Reviewer's report

**Title:** Linear Echoendoscope-Guided ERCP for the Diagnosis of Occult Common Bile Duct Stone

**Version:** 1  **Date:** 13 September 2012

**Reviewer:** Hjalmar van Santvoort

**Reviewer's report:**

This is a prospective observational cohort study on the diagnostic accuracy of linear EUS in detecting CBD stones. The authors are to be commended for performing an nice study on this interesting new diagnostic modality on which new data are welcomed. There are, however, substantial shortcomings to the study design that need to be acknowledged by the authors and require toning down the conclusion of the paper.

I have some suggestions for improving the manuscript:

Major Compulsory Revisions:

**INTRODUCTION:**

1. The current aim of the study as formulated at the end of the introduction is misleading; please delete “as an alternative to both MRCP and radial EUS” as this was not a comparative study. Moreover, “the potential” is rather vague. I would rephrase the introduction to state clearly the goal of the study, which in my opinion was: “the aim of this study was to investigate the safety and diagnostic accuracy of linear EUS in detecting occult CBD stones”.

**METHODS:**

2. The inclusion criteria are not clear: what if CBD stones were seen on conventional US; were these patients included in the current study? Moreover, in the aim of the study it is stated that patients with “intermediate risk for CBD stones” are studies; how was “intermediate” defined in the eligibility criteria?

3. An exclusion criterion was the presence of CBD stones on conventional US/CT scan. Hence, the patient population of this study is highly selected and the results of this study can not be extrapolated to all patients with clinical of biochemical suspicion of CBD stones. This is not a problem, as long as the authors clearly state that the study focused only on patients were conventional imaging failed to identify CBD stones. In this respect, it should be reported in the results section whether all 30 patients underwent transabdominal US and/or CT before they were included in the study. The issue should also be emphasized in the discussion section.

4. From a methodological point of view: the diagnostic test in this study was linear EUS. The gold standard was ERCP. However, the gold standard was not
performed in all patients; if EUS was negative patients did not receive ERCP. This may have led to a false negative result, underestimating the diagnostic accuracy of EUS. The issue should be addressed in the discussion section as a major shortcoming.

RESULTS:

5. In 15 patients the reason for inclusion was acute pancreatitis. This was, however, not defined as an inclusion criterion in the methods section. Were there other signs of CBD stones in the patients? Were there other plausible causes for pancreatitis in these patients, as it may be an overkill in diagnosis to perform EUS in every patient with acute pancreatitis.

DISCUSSION

6. As previously stated the fact that the study population represents a subgroup of patients with suspicion of CBD stones and the fact that ERCP was not performed as the gold standard in all patients should be addressed in the discussion. This also means that the conclusion is currently much too strong. Please state in the conclusion only something like “this study suggests that linear EUS can accurately detect CBD stones in patients were conventional imaging techniques have failed”

Minor Essential Revisions

INTRODUCTION

7. The introduction could be shortened; for instance by moving background information on linear EUS to the discussion section.

METHODS

8. In the last paragraph of the methods section (page 9, line 15) the study design is clearly stated. Move this information to the beginning of the methods section.

9. An the authors provide a rationale for the sample size of 30 patients? If this was arbitrarily chosen, please also state this.

RESULTS

10. Of the 12 patients with positive EUS, 2 patients “were false-positive cases”. Why were these false-positives? Did these patients undergo ERCP, and if so, was ERCP performed immediately following EUS? If not, the CBD stones may have migrated before ERCP was performed.

GENERAL

11. Please add an abstract to the manuscript

12. Although the paper is generally well written, there is still some room for improving grammar and style; e.g. (page 4, line 7) do not use past tense “stones
were 77.3%..” but “stones are”; and (page 4, line 10) do not use “has been the gold standard” but “is the gold standard”.

13. Do use decimals when presenting percentages; e.g. 15% instead of 15.1%

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

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

**Declaration of competing interests:**

no