

# Managing Occluded Uncovered Self-expanding Metal Stents in Patients with Malignant Hilar Biliary Obstruction: A Retrospective Cohort Study

Jakub Pietrzak, Adam Przybyłkowski

Department of  
Gastroenterology and Internal  
Medicine, Medical University  
of Warsaw, Warsaw, Poland

*Address for correspondence:*  
**Adam Przybyłkowski**  
Medical University of  
Warsaw, Department of  
Gastroenterology and Internal  
Medicine, Banacha 1A  
Warsaw,  
Mazowieckie, Poland  
[aprzybylkowski@wum.edu.pl](mailto:aprzybylkowski@wum.edu.pl)

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## ABSTRACT

**Background & Aims:** The implantation of uncovered self-expanding metal stents (UCSEMS) is an established method for the palliative treatment of malignant hilar biliary obstruction (MHBO). However, with advances in chemotherapy extending patient survival, individuals treated primarily with UCSEMS increasingly encounter overgrowth of the tumour in the stent lumen and occlusion. In this study, we aimed to compare various methods of managing occluded UCSEMS.

**Methods:** We analyzed a cohort of 49 patients with malignant hilar biliary obstruction who were treated with UCSEMS implantation as first-line endoscopic treatment. We evaluated their follow-up data, recorded complications, and assessed the methods used to manage occluded stents: balloon cleaning, plastic stent in stent implantation, UCSEMS stent in stent implantation, fully covered self-expandable metal stent (FCSEMS) stent in stent implantation and radiofrequency ablation (RFA).

**Results:** Technical and clinical success rates of the reinterventions were 91.2% and 61.4%, respectively. Depending on the type of revisionary drainage method used, clinical success rates were as follows: 50% for balloon cleaning only, 66% for plastic stent placement, 68% for FCSEMS stent placement, 80% for RFA with simultaneous plastic stent placement, and 80% for UCSEMS stent placement ( $p=0.366$ ). The mean time to the second reintervention (second ERCP after UCSEMS placement) was 238, 201, 264, 78, and 205 days, respectively ( $p=0.4999$ ). The mean interval time for all reinterventions was 48, 75, 71, 66, and 95 days, respectively ( $p=0.0326$ ).

**Conclusions:** All techniques demonstrated high technical feasibility. While UCSEMS re-stenting and RFA with plastic stents showed promising trends in clinical success and stent patency, definitive conclusions about superiority cannot be drawn. Further multicentre prospective studies are needed to validate these findings.

**Key words:** biliary obstruction – malignant hilar biliary obstruction – stent – biliary stenting – self-expanding metal stents – SEMs – occluded uncovered SEMs.

**Abbreviations:** ERCP: endoscopic retrograde colangiopancreatography; FCSEMS: fully covered self-expandable metal stent; MHBO: malignant hilar biliary obstruction; PTBD: percutaneous transhepatic biliary drainage; RBO: recurrent biliary obstruction; RFA: radiofrequency ablations; UCSEMS: uncovered self-expandable metal stents.

## INTRODUCTION

Numerous studies have confirmed the superiority of metal stents over plastic stents in the biliary stenting of patients with malignant hilar biliary obstruction (MHBO) [1-3]. Uncovered self-expandable metal stents (UCSEMS) demonstrate longer patency, extended over survival, and a

higher rate of cholangitis compared to plastic stents. Despite the superior outcomes, controversies remain, primarily due to the permanence of UCSEMS implantation. This is associated with challenges in determining the appropriate management strategy during subsequent endoscopic retrograde colangiopancreatography (ERCP) procedures, whether due to cholangitis or recurrent jaundice caused by the overgrowth and ingrowth of the tumour in the implanted stents. Moreover, with advancements in chemotherapy [4] and local treatment modalities such as radiofrequency ablation (RFA) [5] and radiotherapy [6], patients with UCSEMS often require an increasing number of reinterventions. However,

there is still a limited body of research comparing the patency duration (time to subsequent ERCP) of UCSEMS following different reintervention techniques. Current guidelines from the American Society for Gastrointestinal Endoscopy (ASGE) [7], the European Society of Gastrointestinal Endoscopy (ESGE) [8] and Asia-Pacific consensus [9] recommend the implantation of UCSEMS in cases of malignant biliary obstruction. However, there are no established guidelines on the optimal method for managing occluded UCSEMS. To address this gap, we compared various methods of managing obstructed stents in terms of technical success, clinical success, and time to recurrent biliary obstruction (RBO).

## METHODS

We carried out a retrospective analysis of 49 patients who underwent biliary stenting with uncovered self-expandable metal stents (UCSEMS) between 2016 and 2024 at the Endoscopy Unit of the Central Clinical Hospital of the Medical University of Warsaw, Poland. Stent occlusion was defined as the recurrence of jaundice confirmed by elevated bilirubin or gamma-glutamyl transpeptidase and alkaline phosphatase levels, along with imaging evidence (ultrasound or computed tomography) of intrahepatic bile duct dilatation or cholangitis diagnosed in accordance with the Tokyo Guidelines 2018 [10]. Clinical success was defined as a decrease in bilirubin levels below 2.5 mg/dL or a reduction of more than 50% compared to the most recent pre-procedure value. Technical success was defined as the successful cannulation of the bile ducts. Recurrent biliary obstruction was defined as the time between consecutive ERCP procedures. The study included only patients treated with endoscopic interventions, excluding those requiring percutaneous transhepatic biliary drainage (PTBD). We also included patients who required only bile duct balloon cleaning to remove biliary sludge or stones. In cases where cholangiography confirmed stent overgrowth, additional interventions such as repeat stenting or radiofrequency ablation (RFA) followed by plastic stent placement were performed.

All ERCP procedures were performed under intravenous sedation and endotracheal intubation. The endoscopists performing the procedures were highly experienced, having conducted more than 3,000 ERCPs and performing over 300 ERCPs annually. To prevent post-ERCP pancreatitis, 100 mg of rectal diclofenac was administered prior to the procedure. Duodenoscopes used for ERCP were from Olympus Medical Systems Corp., Tokyo, Japan. The stents used included plastic stents (7–10 Fr in diameter and 10–15 cm in length, primarily straight Boston Scientific), UCSEMS (6–10 mm in diameter and 8–12 cm in length; TaeWoong, Zilver 635, Evo, LCD, MicroTech), and fully covered self extended metal stents (FCSEMS) (6–10 mm in diameter and 8–12 cm in length; Hanarostent, WallFlex).

Given the retrospective design and single-centre setting, our analysis is inherently limited in its generalizability. Furthermore, the small sample sizes in certain intervention subgroups limit the power to detect statistically significant differences. As such, the findings should be viewed as hypothesis-generating and interpreted cautiously.

All statistical analyses were performed using the StatSoft Inc. (2014) STATISTICA software (version 12.0; www.statsoft.com) and Microsoft Excel. Quantitative variables were described using the arithmetic mean, standard deviation, median, minimum and maximum values (range). Qualitative variables were presented as frequencies and percentages. The normality of the distribution of quantitative variables was assessed using the Shapiro-Wilk test, while the homogeneity of variances was evaluated with Levene's or Brown-Forsythe's test. Differences between two independent groups were tested using Student's t-test (or Welch's test in the case of unequal variances) or the Mann-Whitney U test (when conditions for the t-test were not met or for ordinal variables). Differences among more than two groups were analyzed using ANOVA (F-test) or the Kruskal-Wallis test (when ANOVA assumptions were not met). Post hoc analyses were conducted with Tukey's test (following ANOVA) or Dunn's test (following Kruskal-Wallis). For paired data, differences between two groups were assessed using Student's t-test or Wilcoxon's signed-rank test (when conditions for the t-test were not met or for ordinal variables). Differences among more than two paired groups were evaluated using repeated-measures ANOVA or Friedman's test (when assumptions for repeated-measures ANOVA were not met or for ordinal variables). The Chi-square test of independence was used for qualitative variables, with Yates' correction applied for expected cell counts below 10, Cochran's conditions checked, or Fisher's exact test when appropriate. Correlations between variables, including their strength and direction, were analyzed using Pearson's and/or Spearman's correlation coefficients. A significance level of  $p < 0.05$  was considered statistically significant for all analyses.

## RESULTS

The baseline characteristic of patients are detailed in Table I. The management of occluded UCSEMS and the efficacy of different type of procedures are depicted in Table II.

**Table I.** Baseline characteristics of patients treated with uncovered self extended metal stents (n=49)

Age, median (range), y	
mean (SD), range	64.1 (10)
range	26 - 87
Gender, n (%)	
men	20 (40.8)
women	29 (59.2)
Etiology, n (%)	
Colangiocarcinoma	33 (67.3)
Gall bladder cancer	11 (22.4)
Malignant lymph nodes due to colorectal cancer	5 (10.2)
Bismuth classification, n (%)	
III	5 (10.2)
IV	44 (89.8)
Mean time to progression to the next stage, days (SD)	224.8 (113.8)
Method of obtaining a histopathological result, n (%)	
ERCP	27 (55.1)

**Table I** (continued)

Surgery	15 (30.6)
CT-guided biopsy	5 (10.2)
PTBD	1 (2.0)
Ultrasound-guided biopsy	1 (2.0)
The average number of ERCP procedures following UCSEMS implantation (SD)	3.1 (3.7)
Median time to occlusion of initial UCSEMS, days (SD)	169.8 (160.0)
Overgrowth of initial UCSEMS, n (%).	31 (63.6)
Initial UCSEMS placement	
Side-by-side	38
Stent-in-stent	11

CT: computed tomography; ERCP: endoscopic retrograde colangiopancreatography; PTBD: percutaneous transhepatic biliary drainage; UCSEMS: uncovered self-expandable metal stents; SD: standard deviation; y: year.

The overall clinical success rate for all procedures was 61.4% (70/114). Depending on the method of stent management, it was demonstrated that technique with balloon cleaning alone had the lowest clinical success rate, reaching only 50%. Slightly better results were observed with plastic stents and FCSEMS, achieving success rates of 66% and 68.75%, respectively. Among the evaluated reintervention methods, RFA followed by plastic stent implantation and UCSEMS re-stenting were associated with numerically higher clinical success rates (80%). However, while a statistically significant difference was observed across groups ( $p=0.0366$ ), the limited subgroup sizes preclude firm conclusions about the comparative effectiveness of these techniques.

All methods demonstrated a high technical success rate of 91.2% (104/114). Reasons for technical failures included: inability to remove a previously placed plastic stent within the UCSEMS lumen, preventing bile duct cannulation in one patient; breakage of a plastic stent during removal in one patient; catheter blockage due to damage to the wire mesh of UCSEMS in seven patients; and duodenal stenosis preventing proper positioning of the endoscope in two patients.

Complications other than RBO included acute pancreatitis in five patients, liver abscesses in four patients, gastrointestinal perforation in one patient, and acute cholecystitis in one patient, which required cholecystoduodenostomy.

The mean time to the first reintervention, defined as the time to the first procedure following initial UCSEMS placement, was 169.8 days. The mean time to the second reintervention varied depending on the method used, as

follows: 238 days for balloon cleaning alone, 201 days for plastic stenting, 264 days for FCSEMS placement, 78 days for RFA followed by plastic stenting, and 205 days for repeat UCSEMS implantation ( $p=0.4999$ ). The mean RBO time for all ERCP procedures was as follows: 48 days for balloon cleaning alone, 75 days for plastic stenting, 71 days for FCSEMS placement, 66 days for RFA followed by plastic stenting, and 96 days for UCSEMS re-stenting ( $p=0.0326$ ).

## DISCUSSION

Stenting in MHBO remains one of the most challenging types of ERCP procedures. When combined with the reinterventional nature of procedures following UCSEMS placement, these interventions become even more demanding. Despite significant technical challenges, the technical success rate we achieved was high. However, this does not translate into an average therapeutic success rate, which remains relatively low.

Regarding our clinical success rates, the outcomes observed in our cohort are generally consistent with trends reported in previous studies [11, 12]. Although UCSEMS re-stenting and RFA appeared to yield numerically higher success rates in our sample, these findings did not consistently reach statistical significance. Notably, in terms of RBO, balloon cleaning during the first reintervention showed a relatively favourable outcome. This may suggest that early stent occlusion is often due to sludge accumulation rather than tumour overgrowth, and that simpler methods such as balloon cleaning or FCSEMS placement can be effective at this stage.

Balloon cleaning was used as a method of stent clearance only in cases where no strictures were visible on the cholangiogram. This suggests that during the first reintervention, stent occlusion is more likely due to mucus sludge rather than tumour overgrowth of the stent's wire mesh. In the long term, plastic stents appear to be the least effective method both clinically and in terms of stent patency. They require more frequent ERCP procedures and seem to serve either as a bridge before UCSEMS or RFA placement or as an option when the stricture is so tight that other stent types cannot be introduced. FCSEMS appear to be a good option, particularly for initial reinterventions. They demonstrate a higher clinical success rate compared to plastic stents and a slightly longer RBO. However, their placement seems to carry an increased risk of liver abscesses (3 out of 4 liver abscess cases occurred after FCSEMS placement). Regarding RFA as a clearance method, it is worth mentioning that RFA is an independent factor

**Table II.** Clinical effects of various techniques used to treat UCSEMS occlusion

	Balloon cleaning only of UCSEMS	Plastic stent in UCSEMS	FCSEMS in UCSEMS	RFA and plastic stent in UCSEMS	UCSEMS in UCSEMS	p
Mean time to second reintervention, days (SD)	238.0 (289.8)	201.8 (143.7)	264.3 (157.7)	78.5 (88.4)	205.1 (219.3)	0.4999
Mean interval time across all ERCP procedure, days (SD)	48.2 (69.2)	74.9 (46.8)	70.9 (45.5)	65.8 (30.2)	95.5 (98.1)	0.0326
Clinical success (%)	9/18 (50)	35/53 (66)	11/16 (68.75)	8/10 (80)	12/15 (80)	0.366

FCSEMS: full covered self extended metal stents; RFA: radiofrequency ablation. For the rest of abbreviations see Table I.

associated with improved overall survival in patients with MHBO [13, 14]. Additionally, it shows good clinical efficacy. Finally, UCSEMS reintervention has the best RBO duration and clinical success rate. This approach is further supported by advancements in thin-profile stent delivery systems, which make their placement significantly easier [15]. In the broader perspective, however, during the second and subsequent reinterventions, the use of UCSEMS and RFA should take on greater importance. This approach seems crucial given the average of three ERCP procedures performed after the initial SEMS placement in our cohort. Unlike previously published studies [16], we were able to gather a relatively large group of patients and include all reinterventions, not just the first ones.

Our intention is not to assert the superiority of any particular method, but rather to share observed trends that could inform future research and clinical decision-making. Importantly, we acknowledge that the descriptive nature of our data, combined with a lack of statistical significance in most comparisons, precludes definitive conclusions.

To strengthen the evidence base, future research should involve multicentre collaborations that allow for larger sample sizes and stratified analyses. This would enable more robust comparisons and inform future guideline development for managing occluded UCSEMS.

## CONCLUSIONS

All evaluated reintervention techniques demonstrated high technical success rates in patients with occluded UCSEMS. Among them, UCSEMS re-stenting and RFA combined with plastic stenting were associated with numerically higher clinical success and longer RBO durations. However, given the retrospective design, single-centre nature, and limited cohort size, these trends should be interpreted with caution. Our findings underscore the need for larger multicentre studies to determine the most effective strategy for managing UCSEMS occlusion in MHBO.

**Conflicts of interest:** None to declare.

**Authors' contributions:** J.P. conceived the study and designed the methodology, J.P. collected and analyzed the data, and drafted the manuscript. A.P. conducted a critical review and manuscript revision. All authors participated in the final review, approved the manuscript, and ensured the accuracy and integrity of the work.

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