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CONTROLLED CLINICAL TRIAL

Laparoscopic versus conventional ileoanal pouch procedure in patients undergoing elective restorative proctocolectomy (LapConPouch Trial)—a randomized controlled trial

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Abstract
Purpose Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the standard surgical procedure for ulcerative colitis (UC) and familial adenomatous polyposis (FAP). While minimal invasive techniques have been applied increasingly, clear evidence of superiority for laparoscopic pouch procedures is not yet available. The aim of the LapConPouch Trial was to compare the effectiveness of laparoscopic (LAP) versus conventional (CON) ileoanal pouch procedure in patients undergoing elective restorative proctocolectomy.
Methods The trial was designed as a single-centre, preoperatively randomized, controlled trial using a two-group parallel superiority design. Eligible for participation were patients scheduled for restorative proctocolectomy either for FAP or for UC. Patients and outcome assessors were blinded to group assignment. The primary endpoint was defined as the amount of blood loss. Statistical analyses were explorative since the trial had to be stopped prematurely.
Results A total of 42 patients (21 LAP (50.0 %); 21 CON (50.0 %)) were randomized. The trial had to be stopped prematurely due to insufficient patient recruitment. There was no difference in the amount of blood loss between both groups: LAP 261.5±195.4 ml, CON 228.1±119.5 ml. Secondary endpoints differ in both groups. Laparoscopic surgery was superior regarding the length of skin incision; in contrast, the conventional approach was superior in duration of operation. There were no discrepancies in length of hospital stay, postoperative pain, bowel function, and quality of life between both approaches. The conversion rate from LAP to CON approach was 23.8 %.
Conclusion There was no difference with respect to blood loss between the LAP and the CON group. The LAP approach is feasible for restorative proctocolectomy, and IPAA seems at least as safe as CON surgery. The most obvious advantage of the minimal invasive technique is the improved cosmesis.

Keywords Laparoscopy · Conventional surgery · Proctocolectomy · Blood loss · Ulcerative colitis (UC) · Familial adenomatous polyposis (FAP)

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Introduction

Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the standard procedure in the surgical therapy of ulcerative colitis (UC) and familial adenomatous polyposis (FAP). With advances in laparoscopic (LAP) colorectal surgery and increases in surgical expertise, minimal invasive techniques in pouch surgery have been increasingly applied. Furthermore, well-informed patients ask more and more often for minor surgical trauma and good cosmetic outcome. LAP proctocolectomy with IPAA is a demanding yet technically feasible approach. So far, however, evidence for short-term benefits, as shown for LAP colorectal surgery, could not be shown for LAP ileoanal pouch procedures [1].

In earlier studies between 1992 and 1998, results of observational studies comparing LAP techniques with CON approaches in patients with inflammatory bowel diseases (IBD) were discouraging [2]. Therefore, LAP surgery was not recommended for IBD patients until the first positive case-matched comparative trial was published in 2000, which showed benefits for the LAP approach regarding hospital stay and postoperative reconvalescence, as well as comparative morbidity and mortality [3]. A few studies followed with similar results. However, there is only one prospective randomized controlled trial (RCT) to date that compares hand-assisted LAP proctocolectomy and IPAA with the conventional (CON) approach. This trial showed no benefits for the LAP approach with regard to morbidity and QoL [4]. Moreover, all available data showed that longer operating times in the LAP group were associated with higher costs [3–6]. Therefore, the only obvious current advantage for LAP IPAA seems to be a better individual body image. A recent meta-analysis even showed an increased rate of intra-operative complications associated with LAP colorectal resections in comparison to CON approaches [7] so that the controversy of the issue is more and more becoming a matter of actual debate. The present trial was initiated due to the absence of prospective randomized trials evaluating the role of total LAP ileoanal pouch procedures.

As shown in a series of 50 patients between 1999 and 2003 who underwent total LAP proctocolectomy and IPAA, the median blood loss was 200 ml and no patient required any blood transfusion. Therefore, the intra-operative blood loss was defined as the primary endpoint of our trial [8, 9].

Materials and methods

The LapConPouch Trial was designed as a single-centre, pre-operatively randomized, controlled trial using a two-group parallel superiority design by the Clinical Trials Center Heidelberg. The trial had to be stopped prematurely due to insufficient patient recruitment. Thus, the results are presented as explorative data analysis with hypothesis-generating character.

The study protocol was approved by the ethics committee of the University of Heidelberg, published [8] and internationally registered (ISRCTN61411448).

Participants

Eligible for participation were patients scheduled for elective restorative proctocolectomy either for FAP or for UC. A detailed overview of all eligibility criteria is given in Table 1. All patients signed a written informed consent for study participation. The expected recruitment period was 4 years. All data were collected on a paper-based case report form by the Clinical Trials Center Heidelberg.

Intervention

Colectomy, ileoanal pouch formation, pouch-anal anastomosis and ileostoma were performed using the same standardized technique in both groups. For pouch formation, the apex of the pouch needed to reach at least 1 to 2 cm below the symphysis; otherwise, lengthening manoeuvres had been performed. The root of the mesentery was always mobilized, and the pouch-anal anastomosis was fashioned in a double-stapling technique. All patients received a covering loop ileostomy. Only the approach differed considerably: large median incision in the CON group versus small periumbilical incision in the LAP group. The detailed surgical procedures were described in the study protocol [8]. Randomization was performed after induction of anaesthesia. The pre- and postoperative treatment and assessment were identical in both groups according to the clinical standard.

Objectives

The objective of the LapConPouch Trial was to compare the effectiveness of total LAP versus CON ileoanal pouch procedure.

Outcomes

The primary endpoint was intra-operative blood loss (significance level: distinction of 300 ml). It was estimated independently by a surgeon, an anaesthesiologist and a scrub nurse and measured in millilitres via the suction system and in the sponges. The amount of rinsing fluid used was subtracted from the whole amount of fluid in the suction bag to assess the blood loss. The amount of expressed fluid of the sponges was added, too. The mean of these values defined the final blood loss.

Table 1 Eligibility criteria

Subject inclusion criteria
Age equal or greater than 14 years (providing informed consent by patient and by parents or legal guardian between 14 and 18 years)
Patients with benign disease (familial polyposis or ulcerative colitis) scheduled for elective surgery
Patient or guardian has given informed consent
Both standardized surgical approaches are suitable for treatment at the end of a surgical exploration
Suitable for restorative proctocolectomy
Subject exclusion criteria
Active malignant disease or high suspicion for malignancy (clinical and imaging evidence, e.g. high-grade dysplasia on histology)
Previous median laparotomy or Pfannenstiel incision (excluding limited incision such as appendectomy, cholecystectomy, etc.)
Participation in another intervention trial with interference of intervention and outcome
Severe psychiatric or neurologic diseases
Drug and/or alcohol abuse according to local standards
Coagulopathy (bleeding is prolonged and excessive with abnormal values in the blood laboratory)

Secondary outcome parameters were evaluated in the intention to treat (ITT) population and defined as follows: length of skin incision (cumulated, cm), length of procedure (cut–suture time, in minutes), frequency of major complications on day of discharge (complications necessitating an early revision or invasive intervention within 14 days, e.g. anastomotic leakage, peritonitis, abscess, perforation, postoperative bleeding, burst abdomen, compartment syndrome or other comparable complications), frequency of minor complications on day of discharge (complications not necessitating an early revision or invasive intervention, e.g. wound infection, pneumonia, urinary tract infection, bladder dysfunction or other comparable complications), postoperative pain (visual analogue scale, VAS, 0–100 points; measured on the second postoperative day prior to deblinding), bowel function (time to oral intake in days), postoperative lung function (FEV_1 l, forced expiratory volume in 1 s in litres; VC, vital capacity in %), postoperative length of hospital stay (days), QoL (SF36 [10]) and cosmetic aspects (body image questionnaire—BIQ [11]) and amount of intra-operatively transfused blood units along with amount of transfused blood units within 48 h after surgery (number of blood units). Frequency, intensity and causality of serious adverse events (SAE) and occurrence of at least one adverse event (AE) or SAE were analysed in the safety population (as treated).

Sample size

The initial sample size calculation was based on an assumed blood loss difference of 300 ml between the two groups, which we based on previous data from our department. At least 65 patients per group would have been required to obtain a power of 80 % (β=0.2) with a significance level of 0.025 (one-sided *t*-test).

Randomization

A block randomization list was generated via a computer system (SAS). It was stratified according to indication of operation: UC or FAP. An opaque envelope was available for each included patient. Randomization took place on the day of surgery in order to allow adequate preparation.

Blinding

Patients, pain assessors and the hospital staff were blinded on the technique used, whereas the surgeon, of course, was not. After surgery, the entire abdomen was covered with a wound dressing until day 2.

Data management

All data were entered in a paper-based case report form arranged for each visit. Standard forms were used to document AE and SAE. SAE had to be reported to the principle investigator within 24 h.

Statistical methods

Final analysis after termination was performed in accordance with the ITT principle, except for AE and SAE (safety population, as treated). The null-hypothesis of blood loss was assessed using the one-sided *t*-test at the 0.05 significance level. The secondary endpoints were analysed by chi-square test or *U*-test, which are shown in detail in the statistical analysis plan. Data are presented as mean plus standard deviation (SD) or absolute number plus percentage of the whole population. Statistical analyses were explorative since the initially planned sample size was not reached due to insufficient patient recruitment.

Because the subpopulations of UC and FAP patients were almost equal, the following subgroups—FAP LAP approach (n=8), FAP CON approach (n=9), UC LAP approach (n=13), UC CON approach (n=11)—were evaluated additionally via variance analysis regarding blood loss, length of procedure, postoperative pain and length of hospital stay.

Results

Participant flow

A total of 42 patients [21 LAP (50.0 %); 21 CON (50.0 %)] were randomized between October 2004 and October 2008, out of a total of 140 patients screened. The follow-up period ended in October 2009. The construction of an ileoanal pouch was not possible in one patient of the CON group; thus this one was, therefore, excluded. As a result, the ITT population consists of 41 patients: 21 LAP (51.2 %), 20 CON (48.8 %) (Fig. 1). Overall, six patients were not treated according to protocol. A conversion from LAP to CON technique was performed in five patients according to the surgeon's decision because the LAP approach turned out to be technically unfeasible: adipositas (n=3), extended inflammation (n=1) and a mesenterial desmoid tumour (n=1). One patient of the CON group was operated by LAP approach due to miscommunication. The remaining safety population consists of 41 patients: 16 LAP (39.0 %), 25 CON (61.0 %) (Fig. 2). The pouch failure rate in the LAP group was 9.5 % and in the CON group 14.3 %.

Recruitment

Before reaching the initially planned sample size, the trial had to be terminated prematurely due to insufficient patient recruitment. Most of the patients preferred the LAP approach and declined to participate.

Baseline characteristics

The study groups were comparable for almost all patients and procedure characteristics. Only the ratio between female and male patients was higher in the LAP than in the CON approach (women, n=3, 14.3 %) (Table 2).

Primary and secondary endpoints

There was no difference in the amount of blood loss between both groups. In the LAP procedure, blood loss of 261.5± 195.4 ml was found compared to 228.1±119.5 ml in the CON approach (Fig. 3). Except for one patient in the CON group, no blood transfusion was given intra-operatively; no further blood units were required within 48 h in both groups.

In our population, the length of procedure was longer in the LAP group (313.9±52 min) compared to the CON approach (200.2±53.8 min). The length of the skin incision was longer in the CON group than in the LAP group (20.0±-6.4 cm vs. 9.3±-5.0 cm). A small difference was found in the frequency of major complications until the day of discharge in both groups (LAP 9.5 % vs. CON 5.0 %). A detailed overview is shown in Table 3.

Minor complications did not occur in either group at the end of hospital stay. Postoperative abdominal pain in the

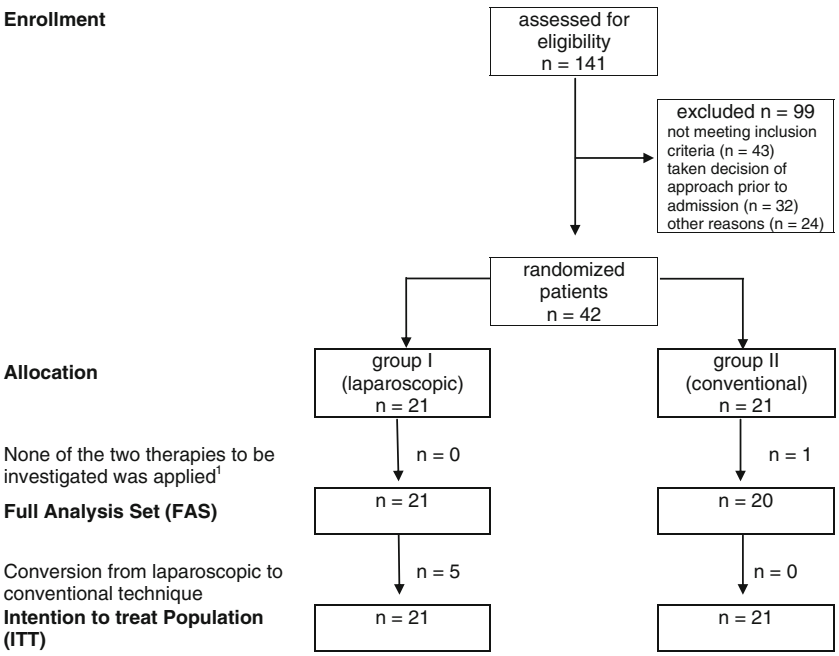

Fig. 1 Flow chart of analysis population—intention to treat population. *Footnote 1*, according to ICH-E9, one patient is excluded from full analysis set due to the lack of any kind of data for assessment of efficacy

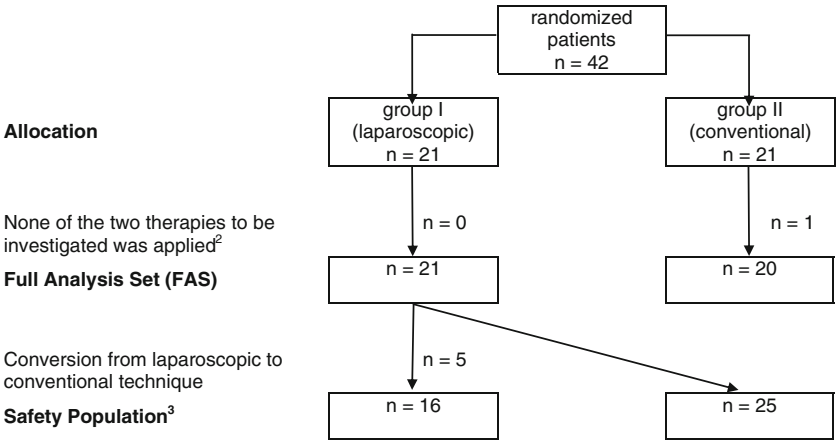

Fig. 2 Flow chart of analysis population—safety population (as treated). *Footnote 2*, according to ICH-E9, one patient is excluded from full analysis set due to the lack of any kind of data for assessment of efficacy. *Footnote 3*, safety population is identical to the full analysis set, but the analysis of adverse events is based on the intervention as treated, not as randomized

LAP group did not differ from that in the CON approach (9.8±13.9 vs. 10.7±16.2 points on VAS at rest; 27.8±29.6 vs. 23.4±27.3 points on VAS in motion). The BIQ score discrepancies between the two groups with respect to the cicatrice were as follows: The patients with a LAP approach were more satisfied with the cosmetic outcome than those with a CON approach (e.g. visit 5 on discharge 6.8±0.4 vs. 5.3±1.5 points). Postoperative bowel function (time to first ingestion) did not show differences (LAP 3.4±2.5 days vs. CON 3.5±2.1 days). Furthermore, postoperative lung function was comparable in the LAP group (FEV_1 2.1±0.9 l; VC 71.0±32.2 %) and in the CON group (FEV_1 2.1±1.3 l; VC 66.8±25.4 %). Additionally, no difference in the length of hospital stay between the two groups was detected (LAP 12.3±5.8 days vs. CON 19.6±20.5 days).

However, analysis of the subgroups of indication showed differences in the parameter length of hospital stay for UC patients with CON approach in contrast to those who had a LAP approach (26.4±4.3 vs. 11.22±4.8 days) (Fig. 4).

Regarding the questionnaire to QoL (SF36), only two items at 3 months' postoperative visit (V6) differed between both approaches concerning the physical functioning (LAP 74.9±23.2 vs. CON 56.9±22.4 points) and the physical component score (LAP 47.7±8.0 vs. CON 39.8±9.0 points) (Table 4).

The analysis of the safety population, referring to patients who had at least one AE, revealed no difference between the LAP (87.5 %) and the CON (92.0 %) study groups; the same with SAE (LAP 37.5 % vs. CON 44.0 %). The frequency (LAP 44.4 %, CON 67.4 %) and the intensity of SAE showed no difference as well (Table 5). A detailed list of all AE and SAE that occurred is given in Table 6. The rate of surgical re-intervention was 14.3 % (n=3) for the conventional group; one of those patients was converted from the laparoscopic to the open approach.

Discussion

The LapConPouch Trial was stopped prematurely after inclusion of 42 randomized patients. The initially planned sample size was not reached due to insufficient patient

Table 2 Baseline characteristics (mean ± SD, *n* (%))

Patient characteristics		Laparoscopic n=21	Conventional n=20	Total
Gender				
	Male	18 (85.7 %)	8 (40.0 %)	26 (63.4 %)
	Female	3 (14.3 %)	12 (60.0 %)	15 (36.6 %)
Age (years)		36.9±17.0	39.2±14.3	38.0±15.6
Indication for operation				
	Familial polyposis	8 (38.1 %)	9 (45 %)	17 (41.46 %)
	Ulcerative colitis	13 (61.9 %)	11 (55 %)	24 (58.54 %)
BMI	24.3±4.3	25.2±4.4	24.7±4.4	
Co-morbidity				
	Current smoker	5 (23.8 %)	4 (21.1 %)	9 (22.5 %)
Lung function preoperative				
	FEV_1 (l)	3.4±1.1	3.3±1.3	3.3±1.2
	VC (%)	93.6±14.6	88.7±16.2	91.2±15.4

BMI body mass index, *VAS* visual analogue scale, *FEV_1* forced expiratory volume in 1 s, *VC* vital capacity

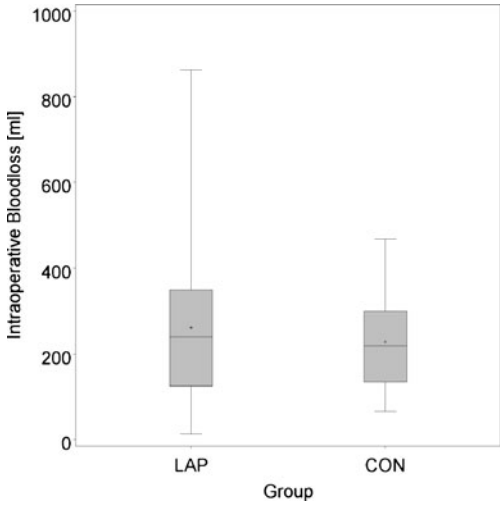

Fig. 3 Primary endpoint—intra-operative blood loss (mean, SD), laparoscopic (*LAP*) vs. conventional (*CON*) approach

recruitment, which was due to the distinct patient's preference for the LAP approach. UC and FAP patients were well informed about the different treatment options and often had provided their decision prior to admission for surgery. However, the discontinuing of the trial was independent of our trial findings so that biases due to prior trial closure seem unlikely. Therefore, statistical analyses were explorative. According to the Conference on Harmonization [12], insufficient patient enrollment is an acceptable reason for premature trial termination [13]. The patient's preference as the main reason for enrollment problems was underestimated during the study design. However, as Schroen et al. already described, preferences for certain treatment options are a patient-side barrier for participating in clinical trials along with concerns about uncertainty of treatment and randomization [14]. The dismissal of patient barriers results in an overestimation of recruitment ability on the clinician's side [15]. Therefore, trials with results of probable interest must be stopped prematurely, not for safety or ethical reasons but for commercial reasons out of the prolonged recruitment period. A possibility to improve recruitment is to include more hospitals (multi-centre trial) [14]. This way, however, was not feasible for the LapConPouch Trial due to differing technical qualifications and performance of surgeons in other hospitals. A special training of surgeons of other hospitals to guarantee the comparability of these complex surgical techniques was not performable because LapConPouch as an investigator-driven trial was not supported financially.

Table 3 Major complications (*n* (%))

	Laparoscopic *n*=21	Conventional *n*=20	Total
Anastomotic leakage	2 (9.5 %)	0 (0.0 %)	2 (4.9 %)
Peritonitis	0 (0.0 %)	1 (5.0 %)	1 (2.4 %)
Abscess	2 (9.5 %)	2 (10.0 %)	4 (9.8 %)
Perforation	0 (0.0 %)	1(5.0 %)	1 (2.4 %)
Burst abdomen	0 (0.0 %)	1(5.0 %)	1 (2.4 %)
Others	2 (9.5 %)	6 (30.0 %)	8(19.5 %)

One lesson that we learned is the need for a more precise estimation of the recruitment rate considering patient barriers. The patient's preference was and still is the main problem in trials comparing conventional versus minimal invasive trials, and therefore it is difficult to conduct such studies. One possible way out of this dilemma is to organize an observational study of those patients, who will not be randomized, and compare their data. Moreover, adequate financial funding of RCT is essential for a successful conduct and termination of such a trial.

The present study is the first RCT comparing the LAP approach with open restorative proctocolectomy and IPAA in patients with UC and FAP. Regarding the primary endpoint, there was no difference in the amount of blood loss between both groups. Differences occurred in the length of skin incision, operating time, QoL and cosmetic aspects. Postoperative abdominal pain, bowel function, lung function and length of hospital stay were almost identical in both groups.

The design of this trial as a single-centre RCT allowed internal validity based on a constant perioperative setting and stable surgical quality due to a limited number of specialized surgeons.

The only randomized trial in this domain so far compared the hand-assisted LAP technique with the CON procedure and showed no benefits for the LAP group regarding QoL, hospital stay, postoperative pain and morbidity. Costs were higher and the duration of the operative procedure was longer [4]. However, there are two systematic reviews [16, 17] and one meta-analysis [18] including predominantly retrospective trials and prospective studies with low evidence levels and only one RCT [4] as mentioned earlier.

According to former studies [3, 4, 6, 11, 19–21], LAP pouch surgery was expected to be associated with shorter hospital stay, earlier convalescence of gastrointestinal function, less incisional hernia and better body image [11, 20, 21], with simultaneously equal complication rates, pouch function and QoL. This was further at the expense of worse sexual function and longer operation times [11, 22].

The primary endpoint of our trial was defined as intra-operative blood loss with a distinction of 300 ml. This postulated difference in intra-operative blood loss was based on the findings of a former series of 50 patients undergoing LAP pouch surgery at our institution [9] which showed a median intra-operative blood loss of 200 ml.

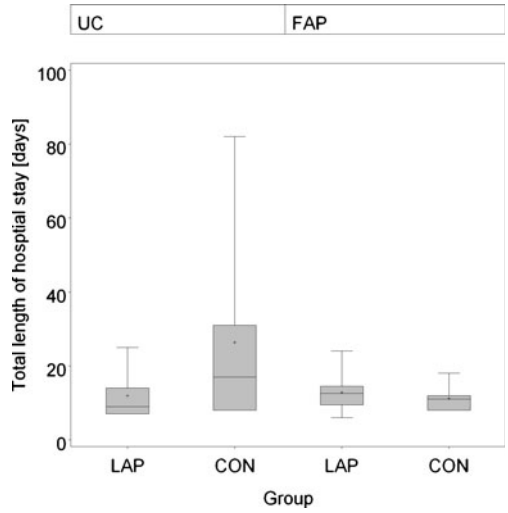

Fig. 4 Subgroup analysis—postoperative length of hospital stay, ulcerative colitis (*UC*), laparoscopic (*LAP*) and conventional (*CON*) vs. familial adenomatous polyposis (*FAP*), laparoscopic (*LAP*) and conventional (*CON*) (mean, SD)

In contrast to our hypothesis, we did not find a difference of intra-operative blood loss between the two groups in our trial population. This may be explained by the increasing experiences in both techniques—in LAP as well as in CON pouch surgery. All other studies addressing intra-operative blood loss [4, 6, 19] failed to reveal a difference as well. Only one out of all 41 patients received a blood transfusion. This patient was in the CON group. Fleming et al. supposed that there is less need for blood transfusion in the LAP group as the only patient who received a blood transfusion in his analyses was in the conventional group as well [5].

The duration of the procedure was considerably longer in the LAP group. This was already shown in several other studies [3–6, 11] and was expected because the LAP technique is a highly specialized and demanding technique that is still in development and requires extended experience in order to decrease the operating time. Only Araki et al. found no difference between both approaches according to the length of procedure [19]. Another disparity—perhaps the most obvious one—in both groups was the cosmetic outcome. Patients in

Table 4 Primary and secondary endpoints (mean ± SD, *n* (%))

	Laparoscopic *n*=21	Conventional *n*=20	Total
Primary endpoint			
Intra-operative blood loss (ml)	261.5±195.4	228.1±119.5	244.4±159.7
Secondary endpoints			
Length of skin incision (cm)	9.3±5.0	20±6.4	14.5±7.8
Length of procedure (min)	313.9±52.0	200.2±53.8	258.4±77.7
No major complications	19 (90.5 %)	19 (95.0 %)	38 (92.7 %)
No minor complications	21 (100.0 %)	20 (100.0 %)	41 (100.0 %)
Abdominal pain (VAS 0–100)			
At rest	9.8±13.9	10.7±16.2	10.3±16.2
In motion	27.8±29.6	23.4±27.3	25.4±28.0
Bowel function (days to ingestion)	3.4±2.5	3.5±2.1	3.5±2.2
Lung function postoperative			
FEV_1 (l)	2.1±0.9	2.1±1.3	2.1±1.0
VC (%)	71.0±32.2	66.8±25.4	69.1±28.9
Length of hospital stay (days)	12.3±5.8	19.6±20.5	15.8±15.2
Quality of life (SF36)			
Physical functioning V6	74.9±23.2	56.9±22.4	66.2±24.3
Physical component score V6	47.7±8.0	39.8±9.0	43.8±9.3
Cosmetic aspects (BIQ)			
Cicatrice satisfaction V5	6.8±0.4	5.3±1.5	6.2±1.2
Own description of cicatrice V6	5.4±1.5	4.1±1.9	4.8±1.8
Own valuation of cicatrice V6	7.7±1.9	6.0±2.5	6.8±2.4
Own description of cicatrice V7	5.3±1.4	4.2±1.7	4.8±1.6
Own valuation of cicatrice V7	7.8±2.0	5.7±2.3	6.8±2.3
Own description of cicatrice V8	5.5±1.0	4.0±1.5	4.8±1.4
No blood transfusion			
Intra-operative	21 (100.0 %)	19 (95.0 %)	40 (97.6 %)
Within 48 h	21 (100.0 %)	20 (100.0 %)	41 (100.0 %)

VAS visual analogue scale, *FEV_1* forced expiratory volume in 1 s, *VC* vital capacity, *BIQ* body image questionnaire, *V5* visit on day of discharge, *V6* visit at 3 months postoperatively, *V7* visit at 6 months postoperatively, *V8* visit at12 months postoperatively, *SAE* serious adverse event

Table 5 Safety analysis (*n* (%)) including all AE and SAE

	Laparoscopic *n*=35	Conventional *n*=74	Total *n*=109
AE			
Patients with at least one AE			
No	2 (12.5 %)	2 (8.0 %)	4 (9.8 %)
Yes	14 (87.5 %)	23 (92.0 %)	37 (90.2 %)
SAE			
Patients with at least one SAE			
No	10 (62.5 %)	14 (56.0 %)	24 (58.5 %)
Yes	6 (37.5 %)	11 (44.0 %)	17 (41.5 %)
Frequencies			
No	10 (55.6 %)	14 (32.6 %)	24 (39.3 %)
Yes	8 (44.4 %)	29 (67.4 %)	37 (60.7 %)
Intensity			
Moderate	8 (100.0 %)	23 (79.3 %)	31 (83.8 %)
Severe	0 (0.0 %)	6 (20.7 %)	6 (16.2 %)
Causality			
Unrelated	1 (14.3 %)	1 (3.6 %)	2 (5.7 %)
Possible	0 (0.0 %)	1 (3.6 %)	1 (2.9 %)
Probably	0 (0.0 %)	1 (3.6 %)	1 (2.9 %)
Definitely	6 (85.7 %)	24 (85.7 %)	30 (85.7 %)
Not assessable	0 (0.0 %)	1 (3.6 %)	1 (2.9 %)
Missing	1	1	2

the LAP group were more satisfied with their cicatrice measured by the BIQ by Dunker et al. [11]. This result corresponds to the findings of several other studies [20, 21]. The location and the size of the cicatrice are clear reasons for this result. Furthermore, FAP and UC patients are usually younger patients. There are studies suggesting that body image differs in respect to the age [23].

Regarding the QoL [10], the only difference between the two groups was found during the 3 months' postoperative visit and had to do with physical function. Patients of the LAP group felt subjectively better in this early postoperative period. This could be explained by the minor operative trauma of the abdominal wall and the correlative result of smaller scars. Another possible aspect influencing the postoperative satisfaction might be the preoperative attitude to the kind of surgical approach. In our experience, during recruitment, some patients initially favoured one distinct approach, although they consented to participate in the LapConPouch study. As a consequence, these patients might have been disappointed when being randomized to the less favoured approach.

Overall, QoL was found to be equal between the CON and the LAP group. Berdah et al. and Larson et al. did not find a difference as well but used other questionnaires to evaluate the QoL [22, 24]. In relation to the functional outcome, there are several studies in the literature [4, 11, 21] showing no difference between the LAP and the CON approaches. This could be considered as one aspect of the comparable QoL in both groups.

Postoperative hospital stay did not differ between the LAP and the CON group in our population. This is in concordance with some other studies [4, 6, 19] which also showed no difference for this time period. However, there are some retrospective trials that report shorter hospital stay for laparoscopically operated patients [3, 11]. On the one hand, a faster recovery process, less abdominal pain and quicker restoration of bowel function after a LAP operation may be expected because of the smaller incisions. On the other hand, the intra-abdominal surgical trauma is comparable in both techniques. Furthermore, the duration of the procedure is even longer for LAP surgery. Regarding these aspects, the equality of hospital stay in both groups seems comprehensible.

Because the subpopulations of patients with UC and FAP were nearly of the same size and were equally distributed in both approaches, we performed an additional variance analysis of these subgroups. The only peculiarity we found was in the parameter postoperative hospital stay, which was longer in the subgroup of UC patients who underwent the CON approach. This might be the result of the sometimes poorer preoperative condition of many UC patients compared to FAP patients, caused by immunosuppressive therapy over long time periods and associated with the need for a longer convalescence period. Kienle et al. have seen

Table 6 Occurrence of AE and SAE (*n* (%))

AE				SAE			
Categories	Laparoscopic	Conventional	Total	Categories	Laparoscopic	Conventional	Total
	n=35	*n*=74	*n*=109		*n*=8	*n*=29	*n*=37
Wound infection	6 (12.0 %)	6 (10.2 %)	12 (11.0 %)	Wound infection	0 (0.0 %)	2 (6.9 %)	2 (5.4 %)
High loss of ileostoma	8 (16.0 %)	4 (6.8 %)	12 (11.0 %)	High loss of ileostoma	1 (12.5 %)	3 (10.3 %)	4 (10.8 %)
Disregulation of electrolytes	2 (4.0 %)	0 (0.0 %)	2 (1.8 %)	Insufficiency or stenosis of anastomosis	2 (25.0 %)	4 (13.8 %)	6 (16.2 %)
Insufficiency or stenosis of anastomosis	4 (8.0 %)	5 (8.5 %)	9 (8.3 %)	Serious abdominal disorders elsewhere than anastomosis	2 (25.0 %)	4 (13.8 %)	6 (16.2 %)
Serious abdominal disorders elsewhere than anastomosis	4 (8.0 %)	5 (8.5 %)	9 (8.3 %)	Gastrointestinal disorders	0 (0.0 %)	1 (3.4 %)	1 (2.7 %)
Gastrointestinal disorders	11 (22.0 %)	8 (13.6 %)	19 (17.4 %)	Intra-abdominal fluid accumulation	2 (25.0 %)	5 (17.2 %)	7 (18.9 %)
Intra-abdominal fluid accumulation	3 (6.0 %)	4 (6.8 %)	7 (6.4 %)	Cutaneous disorders	1 (12.5 %)	0 (0.0 %)	1 (2.7 %)
Cutaneous disorders	3 (6.0 %)	5 (8.5 %)	8 (7.3 %)	Others	0 (0.0 %)	5 (17.2 %)	5 (13.5 %)
Urinary dysfunction or infection	3 (6.0 %)	4 (6.8 %)	7 (6.4 %)	Symptoms of infection	0 (0.0 %)	1 (3.4 %)	1 (2.7 %)
Pain elsewhere than abdomen	3 (6.0 %)	0 (0.0 %)	3 (2.8 %)	Embolic or thrombotic insult	0 (0.0 %)	4 (13.8 %)	4 (10.8 %)
Others	2 (4.0 %)	11 (18.6 %)	13 (11.9 %)				
Symptoms of infection	1 (2.0 %)	2 (3.4 %)	3 (2.8 %)				
Embolic or thrombotic insult	0 (0.0 %)	5 (8.5 %)	5 (4.6 %)				

coherence between the intake of cortisone and the duration of postoperative hospital stay [9]. Usually, FAP patients do not take cortisone and have no health impairment at the stage of operation. Consistent with this finding, the postoperative parameters abdominal pain and bowel and lung function showed no differences in both groups of our population. Some other studies had oppositional findings in respect to bowel function, displaying significantly better bowel functions in the LAP group [3, 19]. These results are incomparable on one level because of the various parameters to measure this aspect. Not everyone used the time to oral intake as we did. Most of the published trials found no difference in both groups [4, 6, 11, 21]. In view of the different size of skin incisions, a discrepancy between the two approaches in postoperative abdominal pain seems possible. No difference, however, was found in our population, similar to the results of Maartense et al. and Fajardo et al. [4, 6]. Maybe the determining factor is not the size of the skin incision but the intra-abdominal wound caused by the proctocolectomy as such. The parameter lung function was not yet surveyed in the literature related to this special operation. In relation to the produced pneumoperitoneum in the LAP surgery, there could have been a difference to the CON approach; however, there was no difference between both groups in our trial population. As is the case with several other studies, we found no difference in the frequency of complications between the two groups on the day of discharge [3, 4, 6, 9, 19]. AE and SAE turned out to appear as comparable in both approaches, although Fleming et al. showed less complication for the LAP group [5]. Considering the fact that the safety analyses were done with the per protocol population, the five converted patients were evaluated in the CON group. These converted patients seem to be difficult cases, and therefore, there might be a shift of complex cases and of complications, respectively, to the CON group. However, no one of these patients had an anastomotic leakage, but one of them needed a relaparotomy for abscesses and wound infection.

The current trial has some limitations since we did not evaluate long-term outcome parameters like pouch function and sexual function, which are important factors, especially because the patients are often very young.

The major drawback though is certainly the poor recruitment of this trial. As these young patients undergo IPAA mostly in an elective setting, they are often well informed about therapeutical options and new techniques. In view of the more and more well-established use of the LAP technique, most patients did not want to take part in this RCT which is reflected in how often they favoured the LAP approach.

Conclusion

In conclusion, there is no obvious difference in respect to blood loss between the LAP and the CON approach. The LAP approach is feasible and is at least as safe as CON surgery. The most striking advantage of the minimal invasive technique is the improved cosmesis. Discrepancies in the length of hospital stay, postoperative pain, bowel function and QoL could not be confirmed in this trial.

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