Hand-assisted Laparoscopy Versus Conventional Median Laparotomy for Aortobifemoral Bypass for Severe Aorto-iliac Occlusive Disease: A Prospective Randomised Study

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Objectives. To demonstrate that hand-assisted laparoscopy for aortofemoral bypass for severe aorto-iliac occlusive disease reduces morbidity with earlier recovery of bowel function and shorter in-hospital stay.

Design. Randomised controlled trial.

Materials and methods. Thirty-six consecutive patients with severe aorto-iliac occlusive disease (TASK C/D) without history of major abdominal surgery necessitating an aortobifemoral bypass were randomised between a hand-assisted laparoscopic (HALS) approach and a conventional median laparotomy. Operative data, early recovery data, quality of life and vascular outcome were analysed.

Results. No significant differences in operative data were found. Fluid and solid diet were resumed earlier (28.8 hrs vs. 76.9 hrs; \( p = 0.016 \)) (45.6 hrs vs. 105.6 hrs; \( p = 0.02 \)) and in-hospital stay was shorter (7.5 vs. 8.9 days; \( p = 0.005 \)) in the HALS group. Six weeks post-operatively social functioning measured by the SF-36 survey score was better in patients randomised to HALS (\( p = 0.023 \)).

Conclusions. HALS is a less invasive approach for aortofemoral bypass.

Keywords: Aorto-iliac occlusive disease; Aortobifemoral graft; Minimal-invasive; Minimal-access; Hand-assisted laparoscopy.

Introduction

The treatment of aorto-iliac occlusive disease has changed dramatically with the introduction of percutaneous angioplasty and stenting. However, according to the TransAtlantic Inter-Society Consensus (TASC) for severe aorto-iliac disease (TASC D) aortobifemoral bypass remains the therapy of choice. For TASC C lesions definitive recommendations must await more convincing evidence, but also for these lesions the preferred therapeutic option tends towards aortobifemoral bypass.\(^1\)

Operative mortality and morbidity rates are traditionally cited as the major drawback of direct aortic reconstruction.\(^2,3\) However, it has been well documented that morbidity can be influenced by the surgical approach.\(^4,5\) Therefore, in analogy with the good results of laparoscopic abdominal procedures, laparoscopic aortic surgery looks very promising.\(^6,7\)

But totally laparoscopic and even laparoscopically assisted aortic surgery remains technically demanding. To minimize the learning curve and in anticipation of increasing surgical experience and better instrumentation that will make advanced totally laparoscopic surgery feasible for every surgeon, hand-assisted laparoscopy (HALS) was successfully introduced.\(^8\)–\(^10\) However, the fact that HALS still requires a mini-laparotomy with stretched wound edges throughout the procedure aroused scepticism whether HALS maintained minimally invasive characteristics. Therefore, we set up a randomised controlled trial to study the clinical outcome of HALS aortobifemoral graft for occlusive disease compared with conventional open technique.

Materials and Methods

Between January 2003 and January 2004 39 patients without history of major abdominal surgery were treated with an aortobifemoral bypass because of severe aorto-iliac occlusive disease (TASC C/D) at our
university hospital. During the same period 33 patients were treated with a femorofemoral crossover bypass or axillofemoral bypass because of contraindications for anatomical revascularisation (severe cardiac dysfunction with ejection fraction <30%, severe pulmonary disease excluding general anesthesia, short life expectancy). All but 3 of the 39 patients considered for aortobifemoral bypass were included in the study and randomised between either hand-assisted laparoscopic (HALS) approach or conventional median laparotomy. The patients not included in the study were selected for totally laparoscopic bypass. No patients were excluded from the study for vascular reasons. Randomisation occurred by alternate allocation from the order the patient entered the waiting list. According to the local legislation at the time of this study no approval by the ethical committee nor an informed consent of the patient was necessary.

Patients were not required to eat a low residue diet before surgery. The evening before surgery all patients received bowel preparation.

Before induction of general anesthesia patients in both groups received an epidural catheter with a loading dose of chirocaine. Postoperatively, a patient-controlled epidural analgesia (PCEA) system was set up.

As described previously, in patients treated by the HALS approach the femoral arteries were dissected free in the conventional way through two groin incisions. A supra-umbilical midline incision was made, the length being determined by the size of the surgeon’s hand. Two additional 10 mm trocars were inserted, one in the hypogastrium, one in the left iliac fossa. The minilaparotomy was sealed with a Gelport® (Applied Medical, Rancho Santa Margarita, CA92688, USA) and a pneumoperitoneum of 12 mmHg was applied. The patient was put in a 30° Trendelenburg position and tilted slightly to the right. The dorsal peritoneum was opened and the infrarenal aorta was dissected free using a combination of blunt digital dissection and harmonic scalpel. Retroperitoneal tunneling to the groins was performed by blunt digital dissection. After finishing the dissection the pneumoperitoneum was deflated and an orthostatic retractor was put in place. Through the minilaparotomy, the aorta was clamped and the proximal anastomosis was performed using conventional vascular instruments. The graft was pulled to the groins and the distal anastomoses were performed. After completion of the distal anastomoses, laparoscopy was performed to inspect the abdominal cavity. Special care was taken to close the dorsal peritoneum over the graft.

The conventional open aortobifemoral bypass was performed through a midline laparotomy and two groin incisions.

Data analysed in this study include patient demographics (age, gender, body mass index (BMI), cardiovascular risk factors, ASA-score, TASC classification, Fontaine classification), operative data (incision length, operative time, estimated blood loss, open conversions, type of proximal anastomosis, complications) and patient recovery data (time to PCEA removal, time to return to fluid diet, time to return to solid diet, time to ambulation, time to discharge). To evaluate differences in lung function vital capacity and forced expiratory volume in one second were measured pre-operatively and on the second post-operative day. To evaluate quality of life all patients were asked to complete a SF-36® survey pre-operatively and 6 weeks post-operatively. The SF-36® survey is a well validated health status scale including 36 questions and a standardised scoring scale measuring eight health concepts: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and mental health. In the long-term follow-up special attention was given to graft patency and incisional hernia.

We hypothesised that HALS would result in reduction of morbidity, resulting in shorter recovery and hospitalisation.

The sample size needed to be able to demonstrate a reduction of in hospital stay of 25% with 80% power and \( p = 0.05 \) was calculated in advance using the Altman nomogram. In a historical control group of 50 patients undergoing aortobifemoral bypass by conventional surgery the mean hospital stay was 7.7 days with a standard deviation of 1.99. The calculated sample size was 30, i.e. fifteen in each group.

Statistical analysis included the unpaired t-test for data with a normal distribution and the Mann-Whitney test for data not normally distribution.

Results

Thirty-six patients were included in the study: 18 in the HALS group and 18 in the conventional open group. Fig. 1 gives an overview of the study.

The demographics of patients are summarised in Table 1, for patients who underwent HALS aortobifemoral bypass or conventional open bypass respectively. There were no significant differences between these two groups with respect to sex, age, BMI, cardiovascular risk factors and severity of disease. However, in the HALS group more patients belonged to ASA class III (56% vs. 17% in the conventional group).

The operative data are summarised in Table 2. Operation time, estimated amount of blood loss and
body temperature were similar for both groups. The incision length was shorter in the HALS group (5.4 cm vs. 24.8 cm; \(p < 0.0001\)). In the HALS group one patient developed a trash foot intra-operatively, no intra-operative complications occurred in the conventional open group. In the HALS group no conversions to conventional open surgery were necessary.

When looking at patient recovery data (Table 3), both fluid and solid diet were resumed significantly earlier in the HALS group (28.8 hrs vs. 76.9 hrs; \(p = 0.017\)) (45.6 hrs vs. 105.6 hrs; \(p = 0.02\)) and the length of hospital stay was shortened (7.5 days vs. 8.9 days; \(p = 0.005\)). In the HALS group the patient with the trash foot stayed 26 days for further conservative care of the foot without major amputation. In both groups one patient needed prolonged intubation leading to prolonged hospitalisations of 25 and 30 days. Excluding these patients, the median length of stay was reduced from 7 days in the conventional open group to 5 days in the HALS group.

Also the PCEA system could be removed earlier in the HALS group (1.2 days vs. 3.5 days; \(p < 0.0001\)). The decision to remove the PCEA system was taken when patients did not press for an extra bolus over the past 12 hours or on the 4th postoperative day.

Three serious post-operative adverse events occurred (8.3%). In the HALS group, one patient (5.6%) died on the third postoperative day of arrhythmia. Another patient developed overwhelming pneumonia.

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Table 1. Patient demographics

<table>
<thead>
<tr>
<th></th>
<th>HALS</th>
<th>Conventional</th>
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</thead>
<tbody>
<tr>
<td>Age (mean, range))</td>
<td>57.4 (37–76)</td>
<td>60.1 (48–75)</td>
</tr>
<tr>
<td>Gender (M/F (n))</td>
<td>13/5</td>
<td>14/4</td>
</tr>
<tr>
<td>BMI (mean, range)</td>
<td>23.6 (18.6–28.4)</td>
<td>23.6 (16.5–31.2)</td>
</tr>
<tr>
<td>Smoking (n)</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Diabetes (n)</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>ASHD (n)</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Hypertension (n)</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>ASA (I/II/III) (n)</td>
<td>2/6/10</td>
<td>3/12/3</td>
</tr>
<tr>
<td>TASC C/D (n)</td>
<td>9/9</td>
<td>8/10</td>
</tr>
<tr>
<td>Fontaine II/III/IV (n)</td>
<td>13/5/0</td>
<td>14/4/0</td>
</tr>
<tr>
<td>Pre-operative ankle-brachial pressure index at rest (mean, range)</td>
<td>0.5 (0.1–0.8)</td>
<td>0.5 (0.2–0.7)</td>
</tr>
</tbody>
</table>

Table 2. Operative data

<table>
<thead>
<tr>
<th></th>
<th>HALS</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision length (cm, mean (95% CI))</td>
<td>5.4 (5–5.9)</td>
<td>24.8 (22.8–26.7)</td>
</tr>
<tr>
<td>Type of proximal anastomosis (E-to-E/E-to-S (n))</td>
<td>5/13</td>
<td>3/15</td>
</tr>
<tr>
<td>Operation time (min, mean (95% CI))</td>
<td>207 (190–223)</td>
<td>205 (172–238)</td>
</tr>
<tr>
<td>Estimated blood loss (ml, mean (95% CI))</td>
<td>794 (399–1190)</td>
<td>642 (478–807)</td>
</tr>
<tr>
<td>Body temperature at termination (°C, mean (95% CI))</td>
<td>36.4 (36–36.9)</td>
<td>36.5 (36.1–37)</td>
</tr>
</tbody>
</table>

* AtheroSclerotic Heart Disease.
& ASA: American Society of Anesthesiologists; ASA 1 denotes a healthy individual, ASA 2 denotes a mild systemic disease, ASA 3 denotes a severe but not incapacitating disease.
& Fontaine II denotes claudication, Fontaine III denotes rest pain and Fontaine IV denotes tissue loss.
requiring prolonged intubation. In the conventional open group, one patient developed severe cardiopulmonary insufficiency, needing prolonged intubation.

In the HALS group 4 patients did not perform the post-operative lung function test. In two patients this was for logistic reasons, in 2 patients (12.5%) either the patient or the lung function technician decided the patient was not capable of doing so. In the conventional group 9 patients did not perform the post-operative lung function tests. In one patient this was for logistic reasons, but in 8 patients (47%) the lung function test was not performed because either the patient or the lung function technician decided the patient was not capable of doing so. Delaying the post-operative lung function test could have reduced the amount of patients not able to perform the test. However, when writing the protocol for this study it was thought that the difference in lung function would be an early effect. No differences in lung function could be detected in patients who completed testing.

Table 4 shows the analysis of the SF-36 survey scores in both groups 6 weeks after surgery. No significant difference could be demonstrated except for social functioning ($p = 0.023$). Patients 6 weeks after HALS had a significantly better social functioning than patients after conventional open surgery.

In the HALS group 2 patients were lost to follow-up and one patient died in hospital, leaving fifteen patients for long-term follow-up. The mean follow-up for these patients was 19.8 months (range 12–32). Of these patients one patient developed an incisional hernia, treated conservatively. One patient experienced recurrence of unilateral claudication 11 months post-operatively for which a correction of the distal anastomosis was needed. Two patients developed occlusion of one limb (at 10 months and 26 months respectively). One of them was treated with a femoro-femoral crossover bypass and one was treated conservatively. The limb-related assisted primary patency after 1 and 2 years was 96.6% (Fig. 2).

In the conventional group 1 patient was lost to follow-up, leaving 17 patients for long-term follow-up. The mean follow-up for these patients was 18.4 months (range 9–29). One patient died 9 months post-operatively due to myocardial infarction with a good functioning graft. Two patients developed an incisional hernia treated conservatively. Two patients developed recurrence of claudication due to distal anastomotic problems necessitating an interposition graft in the groin. One patient developed an occlusion of one limb (at 18 months) treated with a femoro-femoral crossover bypass. The calculated limb-related assisted primary patency after 1 and 2 years was 100 and 95% respectively (Fig. 2).

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**Table 3. Patient recovery data**

<table>
<thead>
<tr>
<th>Time to Recovery</th>
<th>HALS $n = 18$</th>
<th>Conventional $n = 18$</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to return to fluid diet (hours, mean (95% CI))</td>
<td>28.8 (16.7–40.7)</td>
<td>76.9 (39.8–114)</td>
<td>0.017</td>
</tr>
<tr>
<td>Time to return to solid diet (hours, mean (95% CI))</td>
<td>45.6 (30.9–60.2)</td>
<td>105.6 (57.6–153.6)</td>
<td>0.02</td>
</tr>
<tr>
<td>Time to ambulation (hours, mean (95% CI))</td>
<td>41.6 (29.7–53.4)</td>
<td>101.1 (53.7–148.5)</td>
<td>0.019</td>
</tr>
<tr>
<td>Time to discharge (days, mean (95% CI))</td>
<td>7.5 (3.9–11)</td>
<td>8.9 (6.16–11.7)</td>
<td>0.005</td>
</tr>
<tr>
<td>Time to removal of PCEA (rev.2) (hours, mean (95% CI))</td>
<td>28.2 (22.7–33.8)</td>
<td>72.4 (65.1–79.8)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**Table 4. SF-36 survey 6 weeks after surgery**

<table>
<thead>
<tr>
<th></th>
<th>HALS $n = 12$ (mean (95% CI))</th>
<th>Conventional $n = 9$ (mean (95% CI))</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>47.4 (42.4–52.4)</td>
<td>43.5 (36.6–50.3)</td>
<td>0.382</td>
</tr>
<tr>
<td>Role limitation-physical</td>
<td>37.3 (30.9–43.6)</td>
<td>35.2 (27.4–43.0)</td>
<td>0.702</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>44.2 (36.1–46.9)</td>
<td>41.2 (35.1–46.1)</td>
<td>0.464</td>
</tr>
<tr>
<td>General health</td>
<td>47.7 (42.9–51.0)</td>
<td>45.8 (41.5–51.5)</td>
<td>0.808</td>
</tr>
<tr>
<td>Vitality</td>
<td>43.7 (39.6–48.6)</td>
<td>41.7 (38.4–45.5)</td>
<td>0.508</td>
</tr>
<tr>
<td>Social functioning</td>
<td>47.3 (41.8–50.7)</td>
<td>34.4 (29.8–40.1)</td>
<td>0.023</td>
</tr>
<tr>
<td>Role limitation-emotional</td>
<td>41 (37.6–48.3)</td>
<td>36 (29.7–45.4)</td>
<td>0.554</td>
</tr>
<tr>
<td>Mental health</td>
<td>48.8 (46.0–54.9)</td>
<td>43.1 (39.6–47.7)</td>
<td>0.219</td>
</tr>
</tbody>
</table>

Fig. 2. Kaplan-Meier Curve of limb related primary assisted patency.

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Discussion

Our initial experience suggested patient advantages of HALS over conventional aortic bypass, such as early return to oral diet and ambulation and short in-hospital stay.10 This was in accordance with the findings in other studies.8,11–15 In order to clarify this with a higher level of evidence a prospective randomised study comparing HALS with conventional open aorto-iliac reconstruction was required.

All consecutive patients with severe aorto-iliac occlusive disease TASC C or D and without history of previous major abdominal surgery were considered for randomisation.

Patients with a history of abdominal surgery were excluded to improve the homogeneity of study groups as longer operation times can be expected in these patients. No patients were excluded for vascular reasons as the vascular indications are the same for both approaches.

The absence of differences in operative data in both study groups is in accordance with earlier findings that HALS is feasible for the average vascular surgeon without a steep learning curve.9,10,12,14 To interpret the operation time more correctly, it should be mentioned that in half of the patients we had to deal with redo-groin dissection and that in all patients the distal anastomosis was performed end to side on the common femoral artery extending several centimetres into the profunda femoris artery.

We found an earlier return to fluid and solid diet, earlier ambulation and a shorter in-hospital stay for patients treated by HALS. For practical reasons it was not possible to blind assessment in this study. However, we believe that any bias introduced because of this favoured the conventional group. We believe that normal ward practises would likely have made it more difficult to detect difference in the outcome of HALS and conventional surgery. For example, as the nursing staff were familiar with a much slower post-operative recovery patients in the HALS group were generally discouraged from early ambulation and diet intake.

We also found a significantly earlier removal of the PCEA system, reflecting a reduction in need for analgesia. Most of the PCEA systems in the HALS group could be removed within the first postoperative day suggesting that this form of analgesia may not be required for these patients. However, the epidural catheter is a major adjunctive during anesthesia for aortic surgery improving the outcome.16

No differences in lung function were found. This finding may have been affected by the timing of the assessment and the number of patients unable to complete the tests. Forty-seven percent of patients in the conventional group were not able to complete spirometry compared to 12% of the HALS group. This finding suggests that patients were more physically recovered from surgery in the HALS group.

Analysis of the SF-36® survey score 6 weeks postoperatively showed significant better social functioning in patients after HALS than after conventional open surgery. We expected to identify differences in other domains of the assessment. While the SF-36 is recognised as a good generic measure of quality of life we may have failed to detect differences which would have been identified by a disease-specific questionnaire.

A concern of the HALS approach is the continuous stress on the wound edges throughout the procedure, which may influence wound healing. However, in contrast with the experience of some urologists, no early wound healing problems at the site of the mini-laparotomy were seen.17 Similarly the incidence of incisional hernia was only 6.7% in the HALS group. We recently published the midterm results of a series of 45 patients receiving aortobifemoral bypass by HALS approach and in that series the incidence of incisional hernia was 19.5%.4,10 The use of a polypropylene mesh could be considered in patients following HALS.18

The assisted primary graft patency was 97.5% at 1 and 2 years in the HALS group and 100% and 95% respectively in the conventional open group. The similarity in outcome suggests that the limited access in HALS did not reduce the technical success of the procedure.

Limitations of the Study

It should be noticed that this study has limitations due to some methodological flaws.

First, a concern of duplicated publication could be raised as we recently published the early and mid-term results of HALS aortobifemoral bypass for aorto-iliac occlusive disease in 46 patients, including the 18 patients of the HALS group in this study.10 However, the data of these 18 patients are analysed much more extensively in this study (including lung-function, need for analgesia, SF-36 survey, longer follow-up) and the comparison with data of the patients in the conventional group adds a lot of value. The previous published series was published as a prospective survey, intending to report our complete experience with the HALS technique, including the patients from our first non-randomised experience as well as the patients from our later randomised experience.
Second, the atypical randomisation method of alternate allocation could raise the fear for bias. We are aware of the weakness in methodology, but, as the order of entering the waiting list, determined by the administration, was respected, the risk of bias was rather low. That this type of randomisation did not cause any bias is illustrated by the fact that patient demographics are quite comparable in both groups. The differences in ASA scores between groups, favouring the operative group, did not cause any bias is illustrated by the fact that patient demographics are quite comparable in both groups. The differences in ASA scores between groups, favouring the operative group, did not cause any bias. Noteworthy is that due to this type of randomisation it was not feasible to introduce any other type of randomisation as the order of entering the waiting list, determined by the administration, was respected. Second, the atypical randomisation method of alternate allocation could raise the fear for bias. We are aware of the weakness in methodology, but, as the order of entering the waiting list, determined by the administration, was respected, the risk of bias was rather low. That this type of randomisation did not cause any bias is illustrated by the fact that patient demographics are quite comparable in both groups. The differences in ASA scores between groups, favouring the operative group, did not cause any bias. Noteworthy is that due to this type of randomisation it was not feasible to introduce any other type of randomisation as the order of entering the waiting list, determined by the administration, was respected.

Third, the sample size of 18 patients in each group was small. However, a sample size calculation was performed in advance to determine the sample size needed as mentioned above. The calculated needed sample size was 30, i.e. fifteen in each group.

Conclusion

HALS aorto-femoral reconstructions is a minimal access surgical technique without a steep learning curve. According to the results of this study HALS is associated with a more rapid recovery of bowel function and shorter in-hospital stay. HALS should be considered an option for aortic bypass when total laparoscopic repair is considered appropriate but not feasible.

Preliminary results of this study have been presented at the 2nd International Endovascular Laparoscopy Congress, Québec City, Canada in May 2004 and at the Controversies and Update in Vascular Surgery Meeting, Paris, France in January 2005. ‘Controversies and updates in Vascular Surgery, January 2005, Paris."

References


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