

Reviewer 1.

In this manuscript the authors reported the results on the use of a new biliary uncovered metal stent for unresectable biliary malignant obstruction. They described a good number of clinical cases with interesting results.

Answer:

Thank you for your reviewing our paper.

Reviewer 2.

This manuscript, reports on the effectiveness and safety of a newly developed an uncovered self-expandable 14mm X 60 -80mm nitinol stent for the treatment and prevention of the recurrent biliary obstruction due to tumor ingrowth or migration. Based on the data obtained with 38 patients, it is concluded that application of the self-expandable stent, Niti-S 14, resulted in a lower rate of recurrent biliary obstruction, no stent migration, and extended the patient survival rate by about 6 months. This paper is clearly written, well-illustrated with figures showing the stent, stent placement and the endoscopic view after the placement. The number of patients utilized in data analysis is low, indeed.

Answer:

Thank you for your reviewing our paper.

Our study is limited because of the small number of patients. We think that further randomized studies are needed.

Reviewer 3.

This is a retrospective study on palliative treatment of unresectable distal biliary malignant obstruction using uncovered self-expandable metal stent with a large diameter of 14mm (Niti-S 14). The authors concluded that larger diameter Niti-S 14 stent had low rate of recurrent biliary obstruction. There are some major issues: 1. The issue of palliative treatment of distal malignant biliary obstruction is not new. Many different type of stents have been used with more or less equal efficacy. The superiority of one drainage policy over other is too difficult to be proved by pure scientific evidence. There is no standard accepted policy instead individualized strategies based on the availability of stents, cost and education to every center. 2. It is not clear to which was

used as standard in this study? Studies on stent placement are controversial, operator dependent and confusing based on different types of stents. 3. Larger diameter stents up to 14cm as in this study might be a problem of biliary rupture in cases of tight structures. No comment on this has been done in this study. 4. Although the authors stated: <> This is not totally true as no comparison to other stents has been done in this study. Instead authors compared their 5% stent occlusion to 18% reported to other studies. In partially covered SEMs reported occlusion rate was also 5% as the authors themselves stated in discussion page 13, ref 16, 17. Tumor ingrowth was also reported up to 5% of patients despite large diameter and one death 17 days after stent placement!! 5. The 6-month patency was not superior to previous studies but comparable 91%. In some other studies the 6month patency was even better up to 94%. So this stent is equal but not superior to previous stents.

Answer:

Thank you for your suggestive comments.

1, 2. We agree with you. Any type of a stent can be selected by a doctor. Some patients do not wish any treatment for malignant biliary obstruction (MBO) by pancreatic cancer with poor prognosis. In our study, we are glad if we could provide a better material, Niti-S 14, to treat MBO when the treatment is intended. It is regrettable if it is not clear which was used as standard in our study.

3. We did not experience bile duct perforation by the stent, and added the description about that in *Adverse events*.

4, 5. It is true that one patient suffered from liver abscess and died on day 18 due to abscess rupture toward the peritoneal cavity. However, as described in discussion, the abscess was large at diagnosis, and the possibility that the abscess had already developed by the time of stent placement was presumed.

As you pointed out, stent patency was not superior to previous stent, but we think that our results were totally preferable to previous reports.

This is a well-written, multicenter retrospective study on palliative treatment of unresectable distal malignant biliary obstruction, using uncovered self-expandable metal stent (USEMS) with a large diameter of 14mm (Niti-S 14). The authors concluded that larger diameter Niti-S 14 USEMS stent had low rate of recurrent biliary obstruction (RBO) and made detailed literature review and discussion. Although the issue of palliative treatment of distal malignant biliary obstruction is not new, this study is well written and suitable for publication.

There are some minor issues:

1. A statement is necessary that: <<further prospective, multicenter, international double-blind controlled studies, comparing different type of stents (e.g. UCSEMS v/s partially covered SEMs) are necessary, in order to standardize the best drainage policy.
2. No comment regarding cost was done, which could be of interest.

Thank you for reviewing our manuscript and giving us valuable comments.

1. We added the sentence “further prospective, multicenter, international double-blind controlled studies, comparing different type of stents (e.g. UCSEMS v/s partially covered SEMs) are necessary, in order to standardize the best drainage policy. “ at the end of the text.
2. We regret that we could not decide which we should describe the price the EMS or the cost for placing a EMS.