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ORIGINAL ARTICLE

A prospective randomized study comparing transnasal and peroral 5-mm ultrathin endoscopy

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Background/Purpose: Differences in patient tolerance, acceptance, and satisfaction of esophagogastroduodenoscopy (EGD) between transnasal (TN) and peroral (PO) routes using a 5-mm video endoscope.
Methods: A total of 220 enrolled patients were assigned randomly to two groups undergoing EGD—110 patients each for TN and PO. The successful rate, procedure time, and adverse events were recorded. After the procedure, patients answered a validated questionnaire of tolerance, acceptance, and satisfaction.
Results: There were 6 failures (5.7%) of nasal intubation and two nasal bleeding (2%) among 105 TN-EGD procedures. All PO patients ($n = 102$) completed EGD successfully without adverse event. Compared to PO, the procedure of TN achieved lower successful rate (94% vs. 100%, $p = 0.01$), was complicated with epistaxis (2% vs. 0%) and took longer (mean $\pm$ SD 19.9 ± 6.1 min vs. 16.8 ± 6.4 min, $p = 0.0001$). The patients undergoing TN-EGD indicated less discomfort during passing pharynx (scores of 2.1 ± 2.0 vs. 3.1 ± 2.6, $p = 0.011$) but more pain during inserting scope (scores of 2.2 ± 1.6 vs. 1.5 ± 1.8, $p = 0.0001$). Eventually, there were no significant differences between TN and PO regarding the overall procedure discomfort (scores of 10.7 ± 6.6 vs. 11.1 ± 7.8 scores, $p = 0.9$), satisfaction (scores of 41.2 ± 4.2 vs. 41.3 ± 4.6, $p = 0.91$), and acceptability (87.8% vs. 94.2%, $p = 0.91$).
Conclusion: PO intubation seems an excellent alternative method when using a 5-mm ultrathin endoscopy because it achieves comparable patient tolerance, acceptance, and satisfaction as TN intubation, takes less time and causes lower intubation failure and epistaxis.

Conflicts of interest: The authors have no conflicts of interest relevant to this article.

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Introduction

Esophagogastroduodenoscopy (EGD) is frequently performed for the diagnosis of esophagogastroduodenal disease. Standard EGD entails oral passing of flexible endoscope with a diameter of 9 to 10 mm after local anesthesia of the pharynx. In western countries, this procedure is often performed with patient under conscious sedation, to reduce agitation resulting from discomfort and pain.[1] However, sedation may increase the costs and cause additional cardiopulmonary complications.[1,2] Many efforts have therefore been made to improve feasibility and the tolerance of unsedated endoscopy.[3–5] In addition, new small-caliber video endoscopes (with diameter 5—6 mm) have been developed to facilitate peroral (PO) and transnasal (TN) endoscopy for the upper gastrointestinal tract without sedation.[6–17]

Previous research has reported conflicting results regarding the acceptance and tolerance of small-caliber endoscopy.[8,11,13,14] While some studies have underlined the importance of a small-diameter instrument for patient tolerance,[11,15] others have pointed out that the route is the determining factor.[12] In addition to patient tolerance, other factors associated with patient satisfaction of the endoscopic procedure include age, sex, marital status, social-economic status, anxiety, doctor skill, and schedule time.[18,19] However, the endoscopic effect on patient satisfaction, such as scope size and scoping route, have rarely been discussed previously. TN endoscopy is reported to have better acceptance and tolerance than conventional endoscopy for conscious procedures.[7–10,17]

However, a 2% to 22% failure rate of nasal intubation and nasal bleeding is reported to be inevitable on series studies of nasal endoscopy.[8,9,12–14,16,20] It is supposed that PO intubation of a 5-mm ultrathin nasal endoscope is as patient-friendly as nasal endoscopy and does not have the complications of epistaxis and intubation failure. The PO route may be a good alternative when using the ultrathin 5-mm endoscope. Therefore, we conducted this study to compare differences in clinical outcome and patients' tolerance, acceptance, and satisfaction between TN and PO routes using a 5-mm video endoscope.

Materials and methods

The study was conducted in the outpatient clinic of Pingtung Christian Hospital in Taiwan, and approved by the institutional review board of the hospital (IRB157A). The study cohort included patients aged between 18 and 80 years, who were willing to undergo TN- or PO-EGD after receiving an explanation of the endoscopic procedure. Exclusion criteria consisted of a scheduled therapeutic endoscopic intervention, and known bleeding or psychiatric disorders. Informed consent was obtained from all participants. Patients were randomly and equally, by the order of visiting, assigned alternately to TN and PO groups. For both groups, a 5-mm ultrathin endoscope (Olympus GIF-N-260; Olympus, Tokyo, Japan) was used, with outer diameter at distal end 5 mm, 2-way angulations-210° up and 90° down, with no right/left deflection, and working channel 2 mm.

All patients were prepared with pharyngeal anesthesia with 10% lidocaine spray (AstraZeneca Company, London UK), after which, TN patients were additionally prepared with endoscope guided nasal anesthesia, spraying 2 to 3 ml of 2% lidocaine and 2 to 3 ml of 0.05% epinephrine to the inserting nasal meatus via a catheter (Olympus PW-6p-1 spray-type washing pipe, 2 mm channel, working length 190 cm) through the working channel of the ultrathin scope.[20] No sedative agent was administered to the patients. The EGD procedure was performed by a single senior endoscopist experienced with both TN ultrathin EGD and PO ultrathin EGD in at least 100 individuals.

The primary outcomes of our study were patient tolerance, acceptance, and satisfaction of the procedural performance of unsedated ultrathin EGD, via either the TN or PO route. Tolerance was defined as the discomfort such as pain or gagging or any suffering during the anesthesia, insertion of the endoscope, checking of the stomach, and endoscope extraction measured using a 10-point visual analogscale (VAS) – 0 means no discomfort, 10 means severe and unbearable discomfort.[21] Acceptance was defined as the willingness to receive the same procedure in the future. Validated questionnaires of patient satisfaction for EGD was modified from Rubin's rating.[22] Patient satisfaction was measured with a Likert 5-scale, asking about perceptions for endoscopic procedures, physician's technical skill, the time spent in waiting and procedure, privacy during endoscopy, physician's explanation of procedure as well as result of endoscopy, and physician's/nurse's serving manner. The total sum score is 50 for validated satisfaction questionnaire of which expert validity by 5 experts is 4.2 and reliability by Cronbach's alpha is 0.86.

Before the procedure, each patient's demographic characteristics, anxiety, EGD experience, and EGD knowledge (7 questions about EGD procedure were asked) were obtained. Heart rate and oxygen saturation from patient were recorded before the procedure and at 2 min, 4 min, 6 min, and 8 min during the procedure. The frequencies of gaggling and choking, procedure time, and intubation time were also observed and recorded by a single observer. If nasal intubation failed, patients were crossed over to PO-EGD and were not given postprocedure questionnaires. The failure rate of intubation and adverse episodes such as bleeding were observed. All interventions were recorded on a standardized form and all patients were asked to complete the validated questionnaires. The secondary outcome were defined as the change of heart rate and oxygen saturation before and after the procedure, the number of successfully completed procedures in each group, time taken in endoscopic intubation and the whole procedure, and the number of adverse events in each group.

Statistics

Results are expressed as mean ± standard deviation for quantitative variables and frequency for categorical variables. Normally distributed quantitative variables were analyzed by the Student's *t* test. If normal distribution was not expected and no significant difference was found by Student's *t* test, nonparametirc analysis using Kruskal-Wallis and Mann-Whitney *U* tests were performed.

Table 1 Patient characteristics between group TN and PO.

	TN	PO	*p* value
Patient number	110	110	
Sex (M%)	48%	50%	0.94*
Age (mean ± SD)	49.9 ± 12.2	47.6 ± 14.2	0.2†
BMI (mean ± SD)	23.49 ± 3.55	23.4 ± 3.3	0.56†
EGD knowledge (0–7)	5.6 ± 1.1	5.66 ± 1.15	0.88†
Marriage status Single/married/divorced/widowed	13/77/3/6	18/72/6/5	0.37*
Years of education <1/1–6/6–9/9–12/12–16/>16 y	5/17/14/40/27/6	6/15/16/38/30/5	0.7*
EGD experience (%)	52.8%	47.2%	0.19*
Anxiety for EGD (1–5)	2.69 ± 1.05	2.85 ± 1.18	0.29†

*Chi-square test; † Student *t* test.
PO = peroral and TN = transnasal.

Categorical variables are analyzed with the Chi-square test. All statical analysis were carried out using SPSS software (Version 12).

In this study, we aimed to compare the performance of transoral intubation with that of TN intubation. In a previous study comparing TN and transoral intubation of a 5.5 mm scope, the discomfort score of nasal discomfort was 2.3 ± 0.3 vs. 4.3 ± 0.3 and the proportion of patients willing to receive the same treatment was 95% vs. 75%.[12] Based on this information, to detect the difference at a 5% significance level, an 80% power, and a single-tail hypothesis, the sample size of 100 for each group would suffice.

Results

A total of 220 patients consented to participate in this study and were assigned randomly to two groups of 110 patients. Statistically, there were no differences in terms of patient's demographic characteristics including age, sex, marriage, BMI, education, anxiety degree before procedure, frequencies of previous EGD experience, and knowledge of EGD between group TN and PO (Table 1). There were 5 and 8 patients withdrawn, respectively, for the TN and PO routes after they had been allocated because they did not attend at the scheduled time. Thus, 207 patients (age 48.7 ± 13.3 years, BMI 23.4 ± 3.4, male 48.8%, married 74%, and experienced EGD 63.2%) attended to complete the EGD procedure and answered the questionnaires.

Less gagging reflex was noted objectively by the observer in TN-EGD than in PO-EGD (scores of 1.7 ± 3.3 vs. 2.8 ± 3.8, $p = 0.004$) (Table 2). The patients undergoing TN-EGD also indicated better tolerance during passing pharynx (scores of 2.1 ± 2.0 vs. 3.1 ± 2.6, $p = 0.011$) but less during insertion of the scope (scores of 2.2 ± 1.6 vs. 1.5 ± 1.8, $p = 0.0001$). Eventually, there were no difference of total VAS scores for the whole procedure between TN and PO (scores of 10.7 ± 6.6 vs. 11.1 ± 7.8, p = 0.9; Table 3). There were no significant difference between TN and PO regarding satisfaction (scores of 41.2 ± 4.2 vs. 41.3 ± 4.6, $p = 0.91$) and acceptability (87.8% vs. 94.2%, $p = 0.91$; Table 4).

There were six failures (5.7%) of nasal intubation due to anatomic problem in the 105 TN-EGD procedures and two nasal bleeding (2%) which stopped spontaneously or after spraying epinephrine solution. All PO patients ($n = 102$) completed EGD successfully without adverse events (Fig. 1 and Table 1). The endoscopic diagnosis and number of biopsy taken, heart rate, and oxygen saturation before and after the procedure were not different between groups

Table 2 Patient outcomes between TN and PO.

	TN	PO	*p* value
EGD success (%)	94%	100%	0.01*
Bleeding	2	0	
Pre-EGD HR	98 ± 16	98 ± 17	0.99†
Pre-EGD PaO_2	98.3 ± 1.8	98.1 ± 1.7	0.85†
Scoping HR	102 ± 19	103 ± 20	0.67†
Scoping PaO_2	98.5 ± 1.9	98.4 ± 1.7	0.17†
Procedure time (min)	19.9 ± 6.1	16.8 ± 6.4	0.0001†
Intubation time (s)	195 ± 59	168 ± 39	0.0001†
Observed gagging	1.7 ± 3.1(0-13)	2.8 ± 3.8(0-20)	0.004‡
No/CLO test/biopsy	53/31/15	55/34/14	0.95*
Endoscopy diagnosis (Np/GI/GERD/PU/polyp)	1/35/8/47/8	3/43/13/40/4	0.28*

*Chi-square test; † Student *t* test; ‡ Nonparametric Kruskal-Wallis test.
GERD = gastroesophageal reflux disease; GI = gastritis; HR = heart rate; Np = normal; PaO_2 = oxygen saturation; PU = peptic ulcer.
PO = peroral and TN = transnasal.

Table 3 Patient's discomfort visual analog scales (0—10) during anesthesia, inserting scope, passing pharynx, checking GI tract and extracting scope.

	TN	PO	*p* value
Anesthesia	2.7 ± 1.7	2.8 ± 2.2	0.84
Insertion	2.2 ± 1.6	1.5 ± 1.8	0.0001
Passing pharynx	2.1 ± 2.0	3.1 ± 2.6	0.011
Examination	2.0 ± 1.9	2.3 ± 2.1	0.347
Extubation	1.7 ± 1.6	1.3 ± 1.7	0.45
Total (0—50)	10.7 ± 6.6	11.1 ± 7.8	0.9

Nonparametric analysis, Mann-Whitney *U* test, significant if $p < 0.05$.
PO = peroral and TN = transnasal.

(Table 2). Compared to PO, TN took more time from premedication to the end of procedure (19.9 ± 6.1 min vs. 16.8 ± 6.4 min, $p = 0.0001$) and from endoscopic intubation to extubation (195 ± 59 s vs. 168 ± 39 s, $p = 0.0001$).

Discussion

TN-EGD with a small-diameter endoscope has became popular in recent years for diagnosing upper gastrointestinal disorders. Reports suggested that it is significantly more patient-friendly than standard EGD. Is this because that TN endoscope is inserted without touching the tongue base and induces less gagging reflex,[7] or it is due to the decreased stimulation of the smaller endoscopic size? We designed this randomized study to compare the tolerance, acceptance and satisfaction of the unsedated ultrathin EGD in the patient's perspectives, between TN and PO routes.

This study demonstrates that using 5-mm ultrathin endoscope performed through either nasal or oral route achieves no statistically significant difference in terms of patient perception. However, there were two (2%) developments of epistaxis and six (5.7%) failures of nasal insertion due to anatomic reasons among the 105 patients undergoing the TN-EGD procedure. The incidence of epistaxis and insertion failure rate was reported to be 1.9% to 6.7%, and 5 to 10.9% respectively for 5.3-mm and 5.9-mm diameter endoscopes, respectively.[12,13,20] In this study, we prepared the nasal cavity with a more acceptable method in which less anesthesia discomfort and insertion pain were reported: endoscope-guided spraying with anesthesia agent and vasoconstrictor. [20]The epistaxis incidence and insertion failure rate of our group is also similar to that reported by Hu (2% vs. 1.9% and 5.9% vs. 7.7%).[20]

Table 4 Patient satisfaction and acceptability in Group TN and PO.

	TN	PO	p value
Satisfaction (mean ± SD) *(total 0—50 scores)*	41.2 ± 4.2	41.3 ± 4.6	0.91*
Willing to choose the same procedure (Yes%)	87.8%	94.2%	0.12†

*Student *t* test; † Chi-square test.
PO = peroral and TN = transnasal.

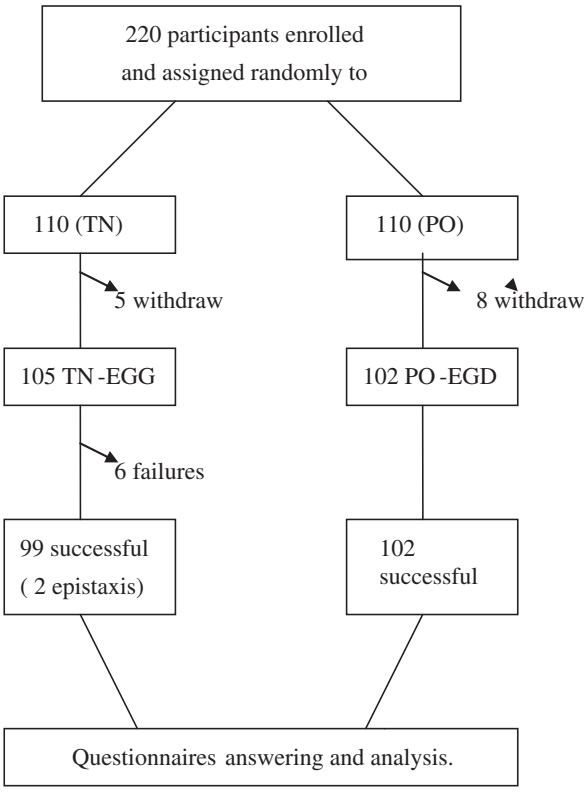

Figure 1 Flow chart from enrolment to treatment.

No significant change of the heart rate or oxygen saturation before or after procedure was observed between TN and PO groups, comparable with previous results.[8] Duration of procedure, regardless of total examination or intubation time, is longer in TN-EGD than PO-EGD, as reported in previous studies.[10,12] Longer insertion distance to esophagus and the endoscopist's concern for nasal pain during intubation are the hypothesized reasons.

Previous studies have described being elderly, of male sex, and having low anxiety as important factors for patients' acceptance and tolerance.[5,18] Patients with TN endoscopy reported better tolerance and higher willingness to choose the same procedure than standard unsedated endoscopy,[7,8,10] and even responded comparable acceptance with sedated endoscopy.[17,23] Mulcahy et al reported that smaller endoscope size was the major factor for acceptance of oral intubation.[10] There are conflicting results about the scoping route; Rey et al and Zaman et al reported that 6-mm TN-EGD patients ($n = 29$) experienced significantly more pain on insertion than 6-mm PO-EGD ($n = 30$) but there was no difference in overall discomfort and acceptance between them.[14,15] Thota et al suggested that 4-mm TN-EGD($n = 44$) had better tolerance than 4-mm PO-EGD.[11] Murata et al found lower discomfort in 5.9-mm TN-EGD ($n = 62$) than 5.9-mm PO-EGD ($n = 62$) and favored 5.9-mm TN over 5.9-mm PO endoscopy in patient's acceptance.[12] A common theme appears: when using a 6-mm endoscope, the TN route was not preferred over the PO route because of the difficulty of insertion, more insertion pain, and longer procedure time in spite of comparable tolerance; as the endoscope diameter decreases, the TN route may be the preferred option.

However, using a larger sample size, Watanabe et al described no significant difference of tolerance between 5.5-mm TN-EGD ($n = 100$) and 5.5-mm PO-EGD ($n = 100$) but found higher acceptability in PO-EGD.[13] They concluded that the PO route is superior to TN when using an ultrathin endoscope because of the adverse epistaxis and insertion failure of TN. Most western studies favored TN insertion when using a small-caliber endoscope. Watanabe reported different results in the East when using smaller 5.5-mm endoscope. Our study, using nasal anesthesia with less insertion pain, supports Watanabe's finding. That may be the result of the difference in anatomy of the nasal cavity and culture of the East.

The sample size ($n = 110$) and primary outcome of tolerance and acceptance of this study were comparable with Watanabe's randomized study in which all Japanese patients experienced EGD, TN-EGD patients were anesthetized with viscous lidocaine and vasoconstrictor spraying, and the procedures were performed by different experienced physicians with a 5.5-mm endoscope (XP260N, Olympus) with a 5% failure of nasal intubation. We used endoscope-guided nasal anesthesia to reduce the discomfort of nasal anesthesia and nasal insertion,[20] and all examinations were performed by a single experienced physician to exclude skill bias. PO-EGD was still comparable with TN-EGN in tolerance and acceptability. Although 53% of TN-EGD patients had never experienced EGD previously, this was not significantly different from 48% of PO-EGD patients ($p = 0.7$). A possible causes for comparable results between TN and PO routes in this study is that the smaller scope size decreases pharyngeal stimulation and improves tolerance in oral intubation.[10] Attempting higher success of nasal intubation may conflict with the tolerance of TN-EGD. In our patients, six failures of nasal intubation were due to anatomic problem rather than unbearable discomfort and the failure rate is better than that seen by Hu (5.7% vs. 7.7% with similar anesthesia in Taiwanese patients). The failure rate in Zaman's group was 14% and 1/4 of these were due to unbearable discomfort[14]; this may be a bias from the physician's attempt and only a crossover study could counteract this problem.

Few studies on the satisfaction of endoscopy procedures have been published. Previously, Ross reported physician's skills as the best predicting factor for satisfaction.[24] Raymond et al concluded that young age, high income, high social status, female sex, and psychogenic disorder were associated with dissatisfaction.[25] However, the effects of endoscope size and scoping route on satisfaction have not been considered previously. Satisfaction is difficult to define and measure objectively. Our study measured satisfaction scales by modifying Rubin's rating of outpatient visits, in which access by telephone and convenience of office location were replaced by privacy during endoscopic examination and the perceptions of endoscopic procedures. In this study, patients completed the questionnaires immediately after endoscopy. The benefit of on-site questionnaires is that patients can respond while their perceptions are fresh; however, they may feel under pressure and respond with higher satisfaction. As the data show, the mean satisfaction scores is 41 (4.1 score for each item, which means excellent) for both groups. The demographic factor was controlled by randomization, and the bias of physician's skill was controlled by a single operator and single endoscopy center in this study. This study demonstrated that no difference of satisfaction was observed between TN and PO intubation of 5-mm small scope.

A limitation of this study is that a two-way endoscope was used for the EGD examination, which is not as good as a four-way endoscope. Thota[11] suggested using a little torque to overcome the absence of right and left dials. In our single-center experience, it has proved easy with practice to enter the second portion of duodenum and to approach the target of biopsy. A second limitation is that it was not a crossover study. Therefore, a large case number was enrolled in both groups to counteract intergroup bias. Besides, the design of single center, single operator, and single observer eliminates the interpersonal bias and the crossover study could also overcome the personal bias.

In conclusion, this study showed no significant difference in patient tolerance, acceptance, or satisfaction between PO and TN routes when using 5-mm endoscopy but the success rate is higher (100% vs. 94%), the procedure time shorter (16.8 ± 6.4 min vs. 19.9 ± 6.1 min) and rate of adverse events is lower (0% vs. 2 %) with the PO route. Our study suggests that PO intubation is an excellent alternative method when using ultrathin endoscope because it has comparable tolerance, acceptance, and satisfaction as TN intubation but is less time consuming, and has lower complication and failure rates.

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