A novel ultrasound-based algorithm for the detection of pancreatic stents placed for prophylaxis of post-ERCP pancreatitis: a prospective trial

Evaluation eines ultraschallgestützten Algorithmus zur Erkennung von prophylaktischen Pankreas-Stents zur Vermeidung einer Pankreatitis nach ERCP: eine prospektive Studie

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Authors

Florian Alexander Michael[1], Clara Feldmann[1], Hans-Peter Erasmus[1], Alica Kubesch[1], Esra Goerguelue[1], Mate Knabe[1,2], Nada Abedin[1], Myriam Heilani[1], Daniel Hessz[1], Christiana Graf[1,3], Dirk Walter[1], Fabian Finkelmeier[1], Ulrike Mihm[1], Neelam Lingwal[4], Stefan Zeuzem[1], Joerg Bojunga[1], Mireen Friedrich-Rust[1], Georg Dultz[1]

Affiliations

1 Medical Clinic 1, Goethe University Frankfurt Frankfurt University Hospital, Frankfurt am Main, Germany
2 Centrum Gastroenterology Bethanien, Bethanien-Hospital, Frankfurt am Main, Germany
3 Medical Clinic 2, LMU Hospital, Munchen, Germany
4 Institute for Biostatistics and Mathematical Modeling, Goethe University Frankfurt Frankfurt University Hospital, Frankfurt am Main, Germany

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Correspondence

Dr. Florian Alexander Michael, MD
Medical Clinic 1, Goethe University Frankfurt Frankfurt University Hospital, Theodor-Stern-Kai-Straße 7, 60590 Frankfurt am Main, Germany
fmichael@med.uni-frankfurt.de

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ABSTRACT

Purpose Before removal of retained pancreatic stents placed during endoscopic retrograde cholangiopancreatography to avoid post-ERCP pancreatitis, imaging is recommended. The aim of the present study was to evaluate a new ultrasound-based algorithm.

Materials and Methods Patients who received a pancreatic stent for PEP prophylaxis were included. Straight 5Fr (0.035 inch) 6 cm stents with an external flap that were visualized by ultrasound were removed endoscopically with no further imaging. If the ultrasound result reported the stent to be dislodged or was inconclusive, X-ray imaging was performed. The endpoints were positive and negative predictive value, specificity, sensitivity, and contingency coefficient between ultrasound and X-ray and/or endoscopy.

Results 88 patients were enrolled in the present study. X-ray was performed in 23 (26 %) patients. Accordingly, the ultrasound algorithm saved an X-ray examination in 65 cases, leading to a reduction of 74 %. Stents were retained in 67 patients (76 %) and visualized correctly by ultrasound in 54 patients with a sensitivity of 81 %. The positive predictive value was 83 %. The specificity was 48 %, because ultrasound described 10/21 dislodged stents correctly. The negative predictive value was 43 %, since 10/23 stents were correctly classified by ultrasound as dislodged. In 11 patients (13 %), esophagogastroduodenoscopy was performed even though the pancreatic stent was already dislodged.

Conclusion A novel ultrasound-based algorithm reduced the need for X-ray imaging by three quarters. To avoid unnecessary endoscopic examinations, the algorithm should be implemented with a learning phase and procedures should be performed by experienced examiners. An important limitation might be stent length since shorter stents might be more difficult to visualize by ultrasound.

ZUSAMMENFASSUNG

Hintergrund Aktuell wird vor der Entfernung von prophylaktisch gelegten Pankreas-Stents nach einer endoskopischen retrograden Cholangiopankreatikografie eine Bildgebung empfohlen. Ziel der vorliegenden Studie war es, einen neuen ultraschallbasierten Algorithmus zu evaluieren.

Material und Methoden Eingeschlossen wurden Patienten nach prophylatischer Pankreas-Stent-Anlage. Gerade 5 Fr-Stents (0,035 inches) mit 6 cm Länge vom externen Flansch, die mittels Ultraschall sichtbar waren, wurden endoskopisch ohne weitere Bildgebung entfernt. Wenn das Ultraschall-Ergebnis den Stent als disloziert beschrieb, wurde eine Röntgenaufnahme durchgeführt. Die Endpunkte waren der positive und negative Vorhersagewert, die Spezifität, Sensitivität und der Kontingenzkoeffizient zwischen Ultraschall und Röntgen und/oder Endoskopie.

Ergebnisse 88 Patienten wurden in die Studie eingeschlossen. Bei 23 (26 %) Patienten musste eine Röntgenaufnahme durchgeführt werden. Entsprechend hat der Ultraschall-Algorithmus in 65 Fällen (74 %) eine Röntgenuntersuchung eingespart. Stents waren bei 67 Patienten (76 %) verblieben und wurden bei 54 Patienten korrekt mit einer Sensitivität von 81 % mittels Ultraschall visualisiert. Der positive Vorhersagewert betrug 83 %. Die Spezifität betrug 48 %, da der Ultraschall 10/21 dislozierte Stents korrekt beschrieb. Der negative Vorhersagewert betrug 43 %, da 10/23 Stents korrekt als dislozierte klassifiziert wurden. Bei 11 Patienten (13 %) wurde eine Ösophagogastroduodenoskopie durchgeführt, obwohl der Pankreas-Stent bereits dislozierte war.

Fazit Ein ultraschallbasierter Algorithmus reduzierte den Bedarf an Röntgen-Bildgebung um 3/4. Um unnötige endoskopische Untersuchungen zu vermeiden, sollte der Algorithmus mit einer Lernphase implementiert und das Verfahren von erfahrenen Untersuchern durchgeführt werden. Eine wichtige Einschränkung könnte die Länge der Stents sein, da kürzere Stents mit Ultraschall schwieriger zu visualisieren sein könnten.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the primary therapeutic modality for biliary and pancreatic ductal diseases [1]. Due to the technically demanding examination and the anatomical proximity between the bile and the pancreatic ducts, there is still a 3.5–9.7 % risk of developing post-ERCP pancreatitis (PEP) and an overall mortality rate of 0.1–0.7 %, despite sophisticated preventive measures [2, 3].

Accordingly, PEP prophylaxis has high clinical relevance. The prophylactic placement of a pancreatic stent (PS) has been shown to significantly reduce PEP by several large meta-analyses (odds ratio 0.22–0.39) [4, 5]. Therefore, international guidelines recommend the placement of prophylactic plastic stents in the pancreatic duct to secure drainage in the case of accidental cannulation or the application of contrast agent in the pancreatic duct [6, 7, 8, 9]. 5-Fr stents that remain for at least 12 to 24 hours after the ERCP procedure are used as the standard [10, 11, 12].

Although a significant number of stents dislodge spontaneously in the first days after placement, endoscopic removal of retained PSs is currently recommended after at least five to ten days by international guidelines to prevent complications [9, 11, 13, 14, 15]. To avoid unnecessary esophagogastroduodenoscopy (EGD), imaging before stent removal is recommended to visualize retained stents [9, 13]. In most centers a fluoroscopic image is performed in the ERCP unit [9]. Accordingly, this procedure takes up pivotal resources of the endoscopy department. Furthermore, radiation exposure poses a risk to patients and staff [16].

Recently, in a pilot trial with 41 patients, we investigated the feasibility and technical aspects of detecting prophylactic PSs by ultrasound. In this pilot study, all patients underwent ultrasound and fluoroscopic imaging, and a positive predictive value of above 90 % for the detection of PSs by ultrasound was reported [16].

The aim of this trial was to evaluate a novel ultrasound-based algorithm as primary directive imaging before endoscopic stent removal.

Methods

Study design

The present study is a prospective single-center study to evaluate a novel algorithm for the extraction of PSs placed to prevent PEP. All patients provided written informed consent before study participation.

All PSs were placed in patients at risk of undergoing ERCP to prevent PEP if indicated by current guidelines [9]. The placed stents were straight 6 cm, 5-Fr (0.035 inch) polyurethane stents with a single external flap and no internal one (Pancreatic Stent, Optimed, Ettlingen, Germany).

Inclusion criteria were I) placement of a prophylactic PS to prevent PEP during ERCP, II) patients older than 18 years of age, and III) written informed consent.

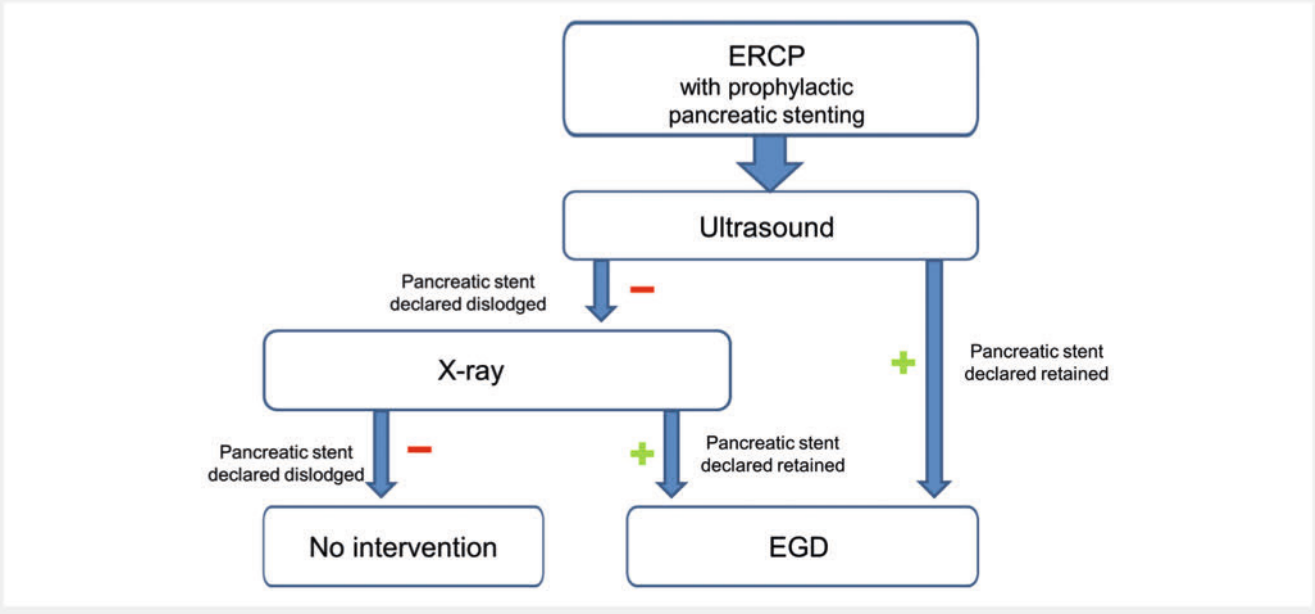
Excluded were all patients with I) a condition prohibiting ultrasound examination, X-ray, or EGD, II) patients unable to give informed consent or III) PSs for indications other than PEP prophylaxis.

Patients included in the trial underwent a bedside ultrasound examination in the ward before being transferred to the high-end ultrasound device for a second examination with optimal external conditions (e. g., darkened room, avoidance of disruption). All ultrasound examinations were performed using a transducer with a frequency of 4.5 to 5 MHz. ▶ **Table 1** summarizes the used devices. Both ultrasound examinations were performed by independent examiners who were required to have undergone training of at least 250 examinations in the sonographic department. If there was no sufficiently experienced examiner in the ward, the examination was performed by one of the study authors. The results were blinded. The number of ultrasound examinations and years of experience of the examiners were documented. The time of the first study examination was used to determine the time of the definition.

All patients were fasting on the day of the examination. The examination was performed in the supine position. If visibility of the

▶ **Table 1** Summary of the ultrasound devices and transducers used in the study.

Group	Ultrasound device	Transducer	Company and origin
Bedside ultrasound	Acuson × 300	CH5–2 transducer (frequency: 5.0 MHz, range: 1.4–5.0 MHz, field of view: 66°)	Siemens, Munich, Germany
High-quality ultrasound	Aplio 500	PVT-375SC transducer (frequency: 5.0 MHz, range: 1.5–6.0 MHz, field of view: 70°)	Toshiba, Tokyo, Japan
	Aplio i800	i8CX1 transducer (frequency: 5.0 MHz, range: 1.8–6.2 MHz, field of view: 70°)	Canon, Ōtawara, Japan
	Hi Vision Ascendus	EUP C715 transducer (frequency: 5.0 MHz, range: 1.0–5.0 MHz, field of view: 70°)	Hitachi, Tokyo, Japan
	Acuson S2000	a 4C1 transducer (frequency: 4.5 MHz, range: 1.0–5.0 MHz, field of view: 66°)	Siemens, Munich, Germany
	Acuson Sequoia	5C1 transducer (frequency: 5 MHz, range: 1.4–5.0 MHz, field of view: 70°)	Siemens, Munich, Germany



▶ **Fig. 1** Sonography-favoring algorithm to remove pancreatic stents*. All pancreatic stents being placed to prevent post-ERCP pancreatitis (PEP) are primarily visualized by sonography. Stents being retained in the pancreatic duct were then directly removed by esophagogastroduodenoscopy (EGD) omitting further imaging. To prevent false-negative results, stents being described as dislodged by sonography underwent subsequent X-ray imaging. Only stents then described as retained were removed via EGD. No further intervention was needed in the case of pancreatic stents being identified as dislodged by both sonography and X-ray. EGD = esophagogastroduodenoscopy; ERCP = endoscopic retrograde cholangiopancreatography; PEP = post-ERCP pancreatitis. *The algorithm was first published by Michael et al. [17] during a first pilot trial.

pancreatic head region was limited, the patient was turned into the left lateral position. The stomach was never filled with fluid, as this could pose a risk for the subsequent EGD. Poor examination conditions were defined as those where reliable visualization of the target structures (pancreatic head, pancreatic duct, common hepatic duct and confluence of the lienal and superior mesenteric veins) was not possible (e. g., due to overlaying gas, abdominal fatty tissue).

Results of the ultrasound examinations were PS visualized in the pancreatic duct or stent not being visualized. All patients underwent at least one of the two possible ultrasound examinations. If patients underwent both examinations, high-end ultrasound defined the subsequent process.

▶ **Fig. 1** shows the implemented algorithm. If the stent was classified as dislodged, a fluoroscopic image was obtained in the ERCP unit to rule out retained stents by false-negative sonographic results. In the case of stents being classified as retained, fluoroscopic imaging was omitted, and the stent was removed directly via EGD.

Patient transport between the ward, the ultrasound room, and the endoscopy unit was performed on a bed and in quick succession to reduce the minor risk of stent dislodgment between examinations. In this single-arm study, neither randomization nor blinding was required.

Outcomes

There were three ultrasound groups: I) ultrasound procedure overall (defined as either the high-end ultrasound procedure or the bedside ultrasound examination in the absence of a high-end ultrasound examination), II) high-end ultrasound, and III) bedside ultrasound.

The primary outcome of the study was to calculate the positive predictive value of sonography for the detection of pancreatic and biliary stents in each group. The fluoroscopic image or the EGD result was used as the reference method. Secondary outcomes were to calculate the negative predictive value, sensitivity, and specificity. Contingency coefficients were determined to compare the agreement between the different types of ultrasound examinations and X-ray or EGD.

Statistical analysis was performed to determine associations between baseline characteristics and success of sonographic stent detection in high-end and bedside ultrasound examination and PS dislodgement.

Statistical analysis

Data collection, data management, and statistical analyses were performed using the SPSS software package, release 21 (IBM, Armonk, USA).

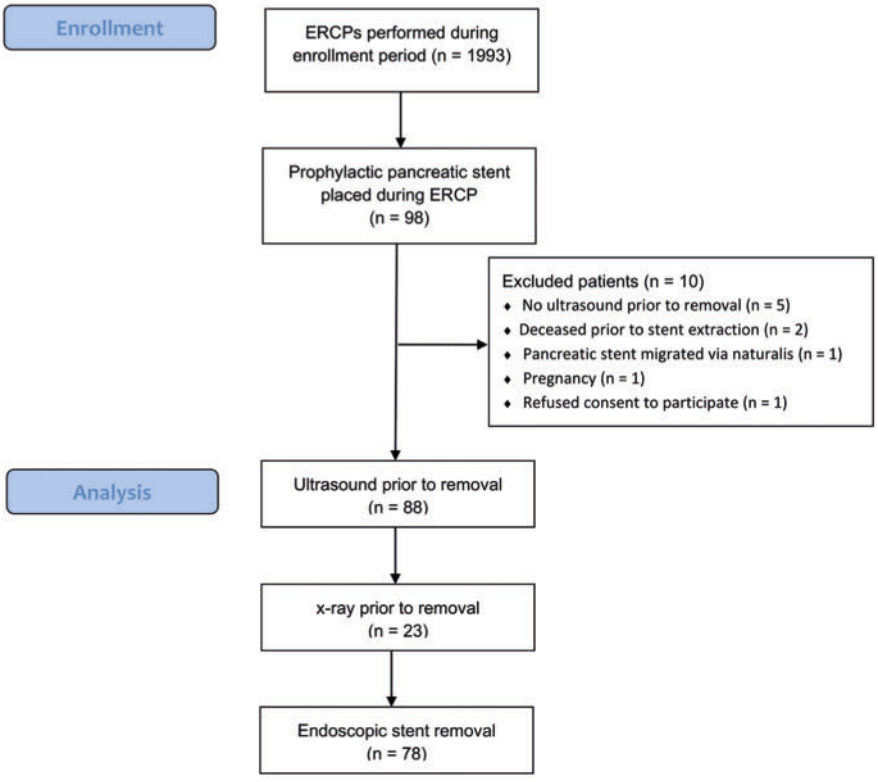
The sample size was calculated on the basis of the data from a previous pilot trial on the same topic [16]. Assuming a sensitivity of 93.5 %, a desired confident P for the confidence interval of 95 %, and a desired length of the confidence interval of 12 %, a case number of 64 patients was obtained. This refers to patients in whom a PS could be visualized sonographically in the duct. According to the previous study, this was the case in approximately 73.1 % of patients on the day of removal. As a result, 88 subjects were identified as meeting the study goal.

Descriptive statistics were computed to provide frequencies and percentages for categorical variables and median and 25 %/75 % quartiles for continuous values. The positive predictive value, negative predictive value, sensitivity, and specificity were calculated. The mean contingency coefficient (φ) was calculated to evaluate the correlation between the ultrasound device and X-ray and/or endoscopy. Univariate and multivariate analyses were performed to detect risk factors for PS dislodgement and the success of sonographic stent detection. All reported p-values are two-sided. Statistical significance was considered if the p-values were below 0.05.

Results

Study characteristics

▶ **Fig. 2** shows a flowchart of the patient inclusion. A total of 98 patients were assessed for eligibility. Ten patients had to be excluded: five patients did not undergo sonography before endoscopy, two patients died before stent extraction due to end stage cancer, one PS migrated via naturalis, one patient was pregnant, and one patient refused stent extraction after screening. Therefore, 88 patients underwent the intended study protocol and



▶ **Fig. 2** Study flowchart. ERCP = endoscopic retrograde cholangiopancreatography.

▶ **Table 2** Patient and procedural characteristics.

Patient characteristics	
Female gender	41 (47 %)
Age (years)	62 (52/69)
BMI (kg/m²)	24.5 (21.3/29.0)
Pancreatic disease	18 (20 %)
Pancreatic carcinoma	12 (14 %)
Pancreatitis	6 (7 %)
Pancreas lipomatosis	9 (11 %)
Liver disease	40 (45 %)
Liver metastasis	10 (11 %)
Liver transplantation	10 (11 %)
Cholangiocarcinoma	6 (7 %)
Sclerosing bile duct disease	4 (5 %)
Liver cirrhosis	9 (10 %)
Budd-Chiari-Syndrome	1 (1 %)
Abdominal surgery	24 (27 %)
Procedural characteristics	
ERCP indication	
Malignant stenosis	35 (40 %)
Choledocholithiasis	29 (33 %)
Anastomotic stenosis after liver transplantation	8 (9 %)
Biliary leakage	5 (6 %)
Prophylactic stenting after ampullectomy	4 (5 %)
Sclerosing bile duct disease	4 (5 %)
Others	3 (3 %)
ERCP complications	15 (17 %)
Post-ERCP pancreatitis	12 (14 %)
Perforation	1 (1 %)
Cholangitis	1 (1 %)
Hypoxemia*	1 (1 %)
Days between pancreatic stent placement and removal	2 (2/3.75)
Ultrasound procedures overall	88 (100 %)
Bedside ultrasound procedures	77 (88 %)
High-end ultrasound procedures	86 (98 %)
Aplio i800 (Canon)	28 (32 %)
Hi Vision Ascendus (Hitachi)	24 (28 %)
Aplio 500 (Toshiba)	17 (20 %)
Acuson Sequoia (Siemens)	8 (9 %)
Acuson S2000 (Siemens)	5 (6 %)
Undocumented	4 (5 %)
Sonographic conditions evaluated as difficult by the examiner	26 (30 %)
Number of X-rays performed	23 (26 %)
Number of EGDs performed	78 (89 %)
Adverse events during EGD	1 (1 %)*
Adverse events after EGD	0 (0 %)

Continuous parameters are expressed as medians with range, nominal parameters as number of patients with percentage of occurrence.
* Hypotension was treated by IV infusion with no delay of the procedure and no further complications.
ERCP: endoscopic retrograde cholangiopancreatography; EGD: esophagogastroduodenoscopy

were analyzed for the primary outcome. 86 patients underwent sonography with a high-end device and 77 patients were examined with bedside ultrasound. The predefined number of cases was reached. Patient and procedural characteristics are summarized in ▶ **Table 2**. ▶ **Fig. 3** illustrates the methods.

Simultaneous stenting of the common bile duct during ERCP was performed in 79 (90 %) patients. One stent was placed in 73 (92 %), and two stents in 6 (8 %) patients. Plastic stents were placed in 75 (95 %) patients, and self-expandable metal stents in 4 (5 %) patients. 15 patients (17 %) developed an ERCP-related complication, with mild PEP (12, 14 %) being the most common.

PS extraction according to the algorithm was performed between days 1 and 13 (median: 2 days) after stent placement. A total of 67 stents (76 %) were retained on the day of extraction and 21 stents were dislodged. ▶ **Table 3** shows whether the PS was retained on the particular day of stent visualization and extraction.

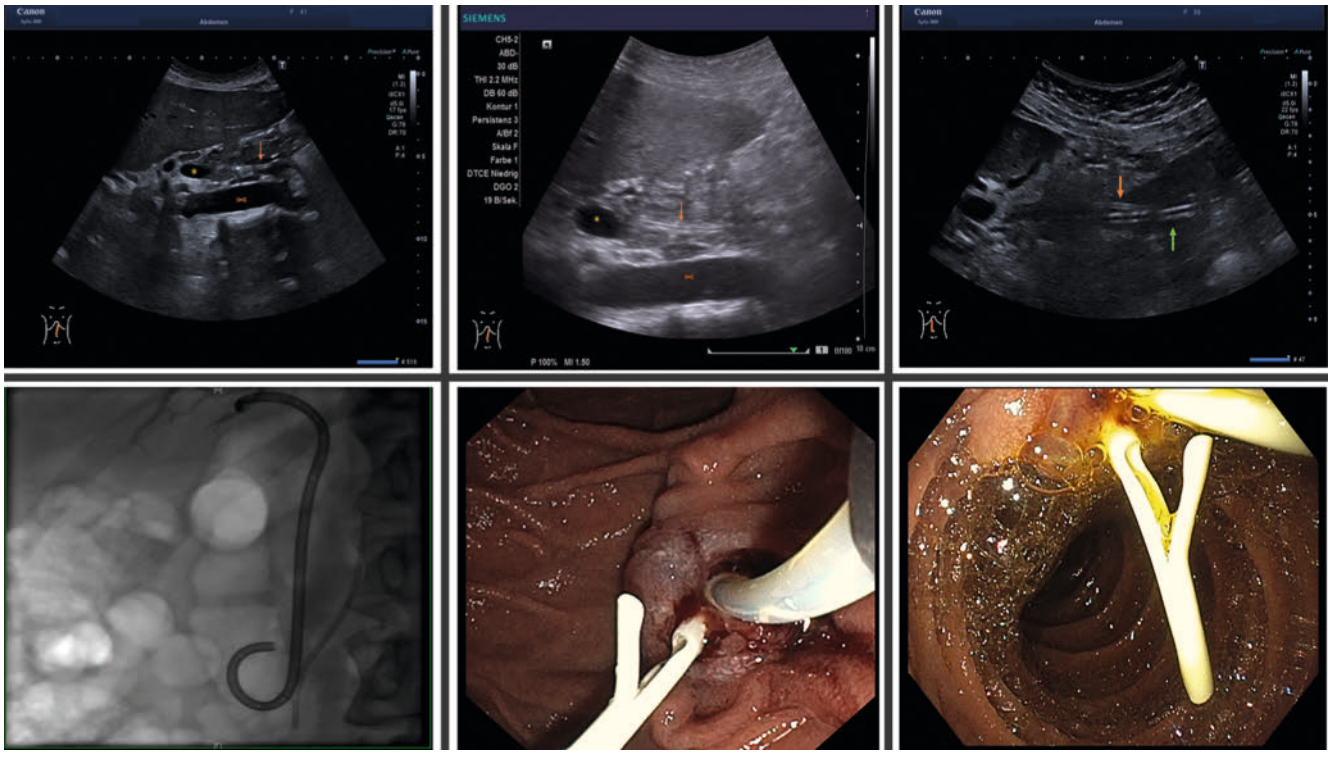
Outcome of pancreatic stent detection using ultrasound

The results of PS detection according to the presented algorithm are shown in ▶ **Fig. 4**.

Ultrasound reported 65 retained stents, 54 stents were confirmed and extracted by EGD. Thus, the positive predictive value was 83 % (95 %-CI: 71–91 %). The negative predictive value was 43 % (95 %-CI: 23–65 %), with 10/23 stents correctly being reported to be dislodged.

The sensitivity was 81 % (95 %-CI: 69–89 %) with ultrasound correctly reporting 54 of 67 stents to be retained in the pancreatic duct. The specificity was 48 % (95 %-CI: 26–70 %), as ultrasound correctly reported 10/21 stents as dislodged. The mean contingency coefficient describing the correlation between ultrasound and X-ray/EGD was 0.26 ($p < 0.01$). **Supplementary Table 2** gives an overview of the examiners' experience and their performance during the trial.

X-ray was performed in 23 patients only and was avoided in the remaining 65 cases (74 %). EGD was performed in 78 patients (89 %). In 11 patients (13 %), EGD was performed although the PS was already dislodged, even though sonography reported a retained stent (false-positive rate). No complications were recorded during stent removal via EGD, and no procedure-related pancreatitis was documented. In one case, arterial hypotension occurred during EGD, which was treated with intravenous fluid.



▶ **Fig. 3** Images of the applied procedures. The upper row presents sonographic pictures in B-mode made by devices of the high-end ultrasound group (left and right picture) and of the bedside ultrasound group (middle picture). Displayed is the head region of the pancreas in a longitudinal section tilted slightly clockwise. The left and the middle pictures are of the same patient on consecutive procedures. The orange arrow points at the pancreatic stent. The orange x is placed in the vena cava inferior and the orange * is placed in the portal vein. The green arrow in the right picture indicates a plastic biliary duct stent. In the lower row, a fluoroscopic image of a pancreas stent and a biliary duct stent is displayed. The picture in the middle shows an endoscopic image of a side-viewing scope. On the image, a straight 5-Fr 6 cm plastic pancreatic stent with an external flange and a plastic pig tail stent enter the papilla. On the endoscopic picture on the right side, a prophylactic pancreatic stent and a biliary stent are displayed using a diagnostic front-view gastroscope.

▶ **Table 3** Status of pancreatic stent position on the day of removal.

Days after placement of pancreatic stent	Pancreatic stent retained		Total n = 88
	No n = 21	Yes n = 67	
1	3	12	15
2	10	27	37
3	3	11	14
4	3	7	10
5	1	4	5
6	0	1	1
7	1	1	2
8	0	1	1
10	0	1	1
12	0	1	1
13	0	1	1

		Stent verified by x-ray/EGD		
		Yes	No	
Stent visualized by ultrasound overall	Yes	54 (61%)	11 (13%)	83% [1] (71-91%)
	No	13 (15%)	10 (11%)	43% [2] (23-65%)
		81% [3] (69-89%)	48% [4] (26-70%)	88

▶ **Fig. 4** Contingency table with ultrasound outcomes of pancreatic stent detection. The table displays the trial outcomes comparing ultrasound results with esophagogastroduodenoscopy and/or X-ray results given as absolute values and proportion in brackets. Positive predictive value (1), negative predictive value (2), sensitivity (3), and specificity (4) are calculated as proportion and 95 % confidence interval in brackets. EGD = esophagogastroduodenoscopy.

▶ **Table 4** Regression analysis of success of sonographic procedure to detect a pancreatic stent.

Characteristics	Success of ultrasound					
	Univariate analysis			Multivariate analysis		
	p-value	OR	95 %-CI	p-value	OR	95 %-CI
Age	0.43	0.98	0.94–1.03	0.66		
BMI > 25	0.92	0.93	0.20–4.33	0.92		
BMI > 30	0.13	4.07	0.67–24.72	0.70		
Pancreatic disease	0.98	1.02	0.24–4,31	0.21		
Liver disease	0.64	1.35	0.38–4.72	0.16		
Previous abdominal surgery	0.46	0.59	0.14–2.44	0.71		
Time from ERCP	0.30	0.63	0.27–1.50	0.97		
Indication for ERCP	0.36	0.82	0.54–1.25	0.11		
PEP	0.18	0.27	0.04–1.82	0.84		
Placement of biliary stent	0.25	0.34	0.05–2.15	0.94		
Pancreas lipomatosis	0.32	0.36	0.05–2.68	0.35		
No visualization of the target structures*	**0.016**	5.27	1.37–20.37	**0.031**	4.91	1–14–20.96
Sonography device	0.76	0.95	0.70–1.30	0.45		

* the target structures: pancreatic head, pancreatic duct, common hepatic duct, and confluence of the lienal and superior mesenteric veins

Outcome of biliary stent detection using ultrasound

The positive predictive value was 97 % (95 %-CI: 91–100 %), with 76/78 biliary stents being correctly described as retained by ultrasound. Stent dislodgement was assessed correctly by sonography in 1/3 cases (specificity: 33 %, 95 %-CI: 8–91 %). The sensitivity and negative predictive value were 100 %.

Univariate and multivariate logistic regression analyses

No significant association was observed between PS dislodgement and the time from ERCP to stent visualization (p > 0.2), BMI > 25 kg/m^2 (p = 0.09), BMI > 30 kg/m^2 (p = 0.12), pancreatic disease (p > 0.2), liver disease (p > 0.2), previous abdominal surgery (p > 0.2), indication of ERCP (p > 0.2), coincidental biliary stent placement (p > 0.2), and PEP (p = 0.09).

The success of sonographic stent detection was significantly associated with the ability of the examiner to visualize the target structures (OR: 5.27, 95 %-CI: 1.37–20.37, p = 0.016). The association was also significant in the multivariate analysis (OR: 4.91, 95 %-CI: 1.14–20.96, p = 0.031). ▶ **Table 4** shows the results of the risk regression analysis.

Comparison of high-end ultrasound and bedside ultrasound

Supplementary Figure 1 describes the results of PS detection (A–C) and biliary stent detection (D–F) according to the presented algorithm in the pivot tables for the three ultrasound groups. There was no clinically relevant difference regarding sensitivity, specificity, positive predictive value, and negative predictive value between the high-end ultrasound and the bedside ultrasound groups for pancreatic and biliary stent detection. The correlation between both ultrasound groups was statistically significant for PSs (φ = 0,3; p < 0.01) and for biliary stents (φ = 0,9; p < 0.001).

No visualization of the target structures was associated with less accurate stent assessment in the high-end ultrasound group (OR: 8.2, 95 %-CI: 1.7–41, p = 0.01) and the bedside ultrasound group (OR: 268, 95 %-CI: 8.7–8315, p = 0.001). Furthermore, pancreas lipomatosis was beneficial for PS detection only in the high-end ultrasound group (OR: 0.06, 95 %-CI: 0.004–0.88, p = 0.04) and the time from ERCP in the bedside ultrasound group (OR: 0.41, 95 %-CI: 0.19–0.93, p = 0.03). All other baseline variables had no statistically significant effect on the successful detection of a PS in the subgroups (as shown in **Supplementary Table 1a**). In multivariate logistic regression analysis, only the visualization of the target structures remained an independent risk factor in the high-end ultrasound group (OR: 5.27, 95 %-CI: 1.29–21.59, p = 0.021) but not in the bedside ultrasound group (as shown in **Supplementary Table 1b**).

Discussion

The current trial evaluated a new ultrasound-based algorithm for detecting prophylactic PSs before their removal. The algorithm reduced the need for an X-ray examination by 74 %. This was even higher than the reported 71 % of the previously published pilot trial [16]. Accordingly, the algorithm reduces radiation exposure

for the patient and staff. Furthermore, pivotal resources in the endoscopy unit are saved, leading to increased flexibility in the organization of examinations.

To the best of our knowledge, there are no further trials evaluating the accuracy of sonographic detection of PSs besides the feasibility trial performed at our department [16]. The sensitivity in both trials is comparable with the sensitivity of 81 % achieved in the present trial and 85 % in the previous trial, but the positive predictive value of 83 % achieved in the present trial is lower than the 97 % achieved in the previous one [16]. However, our results seem to be consistent with the sensitivity of 67 % to 89 % in trials using transabdominal ultrasound to detect small pancreatic lesions in the head region [18, 19].

The targeted structures were not visualized in 30 % of the procedures. In another prospective trial focusing on chronic pancreatitis, visualization of the entire pancreas was achievable in only 61 % of the patients, with the pancreatic tail being the most difficult part [20]. Better technical features have improved imaging of the pancreas [21]. However, overlying gas represents an insurmountable technical limitation. In addition, artifacts often resembling the stent may have led to false-positive results and unnecessary EGDs. In this trial, EGD for stent removal was performed in 89 % of the patients. However, in 13 % of all patients, no PS was retained, although this was reported by ultrasound. Nevertheless, EGD is a safe procedure according to the literature with a complication rate between 0.1 % and 0.5 % [22]. In the present trial, sedation-related hypotension occurred in one patient and was treated with intravenous fluid without further harm to the patient and without delay to the procedure. No further adverse events were reported during or after endoscopic stent removal. Notably, there were no pancreatitis events associated with stent removal in the present trial or in a previously published feasibility trial [16]. Moffatt et al. [17] reported a 3 % pancreatitis rate associated with prophylactic PS removal. ESGE guidelines, therefore, suggest that stent removal should be performed using side-viewing scopes [9]. However, all stents in this trial and the past feasibility trial were removed by standard gastroscopes with front-view using either forceps or a snare.

In this trial most PSs were removed within the same hospital stay, thus making it convenient for the patients. We found that most stents dislodged within the first four days, and none dislodged after one week.

In the literature, there is still a debate regarding the necessity to remove retained PSs to avoid pancreatitis [11, 13]. In the present trial, no patient returned with delayed pancreatitis, even if the patient disagreed on stent removal and was excluded. Contrary to the recommendation of the ESGE guidelines to remove the PS after five to ten days, leaving PSs in place until the next ERCP could be a safe, cost-reducing, and resource-saving alternative based on the present data and two previous studies [9, 11, 13]. In our study, imaging and EGD could have been reduced by 90 %. A prospective safety study is recommended.

In a subgroup analysis, a high-end ultrasound device group and bedside ultrasound group were compared. Both groups had clinically comparable outcomes and statistically significant correlation. Therefore, ultrasound could be performed in the ward, which is a logistical advantage.

As a secondary endpoint, the detection of bile duct stents was also evaluated. In 96 %, bile duct stents were still in place. The sensitivity and negative predictive value were 100 %, and the positive predictive value was 97 %. The specificity was poor at 33 %, which might be due to the small number of dislodged stents. In a comparable trial with 221 patients, the results showed a sensitivity of 77.3 %, a positive predictive value of 93.4 %, a specificity of 94.6 %, and a negative predictive value of 80.8 % [23]. Imaging of bile duct stents might be more accurate than that of prophylactic PSs because of the larger size and extended length of the stent. Even though there might be difficulties with overlying gas, especially in the hilus area, biliary stents are usually well detectable.

The main limitation of this trial might be the single-center design. A multicenter design is required to evaluate the presented algorithm on a higher scale. Another limitation may be that different sonographic devices and shorter PSs might yield different results. Nevertheless, we used a variety of sonographic devices from different manufacturers in the high-end ultrasound group to minimize this effect.

If centers implement our algorithm, we highly recommend a learning phase in which sonographic results are controlled by X-ray until the accuracy rate is sufficient. Even though transabdominal ultrasound is a simple and inexpensive alternative to X-ray without radiation exposure, there are patients in whom reliable imaging of the pancreatic duct in the head region cannot be achieved even by highly experienced examiners. In these cases, further imaging should be performed.

A strength of the study is the prospective design in a real-world environment. The patient population is representative of almost all gastroenterology units.

In conclusion, a new algorithm primarily based on ultrasound was presented. X-ray was avoided in 74 % of examinations. Both high-end and bedside ultrasound procedures yielded comparable results which implies that sonography can be performed in the ward. However, to avoid false results, only experienced examiners should perform the examination after a learning period. As shown by our data, ultrasound experience in general does not serve as a good predictor of the ability to detect PSs by ultrasound. Instead, an individualized approach seems to be necessary. When in doubt, fluoroscopy should be indicated.

Conflict of Interest

The authors declare that they have no conflict of interest.

Clinical Trial

Registration number (trial ID): NCT04546867 | ClinicalTrials.gov (http://www.clinicaltrials.gov/) | Type of Study: Prospective, interventional Mono-Center Study

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