

# Balloon Dilation-assisted Extraction of Embedded Self-Expandable Metal Stents

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## Abstract

**Background and study aims:** Embedded transpapillary self-expandable metal stents (SEMS) may require extraction over time and standard approaches often fail. In the current study we describe a newly developed approach to refractory embedded SEMS, using balloon dilation-assisted extraction. Our aim was to evaluate the feasibility and outcomes of this novel technique.

**Patients and methods:** This is an exploratory single-center retrospective analysis of all consecutive patients undergoing endoscopic balloon-assisted stent extraction. Baseline, procedural and follow-up data were collected and analyzed.

**Results:** Twelve patients with embedded transpapillary SEMS were identified (60.0% female, mean age 70.1 [SD±18.1] years, uncovered SEMS 33.3%) with median dwell time of 457.5 (IQR 175.8-1042) days. Previous extraction attempts were undertaken in the majority of cases (83.3%), including SEMS-in-SEMS placement (41.7%). Using the balloon-assisted stent extraction technique, successful SEMS extraction was achieved in 10 out of 12 cases (83.3%). Adverse events occurred in 3 patients (Grade II [n=2, 16.7%] - Grade III [n=1, 8.3%]). After a median follow-up time of 171 (58-260) days, 1 biliary recurrence occurred for which endoscopic re-evaluation was performed.

**Conclusions:** Our data suggest that endoscopic balloon-assisted stent extraction should be considered for extraction of embedded self-expandable metal stents, as it showed high efficacy without any major procedure-related adverse events, using readily available endoscopic tools. (*Acta gastroenterol belg.*, 2025, 88, 103-108).

**Keywords:** SEMS, uncovered self-expandable metal stents, fc-SEMS, ingrowth, impacted stents.

## Abbreviations:

AE: adverse event  
 BASE: balloon dilation-assisted SEMS extraction  
 ERCP: endoscopic retrograde cholangio-pancreatography  
 SEMS: self-expandable metal stent  
 FC-SEMS: fully-covered self-expandable metal stent  
 UC-SEMS: uncovered self-expandable metal stent

## Introduction

In 1969, the first canine case of self-expandable metal stent (SEMS) placement was published by Charles T. Dotter (1). Then termed ‘transluminally-placed coilspring tube grafts’, this SEMS avant la lettre seem to provide significant advantages when compared to catheter-based dilation of atheromatous vascular strictures. Also in biliary diseases balloon dilation did not provide long lasting effects, fueling the development of plastic stents and adoption of the first biliary uncovered SEMS (UC-SEMS) in the late eighties (2). In the decades to follow, stent design, insertion techniques and indications were refined, leading up to metal stents being

preferred for preoperative and palliative drainage of extrahepatic strictures, as well as palliative treatment of malignant hilar strictures (3). For benign extrahepatic biliary strictures, both multiple plastic stents and fully-covered SEMS (FC-SEMS) can be considered, although the latter led to a reduced need for endoscopic revisions in the context of chronic pancreatitis-related strictures (4).

For all these individual indications, it is crucial to consider SEMS type. Covered SEMS have been shown to carry a potentially longer duration of patency, at the cost of higher migration risk when compared to their uncovered counterparts, yet are easier to remove over time (3, 5, 6). On the other hand, UC-SEMS may carry a lower risk of migration but are contraindicated in patients with benign or indeterminate strictures, as long-term patency is poor and UC-SEMS removal is only possible in a minority of cases (3, 7). These embedded SEMS, either FC-SEMS with extensive dwell-time or UC-SEMS, frequently become a source of recurrent biliary obstruction and are notoriously difficult to remove (7, 8). Various techniques have been described to remove these embedded SEMS, such as the ‘covered-stent-in-uncovered-stent’ (8) or more recently termed ‘SEMS-in-SEMS’ technique (9). It has been suggested that FC-SEMS placement inside the previously placed stent leads to pressure necrosis of intraluminal tissue hyperplasia, facilitating SEMS removal after several weeks. It is however our experience that if SEMS dwell time exceeds 1 year, also SEMS-in-SEMS placement will often prove unsuccessful. Recently, a lithotripter-based extraction technique was described (10), describing effective stent removal in a case with short-term UC-SEMS placement. For this particular technique, transpapillary SEMS extension seems a prerequisite and larger series are lacking.

Considering these available approaches, it seems that there is a clear need for a technique that can be performed in a single session without labor-intensive

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tools or even when proximal SEMS migration has occurred.

In the current study we describe a newly developed technique, using endoscopic balloon dilation to extract refractory embedded SEMS where standard extraction techniques have failed. Our aim was to evaluate the feasibility and outcomes of this novel approach.

## Materials and Methods

This is a tertiary single-center retrospective analysis of all consecutive patients that underwent balloon-assisted SEMS extraction (BASE) from November 2020 to February 2023. Patients with embedded biliary SEMS were included if standard extraction methods using snares, forceps or SEMS-in-SEMS placement had failed. Exclusion criteria were: 1) follow-up <30 days and 2) embedded SEMS following endoscopic ultrasound-guided hepaticogastrostomy. Variables were extracted from patients' electronic medical charts, including age, gender, underlying disease, indications and previous procedural information, SEMS type and size, dwell-time, procedural time, technical and clinical outcomes, hospital stay and post-procedural survival. Each patient gave his or her written consent with regards to the individual procedures. Institutional Review Board-approval was attained at the University Hospitals Leuven (study identifier: s67820).

### Endpoints

Primary endpoint was technical success, defined as successful SEMS extraction using the balloon dilation-assisted SEMS extraction (BASE)-technique only (as described below). Key secondary outcomes were adverse events (AE), recurrent biliary obstruction and reintervention rates. Regarding safety, the AGREE classification for adverse events was used to stratify AE into five grades (I to V) (11). Previous attempts at SEMS extraction were also defined and recorded, as well as type and sizes of stents placed following successful BASE. Recurrent biliary obstruction was defined as reoccurrence of biliary obstruction over time, as evidenced by increased cholestatic parameters (2x upper limit of normal) and/or occurrence of cholangitis, with or without reintervention. Reinterventions were also recorded and were subdivided in endoscopic, surgical or percutaneous reinterventions. Hospital stay was calculated from the procedural date onwards to discharge.

### *Procedure: balloon-assisted SEMS extraction (BASE)-technique*

All procedures were performed under general anesthesia and a prophylactic broad-spectrum antibiotic was administered. Before bile duct cannulation all previously placed plastic or metal stent-in-stents were

removed. A diagnostic catheter was used to insert a 0.025-inch hydrophilic guidewire (VisiGlide, Olympus Corporation, Tokyo, Japan), through the stent lumen, into one of the intrahepatic bile ducts (Figure 1 – Upper left). Then, a 12-13.5-15mm dilation balloon was inserted (CRETM, Boston Scientific, Marlborough, Massachusetts, USA) and inflated to maximum (15mm) diameter (Figure 1 – Upper right). Care was taken not to insert the full length of the dilation balloon into the common bile duct, but to keep approximately 1/3 length exteriorized. After full insufflation had been achieved, the balloon catheter was fixed manually onto the scope and both were evacuated transorally with continuous firm traction and continuous fluoroscopic guidance. If placed correctly, the balloon was extracted simultaneously together with the embedded SEMS. Following SEMS extraction, the bile duct was cannulated once more and contrast was injected to check for complications. If required, an occlusion cholangiogram was performed to check for leaks or residual strictures. In case of uncertainty of complications or when edema/bleeding was expected, temporary protective stenting was considered and short-term elective stent extraction was planned. All procedures were performed or supervised by endoscopists with extensive experience in ERCP and therapeutic endoscopy.

### *Statistical analysis*

Descriptive statistics were used to describe the patient population and outcomes. Continuous variables were reported as medians and interquartile range (IQR) or means  $\pm$  standard deviation (SD), whereas categorical variables were reported as frequencies (%). To determine normal distribution of continuous variables, the Shapiro Wilk test was used. Microsoft Excel (2021, Redmond, Washington, USA) was used for the statistical analysis.

## Results

Twelve patients undergoing BASE were identified (60.0% female, mean age 70.1 [SD $\pm$ 18.1] years) with benign underlying disease in the majority of patients (n=8, 66.7%). Ampullary cancer and metastatic colorectal cancer, neuroendocrine tumor and breast cancer were seen in 1 patient each (8.3%). Previously placed SEMS consisted of FC-SEMS and UC-SEMS in 8 (66.7%) and 4 patients (33.3%) respectively with varying SEMS sizes (Table 1). Median SEMS dwell time was 457.5 (IQR 175.8-1042) days.

Previous procedures aimed specifically at SEMS extraction had been undertaken in 10 out of 12 cases (83.3%), with a median number of 1.8 attempts at removal (IQR 0.8-2.5). Techniques applied during previous extraction attempts included forceps traction (n=6, 50%), SEMS-in-SEMS placement (n=5, 41.7%), Fogarty balloon extraction (n=4, 33.3%), snare extraction (n=2, 16.7%) and simple balloon dilation (n=2, 16.7%).

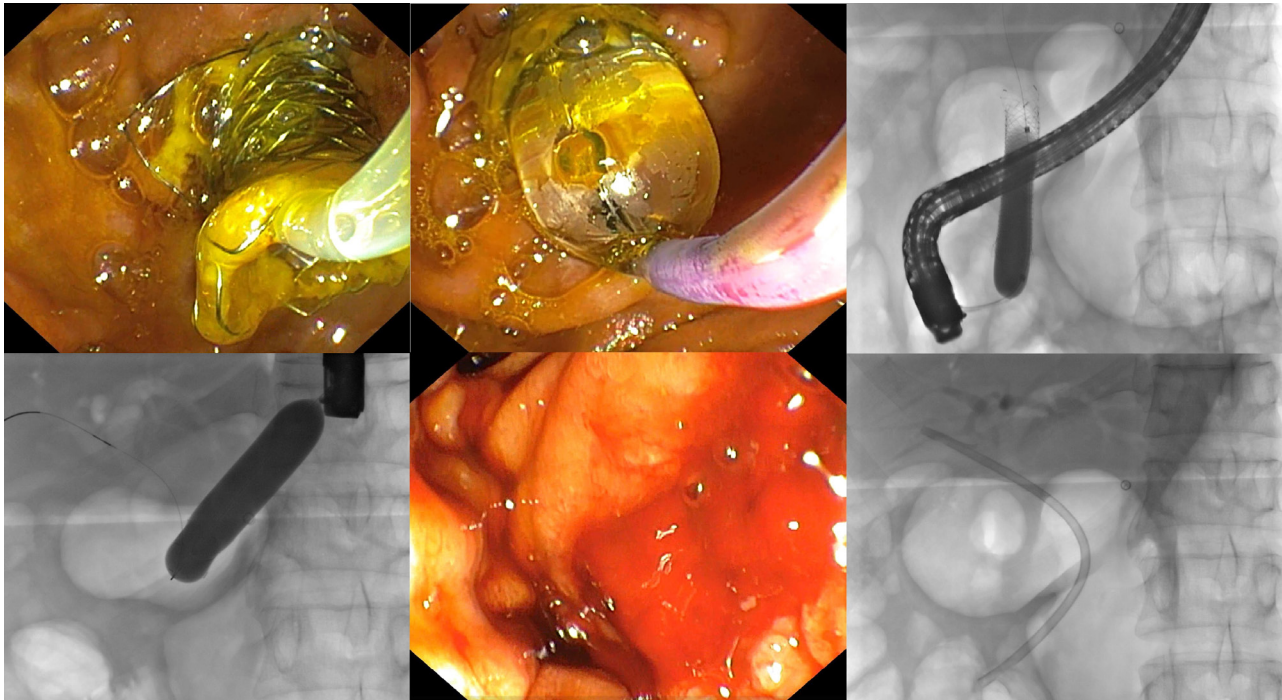


Figure 1. — Balloon dilation-assisted SEMS extraction (BASE).

Upper – left: Endoscopic view following unsuccessful extraction using SEMS-in-SEMS placement. The both stents are cannulated with a diagnostic catheter and a 0.025-inch guidewire is inserted into the bile duct.

Upper – middle: Through-the-scope balloon dilation is performed up to 15mm, depending on bile duct size.

Upper – right: Fluoroscopic image, showing balloon-dilation of both SEMS with approximately 1/3 of the balloon length exteriorized in the duodenum.

Lower – left: After manually fixing the balloon catheter to the scope, continuous firm traction is applied under fluoroscopic control until SEMS evacuation has been confirmed.

Lower – middle: Endoscopic view following balloon dilation-assisted SEMS extraction, mild self-limiting bleeding is noted.

Lower – right: Following a confirmatory balloon sweep, a mild residual stenosis mid-CBD was identified, for which plastic stenting was performed.

Table 1. — Baseline characteristics.

Variable	Total n=12	
Age (years), mean $\pm$ SD	70.1	$\pm$ 18.1
Female, n (%)	7	60.0%
Primary disease		
Benign disease	8	66.7%
Ampullary cancer	1	8.3%
Neuroendocrine tumour	1	8.3%
Colorectal cancer	1	8.3%
Breast cancer	1	8.3%
Baseline SEMS characteristics		
Covered	8	66.7%
Uncovered	4	33.3%
60x10mm	6	50.0%
80x10mm	4	33.3%
Other size	2	16.7%
Median dwell time, days (IQR)	457.5	(175.8-1042)
Previous procedures		
Previous extraction procedures, n (%)	10	83.3%
Median number of attempts, n (IQR)	1.8	(0.8-2.5)
Forceps traction, n (%)	6	50.0%
SEMS-in-SEMS, n (%)	5	41.7%
Fogarty balloon extraction, n (%)	4	33.3%
Snare, n (%)	2	16.7%
TTS Balloon, n (%)	2	16.7%

SD; standard deviation, SEMS: self-expandable metal stent, TTS: through-the-scope.

## Outcomes

Technical success was achieved in 10 out of 12 procedures (83.3%) (Table 2). In both patients experienced technical failure, also SEMS-in-SEMS placement and Spyglass were attempted, the latter to facilitate guidewire placement for lithotripter-based removal. In the first patient, antegrade stenting was performed using a percutaneous approach, whereas in the second patient, palliative stenting was chosen with a FC-SEMS through stent-in-stent placement, mainly due to advanced age (91 years old). In the majority of patients 15mm balloon dilation was used (n=8, 66.7%), whereas smaller or larger sizes were used in the remaining cases, based on bile duct diameter. In half of patients with successful SEMS extraction, stent(s) were exchanged (n=5, 41.7%). Median procedure duration was 39 (IQR 24.3-49.3) minutes.

## Safety

Procedure-related adverse events occurred in 2 patients (16.7%), both consisting of postprocedural cholangitis within 24h following the procedure. In both cases, antibiotics were administered intravenously and no endoscopic reintervention were required. In the first case, fever occurred on day 1 post-procedure with cultures showing presence of Enterococci (Grade I). In the second case, E.coli sepsis occurred which was

successfully treated with several days of IV antibiotics (Grade II). No higher grade adverse events occurred.

## Follow-up

After a median follow-up of 171 (IQR 58-260) days, one biliary recurrence occurred (8.3%) after 27 days. This patient remained jaundiced despite SEMS extraction and showed no further endoscopic signs of ongoing biliary obstruction. Jaundice resolved spontaneously after several weeks, suggesting a cellular etiology. Median hospital stay following BASE was 1 (IQR 0-4) day(s).

## Discussion

Embedded SEMS often lead to recurrent biliary symptoms, requiring multiple reinterventions and frequently complicate future procedures if these stents cannot be extracted safely. Inherently, this influences quality of life, might compromise liver function and/or oncological therapy, increasing the risk of morbidity and mortality for the individual patient. Whereas some studies have suggested SEMS-in-SEMS or device assisted techniques(10, 12), these techniques often fail in patients with FC-SEMS with extended dwell-time or following UC-SEMS placement. In the current study we evaluated the results of balloon dilation-assisted SEMS extraction or 'BASE', showing that this technique facilitated effective stent extraction in nearly

Table 2. — **Outcomes.**

Variable	Total n=12	
<b>Efficacy</b>		
Technical success, n (%)	10	83.3%
Balloon diameter used		
15mm	8	66.7%
18mm	2	16.7%
13.5mm	1	8.3%
12mm	1	8.3%
Restenting following technical success, n (%)	5	41.7%
Median procedure duration, min (IQR)	39	(24.3-49.3)
<b>Safety</b>		
Overall adverse events, n (%)	2	16.7%
Grade I, n(%)	1	8.3%
Grade II, n(%)	1	8.3%
Grade III, n(%)	0	0.0%
Grade IV, n(%)	0	0.0%
Grade V, n(%)	0	0.0%
<b>Follow-up</b>		
Biliary recurrence, n (%)	1	8.3%
Median time to dysfunction, days (IQR)	27	N/A
Unplanned reintervention, n (%)	1	8.3%
Median hospital stay, days (IQR)	1	(0-4)
Median follow up duration, days (IQR)	171	(58.0-260)
QR: interquartile range, N/A: not applicable.		

all patients with embedded SEMS, without any major procedure-related adverse events.

Uncovered biliary SEMS only need a short time interval to become embedded, with extraction becoming increasingly challenging as time goes by. Extraction rates have been reported to vary between 0 and 38%(8). FC-SEMS on the other hand, can be left in place for extended periods of time, although risk of embedment increases after prolonged dwell-time with subsequent degradation of the SEMS lining. In our cohort, one third of patients presented with embedded UC-SEMS after an overall median dwell time of 457.5 (IQR 175-1042) days, remarkably longer than other cohorts out there (9, 10, 13). Majority of these SEMS were placed in cases where the underlying disease eventually was considered to be benign. In these patients SEMS extraction may prove crucial with regards to the reduction of long-term complication risk and quality of life. Previous procedures aimed at SEMS extraction were undertaken in 83.3% of patients, which included forceps traction as well as SEMS-in-SEMS placement amongst other techniques. The effectiveness of SEMS-in-SEMS placement has only been reported in small case series and larger studies have been lacking. In our experience this approach may often fail, especially in patients with UC-SEMS placement or extended dwell-time, as also illustrated by the fact that this particular technique was employed at previous extraction attempt in 41.7% of cases.

Other approaches have been published, such as lithotripter-assisted SEMS extraction (12). However with this technique, the SEMS' meshes should be accessible to allow for guidewire fixation. In cases where proximal SEMS migration has occurred, this technique might be less useful as it may become very challenging to insert a guidewire through the meshes of these intraductal stents. Our technique on the other hand can be applied regardless of migration status, although we also encountered technical failure in a case where proximal SEMS migration had occurred and lithotripter-assisted extraction had also failed. Two patients in our cohort had already undergone attempts at extraction with a through-the-scope dilation balloon elsewhere. However, after revision of these preceding procedures, dilation had only be performed to a maximum size of 12mm. This underlines the importance of adequate dilation, which ideally should be up to 15mm diameter depending on the patient's bile duct diameter.

#### *Limitations and strengths*

Although the current study may provide a novel and effective approach to embedded SEMS, it also carries several disadvantages. First, no comparator group was included. Secondly, the retrospective single-center design increases the potential for bias and confounding. And last, these procedures were performed in a

high-volume setting, suggesting reproducibility in lower-volume setting may not be guaranteed. Due to these limitations our findings should be regarded as exploratory. However, given the challenging situations in which this technique was used successfully, we believe this approach may still form an important addition to the endoscopic armamentarium.

In conclusion, our data suggest that BASE can be considered for extraction of embedded self-expandable metal stents, as it showed high efficacy without any major adverse events, using readily available tools.

#### **Declarations**

*Conflict of interest:* Michiel Bronswijk received study grants from Boston Scientific and holds consultancy agreements with Dekra and Prion Medical-Taewoong. Ann Reekmans declares no competing interests. Schalk van der Merwe holds the Cook chair in Interventional endoscopy, has consultancy agreements with Cook, Pentax and Olympus and co-chairs the Boston-Scientific Chair in Therapeutic Biliopancreatic Endoscopy.

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*Author statement:* MB performed the statistical analysis, performed procedures and drafted the initial versions of the manuscript. AR was responsible for data collection and critical revision the manuscript, as well as performing the procedures. SVDM performed the procedures, developed the technique, was involved in the study design, provided critical mechanical insights and revised the final version of the manuscript.

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