971</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 172.5±69.73</td>
<td>175.5±108.12</td>
<td></td>
</tr>
<tr>
<td>Bowel injury (%)</td>
<td>1 (5)</td>
<td>1 (5)</td>
<td>0.387</td>
</tr>
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</table>

Table 3: Post-procedural work up.

<table>
<thead>
<tr>
<th>Variables</th>
<th>LHR group (n=20)</th>
<th>OHR group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to pass flatus (days)</td>
<td>Range 1-3</td>
<td>1.50-4</td>
<td>0.004*</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 1.78±0.68</td>
<td>2.49±0.78</td>
<td></td>
</tr>
<tr>
<td>Oral feeding (days)</td>
<td>Range 1-3</td>
<td>1.5-4</td>
<td>0.004*</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 1.78±0.68</td>
<td>2.49±0.78</td>
<td></td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>Range 4-12</td>
<td>6-14</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 6.1±2.47</td>
<td>9.3±2.20</td>
<td></td>
</tr>
<tr>
<td>Pain score in POD1 (NRS)</td>
<td>Range 1-4</td>
<td>1-7</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Mean±SD 2.1±1.02</td>
<td>4.095±2.00</td>
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</tbody>
</table>

Table 4: Post-operative complications.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group LHR (n=20) (%)</th>
<th>Group OHR (n=20) (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>1 (5)</td>
<td>0 (0)</td>
<td>1</td>
</tr>
<tr>
<td>Wound infection</td>
<td>1 (5)</td>
<td>7 (35)</td>
<td>0.018</td>
</tr>
<tr>
<td>Distension and ileus</td>
<td>3 (15)</td>
<td>1 (5)</td>
<td>0.605</td>
</tr>
<tr>
<td>Leak and recolostomy</td>
<td>1 (5)</td>
<td>0 (0)</td>
<td>1</td>
</tr>
<tr>
<td>Incisional hernia</td>
<td>1 (5)</td>
<td>4 (20)</td>
<td>0.342</td>
</tr>
<tr>
<td>Urinoma</td>
<td>1 (5)</td>
<td>0 (0)</td>
<td>1</td>
</tr>
</tbody>
</table>

DISCUSSION

Reversal of Hartmann’s procedure is a major operation that requires a long, midline, abdominal incision. Wound-related, pain-related complications, morbidity and perioperative mortality are common.

Laparoscopic reversal has been increasingly practiced worldwide since the laparoscopic era. However, so far only a few studies have been published regarding the results of LHR procedure.

In this study, the difference in time interval to reversal was statistically insignificant (p=0.462) when comparing the LHR group to the OHR group, with mean value 5.225±2.99 months in the LHR group and 5.85±2.28 months in the OHR group.

These results were consistent with results reported by Brathwaite et al and Mazeh et al in which time interval to reversal was with a mean value of (7.9 months vs 8.8 months; p=0.22) and (4.95 months vs 7.71 months; p=0.02) respectively in the LHR group vs the OHR group.16-17
These results were different from the results reported by Kwak et al and Haughn et al in which the time interval to reversal was with a median value of (17.6 months vs 9.3 months; p=0.433) and (5.7±2 months vs 14±15.5; p=0.001) respectively in the LHR group vs the OHR group.\textsuperscript{16-19}

Regarding operative time in this study, it was significantly higher in the LHR group than in the OHR group (p<0.001). Operative time was with a mean value 274.75±80.65 mins in the LHR group and 156.75±32.81 minutes in the OHR group.

These results were consistent with results reported by Yang et al in which the operative time was with a mean value 276.4±70 min in the LHR group and with a mean value 242±78.3 min in the OHR group which is statistically significant (p=0.02).\textsuperscript{20}

Brathwaite et al also showed a longer operative time in the LHR group (336.6 min vs 316.9 min; p=0.38) but the results are different from this study.\textsuperscript{16}

The results reported by Kwak et al, Mazeh et al and Haughn et al were inconsistent with this study as the mean operative time in the OHR group was longer than the LHR as (212.5±75.2 min vs 251.8±102.4 min; p=0.243), (193.1 min vs 209.2 min; p=0.33), (154±21 min vs 210±70 min; p=0.001) respectively in the LHR group vs the OHR group.\textsuperscript{17-19}

These diversities of results between studies may be due to different levels of experience in laparoscopic skills and also according to different indication of Hartmann’s procedure.

In this study, Difference in blood loss was statistically insignificant (p=0.971) when comparing the LHR group to the OHR group. Blood loss was with mean value 172.5±69.73 ml in the LHR group and 175.5±108.12 ml in the OHR group.

These results were comparable with results reported by Brathwaite et al in which the blood loss was with a mean value 134 ml in the LHR group and 209 ml in the OHR group which is statistically insignificant (p=0.06).\textsuperscript{16}

The results reported by Mazeh et al, Haughn et al and Kwak et al were different from this study as the mean of estimated blood loss was larger in the OHR group than the LHR group as (166.6 ml vs 326.6 ml ; 0.0003) , (254±59 ml vs 363±318 ml; p=0.174) and (114.1±264.6 ml vs 594.2±630.2 ml; p=0.026) respectively in the LHR vs the OHR group.\textsuperscript{17,19}

In this study, the difference in time to pass flatus was significantly (p=0.004) lower in the LHR group than that in the OHR group with a mean value 1.78±0.68 days in the LHR group and 2.49±0.78 days in the OHR group.

These results were consistent with the results reported by Kwak et al in which the time to pass flatus was with a mean value 1.8 days in the LHR group and with a mean value 2.8 days in the OHR group which is statistically significant (p=0.020).\textsuperscript{18}

The results reported by Yang et al, Mazeh et al and Haughn et al although they show statistical significance between both groups with faster passage of flatus in the LHR group, but the data were different from this study as the mean value of time to pass flatus was (2.8±0.9 days vs 4±1.5 days; p<0.001), (4.2 days vs 5.3 days; p=0.023) and (1.9±0.5 vs 5.1±2.7 days; p=0.001) respectively in the LHR vs the OHR group.\textsuperscript{17,19,20}

In this study, the difference in the hospital stay was significantly (p<0.001) lower in the LHR group than that in the OHR group with mean value 6.1±2.47 days in the LHR group and 9.3±2.20 days in the OHR group.

These results were comparable with results reported by Brathwaite et al, Yang et al, Mazeh et al and Haughn et al in which the mean of the hospital stay was shorter in the LHR group as (5.7 days vs 7.9 days; p=0.01), (6.7±2.6 days vs 10.8±6.4 days; p<0.001), (6.5 days vs 8.1 days; p=0.001) and (4.1±0.6 days vs 8.5±8.8 days; p=0.001) in the LHR group vs the OHR group.\textsuperscript{16,17,119,20}

These results are inconsistent with the results reported by Kwak et al in which the hospital stay was with a mean value 11.7 days in the LHR group and with a mean value 14.8 days in the OHR group which is statistically insignificant (p=0.243).\textsuperscript{18}

Regarding post-operative complications; difference in the total number of complicated cases was statistically insignificant (p=0.243) when comparing the LHR group to the OHR group. In the LHR group, 6 patients (30\%) developed post-operative complications while in the OHR group 10 (50\%).

These results were consistent with the results reported by Kwak et al in which the post-operative complications were in 29.4\% of patients in the LHR group and in 41.7\% of patients in the OHR group which is statistically insignificant (p=0.913).\textsuperscript{18}

Although Yang et al and Haughn et al showed that there was less rate of post-operative complications in the LHR group, there results were not similar to this study as (14\% vs 31\%; p=0.04) and (13.1\% vs 18.1\%; 0.454) respectively in the LHR group vs the OHR group.\textsuperscript{19,20}

On a contrary, other studies showed more post-operative complication rates in the LHR group than the OHR group as Mazeh et al and Brathwaite et al as the rate of post-operative complications was (29.3\% vs 21\%); and (68.4\% vs in 62.9\%) respectively in the LHR group vs the OHR group.\textsuperscript{16,17}
In this study, post-operative wound infection occurred in 1 patient (5%) in the LHR group and 7 patients (35%) in the OHR group which was statistically significant (p=0.018).

Other studies reported less rate of wound infection in the LHR group, but failed to show statistical significance like by Brathwaite et al and Mazeh et al with a rate of (15.8% vs 21%; p=0.75) and (14.6% vs 19.5%; p=0.557) respectively in the LHR group vs the OHR group.16,17

Also, the results reported by Toro et al which were done on 684 patients undergoing LHR showed incomparable results to this study with high rate of post-operative wound infection of 36.6% of cases.21 Meanwhile the results reported by and Richards et al which were done on 252 patients undergoing OHR showed that rate of post-operative wound infection was 31% of cases.22

In this study, the difference in post-operative ileus was statistically insignificant (p=0.605) when comparing the LHR group to the OHR group. In the LHR group, 15% of patients developed ileus while in the OHR group 5% of cases developed ileus.

These results were similar to results reported by Toro et al which were done on 684 patients undergoing LHR showed that rate of post-operative ileus was 11.6% of cases.21

On a contrary, the studies reported by Brathwaite et al, Mazeh et al and Daniel et al showed that the post-operative ileus was more in the OHR group as (5.3% vs 18.8%; p=1), (9.75% vs 17.1%; p=0.331) and (2% vs 17%; p=0.331) respectively in the LHR group vs the OHR group.16,17,23

In this study, the difference in post-operative leak was statistically insignificant (p=1) when comparing the LHR group to OHR group. In LHR group, 1 patient (5%) developed leak while in OHR group (0%) developed leak.

The results reported by Toro et al.21 which were done on 684 patients undergoing LHR showed comparable results in which the rate of post-operative leak was 4.7% of cases, also the results reported by and Richards et al which were done on 252 patients undergoing OHR showed similar results in which that rate of post-operative leak was 4% of cases.21,22

These results were different from the results reported by Kwak et al in which the leak occurred in 11.8% of patients in the LHR group and in 16.7% of patients in the OHR group which is statistically insignificant (p=0.706).18

In this study, incisional hernia developed in 1 patient (5%) in the LHR group while in 4 patients (20%) in the OHR group, the difference was statistically insignificant (p=0.342).

The results reported by Haughn et al and Daniel et al showed a higher rate of incisional hernia in the OHR group but the results were different as (0% vs 4.9%) and (0% vs 14%; p=0.012) respectively in the LHR group vs the OHR group.19,21

**Limitations**

Studies with a larger number of cases are needed to answer some questions like whether patient selection is needed according to the indication of the Hartmann’s procedure and to assess the benefit of the primary anastomosis with diverting ileostomy (PADI) in comparison with Hartmann’s procedure.

**CONCLUSION**

LHR is highly demanding technique and needs an experienced surgeon with techniques of laparoscopic dissection and adhesiolysis.

It is safe and feasible, with more favourable surgical outcomes, compared with open surgery. The total complication rate of the laparoscopic reversal was comparable to the literature with less wound infection, less incisional hernia, shorter hospital stays, less post-operative pain, faster return of bowel habit than the open approach and lastly the conversion rate is acceptable.

In this era of minimal-access surgery and with increasing attention to fast-track protocols, we believe the laparoscopic approach should be the standard technique for patients undergoing reversal of Hartmann’s procedure. However, LHR procedure needs a surgical learning curve.

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**Conflict of interest: None declared**

**Ethical approval: The study was approved by the Institutional Ethics Committee**

**REFERENCES**


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