Reconsidering Abdominal Drainage After Left Pancreatectomy

The Randomized Controlled PANDRA II Trial

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Objective: To evaluate intra-abdominal drainage after left pancreatectomy (LP), as it has been a longstanding practice to mitigate postoperative complications, particularly postoperative pancreatic fistulas.

Background: Recent studies challenge the necessity of routine drainage, suggesting potential benefits in omitting drains.

Methods: The PANDRA II trial was a randomized controlled noninferiority study conducted at the University Hospital Heidelberg between 2017 and 2023. It compared outcomes between patients undergoing open or minimally invasive LP with and without abdominal drainage. The primary endpoint was overall postoperative morbidity assessed by the Comprehensive Complication Index (CCI).

Results: A total of 246 patients were included in the intention-to-treat analysis (125 with drainage, 121 without drainage). The no-drain group demonstrated noninferiority to the drain group in terms of CCI (13.90 ± 16.51 vs 19.43 ± 16.92, $P < 0.001$ for noninferiority). Moreover, the no-drain group had lower overall complication rates (50.41% vs 78.40%, $P < 0.001$). Specific complications such as postoperative pancreatic fistula (14.88% vs 20.8%, $P = 0.226$) and postpancreatectomy hemorrhage (4.96% vs 4.80%, $P > 0.999$) did not differ significantly between groups.

Conclusions: The results of the PANDRA II trial demonstrate that omitting routine abdominal drainage after LP is noninferior to placing routine abdominal drainage regarding morbidity measured by the CCI. Omitting a routine abdominal drainage even led to a significant reduction in the overall complication rate.

Key Words: complication, drainage, left pancreatectomy, outcome, pancreas, pancreatic fistula

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INTRODUCTION

For decades, the use of intra-abdominal drains has been common practice in abdominal surgery. However, recent studies have shown no benefit from routine drainage in many abdominal operations, including hepatobiliary,[1,2] gastric,[3,4] and colorectal[5,6] surgeries. Despite that, until now, many surgeons are concerned that abandoning drainage after pancreatic resections could be unwise harmful due to the high rate and severe consequences of postoperative pancreatic fistulas (POPFs), which could be earlier detected and even treated by a drain in place. With morbidity rates of 40% to 50% even in specialized centers,[7–9] the rationale for inserting drains in pancreatic surgery includes the evacuation of blood, bile, pancreatic juice, or chyle as well as indicating early signs of postpancreatectomy hemorrhage (PPH) allowing for timely diagnostic and therapeutic interventions. However, most patients do not develop POPF, and previous studies in other operations[1–6] have shown that drains can even lead to complications. Drains might act as entry points for bacteria, turning noninfected postoperative fluid collections into abscesses and infected fistulas. In addition, drains may cause tissue trauma by suction, might affect anastomoses, or might cause intestinal leaks.[10] In pancreatic surgery several randomized and nonrandomized trials have attempted to find out if and when abdominal drains are beneficial.[7,10–13]

The presented PANDRA II trial is the successor to the dual-center, randomized, controlled, noninferiority PANDRA trial, conducted from 2007 to 2015 in Dresden and Heidelberg, which demonstrated that omitting drains following pancreatic head resection was noninferior to intra-abdominal drainage in terms of postoperative reinterventions and was superior regarding clinically relevant POPF rates and associated complications.[14]

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The PANDRA II trial aimed to evaluate the clinical outcomes of drain versus no drain after open or minimally invasive (laparoscopic/robotic-assisted) left pancreatectomy (LP), with respect to postoperative complications.

METHODS

Before the inclusion of the first patient, the PANDRA II trial protocol received approval from the Ethics Committee of the University of Heidelberg (Ethikkommission Medizinische Fakultät Heidelberg, S-675/2017), was published[15] and internationally registered (DRKS00013763; UTN: U1111-1207-3031). The trial was conducted at the Clinical Trial Center (Klinisches Studienzentrum der Chirurgie) of the Department of General, Visceral, and Transplantation Surgery at University Hospital Heidelberg, adhering to Good Clinical Practice and the principles of the Declaration of Helsinki. The Klinisches Studienzentrum der Chirurgie was responsible for randomization and data management, while the Institute of Medical Biometry and Informatics at the University of Heidelberg was responsible for the statistical analysis independently.

The PANDRA II trial was structured as a monocenter, randomized controlled, noninferiority study with 2 parallel groups (no-drain group vs drain group). All patient-related information was handled with strict confidentiality following the European General Data Protection Regulation, the Federal Data Protection Act, and the State Data Protection Act. No third parties had access to the original data. The trial report was prepared based on the recommendations of the Consolidated Standards of Reporting Trials guidelines.[16]

Participants and Study Visits

All patients scheduled for LP at the Department of General, Visceral, and Transplantation Surgery at the University of Heidelberg underwent preoperative screening to determine their eligibility. This included patients scheduled for open or minimally invasive/robotic LP. Participants were at least 18 years old, able to comprehend the nature and consequences of the clinical trial, and provided written informed consent.

The exclusion criteria were:

- Requirement for pancreatic resection involving a pancreaticojejunal anastomosis.
- American Society of Anesthesiologists physical status classification of 4 or higher.
- Mental impairment or language barriers that hinder the ability to give informed consent.
- Concurrent participation in another interventional study could conflict with the interventions or outcomes of this trial.

During the preoperative visit, patients were educated about the clinical issues related to postoperative complications, the structure and timeline of the PANDRA II trial, and the associated risks and benefits. They were requested to provide their written informed consent.

Postoperative data collection was conducted at specified intervals, with clinical investigators and study nurses regularly visiting patients to gather primary and secondary outcome information and identify complications. This included 2 special postoperative visits on the third and 10th day (or day of discharge) and 2 follow-up phone interviews at 30 and 90 days postsurgery. Surgeons documented their surgical techniques in a standardized

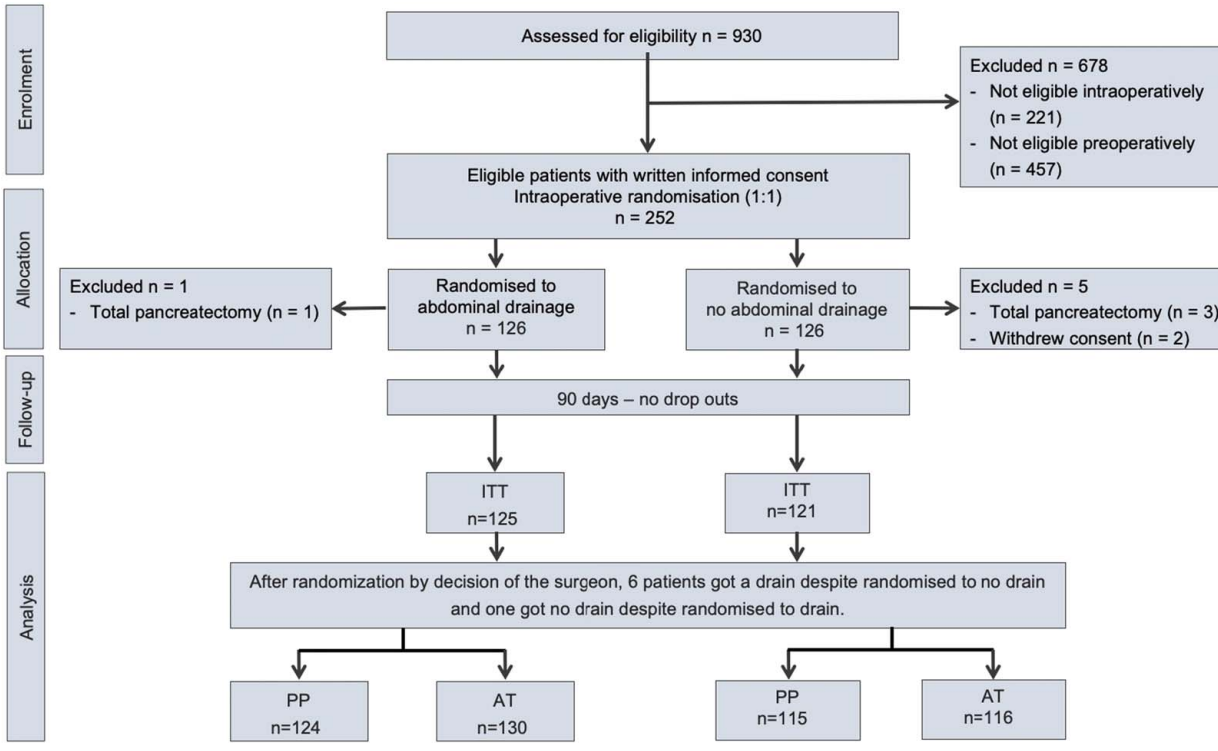

FIGURE 1. CONSORT trial flow diagram.

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TABLE 1. Baseline Demographics, Operations, and Concomitant Interventions in Total Population and the ITT Population

	No-drain group (n = 121)	Drain group (n = 125)
Sex		
Male	58 (47.9)	54 (43.2)
Female	63 (52.1)	71 (56.8)
Age in years*	64 (25-88)	65 (20-86)
BMI*	25.0 (16.1–55.2)	24.8 (17.8–55.0)
Charlson Comorbidity Index*	2.0 (0–7)	1.0 (0–10)
ASA classification		
I	10 (8.3)	10 (8.0)
II	71 (58.7)	75 (60.0)
III	40 (33.1)	40 (32.0)
Neoadjuvant therapy		
Neoadjuvant chemotherapy	13 (10.7)	8 (6.4)
Neoadjuvant radiation	2 (1.7)	3 (2.4)
Localization		
Pancreatic body	71 (58.7)	83 (66.4)
Pancreatic tail	50 (41.3)	42 (33.6)
Type of surgery		
Open surgery	81 (66.9)	75 (60.0)
Minimal invasive surgery	36 (29.8)	48 (38.4)
Converted to open surgery	4 (3.3)	2 (1.6)
Transection level		
Above/right of portal vein	107 (88.4)	101 (80.8)
Left of portal vein	14 (11.6)	24 (19.2)
Transection of pancreas		
Stapler	117 (96.7)	121 (96.8)
Scalpel	4 (3.3)	4 (3.2)
Pancreatic texture		
Soft	53 (43.8)	68 (54.4)
Not soft/not hard	41 (33.9)	39 (31.2)
Hard	18 (14.9)	9 (7.2)
Missing data	9 (7.4)	9 (7.2)
Coverage with falciform ligament		
Yes	65 (53.7)	55 (44.0)
No	56 (46.3)	70 (56.0)
Splenectomy		
Yes	110 (90.9)	118 (94.4)
No	11 (9.1)	7 (5.6)
Vascular resection		
Yes	15 (12.4)	12 (9.6)
No	106 (87.6)	113 (90.4)
Multivisceral resections (eg, stomach, colon, etc)		
Yes	8 (6.6)	5 (4.0)
No	113 (93.4)	120 (96.0)
DP-CAR		
Yes	4 (3.3)	5 (4.0)
No	117(96.7)	120 (96.0)
Postoperative diagnosis		
PDAC	42 (34.7)	37 (29.6)
IPMN	28 (23.1)	23 (18.4)
NET	22 (18.2)	26 (20.8)
SCN	8 (6.6)	12 (9.6)
CP	9 (7.4)	8 (6.4)
MCN	1 (0.8)	7 (5.6)
SPT	2 (1.7)	5 (4.0)
Pancreatic metastasis of other primary	3 (2.5)	2 (1.6)
ASCP	2 (1.7)	1 (0.8)
Other	4 (3.3)	4 (3.2)

Values in parentheses are percentages unless indicated otherwise.
*Values are median (range).
ASA indicates American Society of Anesthesiologists Classification; ASCP, adenosquamous carcinoma of the pancreas; BMI, body mass index; CP, chronic pancreatitis; DP-CAR, distal pancreatectomy with celiac axis resection; IPMN, intraductal papillary mucinous neoplasm; MCN, mucinous cystic neoplasm; NET, neuroendocrine tumor; PDAC, pancreatic ductal adenocarcinoma; SCN, serous cystic neoplasm; SPT, solid pseudopapillary tumor.

form. Blinding of participants, research assistants, surgeons, data collectors, and outcome assessors to treatment allocation was not possible as drain placement was obvious. However, the primary and secondary outcomes were objective endpoints that were not influenced by blinding. Therefore, only the data analysts were blinded in this study.

Randomization

Patients were randomized intraoperatively once the attending surgeon decided to proceed with a LP. Randomization was conducted before the pancreatic resection using block randomization with varying block sizes and a 1:1 allocation ratio. A computer-generated randomization list was prepared, and allocation was determined by sequentially opening opaque, numbered envelopes containing a card labeled either "drainage" or "no drainage."

The randomization process, as well as patient assignment to the respective trial intervention, was managed by staff members of the Klinisches Studienzentrum der Chirurgie at the University Hospital Heidelberg. Patients were excluded from the final analysis if the planned LP was not performed—for example, due to inoperability or the need for a total pancreatectomy.

Standardized Surgical Approach

In both groups, surgeons performed open or minimally invasive LP according to the standard operating procedure of the local institution. Additional resections of veins, arteries, or other organs were allowed. After exploration of the abdominal cavity, the pancreas was isolated and transected by a scalpel with hand-sewn closure or by stapler. Coverage of the pancreatic stump using the falciform ligament could be performed but was not mandatory. In the control group (drain group), at least one drain was placed at the pancreatic remnant, with amylase levels measured on the third postoperative day, and drains were removed based on clinical decision.

Objectives and Outcomes

Overall postoperative morbidity, using the Comprehensive Complication Index (CCI), was selected as the primary endpoint because it encompasses both the patient's perspective and the effectiveness of the surgical procedure. A CCI score of 0 represents no complications, whereas a score of 100 corresponds to death. This index is derived from the established Clavien-Dindo classification and has been validated for use in pancreatic surgery. A difference of 10 points on the CCI is considered clinically significant. The CCI is particularly suitable for comparing the full range of complications associated with 2 different surgical approaches to the abdominal cavity. This score was calculated by accounting for all complications occurring within 3 months after surgery.

Secondary endpoints included in-hospital mortality and postoperative complication rate within 90 days of the initial surgery. Specific complications monitored were

POPF,[17] chyle leak,[18] PPH,[19] reinterventions and reoperations (including radiologic interventions for intra-abdominal fluid collections, bleeding, and fistulas), delayed gastric emptying (DGE),[20] surgical site infections per Centers for Disease Control and Prevention[21] criteria, and abdominal fascia dehiscence. In addition, operation time, length of hospital stay, duration of intensive care unit stay, and the rate of hospital readmissions within 90 days postsurgery were also assessed.

Safety Considerations

All postoperative complications were systematically monitored throughout the hospital stay and during follow-up assessments (up to 90 days). Major complications were categorized as grades IV and V according to the Centers for Disease Control and Prevention. The coordinating investigator was notified of any such complications. Furthermore, mortality evaluations were conducted after the inclusion of 30 and 90 patients, respectively, to ensure ongoing safety monitoring within the study.

Sample Size Calculation

The sample size calculation was based on the primary outcome parameter CCI[22] in a noninferiority design. Assumptions were made on in-house calculations of the CCI on data from the DISPACT-Trial[23] and the NUR-IMAS Pancreas study,[24] (Mean CCI: 30; SD: 20). A decrease of the CCI by 10 points was considered relevant for patients and clinicians. Therefore, a margin of 7.5 CCI points was tolerated as noninferior. With a one-sided significance level of 2.5% and 80% power, 113 patients in each group (Nquery 7.0) had to be analyzed. With an estimated dropout rate of 10% 126 patients had to be allocated to each arm.

Statistical Analysis

Noninferiority of no-drain versus drain in LP was assessed using a 1-sided *t* test. The 1-sided significance level was set to 2.5%. The primary efficacy analysis was based on the intention to treat the population according to the intention to treat principle. In addition, an evaluation of the primary outcome was performed in the per-protocol population and in the as-treated population (where all patients were analyzed as they were treated) as sensitivity analyses. Missing data for the primary outcome variable were replaced by using multiple imputations,[25] which took the covariate treatment group into account by application of the fully conditional specification method. All secondary outcomes were evaluated descriptively, and descriptive *P* values were reported together with 95% CIs for the corresponding effects. All analyses were done using program R 4.4 or higher.

RESULTS

Trial Flow

A total of 252 patients were randomized into the 2 interventional groups between April 11, 2018 and September 28, 2023. With 6 patients excluded from the analysis, the intention-to-treat (ITT) population consisted of 246 patients (125 for abdominal drainage and 121 for no abdominal drainage). Seven patients had major protocol deviations, resulting in a per-protocol (PP) set of 239 patients (124 with abdominal drainage and 115 without abdominal drainage). Consequently, the as-treated (AT) population consisted of 246 patients (130 with abdominal drainage and 116 without abdominal drainage). The Consolidated Standards of Reporting Trials flow diagram is shown in Figure 1.

Patients' Baseline Characteristics

Baseline parameters were well balanced between the two groups. Details are shown in Table 1.

Primary Endpoint—Comprehensive Complication Index

For the ITT population, the CCI was 13.90 ± 16.51 (95% CI: 10.92–16.89) in the no-drain group and 19.43 ± 16.92 (95% CI: 16.42–22.44) in the drain group. The no-drain group was noninferior to the group regarding CCI in the ITT population ($P < 0.001$ for noninferiority; $P = 0.010$ for superiority).

In both the "PP" and the "AT" population, the no-drain group was noninferior to the drain group regarding CCI in the ITT population (both $P < 0.001$ for noninferiority; PP: $P = 0.009$ an AT: $P = 0.008$ for superiority). Details are shown in Table 2.

Secondary Endpoints (Intention-to-Treat Population)

Postoperative complications up to 90 days in the ITT population are shown in Table 3. The 90-day mortality was 0.4% in all patients (no-drain group 0 of 121 patients, 0% vs drain group 1 of 125 patients, 0.80%; $P > 0.999$). The single case of 90-day mortality in our study was indeed not related to surgical complications or the trial intervention. This case involved a patient who chose to end their life by suicide. Overall, there were 61 of 121 patients (50.41%) with one or more complications in the no-drain

TABLE 2. CCI as Primary Endpoint

	ITT no-drain group (n = 121)	ITT drain group (n = 125)	PP no-drain group (n = 115)	PP drain group (n = 124)	AT no-drain group (n = 116)	AT drain group (n = 130)
Mean	13.90	19.43	13.64	19.42	13.70	19.40
SD	16.51	16.92	16.55	16.98	16.50	16.89
95% CI	10.92–16.89	16.42–22.44	10.57–16.71	16.39–22.45	10.65–16.75	16.45–22.34
P (noninferiority)	**< 0.001**	—	**< 0.001**	—	**< 0.001**	—
Median	8.70	21.00	8.70	21.00	8.70	21.00
Minimum	0.00	0.00	0.00	0.00	0.00	0.00
Maximum	58.00	100.00	58.00	100.00	58.00	100.00

$P < 0.05$ was considered statistically significant.

TABLE 3. Postoperative Complications Up to 90 Days in the ITT Population

	No-drain group (n = 121)	Drain group (n = 125)	*P*
POPF according to ISGPS[17]			
Yes	18 (14.9)	26 (20.8)	**0.226**
Grade B	18 (14.9)	26 (20.8)	**0.226**
Grade C	0	0	**> 0.999**
PPH according to ISGPS[19]			
Yes	6 (5.0)	6 (4.8)	**> 0.999**
Grade A	2 (1.7)	3 (2.4)	—
Grade B	2 (1.7)	2 (1.6)	—
Grade C	2 (1.7)	1 (0.8)	—
DGE according to ISGPS[20]			
Yes	6 (5.0)	8 (6.4)	**0.626**
Grade A	3 (2.5)	2 (1.6)	—
Grade B	1 (0.8)	6 (4.8)	—
Grade C	2 (1.7)	0	—
Chyle leak according to ISGPS[18]			
Yes	1 (0.8)	23 (18.4)	**< 0.001**
Grade A	0	22 (17.6)	—
Grade B	1 (0.8)	1 (0.8)	—
Grade C	0	0	—
SSI according to Centers of Disease Control and Prevention criteria[21]			
Yes	17 (14.0)	15 (12.0)	**0.633**
Superficial	16 (13.2)	15 (12.0)	—
Deep	0	0	—
Organ/space	1 (0.8)	0	—
Abdominal fascia dehiscence			
Yes	2 (1.7)	2 (1.6)	**> 0.999**
Nonsurgical infections (eg, UTI, pneumonia, etc)			
Yes	24 (19.8)	27 (21.6)	**0.854**
Length of hospital stay in days*	12.01 (10.84)	12.91 (11.53)	**0.529**
Length of ICU stay*	0.04 (0.50)	0.06 (0.87)	**> 0.999**
90 d mortality	0	1 (0.8)	**> 0.999**

$P < 0.05$ was considered statistically significant.
Values in parentheses are percentages unless indicated otherwise.
*Values are mean (SD).
ICU indicates intensive care unit; ISGPS, International Study Group of Pancreatic Surgery; SSI, surgical site infection; UTI, urinary tract infection.

group and 98 of 125 patients (78.40%) with one or more complications in the drain group ($P < 0.001$). An overview of complications in all populations according to the Clavien-Dindo classification is shown in Table 4. Overall, 64 of 246 (26.0%) patients had reinterventions like CT-guided drainage (no-drain group 33 of 121 patients, 27.27% vs drain group 31 of 125 patients, 24.8%; $P = 0.659$) and 17 of 246 (6.9%) patients had a reoperation (no-drain group 8 of 121 patients, 6.61% vs drain group 9 of 125 patients, 7.20%; $P = 0.856$).

Regarding pancreatic surgery-specific complications, POPF occurred in 44 of 246 patients (17.89%). The 2 groups showed no significant difference in POPF (no-drain group 18 of 121 patients, 14.88% vs drain group 26 of 125 patients, 20.8%; $P = 0.226$). PPH was seen in 12 of 246 (4.88%) patients (no-drain group 6 of 121 patients, 4.96% vs drain group 6 of 125 patients, 4.80%; $P > 0.999$). Chyle leak occurred in 24 of 246 (9.76%) patients (no-drain group 1 of 121 patients, 0.83% vs drain group 23 of 125 patients, 18.40%; $P < 0.001$). A total of 14 of 246 (5.69%) patients suffered from DGE (no-drain group 6 of 121 patients, 4.96% vs drain group 8 of 125 patients, 6.40%; $P = 0.626$). There were 32 surgical site infections in 246 (12.6%) patients (no-drain group 17 of 121, 14.05%; vs drain group 15 of 125 patients, 12.0%; $P = 0.633$), and abdominal fascia dehiscence occurred in 4 of 156 (2.6%) open laparotomy patients (no-drain group 2 of 81 patients, 2.47% vs drain group 2 of 75 patients, 2.67%; $P > 0.999$). There was no difference in operation time (no-drain group 212 ± 64 minutes vs drain group 205 ± 62 minutes; $P = 0.373$). No difference was seen in patients' length of hospital stay (no-drain group 12.01 ± 10.84 days vs drain group 12.91 ± 11.53 days; $P = 0.529$). There were a total of 58 readmissions in 246 (23.58%) patients (no-drain group 24 of 121 patients, 19.83% vs drain group 34 of 125 patients, 27.20%; $P = 0.174$).

All baseline data and results were consistent between the populations regarding statistical significance, that is, if the result was significant (or nonsignificant) in the ITT population, these were also significant (or nonsignificant) in the PP and AT population.

DISCUSSION

The PANDRA II trial is a randomized mono-center trial investigating the use of drains in LP. The analysis of 246 patients of the ITT population demonstrated that no drain was noninferior to drain in terms of overall morbidity (CCI).

The use of routine abdominal drainage in LP has been a topic of ongoing debate in recent years. While putting drains has been standard practice for decades with good intentions, recent evidence shows that this may not always be beneficial.

According to the International Study Group of Pancreatic Surgery Evidence Map of Pancreatic Surgery

TABLE 4. Complications According to the CDC

CDC grade	ITT No-drain group (n = 121)	ITT drain group (n = 125)	PP No-drain group (n = 115)	PP drain group (n = 124)	AT No-drain group (n = 116)	AT drain group (n = 130)
I	33	90	31	90	31	92
II	46	75	40	74	41	80
IIIa	33	31	32	31	32	32
IIIb	8	9	8	9	8	9
IVa	1	5	1	5	1	5
IVb	0	0	0	0	0	0
V	0	1	0	1	0	1

CDC indicates Clavien-Dindo Classification.

(www.EVIglance.com), there are 3 published RCTs and no ongoing RCT on this topic.[26] In 2001, Conlon and colleagues published the first single-center randomized trial that compared the outcomes of using surgical drains versus not using them after pancreatic resections. Their cohort included 139 pancreatoduodenectomies and 40 LP, with 88 patients randomized to drainage and 91 to no drainage. This trial showed no difference in mortality, morbidity, or reintervention rate. Therefore, the authors concluded that drains should not be considered mandatory or standard after pancreatic resection.[27]

In 2017, Van Buren and colleagues conducted a multicenter randomized trial in the USA and Canada. They found no significant differences in the rates of severe complications (26% vs 29%; $P = 0.48$) or grade B or C POPF (12% vs 18%; $P = 0.11$) between the no-drain and routine drain groups after LP.[28]

A systematic review and meta-analysis published in 2022 compared no drain placement versus routine abdominal drainage in patients undergoing LP. This analysis, which included 5 studies with 2153 patients, found that omitting drains was associated with lower rates of major complications (Clavien-Dindo grade III or higher), POPF, and hospital readmissions. Particularly, rates of radiologic intervention and reoperation did not differ between groups.[29]

In 2024, the recently published PANDORINA trial further contributes to this discussion. This international randomized controlled trial compared outcomes between patients with and without intraoperative drain placement after LP. Conducted across 12 centers in the Netherlands and Italy, the PANDORINA study involved 282 patients. Results showed that omitting the drain reduced POPF from 27% to 12% and overall complications from 51% to 33%. The trial concluded that drainless surgery is safe and leads to better patient outcomes.[30]

The results of the PANDRA II trial confirm the results of the mentioned studies. The no-drain group was found to be noninferior to the abdominal drainage group regarding CCI in the ITT, PP, and AT populations (all $P < 0.001$). Moreover, this study demonstrates that both open and minimally invasive LP can be performed with very low mortality. The overall 90-day mortality rate was 0.4% with only one death in the drain group. However, the drain group had significantly more patients with one or more complications (78.40%) compared with the no-drain group (50.41%; $P < 0.001$). In contrast to the previous studies, the PANDRA II trial did not notice a significant difference in postoperative pancreatic surgery-specific complications, such as POPF, PPH, or DGE. Only chyle leaks were significantly more common in the drain group (18.40%) compared with the no-drain group (0.83%; $P < 0.001$).

This difference can probably be explained by the fact that at least some chyle leaks without a drain will never be diagnosed as long as there is no clinical consequence, whereas every drain with chylous output will be classified as a leak regardless of clinical significance. No significant differences were found between groups in rates of reinterventions or reoperations. No significant differences were found between groups in operation time, length of hospital stay, or readmission rates. A limitation of this study is the high splenectomy rate of 90%. This rate, however, reflects our institutional practice and the specific characteristics of our patient population (high percentage of patients with pancreatic cancer). The PANDRA II trial did not include a detailed subgroup analysis comparing POPF risk groups, such as those stratified by the distal fistula risk score (D-FRS).[31] While the D-FRS was utilized in the PANDORINA trial, it was not applied in the present study, limiting the possibility of a direct comparison between PANDORINA and PANDRA II regarding this aspect. A limitation of this study is that the D-FRS was not included in the study protocol. The decision to exclude the D-FRS was based on the fact that the necessary components for its calculation were not planned to be prospectively collected as part of the original study design. Retrospective application of the D-FRS would have introduced methodological challenges and potential biases. For example, different imaging modalities (computed tomography scan vs magnetic resonance imaging) were used preoperatively, which vary in their ability to assess pancreatic duct diameter, a crucial component of the score. Furthermore, a standardized assessment of pancreatic duct size was not consistently performed across all patients. Given these limitations, a retrospective analysis of the D-FRS was not feasible for all patients and could have led to inaccuracies in risk stratification.

The strength of the present study is that the primary endpoint was the CCI. Therefore, all complications occurring up to the last study visit (90th postoperative day) were prospectively documented, tracked, and meticulously analyzed. The study included open surgery and minimally invasive procedures (laparoscopic or robot-assisted). In the subgroup analysis of each surgical technique, it was demonstrated that the results are the same for the different types of operations. According to the inclusion criteria, various pancreatic diseases were included. Thus, patients with hard pancreatic tissue, as seen primarily in chronic pancreatitis or pancreatic carcinoma, as well as patients with very soft pancreatic tissue, typically found in benign pancreatic tumors such as cystic pancreatic neoplasms, were included.

CONCLUSIONS

While routine drainage after LP has been standard practice for long, there is increasing evidence, that omitting drains is safe and even beneficial.

REFERENCES

1. Fong Y, Brennan MF, Brown K, et al. Drainage is unnecessary after elective liver resection. *Am J Surg*. 1996;171:158–162.
2. Budd DC, Cochran RC, Fouty WJ Jr. Cholecystectomy with and without drainage. A randomized, prospective study of 300 patients. *Am J Surg*. 1982;143:307–309.
3. Alvarez Uslar R, Molina H, Torres O, et al. Total gastrectomy with or without abdominal drains. A prospective randomized trial. *Rev Esp Enferm Dig*. 2005;97:562–569.
4. Kim J, Lee J, Hyung WJ, et al. Gastric cancer surgery without drains: a prospective randomized trial. *J Gastrointest Surg*. 2004;8:727–732.
5. Merad F, Yahchouchi E, Hay JM, et al. Prophylactic abdominal drainage after elective colonic resection and supra-promontory anastomosis: a multicenter study controlled by randomization. French Associations for Surgical Research. *Arch Surg*. 1998;133:309–314.
6. Merad F, Hay JM, Fingerhut A, et al. Is prophylactic pelvic drainage useful after elective rectal or anal anastomosis? A multicenter controlled randomized trial. French Association for Surgical Research. *Surgery*. 1999;125:529–535.
7. Correa-Gallego C, Brennan MF, D'Angelica M, et al. Operative drainage following pancreatic resection: analysis of 1122 patients resected over 5 years at a single institution. *Ann Surg*. 2013;258:1051–1058.

8. Strobel O, Hinz U, Gluth A, et al. Pancreatic adenocarcinoma: number of positive nodes allows to distinguish several N categories. *Ann Surg*. 2015;261:961–969.
9. Buchler MW, Wagner M, Schmied BM, et al. Changes in morbidity after pancreatic resection: toward the end of completion pancreatectomy. *Arch Surg*. 2003;138:1310–1314; discussion 1315.
10. Fisher WE, Hodges SE, Silberfein EJ, et al. Pancreatic resection without routine intraperitoneal drainage. *HPB (Oxford)*. 2011; 13:503–510.
11. Kawai M, Kondo S, Yamaue H, et al. Predictive risk factors for clinically relevant pancreatic fistula analyzed in 1,239 patients with pancreaticoduodenectomy: multicenter data collection as a project study of pancreatic surgery by the Japanese Society of Hepato-Biliary-Pancreatic Surgery. *J Hepatobiliary Pancreat Sci*. 2011;18:601–608.
12. McMillan MT, Malleo G, Bassi C, et al. Drain management after pancreatoduodenectomy: reappraisal of a prospective randomized trial using risk stratification. *J Am Coll Surg*. 2015; 221:798–809.
13. Mehta VV, Fisher SB, Maithel SK, et al. Is it time to abandon routine operative drain use? A single institution assessment of 709 consecutive pancreaticoduodenectomies. *J Am Coll Surg*. 2013;216:635–642.
14. Witzigmann H, Diener MK, Kienkotter S, et al. No need for routine drainage after pancreatic head resection: the dual-center, randomized, controlled PANDRA trial (ISRCTN04937707). *Ann Surg*. 2016;264:528–537.
15. Kaiser J, Niesen W, Probst P, et al. Abdominal drainage versus no drainage after distal pancreatectomy: study protocol for a randomized controlled trial. *Trials*. 2019;20:332.
16. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *Brit Med J*. 2010;340:c332.
17. Bassi C, Marchegiani G, Dervenis C, et al. The 2016 update of the International Study Group (ISGPS) definition and grading of postoperative pancreatic fistula: 11 years after. *Surgery*. 2017;161:584–591.
18. Besselink MG, van Rijssen LB, Bassi C, et al. Definition and classification of chyle leak after pancreatic operation: a consensus statement by the International Study Group on Pancreatic Surgery. *Surgery*. 2017;161:365–372.
19. Wente MN, Veit JA, Bassi C, et al. Postpancreatectomy hemorrhage (PPH): an International Study Group of Pancreatic Surgery (ISGPS) definition. *Surgery*. 2007;142:20–25.
20. Wente MN, Bassi C, Dervenis C, et al. Delayed gastric emptying (DGE) after pancreatic surgery: a suggested definition by the International Study Group of Pancreatic Surgery (ISGPS). *Surgery*. 2007;142:761–768.
21. Wente MN, Bassi C, Dervenis C, et al. Delayed gastric emptying (DGE) after pancreatic surgery: a suggested definition by the International Study Group of Pancreatic Surgery (ISGPS). *Surgery*. 2007;142:761–8.
22. Slankamenac K, Graf R, Barkun J, et al. The Comprehensive Complication Index: a novel continuous scale to measure surgical morbidity. *Ann Surg*. 2013;258:1–7.
23. Diener MK, Knaebel HP, Witte ST, et al. DISPACT trial: a randomized controlled trial to compare two different surgical techniques of DIStal PAnCreaTectomy - study rationale and design. *Clin Trials*. 2008;5:534–545.
24. Probst P, Haller S, Bruckner T, et al. Prospective trial to evaluate the prognostic value of different nutritional assessment scores in pancreatic surgery (NURIMAS Pancreas). *Br J Surg*. 2017;104:1053–1062.
25. Van Buuren S. Flexible imputation of missing data. CRC press. 2018.
26. Probst P, Hüttner FJ, Meydan Ö, et al. Evidence map of pancreatic surgery-a living systematic review with meta-analyses by the International Study Group of Pancreatic Surgery (ISGPS). *Surgery*. 2021;170:1517–1524.
27. Conlon KC, Labow D, Leung D, et al. Prospective randomized clinical trial of the value of intraperitoneal drainage after pancreatic resection. *Ann Surg*. 2001;234:487–493; discussion 493-494.
28. Van Buren G, 2nd, Bloomston M, et al. A prospective randomized multicenter trial of distal pancreatectomy with and without routine intraperitoneal drainage. *Ann Surg*. 2017; 266:421–431.
29. van Bodegraven EA, van Ramshorst TME, Balduzzi A, et al. Routine abdominal drainage after distal pancreatectomy: meta-analysis. *Br J Surg*. 2022;109:486–488.
30. van Bodegraven EA, Balduzzi A, van Ramshorst TME, et al. Prophylactic abdominal drainage after distal pancreatectomy (PANDORINA): an international, multicentre, open-label, randomised controlled, non-inferiority trial. *Lancet Gastroenterol Hepatol*. 2024;9:438–447.
31. De Pastena M, van Bodegraven EA, Mungroop TH, et al. Distal pancreatectomy fistula risk score (D-FRS): development and international validation. *Ann Surg*. 2023;277: e1099–e1105.