## A DOUBLE BLIND RANDOMISED CONTROLLED TRIAL OF PERCUTANEOUS ENDOSCOPIC GASTROSTOMY VS. RADIOLOGICALLY INSERTED GASTROSTOMY IN CHILDREN: PEG VS. RIG TRIAL

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**Aim of the Study**: 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 PEG or RIG is superior 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, minimising for diagnosis, age, weight, inpatient status, and presence or absence of reflux and scoliosis. Following the procedure, patients were followed for up to three years by assessors blinded to insertion method. Complications were recorded using a standardised template and analysed by zero-inflated Poisson regression analysis, on an intention-to-treat basis and adjusting for length of follow-up.

**Main Results:** Between Nov 2011 and Nov 2014, 214 patients were randomised (107 PEG, 107 RIG). 100 patients received a PEG and 98 a RIG. All patients had at least one year follow-up. Complications are indicated in Table 1. Major complications include buried bumper (PEG), gastro-colic fistula (RIG) and abscess requiring drainage under general anaesthetic (RIG). Minor complications included leakage and over-granulation. There was no significant difference in number of complications between PEG and RIG (p=0.83). Complications were assigned a severity score. There was no significant difference between PEG and RIG complication score; PEG patients had a 1.04 [0.88-1.22 95% CI] fold higher complication score than RIG patients (p=0.65). As independent factors, older (effect size 0.96 [0.93-0.99] p=0.003, oncological (0.72 [0.54-0.95] p=0.019 and metabolic patients (0.75 [0.57-0.97] p=0.03) all had a significantly lower complication score than neurologically impaired patients.

**Conclusions**: PEG and RIG are equally effective and safe methods of gastrostomy insertion. Longerterm follow up may reveal differences in complications such as gastro-colic fistula.

	Major Complications	Minor Complications
PEG	1	77
RIG	2	76
Total	3	153