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Use of an electromagnetic-guided device to assist with post-pyloric placement of a nasoenteral feeding tube: A systematic review and meta-analysis

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ABSTRACT

Background and study aims While endoscopic-guided placement (EGP) of a post-pyloric nasoenteral feeding tube may improve caloric intake and reduce the risk of bronchoaspiration, an electromagnetic-guided placement (EMGP) method may obviate the need for endoscopic procedures. Therefore, the primary aim of this study was to perform a systematic review and meta-analysis of randomized trials comparing the efficacy and safety of EMGP versus EGP of a post-pyloric feeding tube.

Methods Protocolized searches were performed from the inception through January 2021 following PRISMA guidelines. Only randomized controlled trials were included comparing EMGP versus EGP. Study outcomes included: technical success (defined as appropriate post-pyloric positioning), tube and patient associated adverse events (AEs), time to enteral nutrition, procedure-associated cost, and procedure time. Pooled risk difference (RD) and mean difference (MD) were calculated using a fixed-effects model and heterogeneity evaluated using Higgins test (I^2).

Results Four randomized trials (n = 536) were included. A total of 287 patients were included in the EMGP group and 249 patients in the EGP group. There was no difference between EMGP versus EGP regarding technical success, tube-related AEs, patient-related AEs, procedure time, and time in the right position. Time to enteral nutrition favored EMGP (MD: −134.37 [−162.13, −106.61]; I^2 = 35 %); with significantly decreased associated cost (MD: −127.77 ($) [−135.8–119.73]; I^2 = 0 %).

Conclusions Based on this study, EMGP and EGP were associated with similar levels of technical success and safety as well as time to complete the procedure. Despite this, EMGP was associated with reduced cost and time to initiation of nutrition.

Introduction

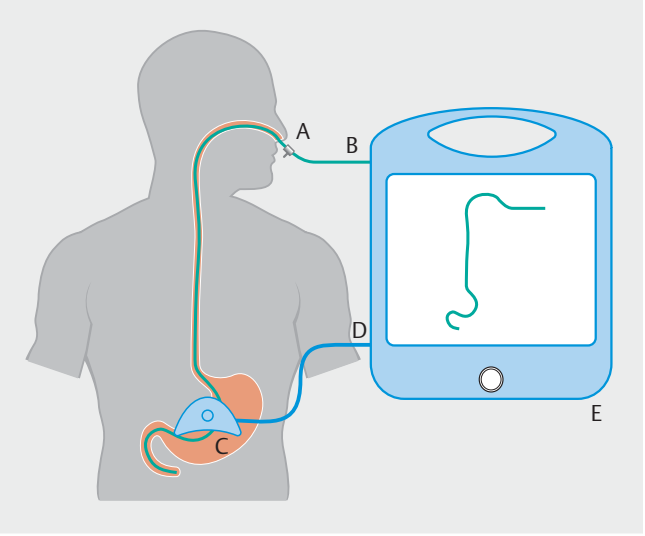
Nasoenteral feeding tubes remain a key procedure to aid clinical conditions that make oral intake impossible and diseases that result in a catabolic state where oral intake becomes insufficient [1]. This type of enteral feeding has the advantage of being temporary and easily removable, with very infrequent adverse events (AEs) occurring as a result of tube placement or use [2]. Despite this advantageous safety profile, some patients

may require post-pyloric placement of a feeding tube with nutrition delivered directly to the small intestine for a variety of reasons [3]. Given the low success rate of post-pyloric placement due to the blind passage of the tube, fluoroscopy or endoscopy may be commonly employed given the ability to afford direct visualization and higher associated success rates with proper placement [3,4].

While endoscopic-guided placement (EGP) may be performed via a variety of techniques, placement of a nasoenteral feeding tube alongside the endoscope is traditionally the most common strategy employed. This method may make use of friction of the gastroscope in parallel to the tube to guide the tube to a post-pyloric location, involving the use of a wire on the distal end of the feeding tube and traction provided with forceps, or include use of a guidewire. While a variety of techniques can be employed to achieve EGP, this is usually the preferred method of choice, with very low complication rates and success rates in the literature approaching 90 % to 95 % [5]. Despite being the most common and widespread method, endoscopy is not without limitations. These include invasiveness of the technique, necessity for a specialist physician or endoscopist, staff mobilization, as well as use of resources (i. e., need for various devices, materials, and cost). As such, newer technologies designed to overcome these limitations have been explored.

In the last several years, use of magnetic energy has emerged as way to assist with feeding tube placement [6]. In 2008, an electromagnetic-guided placement (EMGP) device was introduced, which is capable of real-time tracking and displays both the traveled path and the ultimate location of the feeding tube. This EMGP is performed similarly to the traditional blind passing for a nasoenteral tube and can be performed at the bedside, with no sedation or need for a radiograph to confirm position [7]. However, the system consists of a transmitting guidewire, which is passed inside the feeding tube. A receptor is then placed external to the patient at the xiphoid process to capture the signal emitted by the guidewire, displaying at a monitor the path of the feeding tube in real-time, thus providing instant feedback during placement and confirming the post-pyloric location (▶ **Fig. 1**) [4].

Although EMGP may obviate the need for sedation and endoscopy, this system is not available at all centers. In addition, high-quality comparative data have been lacking for EMGP and EGP of nasoenteral tubes. A previous systematic review showed highly variable results for these techniques; however, important clinical outcomes regarding cost and procedure time have not been evaluated to date [8]. An additional meta-analysis was also performed comparing EGMP, EGP, and fluoroscopic placement techniques; however, that study included lower-quality observational data and fewer randomized studies [4]. The primary aim of this study was to perform a structured systematic review and meta-analysis of randomized trials comparing efficacy and safety of EMGP as well as clinical outcomes versus traditional post-pyloric nasoenteral feeding tube.



▶ **Fig. 1** Illustration of the electromagnetic-guided placement of feeding tubes. **a** Feeding tube. **b** Magnetic guide wire. **c** Receiver. **d** Connection between receiver and monitor. **e** Monitor.

Methods

Protocol and registration

The study was prospectively registered in the International prospective register of systematic reviews (PROSPERO) under the code CRD42020207635 and was approved by the Ethics Committee of the Hospital das Clínicas at the University of São Paulo Medical School. This study followed the principles in the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) [9].

Search strategy and eligibility

We searched through MEDLINE, EMBASE, Central Cochrane, Lilacs, and gray literature, from inception to January 2021. Our search strategy in MEDLINE was "(Enteral Nutrition OR Enteral Feeding OR Force Feeding OR Feeding Tube OR Gastrointestinal Intubation OR Nasogastric Intubation OR nasoenteral tube OR nasoenteral intubation OR duodenal tube OR duodenal intubation) AND (electromagnetic OR magnetic OR navigation OR cortrak)", and on the other databases "(Feeding Tube OR Gastrointestinal Intubation OR Nasogastric Intubation OR nasoenteral tube OR nasoenteral intubation OR duodenal tube OR duodenal intubation) AND (electromagnetic OR magnetic OR navigation OR cortrak)".

Only randomized controlled trials (RCTs) published in full-text form (i. e., full-text published, peer-reviewed manuscripts) were considered. There was no language restriction used when evaluating studies. Study inclusion criteria were limited to patients in need of enteral nutrition provided via post-pyloric feeding tube (i. e., traditional nasogastric tube placement was excluded). In terms of the study population, studies were required to report placement of an electromagnetic-guided nasoenteral feeding tube. The comparison arms included place-

ment of an endoscopic-guided feeding tube, with no alternative procedures or devices included.

Measured outcomes

The primary outcome of this systematic review and meta-analysis was efficacy and safety of EMGP versus EGP. Technical success was defined by ability to achieve post-pyloric placement of the nasoenteral feeding tube (either via endoscopic confirmation and/or radiographic confirmation) [10–13].

AEs were stratified by those that appeared to be feeding tube-related (i. e., tube migration, obstruction, and accidental removal), as well as additional events which included patient-related AEs (i. e., epistaxis, desaturation, and vomiting). Additional measured outcomes included time to enteral feeding (defined as time between physician order and initiation of feeding) as well as procedure-associated cost (in US dollars – $). Duration of procedure (i. e., time between the passage of the tube through the nares to removal of endoscope or EMPG device), and time in the correct position were also abstracted and compared between the two techniques.

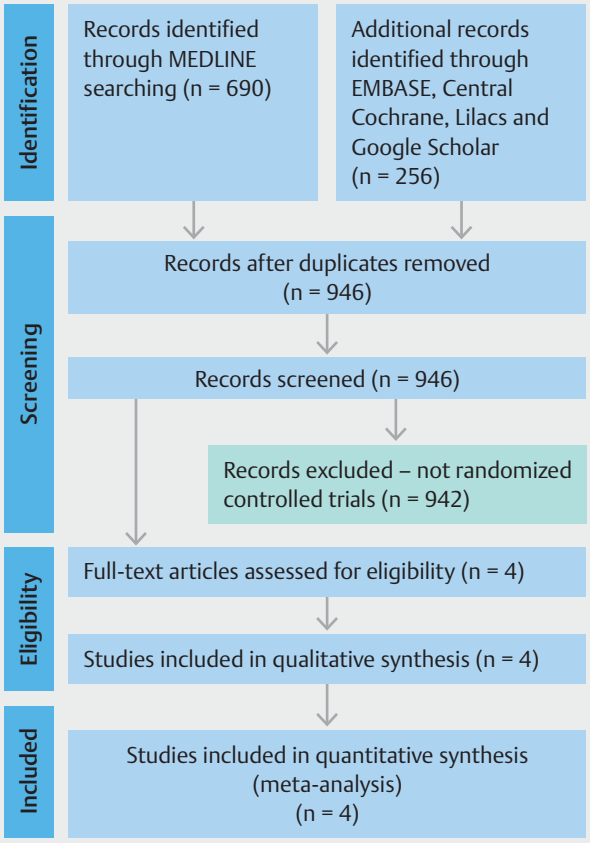
Data analysis, summary measures, and synthesis of results

Data from the selected studies regarding the outcomes (either dichotomous or continuous) were aggregated (meta-analyzed) using Mantel-Haenszel method for dichotomous variables and inverse variance through software RevMan 5.4 (Cochrane Collaboration, Copenhagen, Denmark). For dichotomous variables, risk difference (RD) was calculated, with corresponding 95 % confidence intervals (CIs). For continuous variables, the mean value of difference (MD) was calculated and the results are presented as point estimate with 95 % CI. Such a calculation considered the mean, standard deviation, and size of each sample. For this analysis, all point estimates were presented with 95 % CI and $P < 0.05$ was considered statistically significant.

Results are shown using forest plots. Heterogeneity among studies was quantified using the Higgins test (I^2). Furthermore, pooled proportions and differences between the two techniques were evaluated using a fixed-effects model. For outcomes with $I^2 > 50\,\%$, we utilized Egger's sensitivity test to identify possible outliers through funnel plot analysis

Risk of bias and quality of studies

To assess the risk of bias, we utilized the tool Risk of Bias version 2 for randomized clinical trials of Central Cochrane (RoB-2). This tool comprises five domains applied to each study: 1) randomization; 2) deviations from intended interventions; 3) missing data; 4) measurement of outcomes; and 5) selection of results. Each of these domains was classified as low risk, unclear risk, or high risk. Quality of evidence was then assessed according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group [14, 15].



▶ **Fig. 2** Process flowchart of study selection according to PRISMA.

Results

Study selection

A total of 924 studies were identified through the initial search. After assessing titles and abstracts, four RCTs remained and were included in this study (▶ **Fig. 2**). The characteristics of the included studies are described in ▶ **Table 1** (Population, Intervention, Comparison and Outcomes – PICO). Summarized results and characteristics for each study were simplified for the analyses [10].

Risk of bias and quality of studies

The four assessed studies presented a low risk of bias after applying the RoB-2 tool, as shown in ▶ **Table 2** (Summary of risk of bias in the included studies according to RoB-2) [14].

Technical success

Technical success was reported in three studies [11–13], with a total of 466 patients (243 in the EMGP group and 223 in the EGP group). There was no statistical difference regarding technical success between methods (87 % versus 88 %; RD: –0.01 [–0.07, 0.05]; $I^2 = 0\,\%$) (▶ **Fig. 3**). The GRADE analysis revealed a moderate level of certainty. Results from the assessed outcomes in the four RCTs are highlighted in ▶ **Table 3**.

▶ **Table 1** Summary of characteristics of the included studies.

Study	Holzinger et al [11]	Gerritsen et al [12]	Kappelle et al [13]	Gao et al [14]
Year	2011	2016	2018	2018
Country	Austria	Netherlands	Netherlands	China
Patient	Intubated, mechanically ventilated, and with gastroparesis	Request for enteral feeding by the responsible staff	Request for EGP of feeding tube	Gastroparesis
Number of patients	66	154	160	161
EMGP vs EGP (number of patients per group)	44×22	80×74	84×76	81×80
Evaluated outcomes	Success rate, procedure time, nose bleeding, number of attempts, time in the right position, Intensive Care Unit survival, hospital survival	Reintervention, success rate, complications, procedure time, time between physician's order and procedure, time until feeding, time until goal, time in the right position, use of PN, length of stay, in-hospital mortality	Success rate, position Time, sedation use, Difficulty, patient acceptance, receptor location, safety, cost	Success rate, time in the right position, time between physician's order and procedure, feeding start, time until goal, number of attempts, time in the right position, complications, tube length, length of survival, cost
Follow-up duration	Hospitalization or located tube	Hospitalization or located tube	10 days	Hospitalization or located tube

RCT, randomized controlled trial; NET, nasoenteral tube; EGP, endoscopy-guided placement; EMGP, electromagnetic-guided placement; ICU, intensive care unit; PN, parenteral nutrition.

▶ **Table 2** Summary of risk of bias in the included studies according to RoB-2.

Study	D1	D2	D3	D4	D5	Overall
Holzinger et al [11]	Low	Low	Low	Low	Low	Low
Gerritsen et al [12]	Low	Low	Low	Low	Low	Low
Kappelle et al [13]	Low	Low	Low	Low	Low	Low
Gao et al [14]	Low	Low	Low	Low	Low	Low

RoB-2, Risk of Bias version 2.

Tube-related complications

Feed tube-related AEs were reported in three studies [11–13] with a total of 470 patients (243 in the EMGP group and 237 in the EGP group). There was no statistical difference regarding tube-related complications between methods (33% versus 25%; RD:0.07 [−0.01, 0.15]; $I^2 = 0\%$) (▶ **Fig. 4**). The GRADE analysis revealed a high level of certainty.

Patient-related complications

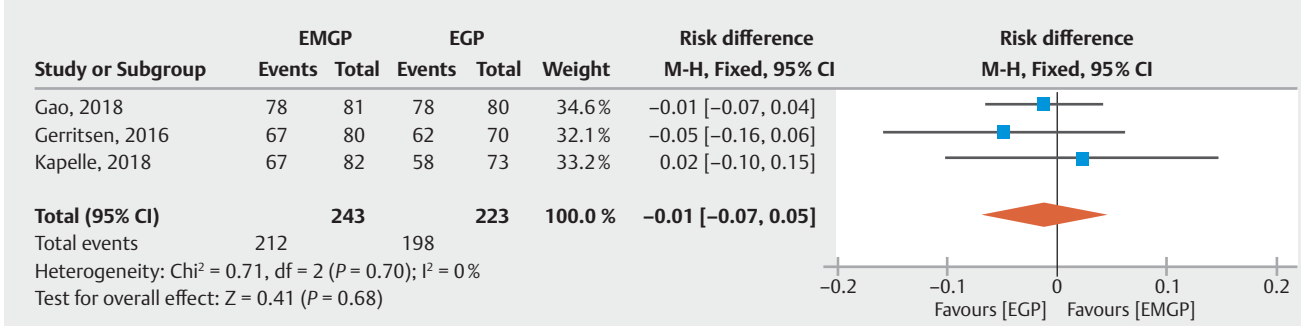
Patient-reported AEs were documented in four studies [10–13] with a total of 536 patients (287 in the EMGP group and 249 in the EGP group). There was no statistical difference between methods (5% versus 6%; RD: −0.01 [−0.05, 0.02]; $I^2 = 0\%$) (▶ **Fig. 5**). The GRADE analysis revealed a moderate level of certainty.

Procedure Time

Procedure duration was detailed in three studies [10, 12, 13] with a total of 382 patients (207 in the EMGP group and 175 in the EGP group). There was no statistical difference between methods (MD:0.65 [−0.20, 1.51]; $I^2 = 99\%$) (▶ **Fig. 6**). The GRADE analysis revealed a very low level of certainty.

Time to enteral nutrition

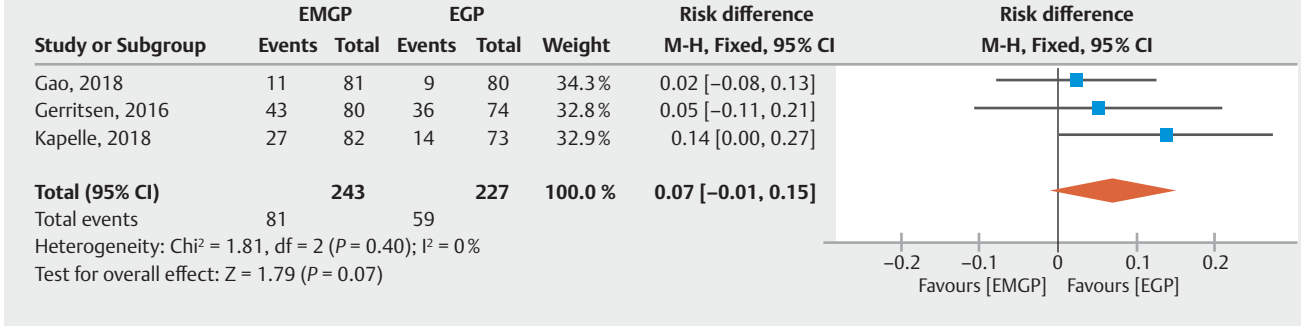
For the outcome of time to enteral nutrition, two studies [11, 13] including a total of 315 patients (161 in the EMGP group and 154 in the EGP group) reported these data. The mean difference showed a 162-minute advantage in the EMGP group (MD: −134.37 [−162.13, −106.61]; $I^2 = 35\%$) (▶ **Fig. 7**). The GRADE analysis revealed a moderate level of certainty.



▶ **Fig. 3** Forest plot of technical success.

▶ **Table 3** Summary of selected outcomes for each study.

	Study	Holzinger et al [10]	Gerritsen et al [11]	Kappelle et al [12]	Gao et al [13]
Post-pyloric position	EMGP	–	67/80	67/82	78/81
	EGP	–	62/74	58/73	78/80
Procedure time (in minutes)	EMGP	11.7 ± 3.7	33 ± 5.8 (16.7 ± 5)	20 ± 5.8	18 ± 3
	EGP	15.2 ± 3.2	61.2 ± 13 (12 ± 2.9)	10 ± 1.75	26 ± 6
Time in the right position (days)	EMGP	9.8 ± 3.5	7.5 ± 2.9	–	8.2 ± 3.7
	EGP	13.7 ± 3.2	6.5 ± 1.7	–	8.3 ± 4
Time until feeding (minutes)	EMGP	–	565 ± 260	–	313 ± 85
	EGP	–	757 ± 334	–	442 ± 102
Patient-related complications	EMGP	8/44	2/80	4/82	2/81
	EGP	4/22	4 + 1/74*	4/73	2/80
Tube-related complications	EMGP	–	43/80	27/82	11/81
	EGP	–	36/74	14/73	9/80
Cost (dollars)	EMGP	–	585.2 ± 47.6	543.3 ± 335.8	333 ± 24
	EGP	–	705 ± 72.1	631.8 ± 332.5	461 ± 28

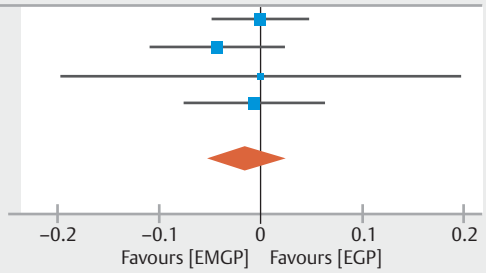


▶ **Fig. 4** Forest plot of tube-related complications.

Study or Subgroup	EMGP Events	EMGP Total	EGP Events	EGP Total	Weight	Risk difference M-H, Fixed, 95% CI
Gao, 2018	2	81	2	80	30.5%	−0.00 [−0.05, 0.05]
Gerritsen, 2016	2	80	5	74	29.1%	−0.04 [−0.11, 0.02]
Holzinger, 2016	8	44	4	22	11.1%	0.00 [−0.20, 0.20]
Kapelle, 2018	4	82	4	73	29.3%	−0.01 [−0.08, 0.06]
Total (95% CI)		**287**		**249**	**100.0 %**	**−0.01 [−0.05, 0.02]**
Total events	16		15			

Heterogeneity: Chi² = 1.09, df = 3 (*P* = 0.78); I² = 0%

Test for overall effect: Z = 0.72 (*P* = 0.47)

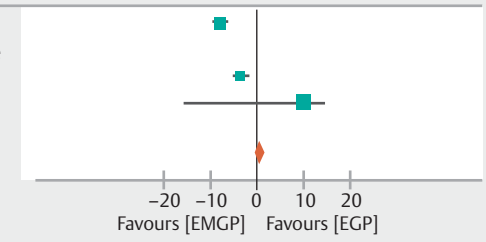


▶ **Fig. 5** Forest plot of patient-related complications.

Study or Subgroup	EMGP Mean	EMGP SD	EMGP Total	EGP Mean	EGP SD	EGP Total	Weight	Mean difference IV, Fixed, 95% CI
Gao, 2018	18	3	81	26	6	80	33.7%	−8.00 [−9.47, −6.53]
Gerritsen, 2016	16.7	5	80	12	2.9	74		not estimable
Holzinger, 2016	11.7	3.7	44	15.2	3.2	22	24.3%	−3.50 [−5.23, −1.77]
Kapelle, 2018	20	5.5	82	10	1.7	73	42.0%	10.00 [8.69, 11.31]
Total (95% CI)		**207**				**175**	**100.0 %**	**0.65 [−0.20, 1.51]**

Heterogeneity: Chi² = 349.87, df = 2 (*P* < 0.00001); I² = 99%

Test for overall effect: Z = 1.51 (*P* = 0.13)

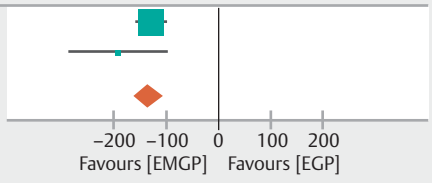


▶ **Fig. 6** Forest plot of procedure time.

Study or Subgroup	EMGP Mean	EMGP SD	EMGP Total	EGP Mean	EGP SD	EGP Total	Weight	Mean difference IV, Fixed, 95% CI
Gao, 2018	313	85	81	442	102	80	91.5%	−129.00 [−158.02, −99.98]
Gerritsen, 2016	565	260	80	757	334	74	8.5%	−192.00 [−287.06, −96.94]
Total (95% CI)		**161**				**154**	**100.0 %**	**−134.37 [−162.13, −106.61]**

Heterogeneity: Chi² = 1.54, df = 1 (*P* = 0.21); I² = 35%

Test for overall effect: Z = 9.49 (*P* < 0.00001)

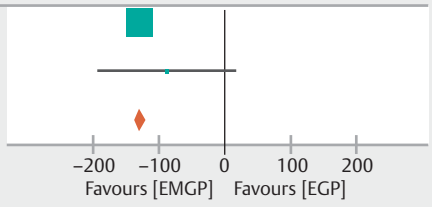


▶ **Fig. 7** Forest plot of time to enteral nutrition.

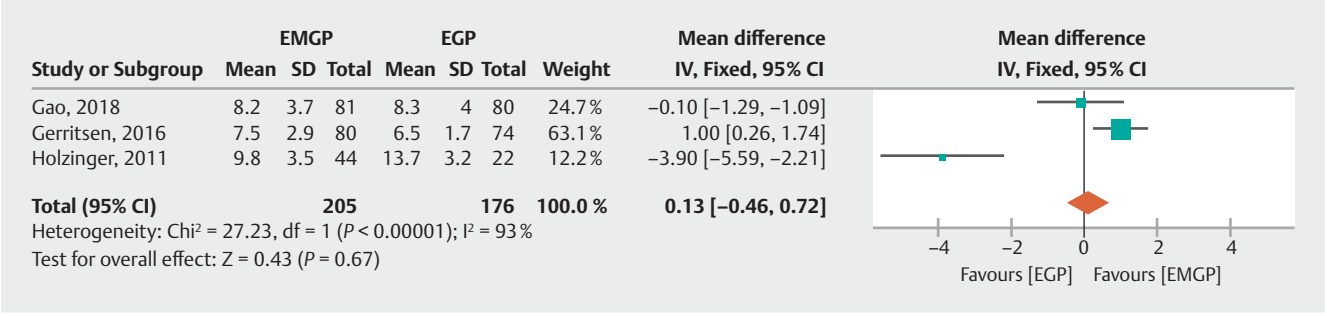
Study or Subgroup	EMGP Mean	EMGP SD	EMGP Total	EGP Mean	EGP SD	EGP Total	Weight	Mean difference IV, Fixed, 95% CI
Gao, 2018	333	24	81	461	28	80	99.4%	−128.00 [−136.06, −119.94]
Gerritsen, 2016	585	47	80	705	72	74		Not estimable
Kapelle, 2018	543	335	82	631	332	73	0.6%	−88.00 [−193.16, 17.16]
Total (95% CI)		**163**				**153**	**100.0 %**	**−127.77 [−135.80, −119.73]**

Heterogeneity: Chi² = 0.55, df = 1 (*P* = 0.46); I² = 0%

Test for overall effect: Z = 31.16 (*P* < 0.00001)



▶ **Fig. 8** Forest plot of cost analysis of methods.



▶ **Fig. 9** Forest plot of time in the right position.

Cost

With regard to cost, three studies [11–13], with a total of 470 patients (243 in the EMGP group and 237 in the EGP group). The mean difference showed a $126 reduction in the EMGP group (MD: −127.77($) [−135.80, −119.73]; $I^2 = 0\%$) (▶ **Fig. 8**). The GRADE analysis revealed a moderate level of certainty.

Time in the correct position

A total of three studies [10, 11, 13] reported the time that the feeding tube remained in the appropriate position. They included a total of 381 patients (205 in the EMGP group, vs 176 in the EGP group). There was no statistical difference between methods (MD:0.13 [−0.46, 0.72]; $I^2 = 93\%$) (▶ **Fig. 9**). The GRADE analysis revealed a very low level of certainty.

Discussion

Based on the results of this systematic review and meta-analysis, EMGP was associated with similar technical success and AEs when compared to EGP. Technical success defined as ability to successfully place the feeding tube distal to the pylorus was no different between the techniques. In addition, tube- or patient-related associated AEs were no different. Despite this lack of difference between techniques, EMGP was associated with lower cost and shorter time to initiation of nutrition. As such, EMGP may be a cost-saving option and increasingly considered in areas with limited healthcare resources or by cost-conscious institutions. Therefore, EMGP may provide an attractive alternative to EGP, although adoption may be limited based on the availability of this device.

EMGP provides many potential advantages over EGP that were not specifically evaluated in this systematic review and meta-analysis. Most importantly, EMGP is less invasive and does not require the use of deep or conscious sedation to achieve placement. Importantly, EMGP may be placed by a trained medical professional without direct involvement of a physician or endoscopist. In this study, outcomes of EMGP were compared to traditional EGP. While EGP traditionally requires sedation (moderate or deep based upon individual patient comorbid conditions and risks of sedation/anesthesia), an additional endoscopic placement strategy, though less commonly available among non-tertiary care centers, includes use of a slim gastroscope that allows for placement of a guidewire through the nose, requiring little or no sedation. Importantly, this study did not specifically evaluate this alternative EGP strategy; however, in Gerritsen et al trial, a slim gastroscope through the nostrils was employed and was found to have a lower rate of technical success compared to EGMP [11].

EMGP has been available since 2008, but the strategy is not widely available at all centers. Acknowledging that is critically important when evaluating novel tools and portending adoption patterns as well as assessing learning curves. Given that the device is placed similarly to a traditional blind passage of an enteral tube, we believe our findings may translate well to everyday, real-world clinical practice. In our own experience, EMGP is intuitive, easy to perform, and can readily be implemented in clinical practice. In addition, it does not require a physician or endoscopist to perform or confirm placement. While formal cost-effectiveness analyses have not been performed, the reduction in cost and time to enteral nutrition suggests a substantial healthcare savings opportunity with reduced length of stay for patients requiring enteral nutrition.

Understanding and recognition of hospital resources is also critically important. Endoscopic placement may require patient transportation to endoscopy suites, staff (including endoscopy and anesthesiology providers), sedation, and the need for confirmatory radiography. These factors likely relate to EMGP being a cost-saving procedure compared to traditional endoscopy. Regarding the cost of procedures, EMGP was shown to be cost-effective compared to a more traditional EGP approach. Regarding cost in this systematic review and meta-analysis, three studies reported associated monetary costs (two in US dollars and one in euros). Removing the European cost, we found EMGP to be cost-saving. However, it remains critically important to consider monetary unit, availability of the devices, staff, and particularities of each institution as well as the cost of endoscopy in different locations when the decision is made to begin enteral nutrition.

Interestingly, the first users of EMGP considered anatomical alterations of the upper digestive tract as a relative contraindication. However, the studies included in this meta-analysis did not incorporate subgroup analyses to determine if altered anatomy impacted placement of nasoenteral feeding tubes. Nevertheless, additional, non-randomized comparative studies have demonstrated equal effectiveness and safety of EMGP among patients with altered anatomy [16, 17]. As such, this technique is likely applicable to a broad patient population; however,

specific anatomic alterations may make placement more challenging (similar to issues with endoscopic placement). While more data specific to patients with surgically altered anatomy are needed to validate these findings, it remains critically important to emphasize that clinicians need to understand the anatomy of all patients before attempting blind, endoscopic, or EMGP of nasoenteral feeding tubes.

While important, it should be noted that a traditional blind approach is likely to remain a first-line strategy for nasogastric tube placement in patients with unremarkable anatomy. However, for some patients, such as those with Zenker's diverticulae, J-shaped stomach, or duodenal anatomic abnormalities, EGP may be preferred to EMGP, and also in cases of failed EMGP placement. At this time, endoscopy offers the additional ability to provide direct visualization as well as use of endoluminal instruments, including a guidewire, forceps, or countertraction from the endoscope itself [18, 19]. Importantly, studies to assess the role of EMGP in the setting of failed traditional placement or EGP as a rescue technique after inability to place a nasoenteral tube after EMGP have not been performed to date.

Despite the findings in the systematic review and meta-analysis, it is important to acknowledge this study is not without limitations. Although all included studies were RCTs, outcomes were not included uniformly across the studies. Furthermore, variable definitions of technical success were used by various study authors (i. e., endoscopic and/or radiographic confirmation of post-pyloric placement) which may limit the generalizability of these results. Procedure time was also noted to be highly variable based upon variable definitions used by the study authors, with one study by Gerritsen removed due to poor definition. In addition, familiarity with the EMGP device as well as interoperator variability (i. e., EGP and EMGP) may impact these results. While technical success rates were lower for EGP than some reported in the literature, this may be related more to exclusion of retrospective data (i. e., selection bias). Therefore, to resolve any lingering questions, it may be necessary to perform a new RCT to evaluate the outcomes objectively.

Despite these limitations, this systematic review and meta-analysis has several strengths. Most importantly, this study included only RCTs, minimizing the potential for selection bias and controlling for measured and unmeasured confounders. Furthermore, given the frequent need for nasoenteral feeding, the topic is of high clinical importance with easy translation into direct clinical practice. Lastly, outcomes were chosen based upon objective measures, further increasing the generalizability and applicability of these results, including cost, which may be a consideration more and more when implementing novel technologies or strategies in healthcare.

Conclusions

In this study, EMGP and EGP appeared equivalent regarding technical success and AE rates, as well as procedure duration. However, EMGP was associated with lower costs and reduced time to nutritional intake. As such, EMGP of post-pyloric enteral feeding tubes may be recommended as the first-line strategy, with EGP reserved for particular patients, such as those with altered anatomy, postoperative scenarios, or when EMGP fails.

Competing interests

Dr. Hourneaux de Moura is a consultant for Boston Scientific and Olympus.

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