



PEKING UNIVERSITY

[DATE] August 2023

Lian-Sheng Ma

Editorial Office Director, Company Editor-in-Chief, Editorial Office

World Journal of Gastrointestinal Surgery

Dear Dr. Ma,

Thank you for the opportunity to re-submit our revised manuscript titled “**Stent fracture after transjugular intrahepatic portosystemic shunt placement using the bare metal stent/stent-graft combination technique: a retrospective cohort study**” for possible publication in the *World Journal of Gastrointestinal Surgery*.

In this minor revision, we have carefully addressed the helpful Editor and Reviewer comments received on our original manuscript (**NO. 85305, Retrospective Cohort Study**). We have made three major changes.

First, following Reviewer #1’s suggestion that post-procedure PSG might also be a potential predictor of stent fracture. In the revised manuscript, we added this variable to the univariable analysis.

Second, as for the statistical analysis section, we consulted the multivariable regression model with a statistical expert. In the revised *Methods* and *Results* section, in addition to covariates found to be statistically significant in the univariable analysis, we also adjusted covariates with clinical meaning into the logistic model.

Third, we cross-checked and corrected all data reported throughout the manuscript and exhibits as suggested by Reviewer #2. We truly appreciate the reviewer for his/her helpful review to make our research more rigorous.

We highlighted the revisions we made below. Additionally, we have uploaded both “marked”



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(i.e., the revised/added contents highlighted with yellow color) and “clean” copies of the revised manuscript. Please find enclosed documents.

We believe these changes have strengthened our paper. If there is anything we still need to improve, please let us know. Thank you once again for your consideration of our work. We look forward to your decision.

Yours sincerely,

Changming Wang, MD

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EDITORIAL OFFICE'S COMMENTS

Company editor-in-chief:

I recommend the manuscript to be published in the World Journal of Gastrointestinal Surgery. However, the quality of the English language of the manuscript does not meet the requirements of the journal. Before final acceptance, the author(s) must provide the English Language Certificate issued by a professional English language editing company. Please visit the following website for the professional English language editing companies we recommend: <https://www.wjgnet.com/bpg/gerinfo/240>.

Authors: Thanks. Following this recommendation, we chose American Journal Experts to further polish our manuscript. Please see the attached English Language Certificate.

[Figure: English Language Certificate]

Before final acceptance, when revising the manuscript, the author must supplement and improve the highlights of the latest cutting-edge research results, thereby further improving the content of the manuscript. To this end, authors are advised to apply a new tool, the Reference Citation Analysis (RCA). RCA is an artificial intelligence technology-based open multidisciplinary citation analysis database. In it, upon obtaining search results from the keywords entered by the author, "Impact Index Per Article" under "Ranked by" should be selected to find the latest highlight articles, which can then be used to further improve an article under preparation/peer-review/revision. Please visit our RCA database for more information at: <https://www.referencecitationanalysis.com/>.

Authors: Thank you for this advice. We reviewed the website and searched the RCA with the terms "stent fracture [Title]". Most of the literature was on coronary and aorta stent fracture. We believe our research can provide more empirical evidence on stent fracture after a transjugular intrahepatic portosystemic shunt placement.

REVIEWER COMMENTS:

Reviewer #1:

Scientific Quality: Grade B (Very good)

Language Quality: Grade B (Minor language polishing)

Conclusion: Accept (General priority)

Specific Comments to Authors: The authors explore a rather uncommon entity of stent fracture post TIPSS as a retrospective cohort study although the technique has been replaced at most centres. The subject being rare is of interest and the manuscript is well written.

Overall Decision: Accept with minor revision.

Comments for improvement prior to acceptance:

1. Abstract: Aim: Remove “The incidence.....unknown”
2. Abstract : Background: “only a few literature” to change “with limited available literature”
3. Abstract: Methods: Remove “Chinese Medical Centre”

Authors: We thank the reviewer for these pieces of advice and revised the Abstract as suggested.

4. Results: In the predictor analysis was post-procedure PSG accounted for as one of the predictors?

Authors: Thank you for your comment. In our previous manuscript, the potential predictors of stent fracture (i.e., patient characteristics, number of deployed stents, and stent bending angle of the proximal segment) were selected in line with relevant literature. We agree with the reviewer that post-procedure PSG might also be a potential predictor of stent fracture. In the revised manuscript, we added the PSG in the univariable analysis (Table 1). No statistically significant difference was observed between the fracture group and integrity group in PSG (14.0 vs 15.0 mmH₂O, $p=0.745$).

5. Please provide detailed univariate and multivariate parameters and adjustment co-variates in Table 3 to provide a more comprehensive table

Authors: We added detailed univariate and multivariate parameters and adjustment co-variates in Table 3 as suggested. In Table 3 legend, we wrote:

“Models were adjusted for covariates with clinical relevance (i.e., stent number;

reoperation and Angle 1) and those found to be significant in univariate analyses (i.e., Angle 2).”

Reviewer #2:

Scientific Quality: Grade D (Fair)

Language Quality: Grade A (Priority publishing)

Conclusion: Major revision

Specific Comments to Authors: This is an interesting manuscript about the risk factors of stent fracture after transjugular intrahepatic portosystemic shunt placement using the bare metal stent/stent-graft combination technique. The data demonstrated that the number of implanted stents and stent binding angle at the IVC end were predictors of stent fracture. The authors have suggested that the incidence of stent fracture could potentially be reduced by procedural modifications. This manuscript is nicely structured. However, the primary criticism of this manuscript is a lack of accuracy for data, especially patient characteristics. Please consider the following comment.

1. Page 10, Table 1, Patient characteristics, the number of patients is 61 in the integrity group. However, as for sex, the total number of patients is 58 ($38 + 20 = 58$) in the integrity group. In addition, as for, age, Child-Pugh classification, stent number, and reoperation, the total number of patients is 68 in the integrity group. Is the one or the other correct?

Authors: We thank the reviewer for his/her careful reading and apologize for the error in Table 1. We cross-checked the raw data and corrected the number used throughout our manuscript. In Table 1, the total number of patients is 61 (34male+27female, $29 \leq 60$ years+32 >60 years, 18 Child-Pugh A+32 Child-Pugh B +11 Child-Pugh C, stent number $51+9+1$, 54 one operation +7 reoperation) in the integrity group.

2. Page 7, Patient characteristics, lines 8-9 “A total 151 stents were implanted, with an average of 2.2 stents implanted in each patient (range: 2-4).” The data (Table 1) shows that 169 stents ($2 \times 55 + 2 \times 4 + 3 \times 11 + 3 \times 2 + 4 \times 2 + 4 \times 1 = 169$) were implanted. Is the one or the other correct? Sorry if I have got it wrong. Please consider.

Authors: We cross-checked the raw data and corrected the number used throughout our manuscript. In the revised Table 1, a total of 151 stents ($2 \times 55 + 3 \times 11 + 4 \times 2$) were implanted. Please check.

3. Page 6, Statistical analysis, lines 9-10 The authors described that the model was adjusted for covariates found to be significant in univariate analysis. A covariate found to be statistically significant is only angle 2 in Table 1. Which kind of covariates except “angle 2” is selected in multivariate analysis? I think the authors should make it clear.

Authors: Thank you for your comment, we are pleased to provide further clarification. We consulted the multivariable regression model with a statistical expert. In the revised Methods and Results section, in addition to covariates found to be statistically significant in the univariable analysis, we also adjusted covariates with clinical meaning into the logistic model. In the *Statistical Analysis* section (Page 6), we wrote:

“The model was adjusted for covariates with clinical relevance and those found to be significant in univariate analyses.”

We also clarified the specific adjusted covariates in the legend of Table 3:

“Models were adjusted for covariates with clinical relevance (i.e., stent number, reoperation and Angle 1) and those found to be significant in univariate analyses (i.e., Angle 2).”

Reviewer #3:

Scientific Quality: Grade D (Fair)

Language Quality: Grade B (Minor language polishing)

Conclusion: Rejection

Specific Comments to Authors: The authors did a retrospective review of bare metal TIPS stents over a 10 years period with a specific emphasis on stent fractures. They identified 7 patients out of 68 (10.3%), subcategorize these in 3 groups and submit these data to extensive statistical analysis. This reviewer appreciates the efforts of the authors but is less convinced about the usefulness of detailed retrospective statistical data analysis from of a single center, a very limited number of cases and of stent types that are increasingly replaced by better types. The help current TIPS placers may obtain from this would appear to be limited short of some practical considerations that certainly could be beneficial. The analysis does not really provide evidence based recommendations

Authors: We thank the reviewer for this critical comment. In the limitation section of

our initial manuscript, we wrote: “This was a retrospective study of a limited sample population treated in one medical center.”

Nevertheless, the VIATORR® TIPS Endoprosthesis was approved in 2019 (please see the attached figure) in China, and, to the best of our knowledge, is still not available in most Chinese medical centers by now.

国家药品监督管理局 National Medical Products Administration 数据查询

首页 网上办事大厅

进口医疗器械(注册) —— “国械注进20143136223”基本信息

注册证编号	国械注进20143136223
注册人名称	戈尔及同仁有限公司 W. L. GORE & ASSOCIATES, INC.
注册人住所	1505 North Fourth Street, Flagstaff, Arizona, USA.
生产地址	1505 North Fourth Street, Flagstaff, Arizona USA; 32360 N. North Valley Parkway, Phoenix, Arizona USA;
代理人名称	戈尔工业品贸易(上海)有限公司
代理人住所	中国(上海)自由贸易试验区基隆路1号塔楼七层714室
Products Name	产品名称 TIPS覆膜支架系统GORE® VIATORR® TIPS Endoprosthesis
管理类别	第三类
型号规格	见附页
结构及组成/主要组成成分	TIPS覆膜支架系统主要由两部分构成:可植入的镍钛合金覆膜支架和经皮输送系统。覆膜支架由一个自膨式电镀锌钛合金(镍钛)支架组成,支架支撑着一个低渗透性的膨体聚四氟乙烯(ePTFE)覆膜。覆膜支架分为两个功能区:肝内覆膜区和门脉裸区。由一个环状不透射线黄金标记带划分覆膜区和裸区。还有另外一个不透射线黄金标记位于覆膜支架的尾端。输送系统与直径小于等于0.038英寸(0.97毫米)的导丝相容。输送系统主要由HDPE, EVA, 304不锈钢, 聚碳酸酯, 硅胶, 膨体聚四氟乙烯, 尼龙, 铂钛合金, 丙烯酸树脂和紫外粘
适用范围/预期用途	TIPS覆膜支架系统适用于初治和修复治疗门静脉高血压及其并发症,如静脉曲张出血、胃病、顽固性腹水和/或肝性胸水。
产品储存条件及有效期	
附件	产品技术要求
其他内容	/
备注	原注册证编号为:国械注进20143466223
审批部门	国家药品监督管理局
Approval Date	批准日期 2019-08-07
生效日期	
有效期至	2024-08-06
变更情况	2022-10-17 产品技术要求变更详见“产品技术要求变化对比表”。 2022-10-17 产品技术要求变更详见“产品技术要求变化对比表”。 2022-10-17 产品技术要求变更详见“产品技术要求变化对比表”。
注	详情

Thus, in China, TIPSs are frequently constructed using the bare metal stent/stent-graft combination technique (Chin Med J (Engl). 2016 Jun 5;129(11):1261-7). Our results, although with a limited sample, showed that stent fractures may be associated with the number of stents implanted and excessive bending of the stent. We believe our findings can provide preliminary but empirical evidence for surgeons in China and other regions with limited medical resources.

Reviewer #4:

Scientific Quality: Grade B (Very good)

Language Quality: Grade B (Minor language polishing)

Conclusion: Accept (General priority)

Specific Comments to Authors: Authors have evaluated data for TIPS stent fracture. Though bare metal stents are uncommon these days. The data is interesting to report. The manuscript has been written well.

Authors: We thank the reviewer for this positive comment.