

PEER-REVIEW REPORT

Name of journal: *World Journal of Gastrointestinal Oncology*

Manuscript NO: 76726

Title: Percutaneous insertion of a novel dedicated metal stent to treat malignant hilar biliary obstruction

Provenance and peer review: Invited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 03727100

Position: Editorial Board

Academic degree: MD, PhD

Professional title: Assistant Professor, Doctor

Reviewer's Country/Territory: Japan

Author's Country/Territory: Italy

Manuscript submission date: 2022-04-08

Reviewer chosen by: AI Technique

Reviewer accepted review: 2022-04-08 08:05

Reviewer performed review: 2022-04-10 11:26

Review time: 2 Days and 3 Hours

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input checked="" type="checkbox"/> Grade B: Very good <input type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Language quality	<input checked="" type="checkbox"/> Grade A: Priority publishing <input type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
Conclusion	<input type="checkbox"/> Accept (High priority) <input type="checkbox"/> Accept (General priority) <input type="checkbox"/> Minor revision <input checked="" type="checkbox"/> Major revision <input type="checkbox"/> Rejection
Re-review	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Peer-reviewer statements	Peer-Review: [<input checked="" type="radio"/>] Anonymous [<input type="radio"/>] Onymous Conflicts-of-Interest: [<input type="radio"/>] Yes [<input checked="" type="radio"/>] No
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SPECIFIC COMMENTS TO AUTHORS

Thank you for the report of new effective SEMS for malignant hilar biliary stricture. My comments were listed below.

1. In page 3, line 22, what does the MSC mean? It is MCS?
2. In page 5, line 1-2, it is written that the outcomes of percutaneous approach are superior to those of endoscopic approach for patients with Bismuth III and IV. The citation is published in 2013. The data might be old? Recently, the SEMSs are improved. Therefore, the outcome of endoscopic approach should have been improved.
3. This is the prospective study. Authors should add the information of clinical trial registration.
4. In stent features, Moving Cell Stent is abbreviated as MSC.
5. How is the delivery system of the new SEMS? If the delivery system of the MCS is thick, the other SEMSs with thin delivery system might be suitable for the second SEMS. Could you describe that in the discussion section?
6. It is difficult to understand the details of procedure. Could you explain the procedure by putting the figure 2-5 in Figure2 a-d?
7. What is the reason of sample size?
8. Could you add the p value in table 4?
9. Why did the authors perform the percutaneous drainage? ERCP and EUS-BD are less invasive than PTBD. Besides, drainage could be achieved by one session of endoscopic drainage. You should discuss this matter in the discussion section.
10. In reference 16, the name of journal is wrong. It is "J Hepatobiliary Pancreat Sci".

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Provenance and peer review: Invited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 05260389

Position: Peer Reviewer

Academic degree: MD

Professional title: Doctor, Surgeon

Reviewer's Country/Territory: Brazil

Author's Country/Territory: Italy

Manuscript submission date: 2022-04-08

Reviewer chosen by: AI Technique

Reviewer accepted review: 2022-04-08 20:21

Reviewer performed review: 2022-04-12 20:18

Review time: 3 Days and 23 Hours

Scientific quality	[<input checked="" type="radio"/>] Grade A: Excellent [<input type="radio"/>] Grade B: Very good [<input type="radio"/>] Grade C: Good [<input type="radio"/>] Grade D: Fair [<input type="radio"/>] Grade E: Do not publish
Language quality	[<input checked="" type="radio"/>] Grade A: Priority publishing [<input type="radio"/>] Grade B: Minor language polishing [<input type="radio"/>] Grade C: A great deal of language polishing [<input type="radio"/>] Grade D: Rejection
Conclusion	[<input checked="" type="radio"/>] Accept (High priority) [<input type="radio"/>] Accept (General priority) [<input type="radio"/>] Minor revision [<input type="radio"/>] Major revision [<input type="radio"/>] Rejection
Re-review	[<input checked="" type="radio"/>] Yes [<input type="radio"/>] No

Peer-reviewer statements	Peer-Review: [<input checked="" type="radio"/>] Anonymous [<input type="radio"/>] Onymous Conflicts-of-Interest: [<input type="radio"/>] Yes [<input checked="" type="radio"/>] No
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SPECIFIC COMMENTS TO AUTHORS

Dear authors, The Moving Cell Stent (MCS) appears to be a promising new device that will improve the management of patients with unresectable biliary obstruction. I congratulate the authors for the project. A study comparing endoscopic and percutaneous Y-stents will be very good to reinforce the benefit and perhaps a multi-centric study with a higher number of patients. I am here only reinforcing what I believe to be the authors' intention. The text must be revised because the acronym MCS has been changed to MSC in several paragraphs.

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Manuscript NO: 76726

Title: Percutaneous insertion of a novel dedicated metal stent to treat malignant hilar biliary obstruction

Provenance and peer review: Invited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 03026716

Position: Peer Reviewer

Academic degree: MD, PhD

Professional title: Doctor, Professor

Reviewer's Country/Territory: Norway

Author's Country/Territory: Italy

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Reviewer chosen by: AI Technique

Reviewer accepted review: 2022-04-08 06:53

Reviewer performed review: 2022-04-20 13:33

Review time: 12 Days and 6 Hours

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input type="checkbox"/> Grade B: Very good <input checked="" type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Language quality	<input checked="" type="checkbox"/> Grade A: Priority publishing <input type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
Conclusion	<input type="checkbox"/> Accept (High priority) <input type="checkbox"/> Accept (General priority) <input type="checkbox"/> Minor revision <input checked="" type="checkbox"/> Major revision <input type="checkbox"/> Rejection
Re-review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Peer-reviewer statements	Peer-Review: [<input checked="" type="checkbox"/>] Anonymous [<input type="checkbox"/>] Onymous Conflicts-of-Interest: [<input type="checkbox"/>] Yes [<input checked="" type="checkbox"/>] No
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SPECIFIC COMMENTS TO AUTHORS

Comments to the Authors The authors describe the practice of using two biliary stents antegradly placed through a percutaneous route using US and fluoroscopy as guidance. The stents are placed in a Y- configuration with a stent in stent technique where the second stent is introduced and dilated through the mesh of the first stent. Technical and clinical effects are excellent, and the procedure probably elongates the lives of these patients with malignant strictures in the hilar region of the liver (Bismuth III and IV). The number of patients are 18 and the registration is done over one nine months from Nov. 2020- July 2021. The study is named an observational, single center study. It is a case series, with no control group. The design is not defined, but from the presentation it seems to be a retrospective study. The researchers have considered technical success, clinical success (relief of jaundice), and secondary endpoints such as stent patency, overall survival, complication rates and stent related complications. The language is of good standard for a scientific journal. The discussion does not include major elements such as the results of ERCP drainage and EUS guided drainage, that represent the standard of care in other centers. This must be included. Tables and images are fine, and illustrate the method well. Figure legends are adequate. The document has no page or line numbers which make it harder to refer to my comments. Major comments: 1. In the method section and according to the document named: Signed informed Consent form and document(s), there is this statement: Patients were not required to give informed consent to the study because the analysis used clinical data that were obtained after each patient agreed to treatment by written consent. However, as this consent form is not presented as a separate document, I suppose patients

consented to the treatment itself with the risks involved, but maybe not to be part of a retrospective or prospective study? The authors should present the consent form in its original format in order to clarify this. 2. M&M section: The Helsinki declaration of 1975 has been revised several times since then, and it would be appropriate to refer to the last version. 3. Introduction: The authors state that for Bismuth III and IV the outcomes are better with percutaneous approach. The reference is a consensus statement (8). However, there are no references to original studies to confirm this. A better reference would be: Paik WH, Park YS, Hwang JH et al. Palliative treatment with self-expandable metallic stents in patients with advanced type III or IV hilar cholangiocarcinoma: a percutaneous versus endoscopic approach. *Gastrointest. Endosc.* 2009; 69: 55- 62. The main approach to malignant hilar stenoses is to use an endoscopic approach first (ERCP with stenting), and the possibilities to place stent in stent in a Y-configuration or side by side stents are similar with this approach. Why is there no control group who receive this more established treatment, either in parallel or historically. Please consider the following papers for discussion and references: Khashab MA, Valeshabad AK, Afghani E, Singh VK, Kumbhari V, Messallam A, Saxena P, El Zein M, Lennon AM, Canto MI, Kalloo AN. A comparative evaluation of EUS-guided biliary drainage and percutaneous drainage in patients with distal malignant biliary obstruction and failed ERCP. *Dig Dis Sci.* 2015 Feb;60(2):557-65. doi: 10.1007/s10620-014-3300-6. Epub 2014 Aug 1. PMID: 25081224. Bill JG, Darcy M, Fujii-Lau LL, Mullady DK, Gaddam S, Murad FM, Early DS, Edmundowicz SA, Kushnir VM. A comparison between endoscopic ultrasound-guided rendezvous and percutaneous biliary drainage after failed ERCP for malignant distal biliary obstruction. *Endosc Int Open.* 2016 Sep;4(9):E980-5. doi: 10.1055/s-0042-112584. Epub 2016 Aug 31. PMID: 27652305; PMCID: PMC5025302. Kongkam P, Orprayoon T, Boonmee C, Sodarat P, Seabmuangsai O, Wachiramatharuch C, Auan-Klin Y, Pham KC, Tasneem AA,

Kerr SJ, Romano R, Jangsirikul S, Ridditid W, Angsuwatcharakon P, Ratanachu-Ek T, Rerknimitr R. ERCP plus endoscopic ultrasound-guided biliary drainage versus percutaneous transhepatic biliary drainage for malignant hilar biliary obstruction: a multicenter observational open-label study. *Endoscopy*. 2021 Jan;53(1):55-62. doi: 10.1055/a-1195-8197. Epub 2020 Jun 8. PMID: 32515005.

4. Another internal approach that has been to use EUS guided biliary drainage with a semi-covered metal stent from the ventricle to the left main bile duct (E.g: Gio-Bor stent). This sometimes allows a similar antegrad cannulation through the papilla with placement of a trans-papillary stent, or it may allow also right sided drainage through the biliary stent from the ventricle.(See attached references above). For drainage of the gall bladder, small LAMS may be placed EUS guided from the duodenum. These alternative approaches should be mentioned and compared based on current literature in the discussion. The main result is a method that results in efficient drainage, with as low invasiveness and risk as possible, without leaving a PTC drain through the skin. Local resources may decide which method to select based on availability and experience.

Minor comments: 1. Ref. 18 is a self-reference in the M&M section and describes the endoluminal biopsy of malignant lesions as part of the work-up. In how many patients was this done in the same session as the stenting? Could be reconsidered, or a different reference could be selected. 2. Introduction page 4 last paragraph: An end-bracket is inserted after ...50% of the liver volume),.... But there is no start of this bracket, please remove it. 3.Under "Core tip" the Moving Cell Stent is not referred by name, producer and country, as in the M&M section, this would be appropriate. 4. There is no mention that in order to place the two stents in its Stent in stent configuration, two separate injection sites passing the skin, peritoneum and liver tissue have to be used in order to angle the stents adequately.