

PEER-REVIEW REPORT

Name of journal: World Journal of Clinical Cases

Manuscript NO: 65443

Title: Primary needle-knife fistulotomy for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis: Importance of the endoscopist's expertise level

Reviewer's code: 05710028

Position: Peer Reviewer

Academic degree: MD, PhD

Professional title: Associate Professor

Reviewer's Country/Territory: Japan

Author's Country/Territory: South Korea

Manuscript submission date: 2021-03-08

Reviewer chosen by: Man Liu

Reviewer accepted review: 2021-03-09 13:41

Reviewer performed review: 2021-03-12 13:30

Review time: 2 Days and 23 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 Grade E: Do not publish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 type="checkbox"/> Grade A: Priority publishing <input checked="" 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 type="checkbox"/> Anonymous <input checked="" type="checkbox"/> Onymous Conflicts-of-Interest: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

This is a manuscript describing primary NKF in accordance with the expertise of physicians. This paper is well written, and the topic of this paper is debatable even now. I have some concerns to be revised.

1. Background and study aim are not clearly noted.

1-1. The sentence of "...most endoscopists believe that a high level of experience is required in order to achieve a sufficiently high rate of successful cannulation and an acceptable rate of adverse events in patients with naïve papilla" is not suitable in this part. Is it concerned successful cannulation in all of patients with native papilla? I think that most physicians believe a high level experiences is required for successful cannulation with a use of primary NKF in patients with native papilla.

1-2. Sentences of "The beginner endoscopist usually requires to perform more than 300 supervised procedures for achieving 80% of successful biliary cannulation using conventional methods. More experience may be necessary to achieve acceptable of success and adverse event with primary NFK." are unnecessary in this position, I think.

1-3. The sentence of "Therefore, it is necessary to determine the effectiveness and safety of NKF for primary biliary cannulation performed by beginners compared to those of experts." cannot be understood. The context is not well constructed.

1-4. The sentence of "We aimed to assess the effectiveness and safety of primary NKF in patients with naïve papilla undergoing bile duct cannulation and determine the role of the endoscopist's expertise level." could not be met. To assess the effectiveness and safety of primary NKF, patients underwent primary NKF should be compared with the patients underwent conventional cannulation method. In this manuscript, only comparison of expert vs. non-expert in each primary NKF group and conventional cannulation method group were performed. In this situation, only "the role of expertise level for primary NKF", which is one of authors' aim, can be assessed.

2. Methods

2-1. Statistical methods which

were used for comparing variables and for univariate/multivariate analyses should be noted. 2-2. In Figure 2, it is unclear which figures are of precut sphincterotomy or primary NKF. Figure legends should be revised in this point. 3. Result 3-1. Table 1, 2. Ampulla configurations, including bulging, distorted, hook-nose shape, should be explained. 3-2. Table 3. In conventional cannulation group, cannulation success and cannulation time are almost same in expert and non-expert. PEP incidence is the only difference between the two endoscopists. It is doubtful whether this non-experienced endoscopist, in whom the cannulation success rate was 95% and mean cannulation time was 4.6 min (less than the experienced endoscopist), can be deemed as beginner or less-experienced endoscopist. Can this result be generalized? This endoscopist have had a sufficiently ability for ERCP already. What is the precise experienced cases of this endoscopist? Please describe, not only >300. 3-3. Table 4, showing prognostic factor for PEP, should be revised. Usually, in such a situation describing factors associating the incidence, odds ratio and 95% CI should be noted in each variable. What kind of statistical method did authors use? I recommend authors to consult the expert of statistics. 4. Discussion. 4-1. In 2nd paragraph, authors mentions "In our study, the incidence rate of PEP was significantly higher in patients managed by the beginner than in those managed by the expert endoscopist, although there was no significant difference in the final rate of successful cannulation." Is that true? In this manuscript, incidence of PEP in entire cohort have not been noted; only incidence of PEP in each of conventional cannulation group and NKF group have been described. 4-2. "However, PEP incidence was lower for primary NKF than for conventional cannulation with sphincterotomy even when the procedure was performed by the beginner." is also controversial. The comparison between conventional cannulation and NKF was not performed. 4-3. In last paragraph. The sentence of "Our findings suggest that primary NKF is associated with reduced PEP risk regardless of the endoscopist's expertise level," is overstatement,

because if primary NKF can reduce the incidence of PEP rather than conventional cannulation has not been proved in this manuscript. There are no direct comparison. And cannulation method was not included in variables of multivariate analysis for the estimate of the prognostic factor of PEP.

RE-REVIEW REPORT OF REVISED MANUSCRIPT

Name of journal: World Journal of Clinical Cases

Manuscript NO: 65443

Title: Primary needle-knife fistulotomy for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis: Importance of the endoscopist's expertise level

Reviewer's code: 05710028

Position: Peer Reviewer

Academic degree: MD, PhD

Professional title: Associate Professor

Reviewer's Country/Territory: Japan

Author's Country/Territory: South Korea

Manuscript submission date: 2021-03-08

Reviewer chosen by: Chen-Chen Gao

Reviewer accepted review: 2021-04-06 21:33

Reviewer performed review: 2021-04-08 01:45

Review time: 1 Day and 4 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 checked="" type="checkbox"/> Accept (General priority) <input type="checkbox"/> Minor revision <input type="checkbox"/> Major revision <input type="checkbox"/> Rejection
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

SPECIFIC COMMENTS TO AUTHORS

Authors revised their manuscript according to reviewer's comment. Revised version is worth publishing. Congratulations! However, there is only one point requiring revision. Authors should describe statistical method for multivariate analysis in method section.