

Peer Review File

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Reviewer A:

Well structured case series and analysis

authors need to avoid making statements that are not data driven

In the Discussion:

"Insertion of PEG tubes by an OLN-HN surgeon, in this study, had similar outcomes compared to the previously described literature for PEG tubes inserted by gastroenterologists and general surgeon, (97.6- 98.9%) (2, 6)."

what 'outcomes' are being referred to here - what does the ' (97.6- 98.9%' refer to? success? complications?

Author response: Thank you for the comment we have adjusted the text to clarify.

Line 217 "Success rate of insertion of PEG tubes by an OLN-HN surgeon in this study (100%), had similar outcomes compared to the previously described literature for PEG tubes inserted by gastroenterologists and general surgeons (97.6- 98.9%) (2, 6).

More discussion on the complications of open/PEG placement in the discussion from the literature.

Author response: Thank you we have expanded on our discussion.

Line 262 "Major (3%), minor (6%) and overall (9%) complication rates demonstrated in this paper is comparable both in nature and numbers to previously described studies of similar populations (major complication rates 2-13.9%, minor rates 11-35%) (2, 3, 6, 8, 9)."

Line 288 "Major complications of this nature have been well documented for as long as PEG insertion has been performed (7)."

Line 295 "Whilst our minor morbidity rate is low compared to the reported literature, studies differ in their definition of complications and the subjectivity of assessment. Other factors that could contribute to our rate include having regular surveillance and care by a stoma therapist and nursing staff, and the reliance on accurate documentation due to the retrospective approach employed. "

Consider data from the literature to support the number needed to perform to achieve proficiency

Author response: Thank you for your comments. Competency of PEG insertion is commonly achieved via a longitudinal assessment with an expert assessor rather than the number needed to achieve proficiency. We have reflected the competency of our surgeon in the methods section.

Line 139 "All procedures were performed under general anesthesia by a single ORL-HN surgeon, fellowship trained and accredited for PEG insertion. They were assisted by either an otolaryngology surgeon or surgical trainee."

Reviewer B:

This is an important Case Series that needs re-working but can ultimately be accepted with minor revision, in particular to identify it as a consecutive case series of patients evaluating PEG insertion in Australia (via Otolaryngology) describing adverse events. This is rather than evaluating a random assignment of 4 "primary outcomes" and 2 "secondary outcomes" - in essence well designed case series don't have primary, secondary, tertiary outcome categories - they just describe exploratory results of interest in new interventions - in this instance the new intervention is PEG insertion via Otolaryngology).

There is some "bias" in highlighting "correct execution of a procedure" as a "primary outcome", as the procedure shouldn't be completed until it is correctly executed - however describing 100% of insertions as placed correctly is reasonable (just not as "the primary outcome" - this could also be described as "0% adverse effects of incorrect placement").

Author response:

Thank you for your comments and suggestions for our paper.

In previous literature the potential failure of insertion is well documented for this population due to anatomical and physiological limitations. This has been presented either as success rate or failure rate previously. We have presented this as success rate to be consistent with similarly aligned papers.

Conclusions drawn are a little bit of over-reach -

e.g. "Percutaneous gastrostomy tubes can be successfully and safely performed by an appropriately trained otolaryngologist-head and neck surgeon with high success rates and low morbidity" does not derive from these data - in an unpowered case series of 96 patients by one single surgeon (could be softened to state the complication rate in the series and the need for controlled studies comparing Otolaryngologist to Gastroenterologist inserted PEGs)

"Additional benefits include continuity of care and logistical benefits including the insertion of PEG tubes concurrent to other procedures" is more a discussion point than a conclusion from these data

Authors response: Thank you for your comment. We agree that this conclusion may be too pointed. Our conclusion has been adjusted to reflect this. (line 294)

Otolaryngologists play an integral part in the assessment, diagnosis and management of head and neck cancer patients. We have described the effectiveness of an Otolaryngology driven PEG placement and reviewed the associated morbidity in an Australian head and neck cancer centre. Success and complication rates were comparable to those previously reported in head and neck cancer patients. Additional benefits of this style of PEG service may include logistical benefits including simultaneous insertion of PEG tubes with concurrent procedures and improved continuity of care.

Abstract conclusion (line 80)

“We have described the effectiveness of an Otolaryngology driven PEG placement in an Australian head and neck cancer centre, integrated as part of patient care. Success of insertion and morbidity rates were comparable with previously reported studies of similar populations. Patient and logistical benefits delivered include ability to perform procedures concurrent to PEG insertion and enhanced continuity of care.”

Many statements need careful review and:

1. Proper referencing (eg the statement "However, the logistics of involving additional surgical teams for ancillary care can lead to delays in insertion, additional anaesthesia, and increased hospital resource utilization." needs at least 1 and possibly 3 references)

Author response: Thank you for this insightful comment. We have removed this statement, leaving a more measured and referenced sentence. (Line 116)

“Advantageously, otolaryngology driven PEG service may be associated with fewer patient appointments, logistical and financial efficiencies, and decreased treatment delay than traditional approaches (2, 3).”

2. Strictly speaking, the sentence at the end of the Introduction is NOT the same as the earlier stated "outcomes" in The Abstract Methods of the paper - although IT IS a more appropriate aim ("The aim of this study is to describe the effectiveness of an Otolaryngology driven PEG placement and to review the associated morbidity in an Australian head and neck cancer centre.")

Author response: Thank you we have aligned our abstract outcome to that of the main body.

Line 54 "We aim to evaluate the effectiveness of an Otolaryngology driven PEG placement and to review the associated morbidity in an Australian head and neck cancer centre."

3. The section OUTCOME MEASUREMENT should be re-written as descriptive of outcomes, rather than "primary" etc and a reference is required in said section as to what defines "Major" and "Minor" events.

Author response: Thank you for these comments. We have altered these as suggested.

The section title has been changed to "Descriptive of outcomes" as per your suggestion (line 165).

Major and minor definitions are referenced on line 173.

"Morbidity was characterised as major and minor complications based on criteria used by Schapiro and Edmundowicz, and Bannister (6, 7). Major complications included: peritonitis, sepsis, intra-abdominal abscess, gastric haemorrhage, intestinal fistula, obstruction at gastric outlet, necrotising fasciitis, buried bumper syndrome, solid organ injury/visceral perforation, PEG site metastasis, and early extrusion of PEG tube. Minor complications included: cellulitis, late extrusion of PEG tube, paralytic ileus, impacted tube lumen, peristomal leakage and haematoma (6, 7)."

4. The word "Serious" probably should be removed from "Serious Coagulation Disorders"

Author response: Thank you this has been adjusted.

Line 129 "Exclusion criteria for insertion of PEG tube included: coagulation disorders (INR > 1.5, PTT > 50 s, platelets < 50000/mm³),"

5. Minor adjustments of wording, sentence structure, punctuation and avoidance of phrases without meaning (eg "appropriately" trained has no real meaning in context; PEG should always be PEG and not peg,etc.)

Author response: Thank you these have been adjusted.

Line 145 “All procedures were performed under general anesthesia by a single ORL-HN surgeon, fellowship trained and accredited for PEG insertion. They were assisted by either an otolaryngology surgeon or surgical trainee.”