A double blind randomised controlled trial of percutaneous endoscopic gastrostomy vs. radiologically inserted gastrostomy in children

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Running head: percutaneous endoscopic gastrostomy vs. radiologically inserted gastrostomy in children

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Abstract

Background: Retrospective reviews have suggested children with radiologically-inserted gastrostomy (RIG) have more complications than those with percutaneous endoscopic gastrostomy (PEG). Our aim was to determine whether RIG leads to more complications in a prospective randomised controlled trial.

Methods: Following ethical approval, children at a single tertiary children's hospital requiring a primary gastrostomy were randomised to PEG or RIG. Patients were followed by assessors blinded to insertion method. Complications were recorded, assigned a severity score, and analysed by zero-inflated Poisson regression analysis, on an intention-to-treat basis and adjusting for length of follow-up.

Results: Between Nov 2011 and Nov 2014, 214 patients were randomised (107 PEG, 107 RIG). 100 patients received PEG and 98 RIG and 193 (97 PEG, 96 RIG) followed up (median of 1 year [range 6 weeks-3 years]). Major complications include buried bumper (PEG), gastro-colic fistula (RIG) and abscess requiring aspiration under general anaesthetic (RIG). There was no difference in number of complications between PEG and RIG (p=0.875). There was no significant difference between PEG and RIG complication score; RIG patients had a 1.04 [0.89-1.21 95% CI] fold higher complication score than PEG patients (p=0.597). As an independent factor, only age had a significant effect on complication score, with older patients having a 0.97-fold [0.95-1.00] fold lower complication score per year.

Conclusions: PEG and RIG are both safe methods of gastrostomy insertion with low rate of major complications. Longer-term follow up may reveal differences in complications such as gastro-colic fistula. NCT01920438

Introduction

Percutaneous endoscopic gastrostomy (PEG) is a widely used and well accepted method for gastrostomy insertion in children[1] Radiologically-inserted gastrostomy (RIG) has similarly become widely accepted[2]. RIG involves pre-placement ultrasonography for localization of the liver, followed by biplane fluoroscopy for puncture of the stomach and gastrostomy insertion. Although both techniques require a general anaesthetic, RIG has a potential advantage from a service provision point of view in that an operating theatre slot is not required, so that gastrostomy waiting times may be shorter. Both PEG and RIG have the benefits of easy insertion and avoidance of a laparotomy incision. However, both techniques are also associated with complications, including gastrocolic fistula, haemorrhage, buried bumper and intra-abdominal leak with sepsis [3-7]. A recent Cochrane review highlighted the lack of evidence in this area, as no randomised controlled trials comparing PEG with RIG were identified, either in adults or in children[8]. We carried out a review of 318 children who had either PEG or RIG insertion in our hospital between 2004 and 2008[9]. In this retrospective review, although the rate of major complications was low in both the PEG and RIG groups, the overall proportion of patients who developed any complication was lower in PEG compared to RIG (28% vs 47%, P=0.001). However, this may have been due to differences in the underlying diagnosis, as more RIG patients were immunocompromised to some degree due to chemotherapy for their underlying oncological illness, whereas more of the PEG patients were neurologically impaired. We concluded that a randomised controlled trial comparing PEG with RIG should be conducted in order to determine which method of gastrostomy insertion gives the lower complication rate; hypothesizing that RIG would lead to a significantly higher number of complications than PEG; we hereby report the results of such a trial.

Methods

The PEG Vs. RIG trial was a double-blinded single centre randomised controlled trial conducted at Great Ormond Street Hospital for Children.

Inclusion and exclusion criteria

Any child referred for gastrostomy insertion was considered for inclusion; these patients were under the care of various clinical teams including: general surgery, oncology, haematology, endocrine, metabolic, gastroenterology and nephrology. Patients were excluded from the trial if they: (i) had gastro-oesophageal reflux and were being considered for anti-reflux surgery including fundoplication; (ii) had previous gastrostomy or fundoplication; (iii) had previous extensive abdominal surgery or (iv) required a concomitant major procedure on the gut or other intra-abdominal organs. There were no specific age or weight inclusion/exclusion criteria, but in order to be eligible, both the interventional radiology and surgical teams had to be potentially willing to perform the procedure.

Ethics and trial registration

The trial had ethical approval (10/H0713/47) from the National Research Ethics Service (NRES) of the Health Research Authority and was registered at ClinicalTrials.gov (registration number NCT01920438 2013). The research was conducted in accordance with the Declaration of Helsinki 2000[10].

Treatments and Schedules

When an eligible patient was identified, the trial was discussed with the parents and informed consent obtained. Patients were then randomised to either PEG or RIG. Procedures were performed by a consultant radiologist or paediatric surgeon; or by a trainee at specialist registrar level under direct supervision by a consultant on site. All consultants had extensive experience with either RIG (interventional radiology consultants) or PEG (general surgery consultants).

All cases were done under general anaesthesia with prophylactic antibiotics (co-amoxiclav unless contraindicated) administered before the procedure. A 9 French gastrostomy tube was used (Freka, Fresenius, Runcorn, UK), which is approved (CE Marked) and marketed in the UK and EU but is not FDA approved.

The two standardized procedures compared in the trial were:

a) Percutaneous Endoscopic Gastrostomy (PEG)

After insufflation of the stomach with an endoscope, indentation of the stomach and transillumination through the abdominal wall was confirmed under endoscopic vision. A small incision was made over the area of maximum transillumination and a catheter mounted on a needle passed through followed by a guidewire. The guidewire was grasped by the endoscope, pulled out through the mouth and attached to the gastrostomy tube which was then pulled antegrade and out through the abdomen. The tube was fixed with an external fastener and no sutures were placed.

b) Radiologically Inserted Gastrostomy (RIG)

Oral contrast was given the night before the procedure to line the colon on the day of procedure; enemas were not used. The stomach was insufflated with air via the nasogastric tube. Glucagon was not routinely used, although whether it was to be used or not was not stipulated in the protocol, and one interventional radiologist used glucagon as standard practise, whereas the others only used glucagon if it was difficult to delineate the stomach. RIG was performed using biplane fluoroscopy[11], with pre-placement ultrasonography for localization of the liver. An orogastric snare was passed and the stomach punctured under fluoroscopic guidance with an 18-gauge needle, which was used to insert a stiff 0.035-inch guidewire. This was snared and withdrawn through the mouth. The snare catheter was introduced in a retrograde direction from the abdominal wall to the mouth, and the gastrostomy tube was grasped and pulled down the oesophagus.

Randomization and blinding

Patients were allocated to groups (1:1 allocation ratio) by weighted minimisation[12, 13], using the following criteria: (i) Diagnosis [Neurological] [Haematology/Oncology] [Metabolic] [Gastrointestinal Diseases] [Miscellaneous]; (ii) Age [< 6months] [6 months – 2 years] [2 – 5 years] [>5 years]; (iii) weight centile [<3%] [3-10%] [10-25%] [25-50%] [>50%]; (iv) inpatient status [Yes][No]; (v) scoliosis [Yes][No]; (vi) documented gastro-oesophageal reflux [Yes-but not requiring anti-reflux surgery][No].

These criteria were based on the conclusions that children from certain diagnostic groups, younger age and greater weight being prone to complications[9]. The patients were randomised using a fast and simple method (SiMin® Windows-based software, developed by the Institute of Child Health, UCL) to either PEG or RIG. The software was installed on a single password-protected computer accessible only by the trial co-ordinator. Concealment of patient allocation was ensured by using minimisation.

The study co-ordinator was responsible for consenting, randomisation and booking procedures on the relevant operating list. The patient and parents or guardian were blinded to the method of gastrostomy insertion used. To ensure the blinding of the patients and assessors, a standard information sheet and consent form was used. The operation note was placed in a sealed envelope in the clinical notes. The post-operative gastrostomy wound for either PEG or RIG was dressed similarly. All patients and their caregivers were counselled after the procedure by the same specialist gastrostomy nurses who were not part of the trial, at which they were given standardized post-gastrostomy care advice and an information pack. Routine clinical follow up was performed as per normal practice. Follow-up for outcome assessment was performed by the research nurses at the Somers Clinical Research Facility in Great Ormond Street Hospital. These nurses had no access to the patients' clinical notes and were blinded to the patient allocation.

Outcomes

The primary end point of the study was the total number of complications (major and minor).

The secondary end points of the study were defined as:

i. major complication rate : colonic injury or gastro-colic fistula or other visceral injury, peritonitis requiring surgery, intestinal obstruction requiring surgery, major gastrointestinal bleed, other complications requiring surgery (including buried bumper)

ii. minor complication rate : infection requiring systemic antibiotics, delay more than 48 hours in establishing feeds, granulation, wound site discharge, tube-related problems (migration, dislodgement, leakage, breakage), other minor

iii. complication score : this is a score devised with weighting assigned to each complication depending on the severity of the complication. The score was devised in a consensus meeting attended by experts in the field (paediatric surgeons, interventional radiologists, junior doctors and specialist nurses) and has been previously described (Nah et al.) [9], the only change from this published version is the addition of buried bumper (score 20).

iv. technical failure : these are the number of PEG or RIG that are unsuccessful and require conversion to open surgical gastrostomy or laparoscopic gastrostomy.

v. Mortality / cause of death (relatedness to procedure / primary disease)

These data were collected on the day of procedure, until discharge of the patient from hospital, and at postoperative follow-ups (by the Research Nurses at Clinical Research Facility) 6 weeks, 6 months, 1 year and 3 years after the procedure. Complications were recorded and scored at each follow-up. If by the time of evaluation, the participant had the gastrostomy removed, and there was no clinical indication for follow-up, the evaluation was stopped.

Sample Size Estimation

The sample size was based on the primary end point of complications and was determined using the best available evidence at the start of the trial. This was based on the previous retrospective review of 331 children who had either PEG or RIG[9]. The review showed that 28% of PEG patients and 47% of RIG patients had complications. For sample size estimation, we used a binary power calculation, i.e. proportion of patients with any complications in each group. One hundred patients per group were needed to detect a difference of 19% (80% power, significance level=0.05) in the proportion of patients with any complication.

Statistical Analysis

Data were entered into Microsoft Excel 2010, analysed using SPSS (Version 22) and Stata InterCooled version 12. Data were analysed by Poisson (number of complications) or zero-inflated Poisson (complication score), with all the minimization criteria as covariates. Follow-up times were compared by a Mann-Whitney test.

Results

Recruitment

Recruitment started in November 2011 and finished in November 2014. The flowchart in Figure 1 demonstrates the flow of participants through each stage of the trial (assessment, enrolment and treatment) according to the CONSORT guidelines for reporting. Three hundred and thirty-nine patients were assessed for eligibility and 214 were enrolled in the trial. Of the 64 patients excluded for reasons other than declining the trial or being ineligible, reasons were: requirement for urgent gastrostomy (n=19), foreign resident so unable to follow-up (n=18), patients with a life-limiting disease process (n=6), or anaesthetic risk too great for procedure to be performed in interventional radiology suite (n=2), gastrostomy no longer required (n=11),

complex patients on neuromuscular clinical pathway necessitating PEG (n=6), child under social care without designated parental responsibility (n=2).

Of the 214 randomized patients, 107 were allocated to each arm (PEG and RIG). Two patients randomized to RIG received a PEG; one for anaesthetic concerns necessitating operating theatre rather than interventional radiology suite. The other patient had a PEG as his RIG slot was cancelled at short notice but a PEG slot was available on the same day. Available demographics and follow up for these patients are included in RIG dataset analysis on an intention to treat basis. Sixteen further patients did not receive their intervention, and five patients had no follow-up, as indicated in Figure 1, so that 97 patients were analysed for the primary outcome (PEG) and 96 in the RIG group. An independent data monitoring and ethics committee was convened and reviewed data on the first 100 patients recruited. The committee did not have any ethical concern and recommended to continue intake into the trial to complete the target of 200 patients having the procedure. 197 patients had the procedure when funding for the research co-ordinator ended.

Demographics

Patient demographics and minimization criteria at recruitment are shown in Table 1; the PEG and RIG groups were well balanced for those criteria thought to influence outcomes.

Primary outcome

Follow-up was for 1 year (range 6 weeks to 3 years) in each group, and was similar between the groups (p=0.474). The number of patients in each group attending each follow-up is shown in supplementary Table 1. The total number of complications after PEG and RIG are shown in Table 2A; only five patients experienced a major complication, two in the PEG group (2%) and

3 in the RIG group (3%). The distribution of number of complications in each group is shown in Figure 2. The number of complications per patient was analysed by standard Poisson regression, as this allows adjustment for different lengths of follow-up (Table 2B). A neurologic 4 year old outpatient on the 25th centile for weight having a PEG, with neither reflux nor scoliosis was used as the reference patient to compare other variables. Compared with this reference patient, RIG patients had a similar rate of complications to PEG patients (0.98 [95% CI 0.80-1.21]-fold lower rate of complications, p=0.875). None of the minimization criteria showed a statistically or clinically significant effect on rate of complications.

Major Complications

A neurologically-impaired one-year old patient in the PEG group developed a buried bumper, which was discovered 2 years later during routine replacement. This was removed endoscopically and replaced by another PEG. Another 5 year old oncology patient had the gastrostomy tube passing through the liver, which was discovered incidentally on a CT scan after 3 years. He is due for surgery to have this removed. One neurologically-impaired two-year old patient in the RIG group had a gastro-colic fistula that required a laparotomy 11 days after initial placement. The fistula was closed and a new gastrostomy fashioned. A two-year old neurologic patient in the RIG group developed an abscess at the gastrostomy site in the immediate post-operative period, which was aspirated under a general anaesthetic. A five year old child with hyperinsulinism developed feeding difficulty with the gastrostomy and was discovered to have a buried bumper during tube replacement and needed a laparotomy and excision of inflammatory mass after 3 years.

Minor complications

The minor complications for the patients were as in Table 3A and included wound infection, discharge, granulation, tube-related problems (such as migration, dislodgement, leakage, breakage) and delay of more than 48 hours in establishing feeds caused by abdominal pain/temperature/nausea. One hundred and eight children (56 PEG and 52 RIG) had more than one minor complication. The proportion of patients having any minor complication was similar between the groups (81% PEG, 81% RIG; p=1.000).

Complication score

The distribution of complication scores in the two groups is shown in Figure 3A and the complication score per year of follow-up is shown by diagnostic group in Figure 3B. Complication scores were compared using zero-inflated Poisson. A neurologic 4 year old outpatient on the 25th centile for weight having a PEG, with neither reflux nor scoliosis was used as the reference patient to compare other variables. Compared with the reference patient, there was no statistically significant effect of having a RIG (1.04-fold higher complication score, p=0.597; Table 3B). Although older patients had a statistically significant lower complication score (p=0.037), the magnitude of the effect (0.97 fold per year) was not great.

Technical failure

There were 2 RIG failures. In a neurologically impaired child, the radiologist could not safely position a gastrostomy into the stomach due to the altered anatomy as a result of previously unrecognised scoliosis. The patient later had a successful PEG placement. In another neurologically impaired child, the radiologist could not find a safe window for gastrostomy placement; the patient later had a successful PEG placement.

There was 1 PEG failure, also in a neurologically impaired child. On attempted PEG placement, there was no recognisable light from the endoscope and the indent visible on endoscopy was immediately below the xiphisternum, which is not suitable for gastrostomy placement. The procedure was converted to open gastrostomy placement under the same anaesthetic.

Mortality

Twenty-five patients died after a PEG/RIG insertion (16 in the PEG group, 9 in the RIG group), 1-36 (median 13) months after the PEG/RIG insertion, all due to progression of their primary disease and none related to gastrostomy insertion or management (the patient who died after one month died as a result of epileptic encephalopathy). There was no significant difference between the two groups (p=0.293 Fisher's exact test).

Discussion

Although a previous retrospective review from the same hospital had suggested that there was a significantly higher rate of complications following RIG than PEG[9], this was not confirmed by this prospective randomised controlled trial, in which it was shown that there is no evidence for a difference in complications between insertion of PEG or RIG. In the current study the randomised groups were well-matched at recruitment, and the difference in conclusions between the retrospective review and the current trial is probably due to demographic differences between the PEG and RIG populations in the retrospective review.

The major complications observed during the trial, i.e. gastro-colic fistula, buried bumper and abscess requiring aspiration under a general anaesthetic are well recognised complications after a percutaneous gastrostomy placement[9] that may present some years following the procedure, during device changes[7, 14]. Although laparoscopic-assisted gastrostomy insertion is becoming

the preferred technique with some surgeons, and this technique has the advantage of the ability to visualise the external wall of the stomach, laparoscopic gastrostomy insertion may be associated with a significant increase in costs (longer theatre time, instrumentation cost etc.) and introduces a potential for additional complications that are not considerations for either PEG or RIG (e.g. anaesthetic considerations of laparoscopy). At the outset of the trial, we did consider whether to undertake a trial comparing laparoscopy with both PEG and RIG, but as laparoscopic gastrostomy was infrequently performed in our hospital, the decision was made to compare the two procedures which were most frequently performed, i.e. PEG and RIG.

One weakness of the trial was difficulty in comparison of the complications in the two groups. Although we developed and used a complication scoring system specific for gastrostomy, a more generalisable scoring system specific for, and validated in, the paediatric population is much needed. Technical failures occurred during the trial; there were two RIG failures necessitating a PEG, and one PEG failure necessitating an open gastrostomy. This is a potential disadvantage to the RIG, in that technical failure would require rebooking a theatre slot and a second general anaesthetic, whereas failure of a PEG can be converted to an open procedure under the same anaesthetic. RIG necessitates a radiation dose, with a dose-area product <0.1 μGy m^2 for patients <15 kg, and <0.2 μGy m^2 for patients 15-30 kg.

Although the trial was powered to detect the total number of patients experiencing complications, on the basis of our own retrospective revew[9], we also acknowledge that the trial was under-powered to detect a significant difference in incidence of any individual complication, such as gastrocolic fistula. The trial was designed to compare the incidence of complications, however, there may be other factors influencing the decision of whether to perform a PEG or a RIG, e.g. availability of procedure slots/ surgeons/ radiologist, relative cost of procedure etc. The finding of no significant difference in complications between the

procedures allows decisions to be made on these other factors without compromising results. There is a limited literature on RIG in children; a recent systematic review and meta-analysis of gastrostomy placement in children[15] identified only our own retrospective review[9]. We believe that the findings from our study are applicable to other centres with a paediatric interventional radiology service. Although many patients in each group experienced complications, most of these are minor complications and we believe that the benefits of insertion of a secured gastrostomy for long-term use outweigh the risks of repeated aspiration and/or accidental tube removal and replacement if a nasogastric tube were to be used for an extended period of time. As our retrospective review suggested a significantly higher rate of complications in the RIG group, we designed the study as a superiority trial. In order to determine equal effectiveness, it would have been necessary to perform a non-inferiority trial with a suitable definition of non-inferiority trial. Nevertheless, major complications were rare in both PEG and RIG and so we feel that both procedures are clinically safe. RIG gave a 0.98 (95% CI 0.80-1.21)-fold lower rate of complications, and a 1.04 (0.89-1.21)-fold higher complication score rate than PEG, so there is no evidence from this trial that PEG is superior to RIG.

In conclusion, in patients for whom a percutaneous gastrostomy is appropriate, there is no evidence that either PEG or RIG leads to a significantly higher number of complications or complication score, which is contrary to our previous retrospective review. Further follow-up of these patients will indicate whether there is any evidence for a difference.

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No preregistration exists for the reported studies reported in this article.

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Table 1 Demographics of patients at recruitment

Criteria	PEG (n=100)	RIG (n=98)
Diagnostic Group		
Neurological	32	29
Haematology/Oncology	24	24
Metabolic	12	13
Gastrointestinal disease	1	2
Miscellaneous	31	30
Age		
<6 months	6	5
6 months-2 years	35	36
2-5 years	26	32
>5 years	33	25
Weight centile		
<3%	35	34
3-10%	18	16
10-25%	11	12
25-50%	15	15
>50%	21	21
Inpatient status		
Inpatient	9	9
Outpatient	91	89
Scoliosis		
Yes	3	0
No	97	98
Gastro-oesophageal reflux		
Yes-Not needing anti-reflux surgery	24	27
No	76	71

Table 2 Complications
[a] Number of patients with complications during the trial

	PEG (n=97)	**RIG (n=96)**	**Total**
Major Complications	2	3	5
Minor Complications	79	78	157

[b] Poisson regression analysis of total number of complications (major and minor) adjusted for length of follow-up, and the minimization criteria. Incidence rate ratios are compared with a neurologically impaired four year old outpatient on the 25th centile for weight, without reflux or scoliosis, having a PEG, in whom the total number of complications is 1.23 (95% CI 0.97 – 1.56, p=0.082).

Factor	**Incidence rate ratio (95% CI)**	**p-value**
RIG	0.98 (0.80 - 1.21)	0.875
Age (per year increase)	0.99 (0.96 - 1.03)	0.700
Haematological/Oncological	0.97 (0.70 - 1.34)	0.846
Metabolic	1.19 (0.85 - 1.66)	0.303
Gastrointestinal	1.06 (0.56 – 2.00)	0.864
Miscellaneous	0.92 (0.70 - 1.20)	0.536
Weight centile (10 centile increase)	1.00 (1.00 - 1.00)	0.601
Inpatient	1.23 (0.79 – 1.91)	0.357
Scoliosis	0.70 (0.17 – 2.85)	0.615
Gastro-oesophageal reflux	1.24 (0.96 - 1.60)	0.105

Table 3 Minor complications and complication score

[a] Minor complications

	PEG (n=97)	**RIG (n=96)**
Number of patients with minor complications	79	78
Number of minor complications	177	175
p-value*	1.00	

*Fisher's exact test comparing proportion of patients having any minor complication

[b] Zero-inflated Poisson regression analysis of complication score adjusted for length of follow-up and the minimization criteria. Incidence rate ratios are compared with a **neurologically impaired four year old outpatient on the 25th centile for weight, without reflux or scoliosis, having a PEG,** in whom there is a complication score of 2.96 (95% CI 2.49 – 3.52), p<0.0005

Factor	**Incidence rate ratios (95% CI)**	**p-value**
RIG	1.04 (0.89 - 1.21)	0.597
Age (per year increase)	0.97 (0.95 – 1.00)	0.037
Haematological/Oncological	0.88 (0.69 – 1.13)	0.321
Metabolic	0.86 (0.67 – 1.11)	0.254
Gastrointestinal	1.45 (0.99 – 2.12)	0.055
Miscellaneous	1.07 (0.88 - 1.31)	0.471
Weight centile (10 centile increase)	1.00 (1.00 - 1.00)	0.566
Inpatient	0.91 (0.63 - 1.32)	0.616
Scoliosis	0.62 (0.19 – 1.99)	0.420
Gastro-oesophageal reflux	1.05 (0.87 - 1.26)	0.597

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

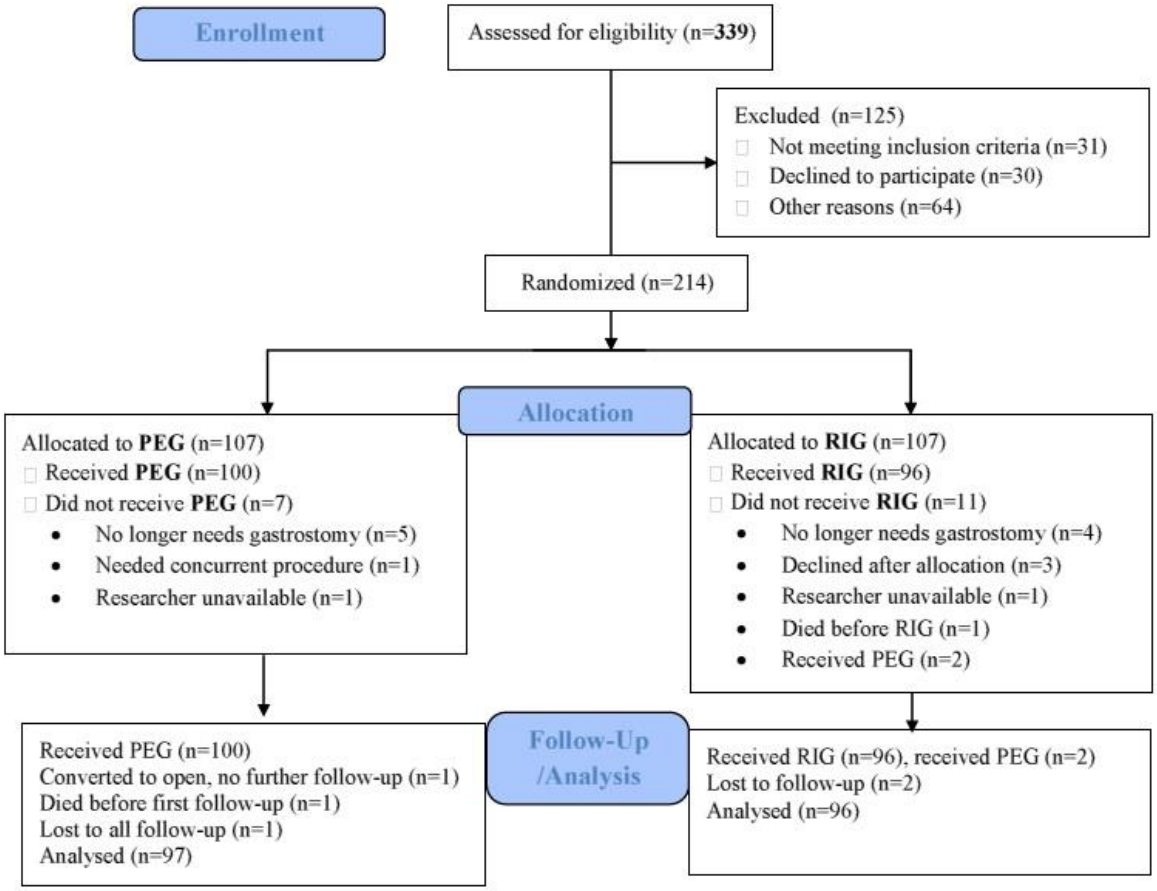


Figure 2

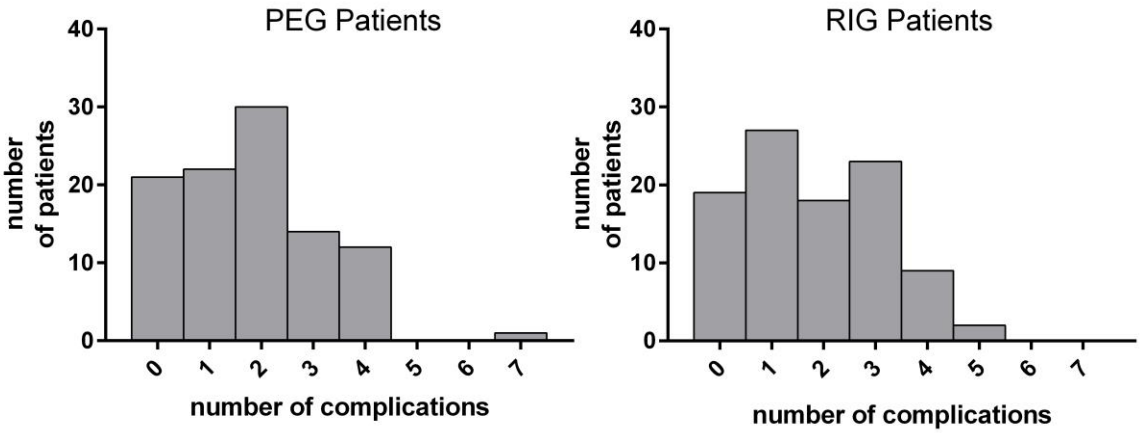
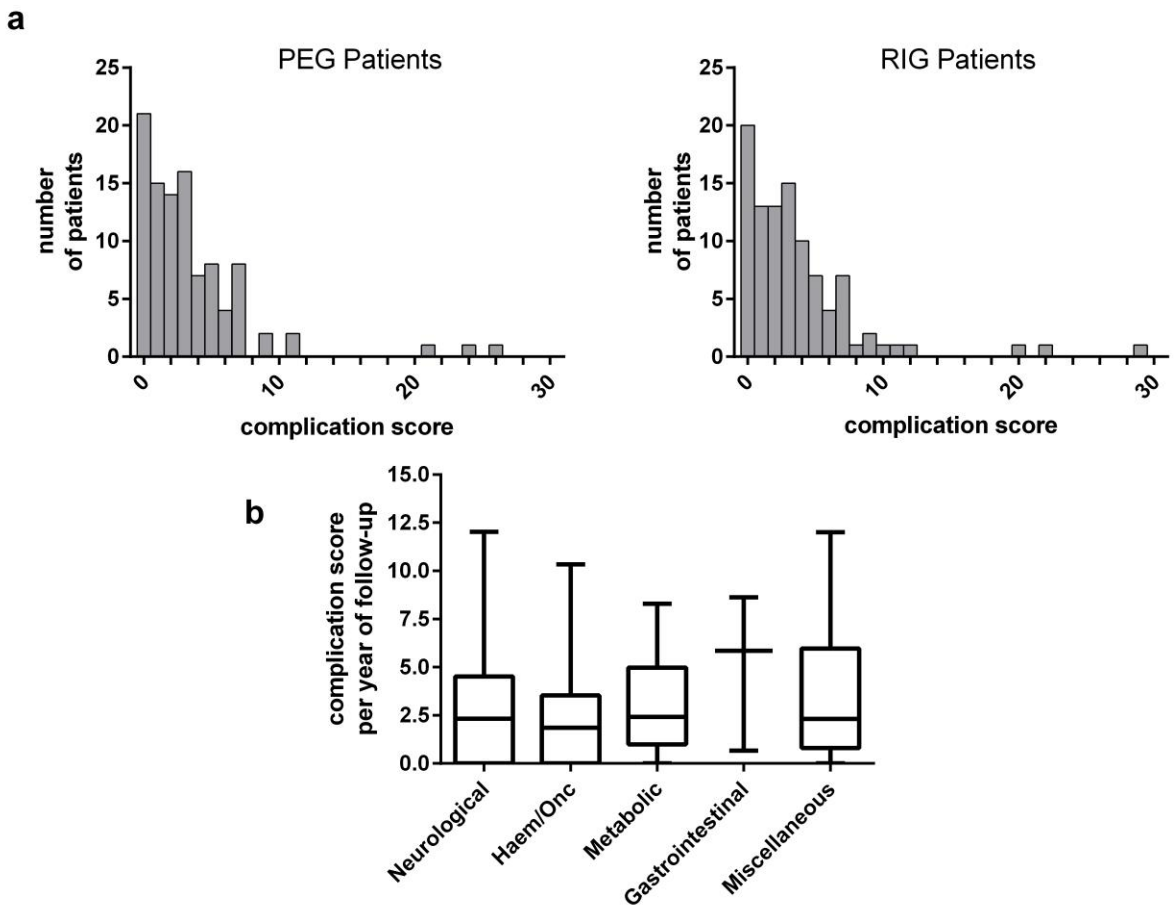


Figure 3



Supplementary table 1

Number of patients attending each follow-up (in addition to patients failing to attend follow-up, and mortalities, other reasons for non-follow up were gastrostomy removal or conversion to a balloon secured device).

	PEG (n=97)	RIG (n=96)
6 weeks	91	94
6 months	86	80
1 year	69	68
3 years	32	36