Reviewer’s report

Title: Management of patients with biliary sphincter of Oddi disorder without sphincter of Oddi manometry

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Reviewer: C Mel Wilcox

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Your retrospective study assesses interventions and outcome in patients with suspected SOD types I-III managed at a single center. The study is potentially worthwhile as it sheds some light on the efficacy of treatment as well as outcome of such patients. The study also assesses response following endoscopic intervention in the absence of using manometry to define the syndrome.

Major Comments

As you accurately state in the “Discussion”, a major limitation is the retrospective nature of the study and the absence of any rigorous quantitative measure of abdominal pain. Thus, other than a subjective impression, the response is difficult to accurately characterize and is a major limitation of the study.

Specific Comments

1. Page 3 – “praxis” should be practice

2. A major emphasis of the paper, both in Background and Discussion, is the lack of using sphincter of Oddi manometry and using prophylactic pancreatic stents. However, the manuscript emphasis is on management of these patients without the use of manometry. Since patients are still undergoing ERCP and treatment at your center, the discussion and emphasis on ERCP is somewhat superfluous since these patients are still getting ERCP and are at essentially the same risk of getting pancreatitis and other complications.

3. Page 5 – Management- specific doses of medications would be important to know, specifically amitriptyline. Do these patients receive proton pump inhibitors which would also be important as a diagnostic trial?

4. As noted above, “patients with no satisfactory symptom relief……..” In the absence of any objective measure this information is difficult to interpret. In addition, we are not told who made these assessments. Assuming it’s the physician, then significant bias is likely.

5. Page 6, bottom – if a patient is discharged from the outpatient clinic, one assumes that they are “cured”. However, were these patients followed long-term to ensure the absence of any recurrence?

6. Page 7, top – when do these patients develop recurrence of symptoms? And from what time point are they being measured? After sphincterotomy?

7. Page 7, top – Again, use of complete, improvement, unchanged are very subjective.
8. In the “Results” section, one must specifically delineate the length and range of follow-up. A table would be essential to characterize your cohort. You initially mentioned that a number of patients had an intact gallbladder. This should have been mentioned in the “Results” section and in your table characterizing these patients. In addition, at most centers, patients with right upper quadrant pain with a gallbladder in situ would undergo radionuclide imaging for gallbladder dyskinesia. While I would agree this is controversial, at most centers in the United States, ERCP and manometry are not considered unless the patient had previously undergone cholecystectomy.

9. Page 8 – ERCP was frequently utilized (41%) in your cohort and I wonder why so many ERCPs were, in fact, performed. As you know, generally if someone undergoes a complete sphincterotomy, there is no residual biliary pressure in contrast to the pancreatic sphincter. This has been supported by studies where patients undergo repeat manometry showing absent sphincter pressures. Indeed up to 7 ERCPs were required in some patients suggesting excess usage! Why would biliary stenting be used in patients who had previously undergone sphincterotomy? Also, if someone has undergone biliary sphincterotomy why would surgery even be considered? Please define “restenosis”.

10. Page 9 – A number of statistical analyses were performed. Were any of these pre-planned? Was any statistical test used to control for multiple comparisons?

11. “Discussion” should be reduced by 25%.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests