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Single-use-Duodenoscopes: A Failure Concept in Times of Need

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**Abstract**

**Background:** Singe-use endoscopes have been used for cholangioscopy for over a decade. Two different single-use-duodeno- scope were launched within the recent 3 years. We established a single-use-duodenoscopy system in June 2022 as a failure concept and for treatment of patients harboring multi-resistant organisms at a tertiary care center in Darmstadt, Hessia, Germany. Due to a technical malfunction we relied on the pre-established failure concept over a period of 13 days in 2023.

**Methods:** patients who had received an ERCP by single-use-duodenoscopes between February 22nd and March 6th 2023 due to a malfunction of the hospital endoscope washer disinfector (ETD) system were identified and analyzed. We report on patient characteristics, ASGE grades, indication, interventional success and adverse events of ERCPs.

**Results:** 18 emergency or urgent ERCPs by the use of single-use-duodenoscopes had been performed within 13 days. ASGE grades were 1 (16.6%), 2 (26.6%), 3 (43.8%) and 4 (27.8%), respectively. Success rates for diagnostic and therapeutic inter- ventions were: stent removal 100% (10/10), cannulation and positive cholangiogram 89% (16/18), stone extraction (> 10 mm) by lithotripter basket 100% (7/7), baby-in-mother cholangioscopy (83%; 5/6), electrohydraulic lithotripsy 100% (3/3), bile duct biopsy 100% (2/2). No related adverse events were observed.

**Summary:** Single-use-duodenoscopy seems feasible as a failure concept even in ASGE grade 3 and 4 procedures.

**Keywords:** Duodenoscopes; Cholangioscopy; Endoscope; Electrohydraulic Lithotripsy

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# Introduction

Reusable endoscopes are a standard-of-care in medicine. Modern endoscope washer disinfector (ETD) sys- tems provide a solid processing of endoscopes after diagnos- tic or interventional procedures [1]. In spite of careful desin- fection of duodenoscopes, the contamination rate of repro- cessed duodenoscopes is 15.25% according to a current me- ta-analysis by Larsen S et al [2]. A series of publications re- vealed the risk of transmitting multi-resistant bacteria into the bile duct system resulting in severe and difficult to treat infections [3,4]. The overall mortality linked to ERCP is about 0.3% [5]. Mortality rates linked to contaminated duo- denoscopes are rarely published, therefore underreported and most likely underestimated [3]. The risk of multi-resis- tant infections has led to new recommendations concerning the architecture and processing of duodenoscopes [6]. Therefore, single-use-duodenoscopes are recommended in the case of MRE, MRSA and VRE colonization or infection of the bile duct system. Furthermore, patients with suspect- ed or proven prion disease should be treated with sin- gle-use-endoscopes, as decontamination is difficult, expen- sive and challenging to the endoscopic material [7].

ERCP is an important diagnostic and intervention- al technique, not only in tertiary care centers. Being the on- ly tertiary care center in southern Hessia and the coordinat- ing hospital of the region, we had decided to invest in a fail- ure concept in 2022 in order to secure ERCP in patients har- boring multi-resistant organisms and in the case of techni- cal malfunction of endoscopes, processors or the hospital en- doscope washer disinfector (ETD) system. Due to a longer lasting malfunction of the ETD system between February 22nd and March 6th 2023 we unexpectedly relied on per- forming ERCPs with single-use-duodenoscopes. We retro- spectively identified all patients who had received an ERCP by single-use-duodenoscopes and report on patient charac- teristics, indication, interventional success, ASGE grades and adverse events in order to describe our novel experi- ence of single-use-duodenoscopes as failure concept.

# Methods

### Study Design and Inclusion Criteria

This research was a retrospective, monocentric study involving the tertiary care center Municipal Hospital Darmstadt, Hessia, Germany. We analyzed all consecutive patients who underwent diagnostic or interventional ERCP with the single-use “Ambu aScope Duodeno” duodenos- cope and Ambu aBox Duodeno processor between Fe- bruary 22nd and March 6th 2023 due to a defect of the hos- pital ETD system, specifically a leakage of the ETD water supply line with consecutive germ colonization. The elec- tronic chart review was performed in order to collect cap- tured variables. The study received institutional ethic board approval (nr. 2023-3418-evBO)**.**

### Procedures

According to our standard procedures written in- formed consent was obtained from all patients prior to the procedure. For prophylaxis of post ERCP pancreatitis, pa- tients received 100 mg diclofenac suppository 30 minutes be- fore ERCP. The endoscopic procedures were performed by two senior endoscopists (ERCP lifetime experience > N=2000 procedures). A single-use sterile duodenoscope (Ambu aScope Duodeno, Ambu aBox Duodeno, Ambu A/S, 2750 Ballerup, Denmark) was used for diagnostic and interventional ERCP, respectively. Stent removal was con- ducted by a 15 mm asymmetric polypectomy snare (MTW Endoskopie W. Haag, 46487 Wesel, Germany). Duct intuba- tion and papillotomy were performed with a sphinctero- tome SU (Endoflex GmbH,46562 Voerde, Germany). For in- tubation and guided intervention, a 0.025-inch 260 cm Jag- wire Straight tip high performance guidewire (Boston Scien- tific, Marlborough, MA 01752, USA) was used. Bile duct stones were removed with a 30 mm lithotripter basket (Fuji- film Medwork GmbH, 91315 Hochstadt, Germany). If indi- cated, a single-use cholangioscope (SpyScope DS II, Spy- glass DS Direct visualization system, Boston Scientific, Marl- borough, MA 01752, USA, respectively) was used. Bile duct biopsies were taken with SpyBiteMax forceps (Boston Scien- tific, Marlborough, MA 01752, USA). Electrohydraulic lithotripsy was performed with a biliary electrohydraulic lithotripter probe and the Autolith Touch generator (Bos- ton Scientific, Marlborough, MA 01752, USA, respectively). If indicated, patients received a 50/70 or 90 mm straight PTFE stent preplaced on a introducer system (MTW En- doskopie W. Haag, 46487 Wesel, Germany).

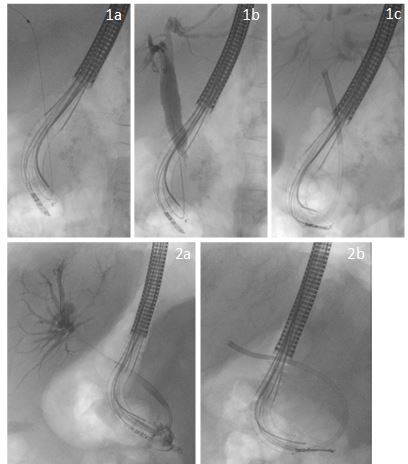
### Definitions and Outcomes

The primary outcome was technical success, defined as successful diagnostic cholangiogram (a) papilloto- my (b), stone removal (c) stenting (d) cholangioscopy. The secondary outcome was the analysis of recorded adverse ef- fects.

# Results

### Baseline Characteristics

Between February 22nd and march 6th 2023 a to- tal of 18 ERCP were performed by use of single-use-duo- denoscopes. Patient age ranged from 37 to 84 years, the aver- age age was 69.3 years. 12 patients (66.6%) were females and 6 patients males. Indications for ERCP were bile duct stones (N=10; pre-verified by oral EUS), suspected extrahepatic cholangiocellular cancer (N=4), suspected DHC leakage (N=1), stenosis of the pancreatic duct (N=1), sclerosis of the papilla (N=1) and sludge of the common bile duct (N=1).



**Figure 1:** 1a-c representing the case of a patient with a distal cholangiocellular carcinoma depicting wire cannulation (a) positive cholangio- gram (b) cholangioscopy (c) 2a-b representing a case of a patient with Klatskin III cancer depicting the positive cholangigramm (2a) and cholangioscopy (2b)

**Clinical Outcomes**

One ERC (double duct sign, 1/18, 5.5%) was diag- nostic, while 17 out 18 (94.5%) had a therapeutic approach. ASGE grades were 1 (16.6%), 2 (26.6%), 3 (43.8%) and 4

(27.8%).

8 patients had already undergone a papillotomy prior to the current ERCP. Cannulation of the papilla Va- terii and the common bile duct was successful in 16 out of 18 cases (89%), papillotomy in 8 of 8 cases (100%) and stone removal by lithotripter basket in 7 of 7 cases (100%).

Stent implantation was successfully performed in 12 of 13

(92.3%) of intended patients. Failure of intubation and stent- ing was due the rigidity of the single-use-duodenoscope tip according to the endoscopist, respectively.

6 patients had been scheduled for single-use cholangioscopy due to cholangiocellular carcinoma (N=2) or complex bile duct stones (N=4). Cholangioscopy was suc- cessfully performed in 5 out of those 6 patients. In 3 pa- tients with choledocholithiasis, complex bile ducts stones were resolved by electrohydraulic lithotripsy prior to stent implantation. In one patient with a complex bile duct stones

cholangioscope intubation of the common bile duct failed due to the rigidity of the endoscope tip according to the en- doscopist. In two patients with a suspected extrahepatic cholangiocellular carcinoma intracanalicular biopsies were gathered by cholangioscopic biopsy, prior to successful stenting of the common bile duct bridging the tumor mass.

## Adverse Events

No procedure derived adverse events were docu-

mented.

**Table 1:** Baseline characteristics of patients undergoing single-use-duodenoscopy

|  |  |
| --- | --- |
| **Baseline characteristics** |  |
| Number of patients | 18 |
| Gender (male / female) | 6 (33.3%) / 12 (66.6%) |
| Indication |  |
| Choledocholithiasis | 11 (61%) |
| Extrahepatic CCC | 4 (22%) |
| Leakage of DHC | 1 (6%) |
| Benign stenosis of pancreatic duct | 1 (6%) |
| Benign stenosis of papilla Vaterii | 1 (6%) |
| ASGE classification of ERCP |  |
| 1 | 3 (16.6%) |
| 2 | 3 (16.6%) |
| 3 | 7 (43.8%) |
| 4 | 5 (27.8%) |

**Table 2:** Procedure characteristics of patients undergoing single-use-duodenoscopy

|  |  |
| --- | --- |
| **Procedure characteristics (N=)** | **18** |
| **Cannulation of DHC /cholangiogram (N=18)** |  |
| Cannulation and cholangiogram | 16 |
| Failed cannulation | 2 |
| **Papillotomy (N=8)** |  |
| Papillotomy | 8 |
| Previous papillotomy | 8 |
| Failed papillotomy | 0 |
| Papillotomy not indicated | 2 |

|  |  |
| --- | --- |
| **Stent extraction (N=10)** |  |
| Snare extraction | 10 |
| No stent in situ | 8 |
| Failed stent extraction | 0 |
| **Stone extraction (N=11)** |  |
| Lithotryptor basket | 7 (incl. 3 cases of parallel EHL) |
| Balloon catheter | 4 |
| Failed stone extraction | 0 |
| **Stent implantation (N=11)** |  |
| Common bile duct | 11 |
| Parallel pancreatic duct | 1 |
| No indication | 3 |
| Failed stent implantation | 2 |
| No indication | 2 |
| **Single-use cholangioscopy (N=6)** |  |
| Proximal cholangioscopy | 5 |
| + Biopsy of bile duct tissue | 2 |
| + Electrohydraulic lithotripsy | 3 |
| Failed cholangioscopy | 1 |

# Discussion

This monocentric, retrospective study demonstrat- ed the effective and safe use of a novel single-use-duodenos- cope for ERCP.

Reusable endoscopes are used in endoscopy units worldwide. Although decontamination and processing after their use is standardized, the specific architecture of duo- denoscopes bears the risk of transmitting germs from one patient to another [3,4]. As the bile duct system is sterile, contamination implicates the risk of biliary infections, such as cholangitis or sepsis, which can be particularly difficult to treat and dangerous in the case of multi-resistant organisms or prion disease. Therefore, the use of single-use-duodenos- copes can be economically and ecologically justified in these specific situations.

The municipal hospital of Darmstadt (Klinikum Darmstadt GmbH, Darmstadt, Germany) is the only ter- tiary care center of southern Hessia, caring for a population

of 1.5 million citizens. In summer 2022 we had established a failure concept for ERCP by introducing the Ambu aScope Duodeno single-use endoscope and the respective Ambu aBox Duodeno processor allowing us to bridge malfunction of the endoscope washer disinfector or to treat patients har- boring the risk of transmitting multi-resistant organisms. European market access of the Ambu aBox and aScope Duo- deno was October 2021 and the system had already been pretested by our institution in December 2021.

Due to a malfunction of the hospital endoscope washer disinfector (ETD) system we were dependent on sin- gle-use-endoscopes over a period of 13 days. During this pe- riod, we performed 18 ERCPs by use of single-use-duodeno- scopes.

The success rates were as follows: stent removal (10/10; 100%), bile duct cannulation and positive cholangio- gramm (16/18; 89%), papillotomy (8/8; 100%), stone remo- val via lithotripter basket (7/7; 100%) and stenting (12/13; 92.3%). Our overall completion rate was 89% and was thus

in line with data generated by two trials [8,9] applicating the Ambu aScope Duodeno (84% and 98%, respectively). In ad- dition our overall completion rate was matching the data generated in 3 prospective trials performed with the sin- gle-use-duodenoscope Exalt Model D (96.7%, 88.5% and 95%, respectively) (Boston Scientific Corporation, Marlbor- ough, MA, USA) [10-13]. Noteworthy, the amount of ASGE grade 3 and 4 ERCPs was high among our patients as com- pared to above cited studies due to nature of indication.

Bang J et al. reported on a similar product (Exalt Model D, Boston Scientific Corporation, Marlborough, MA, USA) used in a prospective, randomized trial compar- ing single-use versus reusable duodenoscopes in ERCP. 98 patients with low-complexity procedures underwent ERCP within this trial 10). The median number of attempts for successful cannulation was surprisingly significantly lower for the single-use cohort, however the ease of passage in to the stomach, image quality and image stability were signifi- cantly worse in the single-use cohort. No significant differ- ence for cannulation success was found between single-use and reusable endoscopes (95.8% vs. 100%), also being in line with our own experience with the Ambu aScope Duode- no in patients with a complex ERCP (89%; >70% ASGE 3 and 4).

Napoleon B et al. reported on a single-use-duo- denoscope tested in a prospective multi-center trial in France. 64 patients underwent ERCP (58.3% ASGE 2, 35% ASGE 3); 95% of procedures were completed using the sin- gle-use-duodenoscope [14]. In another single-center trial with a higher complexity (ASGE 3 and 4 in 51.9%) proce- dures completion using the Exalt Model D was only 90.4% (13). Adverse events occurred in 0-5% of trials, paralleling our own data [13,14].

In addition, we performed a smaller series of sin- gle-use mother-in-baby cholangioscopies with adequate technical success rates (5/6; 83%). The parallel use of both single use endoscopes (duodenoscope and cholangioscope) resulted in successful electrohydraulic lithotripsy and intra- canalicular biopsies, respectively. Therefore, it also seems feasible in selected patients. Only one international, multi- center, retrospective trial did analyze the combination of both single-use endoscope in a total of 66 patients, so far, re-

porting a technical success rate of 98.5% and a high user sat- isfaction score somewhat paralleling our experience [15].

Noteworthy, the endoscopic procedures were per- formed by senior endoscopists, with an ERCP lifetime expe- rience ≥ 2000 procedures. Therefore, the reported success rates could be distorting not matching the reality in other, smaller endoscopy units. The unusual haptic feel, as well as the light weight of 700g and the specific procedural percep- tion of the Ambu aScope Duodeno endoscope can initially be irritating and bothersome, potentially impacting on suc- cess rates. This personal experience is line with data pub- lished by the manufacturer himself, demonstrating a signifi- cant correlation of product usage and satisfaction indicating a learning curve when the endoscopy setup is being changed from reusable to single-use [16]. Increasing the weight of the Ambu aScope Duodeno endoscope mimick- ing the weight of a reusable duodenoscope might increase the endoscopist comfort.

A prospective, comparative study of the most pre- valent reusable- and single-use-duodenoscopes concerning technical success parameters would be feasible and desir- able.

In summary, we were able to demonstrate, that sin- gle-use-duodenoscopes may function as a failure concept for larger endoscopy units. However, due to economic (mar- ket price: 850 € per aScope Duodeno) and ecological rea- sons, the use of single-use endoscopes should be limited to selected emergency patients within a failure concept or pa- tients harboring a risk of transmitting multi-resistant or- ganisms.

# Conclusion

Single-use-duodenoscopes demonstrate solid tech- nical and clinical success rates. They help reducing the risk of biliary infections, which can be particularly difficult to treat and dangerous in the case of multi-resistant organisms or prion disease. In addition, they represent a solid failure concept.

# Declaration of Interest Statement

None

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