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Comparing the diagnostic adequacy of 25-Gauge fork-tip *versus* franseen *versus* reverse-bevel-type needles in EUS–guided tissue acquisition: A prospective randomized study with a retrospective control

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ABSTRACT

Background and Objectives: EUS–guided fine-needle biopsy (FNB) is an established technique for the acquisition of tissue to diagnose lesions of the gastrointestinal tract and surrounding organs. Recently, newer-generation FNB needles have been introduced, including a second-generation reverse-bevel and the third-generation fork-tip and Franseen needles. We aimed to determine if there was any difference between these needles in terms of cytopathological diagnostic yield, sample cellularity, or sample bloodiness.

Methods: One hundred twenty-seven consecutive patients undergoing EUS–guided FNB of any solid lesion were randomized to use either a Franseen or fork-tip needle in a 1:1 ratio and were compared with 60 consecutive historical cases performed with reverse-bevel needles. Patient and procedure characteristics were recorded. Cases were reviewed by a blinded cytopathologist and graded based on cellularity and bloodiness. Overall diagnostic yield was calculated for each study arm.

Results: One hundred seventy-six cases were eligible for analysis, including 109 pancreatic masses, 24 lymphoid lesions, 17 subepithelial lesions, and 26 other lesions. The final diagnosis was malignancy in 127 cases (72%). EUS–guided FNB was diagnostic in 141 cases (80%) overall and in 89% of cases where malignancy was the final diagnosis. There was no difference in diagnostic yield, sample cellularity, or sample bloodiness between the different needle types. There was no difference in adverse events between groups.

Conclusions: EUS–guided FNB performed using 25-gauge Franseen, fork-tip, and reverse-bevel needles resulted in similar diagnostic yield, sample cellularity, and sample bloodiness. Our results may not be extrapolated to larger-caliber needles of the same design.

Keywords: EUS-FNB needles; Fine-needle biopsy (FNB)

INTRODUCTION

EUS-FNA and EUS-guided fine-needle biopsy (EUS-FNB) are well established techniques for the acquisition of tissue to histologically classify a number of lesions of the gastrointestinal tract and surrounding organs.[1] These include pancreatic, lymphoid, subepithelial, and other abdominal lesions. Historically, FNA was the sole available modality used to obtain cytological samples for analysis. The major shortcoming of this technique is the lack of a histological tissue core. Reported diagnostic yield for this technique ranges from 77% to 95% in the sampling of pancreatic mass lesions,[2] 71% to 90% for subepithelial lesions,[3] and approximately 79% for lymph nodes.[4]

The use of rapid on-site evaluation (ROSE) seeks to increase the diagnostic performance of FNA, improving diagnostic adequacy by up to 30%.[5] Unfortunately, ROSE is costly and not available in all centers, and new data suggest it may not be as important as initially thought.[6] As a result, in recent years, attention has turned to optimizing needle design to improve sample quality. New needles have been developed that aim to obtain a core of tissue with preserved architecture. This allows for the diagnosis of disorders such as autoimmune or nonspecific pancreatitis, in which histology is required.[7] It also allows for immunohistochemical staining and molecular analysis, which aids in diagnosis of certain lesions and is required for selection of targeted oncologic therapies.[8]

The first core biopsy needle introduced was a Tru-Cut needle (Quick-Core; Cook Medical, Bloomington, IN). Thereafter, second- and third-generation needles were introduced. One of these second-generation biopsy needles is the Echo Tip HD ProCore (Wilson-Cook Medical Inc, Winston-Salem, NC), released in 2011. It features a reverse-bevel just proximal to the tip, which shears tissue into the needle with retrograde motion. Newer, third-generation biopsy needles include both a Franseen type and a fork-tip type. The SharkCore (Medtronic Inc, Sunnyvale, CA) is a fork-tip needle with

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6 cutting surfaces asymmetrically aligned. The Acquire (Boston Scientific, Marlborough, MA) is a Franseen-type needle with 3 symmetrical cutting points and cutting heels, which aim to make a circular cut in the target tissue to preserve its architecture.

Currently, there is a paucity of studies comparing the performance of the third-generation FNB needles,[9] and only 2 of these are prospective randomized controlled trials (RCTs).[10] Real-world performance of these needles has seldom been reported, with only 1 RCT including nonpancreatic masses in their analysis.

We hypothesized that third-generation needles would have equivalent or better diagnostic performance than the prior second-generation needle. To test this, we conducted a prospective randomized controlled study comparing the performance of fork-tip and Franseen needles for the sampling of pancreatic, subepithelial, lymphoid, and other abdominal or mediastinal lesions. We also included a retrospective control arm of consecutive cases using the second-generation reverse-bevel needle. We assessed the diagnostic yield of each needle, as well as number of needle passes used, and specimen quality.

PATIENTS/MATERIALS AND METHODS

Study design

The study was conducted at a single tertiary center in Australia with approval by the hospital ethics board (LNR/QMS/44303). All patients provided written informed consent for the procedure. The ethics board did not require specific consent to participate in the study as the study protocol did not differ from our standard practice, and all needle types are fully approved and available without restrictions for these indications in Australia. The study consisted of 3 arms: 1 retrospective control arm consisting of cases using the second-generation 25-gauge (G) ProCore needle and 2 prospective randomized arms using a third-generation 25G fork-tip-type needle (SharkCore) and a 25G Franseen needle (Acquire).

In the prospective arm of the study, we randomized 118 consecutive cases between September 2018 and September 2019. Cases were randomized using a computer-generated binary randomization table to either the fork-tip or the Franseen needle group. Sample size was determined pragmatically based on the number of cases that could be recruited in a reasonable timeframe. Post hoc power calculations determined that 59 patients allocated to each of the prospective study arms using an estimated diagnostic yield of 85% and a 2-sided α level of 0.05 would power the study to detect a 20% difference in diagnostic yield between the needles with 80% confidence.

Collected data were also compared with 60 consecutive historical controls (retrospective arm) collected between September 2016 and August 2017, using a second-generation, reverse-bevel core biopsy needle (Procore), which was our first-choice needle for EUS tissue acquisition at the time.

EUS was performed in patients referred with an indication to investigate lesions accessible by EUS-FNB, as determined by a specialist. Cases were included if any solid tissue biopsy was performed at the time of EUS. In cases where mixed solid-cystic lesions were biopsied, only samples from solid components were included in analysis. Fluid samples were excluded. Cases where biopsy was not deemed necessary by the proceduralist based on endosonographic findings, or where biopsy was deemed unsafe, were excluded. Only adult patients were included (defined as older than 16 years).

Data collected at the time of procedure included the type of needle used, number of needle passes taken, the lesion location, approach type, and operator.

Adverse events attributable to EUS-FNB were determined by retrospective review of the electronic medical record.

Technique

In all cases, the same technique was used to avoid confounding by factors other than needle type. A linear array echoendoscope (UCT180; Olympus America Corp, Center Valley, PA) was used, with patients placed under procedural sedation by an anesthetist. A slow stylet pull technique was used in all cases. We preferentially used a fanning technique unless the sampled lesion was very small and would not allow this. All samples were obtained by 1 of 2 consultant proceduralists (A.H., A.S.J.) or a fellow under direct consultant supervision. In cases where a fellow performed the procedure, at least 1 biopsy pass was also performed by the supervising consultant. One to 2 passes were performed to prepare smears for ROSE. Slides were stained using a rapid staining solution (Diff-Quik; Baxter Diagnostics, Inc, McGraw Park, IL) and examined by a laboratory scientist qualified for ROSE. Subsequent passes were performed depending on ROSE sample characteristics. Needle rinsings including any visible cores were collected in Hanks balanced salt solution. They were centrifuged, embedded in agar and then fixed in formalin, and stained using hematoxylin-eosin to prepare cell blocks for interpretation.

Sample assessment

Samples were reported by the cytopathologist on duty on the day of the relevant procedure. The quality of cell blocks and cytological smears for all cases was also retrospectively assessed and graded by a single cytopathologist based on sample bloodiness (1–3), overall cellularity (1–3), and diagnostic material from clinical lesion, as summarized in Table 1. The cytopathologist grading the samples (K.V.) was blinded to the biopsy needle type and the medical record review outcome but was provided with patient demographic information, biopsy approach, and target lesion type.

For nondiagnostic cases, patients were followed up by review of their electronic medical record to determine the final diagnosis. Follow-up was conducted using data available 12 months after biopsy in all cases. Definitions for benign and malignant lesions in these cases were adapted from those presented in the study by Bang et al.[10] Malignant lesions were defined by 1 or more of the following: (1) further tissue sampling or surgical specimen demonstrating malignancy, (2) presence of metastatic disease or significant lesion progression on follow-up imaging, or (3) cancer-related morbidity or mortality at time of follow-up. Benign lesions were defined by the presence of either (1) a surgical specimen without evidence of malignancy, or (2) no lesion progression or metastasis on serial imaging follow-up. Lesions not meeting these criteria were labeled as indeterminate.

Outcome measures

The primary outcome measure was diagnostic yield, which was defined as the percentage of lesions sampled for which a tissue diagnosis was obtained.[11] A sample was considered diagnostic if cytological examination was reported as consistent with a certain condition, or if an adequate number of benign cells were seen such that a benign etiology could be confidently diagnosed, and this

Table 1

Scoring system for the cytological assessment of sample quality.

	Score
Diagnostic target material from clinical lesion	
Absent (no malignant cells)	0
Indeterminate (present, but difficult to distinguish between reactive and neoplastic)	1
Suspicious (present in small numbers or partly obscured)	2
Consistent (present in adequate numbers for diagnosis)	3
Sample bloodiness	
Usual amount of blood in background	1
More than usual amount of blood causing some interference with assessment	2
Excessive blood making assessment impossible	3
Cellularity	
Low	1
Moderate	2
High	3

correlated with the final diagnosis after follow-up. Secondary outcome measures included the number of needle passes, sample bloodiness, and target tissue cellularity.

Statistical analysis

Data were compared between all 3 groups using Fisher exact test or the Pearson χ^2, test depending on appropriateness in each scenario. Results were considered statistically significant with a $P < 0.05$. Post hoc testing was conducted with multiple pairwise comparisons of results appearing to reach statistical significance, and an adjusted cutoff for statistical significance was determined using a Bonferroni correction to minimize the chance of a type I error. The statistics reporting software SPSS (IBM SPSS Statistics for Windows, version 25.0; IBM Corp, Armonk, NY) was used.

RESULTS

A total of 118 cases were included in randomization for the prospective arms of the study: 59 were randomized to the Acquire arm and 59 to the SharkCore arm. Two cases were excluded from analysis in the latter arm, one in which the randomization occurred but no solid lesion was sampled and one in which the FNB needle malfunctioned. All 60 cases from the retrospective arm (reverse bevel) were included. Of note, there were small baseline differences between the target lesions in each group, with the Franseen group containing fewer pancreatic lesions and more lesions classified as "other" [Table 2]. Baseline characteristics between groups were otherwise similar.

We sampled a total of 176 lesions through all arms of the study, including 109 pancreatic lesions, 24 lymph nodes, 17 subepithelial lesions, and 26 other lesions. The approach was transduodenal in 81 cases, transgastric in 81 cases, transesophageal in 13 cases, and dual transgastric and transduodenal in 1 case. The final diagnosis was malignancy in 127 cases (pancreatic adenocarcinoma or advanced intraductal papillary mucinous neoplasm in 80 cases, pancreatic neuroendocrine tumor in 17 cases, gastrointestinal stromal tumor in 8 cases, and other malignancy in 22 cases). The final diagnosis was benign in 43 cases, and no final diagnosis was reached in 6 cases [see Table 4 for further breakdown]. One hundred sixty-eight of 176 cases were available to be reviewed for diagnostic target material, cellularity, and bloodiness—in 8 cases, slides were not available for analysis. At cytopathological review, a further 8 cases were upgraded to be diagnostic (where all had previously been categorized as suggestive of malignancy), following cytopathology review of all cases. Of note, there was adequate tissue to perform ancillary testing (immunohistochemistry) in all diagnostic samples.

Over all groups, EUS was diagnostic in 141 cases (80%) and nondiagnostic in the remaining 35 cases [Figure 1]. The overall diagnostic yield was 76.7% (46/60) for the reverse-bevel group, 84.2% (48/57) for the fork-tip group, and 79.7% (47/59) for the Franseen group. There was no statistically significant difference between each of the 3 needles in overall diagnostic yield, sample bloodiness, sample cellularity, or number of passes. Selected summary performance indicators are reported in Table 3.

Exploratory subgroup analysis was carried out by lesion type (pancreatic *vs.* nonpancreatic), final diagnosis (malignant or nonmalignant), and pretest clinical likelihood of malignancy (likely, indeterminate, unlikely). No statistically significant differences in needle performance indicators were identified in this analysis.

A total of 10 adverse events were recorded, including 3 cases of mild pancreatitis (2 in the reverse-bevel group and 1 in the fork-tip group); 3 cases of nonspecific abdominal pain, one of which required hospital admission; 1 case of mild duodenitis; 1 case of mild aspiration pneumonitis; and 1 case of intraprocedural hypertension without end-organ damage. There was no statistically significant difference in adverse events between groups.

DISCUSSION

Our results demonstrate that both the fork-tip and Franseen third-generation biopsy needles and the second-generation reverse-bevel needle are equivalent with respect to diagnostic yield. This is in keeping with the results of recent RCTs and meta-analyses and is contrary to early data suggesting superiority of the fork-tip needle.[12] To date, 2 other RCTs have been published comparing Franseen with fork-tip needles for EUS-guided tissue acquisition. In 2018, Bang et al.[10] demonstrated equivalence between these needles for the sampling of pancreatic solid mass lesions in a small ($n = 50$) RCT (diagnostic yield 96% [Franseen] *vs.* 92% [fork-tip], $P = 0.32$). More recently, Ashat et al.[13] published similar results in a study where all accessible solid lesions were included ($n = 150$) and confirmed no difference between needle performance (diagnostic yield, 86.7% *vs.* 92%; $P = 0.43$). Of note, both studies used 22-gague needles and ROSE for all cases.

Two meta-analyses have recently been published that also demonstrate minimal difference between the Franseen and fork-tip needles. Mohan et al.[9] included results from 21 studies and reported a pooled diagnostic yield of 92.7% for the Franseen needle and 92.8% for the fork-tip needle. Interestingly, a second meta-analysis published by Facciorusso et al.[14] specifically assessed sample adequacy rather than diagnostic yield and showed a slight advantage of the Franseen needle over the fork-tip (96.1% *vs.* 92.4%). However, there was no difference in diagnostic accuracy or sensitivity between groups. Of note, both studies included predominantly single-cohort noncomparative trials, and high heterogeneity was observed in both, with variable needle sizes and variable use of ROSE.

Table 2

Selected baseline characteristics.

	Reverse-bevel (*n* = 60)	Fork-tip (*n* = 57)	Franseen (*n* = 59)
Age, median (IQR), y	68.1 (13.2)	62.4 (24.0)	64.6 (16.29)
Sex, *n* (%)			
Female	32 (53)	23 (40)	27 (45)
Male	28 (47)	34 (60)	32 (55)
Indication, *n* (%)			
Pancreatic mass	43 (72)	35 (61)	31 (52)
Lymphadenopathy	7 (12)	10 (18)	7 (12)
Subepithelial lesion	3 (5)	6 (10.5)	8 (13)
Other*	7 (12)	6 (10.5)	13 (22)
Lesion size, median (IQR), mm	24.5 (16)	27.0 (15)	27.0 (21)
Approach,† *n* (%)			
Transesophageal	2 (3)	5 (9)	6 (10)
Transgastric	25 (42)	30 (53)	28 (47)
Transduodenal	33 (55)	22 (38)	27 (45)
Operator, *n* (%)			
A	24 (40)	24 (42)	24 (40)
B	36 (60)	33 (58)	35 (59)
Fellow present	34 (57)	34 (60)	32 (53)

*Lesions in the 'other' group included 9 liver or biliary, 6 ampullary, 3 duodenal, 4 peritoneal or retroperitoneal, 3 mediastinal, and a pancreatic stricture.

†Where multiple approaches were used for the same case, all were included in these data.

There is a paucity of reported data comparing the diagnostic yield of the second- and third-generation EUS-FNB needles. There are 2 studies we are aware of that compare the reverse-bevel needle with the fork-tip needle, showing conflicting results. Abdelfatah et al.[15] conducted a large (*n* = 300) retrospective cohort study including all lesion types and showed equivalent diagnostic yield for the fork-tip and reverse-bevel needle (77% *vs.* 74%, respectively). Nayar et al.[16] compared the same needles in a cohort (*n* = 200) that comprised pancreatic lesions and demonstrated superiority of the fork-tip needle (95% *vs.* 75%). Rapid on-site evaluation was not used in the latter study. Our data are very similar to that reported by Abdelfatah et al.[15]

Needle size

Our study is the first to demonstrate equivalence of these needles exclusively using the smaller 25G size and the first to report any data on the performance of the 25G Franseen needle. We chose this size for our study as available evidence suggests there is no improvement in diagnostic yield with larger needles,[17,18] and smaller needles may reduce sample bloodiness[19] and may be easier to use. The reason for this is 2-fold; first, larger needles lead to increased puncture resistance,[17] and second, they may be less flexible, complicating sampling in certain echoendoscope positions—especially for pancreatic head lesions using the transduodenal approach.[20] In addition, literature suggests that a histologic core of tissue can still be obtained using 25G core biopsy needles.[21]

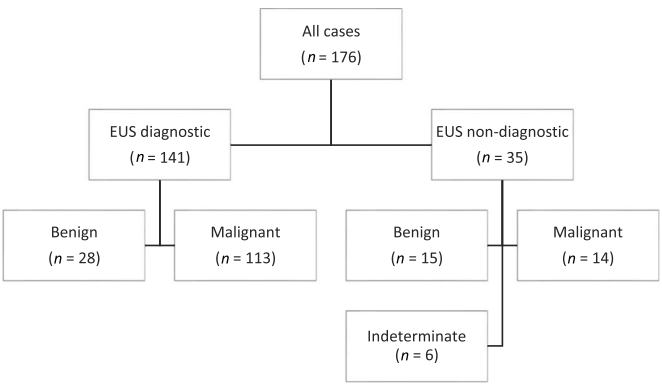

Figure 1. Breakdown of final diagnosis for diagnostic and nondiagnostic EUS–guided fine-needle biopsy.

Tissue preparation

Currently, the optimal method for preparation of EUS core biopsy samples is unclear, and available studies vary in approach. All specimens in this study were prepared as cell blocks and not sent in formalin for direct histologic processing as cores. This was done to ensure uniform treatment of all groups regardless of whether a visible core was obtained. Importantly, centrifuging samples to create a cell block does not destroy tissue architecture,[10] and so cores obtained were still visible for analysis, and histologic techniques such as immunohistochemistry were able to be performed if appropriate.

Use of ROSE

Rapid on-site evaluation was used in all cases, as this is standard practice at our institution, and there is evidence that it may improve diagnostic yield in EUS-Tissue Acquisition.[5] The evidence for this is conflicting, and newer studies have shown that ROSE may not improve diagnostic yield when core biopsy needles are used.[22] In our experience, the use of ROSE increases procedure time, and other evidence shows that it increases procedure costs.[23]

Number of passes

The median number of passes performed across all groups in our study (4 passes) was slightly higher than that in similar studies that use ROSE, many of which used only 2 or 3 passes. This may be because at our institution slides are prepared and evaluated by a cytological scientist and not by the reporting cytopathologist. An

Table 3

Summary performance indicators for the three 25-gauge core biopsy needles.

	Reverse-bevel	Fork-tip	Franseen
Diagnostic yield: diagnostic samples, *n* (%)			
Total	46 (76.7)	48 (84.2)	47 (79.7)
Pancreatic	36 (83.7)	32 (91.4)	26 (83.9)
Nonpancreatic	10 (58.8)	16 (72.7)	21 (75.0)
Cellularity (1–3), mean ± SEM			
Total	2.25 ± 0.10	2.35 ± 0.08	2.49 ± 0.07
Pancreatic	2.35 ± 0.12	2.34 ± 0.12	2.55 ± 0.09
Nonpancreatic	2.00 ± 0.18	2.36 ± 0.12	2.42 ± 0.10
Sample bloodiness (1–3), mean ± SEM			
Total	1.58 ± 0.09	1.35 ± 0.07	1.49 ± 0.07
Pancreatic	1.51 ± 0.10	1.31 ± 0.08	1.42 ± 0.09
Nonpancreatic	1.75 ± 0.19	1.41 ± 0.11	2.42 ± 0.10
No. passes, mean ± SEM	4.10 ± 0.13	4.07 ± 0.12	4.10 ± 0.12

No statistically significant differences between groups were identified for the above performance indicators.

increased number of passes may result in longer procedure time, but importantly does not increase procedure complication rates.[23]

Diagnostic yield compared with other cohorts

The diagnostic yield reported in our study (approximately 79.0% overall and 84.4% for pancreatic lesions) is lower than that reported by other similar trials. We postulate several reasons for this. First, there are no universally accepted definitions for diagnostic and nondiagnostic samples—particularly in the sampling of truly benign lesions. We were conservative in our definitions, and samples confirming benign lesions were considered diagnostic only if adequate sample cellularity was present and clinical follow-up confirmed the presence of a benign lesion. For malignant lesions, we considered only samples reported as "consistent" with malignancy to be diagnostic—samples characterized as suspicious, suggestive, or atypical were all considered nondiagnostic. Our cohort contained many benign lesions (approximately one-quarter) and therefore may underestimate true diagnostic yield. Second, operator experience has been shown to impact diagnostic performance of EUS-TA.[24] Our center is relatively low-volume, performing between 300 and 400 EUS procedures annually, compared with other academic centers; this relatively low exposure may have influenced our overall diagnostic yield.

Table 4

Final diagnoses for all patients undergoing EUS–guided fine-needle biopsy.

Diagnosis	Count (*n*)
Malignant	
Pancreatic adenocarcinoma	76
Pancreatic neuroendocrine tumor	17
Metastatic malignancy	14
Gastrointestinal stromal tumor	8
Advanced intraductal papillary mucinous neoplasm	4
Lymphoma	3
Other malignancy	5
Benign	
Benign lymphadenopathy	9
Pancreatitis	6
Leiomyoma	5
Granulomatous inflammation	4
Accessory spleen	2
Bronchogenic cyst	2
Other benign	15
No final diagnosis	6

Strengths and limitations

The main strength of this study is the similarity with which all 3 groups were treated—the same needle gauge and needling technique were used in every case, and ROSE was always present. In addition, the same 2 operators were used for all cases, minimizing confounding.

There were some limitations to our study as well. The "real-world" nature of the study produced heterogeneous data as all lesions sampled during the study period were included. This produced small subgroups for nonpancreatic lesions, increasing the chance of a type II error. In addition, the decision to select sample size based on pragmatic considerations means that the study was not adequately powered to detect small differences between the needles. Although large differences are confidently excluded, further, more robust studies or meta-analyses are required to validate our results.

Second, we used only 25G needles, and so our results may not be extrapolated to other needle sizes. Finally, the mixed retrospective-prospective nature of the study may introduce confounding when comparing the retrospective cohort data for the reverse-bevel needle to the prospective randomized data of the third-generation needles. We feel the impact of this would be small as the technique used did not change between the retrospective and prospective arms.

CONCLUSION

Overall, our study adds weight to the current literature demonstrating no significant difference in diagnostic yield between the Franseen and fork-tip third-generation EUS 25G core biopsy needles. It also demonstrates equivalent performance of the second-generation reverse-bevel needle in a real-world setting. Therefore, needle choice should be based on other factors such as cost, local availability, and operator preference.

Declaration of Patient Consent

The authors certify that they have obtained all appropriate patient consent. In the form, the patient's guardians have given their consent for her/his images and other clinical information to be reported in the journal. The patient's guardians understand that her/his names and initials will not be published, and due efforts will be made to conceal her/his identity, but anonymity cannot be guaranteed.

Conflicts of Interest

The authors declare that they have no financial conflict of interest with regard to the content of this report.

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Not applicable.

Data Sharing

Not applicable.

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Author Contributions

Alexander Huelsen designed the study, performed EUS procedures as part of the study, collected data, assisted writing the manuscript, and reviewed the manuscript. Andrew St John designed the study, performed EUS procedures as part of the study, collected data, and reviewed the manuscript. Kasturi Vaska reviewed cytopathology for the study and reviewed the final manuscript. Xuan Banh assisted in study design and obtained ethical approval for the study. Adam Haig collected and analyzed data and wrote the manuscript. The manuscript has been read and approved by all the authors and the requirements for authorship as stated in the journal's "instructions to authors" document have been met, and each author believes that the manuscript represents honest work.

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