

# **Multi-centre survey of radiologically inserted gastrostomy feeding tube (RIG) in the UK.**

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## Abstract:

### **Aims**

To evaluate the variance in current UK clinical practice and clinical outcomes for direct percutaneous radiologically inserted gastrostomy (RIG).

### **Methods**

A prospective UK multi-centre survey of RIG performed between October 2008 and August 2010 was performed through the British Society of GI and Abdominal Radiology (BSGAR).

### **Results**

Data from 684 patients were provided by 45 radiologists working at 17 UK centres. 263 cases (40%) were performed with loop retained catheter, and 346 (53%) with balloon retained devices. 60% of all patients experienced pain in the first 24 hours but settled in the majority thereafter. Early complications, defined as occurring in the first 24 hours, included; minor bleeding (1%), wound infection (3%), peritonism (2%) and tube misplacement (1%). Late complications, defined as occurring between day 2 and day 30 post procedure, included; mild pain (30%), persisting peritonism (2%) and 30 day mortality of 1% (5/665). Pre-procedural antibiotics or anti-MRSA prophylaxis did not affect the rate of wound infection, peritonitis, post procedural pain, or mortality.

93% of cases were performed using gastropexy. Gastropexy decreased post procedural pain ( $p < 0.001$ ), but gastropexy-related complications occurred in 5% of patients. However, post-procedure pain increased with the number of gastropexy sutures used ( $p < 0.001$ ). The use of gastropexy did not affect the overall complication rate or mortality. Post-procedure pain increased significantly as tube size increased ( $p < 0.001$ ). The use of balloon retention feeding tubes was associated with more pain than the deployment of loop retention devices ( $p < 0.001$ ).

## **Conclusions**

RIG is a relatively safe procedure with a mortality of 1%, with or without gastropexy. Pain is the commonest complication. The use of gastropexy, fixation dressing or skin sutures, smaller tube sizes and loop retention catheters significantly reduced the incidence of pain. There was a gastropexy-related complication rate in 5% of patients. Neither pre-procedural antibiotics nor anti-MRSA prophylaxis affected the rate of wound infection.



# Full Paper

## Introduction:

Gastrostomy is a well-established method of nutritional support. The commonest indication is neurogenic dysphagia in patients from risk of aspiration after stroke. Other causes include neurodegenerative disorders and patients with mechanical dysphagia from benign or malignant stenoses of the upper GI tract.

Gastrostomy has been in use for over 30 years and a variety of endoscopic and radiologic approaches have been described; placing tubes antegradely from the mouth or directly through the skin. Direct percutaneous insertion carries the risk of the tube not entering the stomach, but displacing the gastric wall and ending up in the peritoneal cavity. For this purpose fixation of the stomach (gastropexy) with modified sutures has been described. It also prevents retraction of the stomach from the gastrostomy tube if the internal fixator fails. Although not universally accepted, this is regarded by most operators as current best practice, due to the reduced risk of intraperitoneal feeding.

Percutaneous endoscopic gastrostomy (PEG) is the most widely available technique, but there are circumstances precluding endoscopy. Oesophageal stenoses or stents may prevent passage of the endoscope and neuromuscular weakness may prevent the use of sedation, which is essentially a requisite for PEG. Furthermore there is a low but well-described risk of seeding upper GI cancer into the stoma, which is generally assumed to be a result of dissemination and implantation of tumour cells caused by the per-oral tube passing through tumour tissue.

Tubes inserted directly through the skin avoid this complication, although the possibility of haematogenous metastasis has been queried. Although bumper-retained tubes can be inserted radiologically using the per-oral route, the majority of operators prefer a direct

percutaneous insertion, termed radiologically inserted gastrostomy (RIG) or percutaneous radiologic gastrostomy (PRG). The retaining mechanism of these tubes must either be deformable or inflatable, as it needs to pass through the tissues of the anterior abdominal wall (Fig. 1).

RIG is particularly well established in the UK and mostly applied in patients with oropharyngeal or oesophageal cancer undergoing curative treatment. This article describes the finding of a national audit on current practice in the UK, performed through the British Society of Gastrointestinal and Abdominal Radiologists (BSGAR).

## **Aims:**

To evaluate and quantify the variance in current clinical practice in the performance of direct percutaneous radiologically-inserted gastrostomy (RIG) in the UK. To quantify the incidence of early complications, defined as occurring in the first 24 hours after the procedure and late complications, defined as occurring between day 2 and day 30 post procedure, including mortality. To evaluate whether patient fitness affects outcome and whether increased mortality and morbidity are predictable. To evaluate whether the use of gastropexy, the tube size or the tube type affects patient outcome. To collect dose data to enable diagnostic reference levels for this examination to be established. To establish whether there is any evidence to provide a consensus view regarding 'best practice for the RIG procedure'.

## **Methods:**

Between October 2008 and August 2010 all BSGAR members performing radiologically inserted gastrostomy were invited to contribute to a prospective multi-centre survey. Data captured included underlying diagnoses and medical fitness of patients referred for the procedure; operator experience; and technical information about all aspects of a practitioner's technique including patient preparation, performance of the procedure, including radiation dose (dose area product DAP), post procedure care and complications. Early complications were defined as occurring in the first 24 hours and late complications as occurring between day 2 and day 30. Data were collected prospectively and sent for collation centrally. Statistical analysis was performed at XXXXXXXX using SPSS. Missing data were excluded from subgroup analysis and respective 'known N' only refers to cases for which data was reported. For this reason, the 'known N' refers to cases for which data was reported. The numerator and denominator are shown along with percentages in these cases.

## Technique;

Radiologically-inserted gastrostomy (RIG) is a common procedure in the UK, and the technique is well described (1,2). There is considerable variation between centres both in the case mix of underlying conditions and in the overall medical fitness of patients referred for this procedure(3). Areas of variation in clinical practice include preparation protocols, the use of gastropexy, the choice of tubes, post procedural analgesia, patient training and discharge procedures;

Pre-procedure preparation; can involve the use of oral contrast to help delineate the transverse colon that can overlie the gastric body and antrum so that it may be more easily visualised during the fluoroscopic procedure. Other practitioners rely on the gas-filled colon being visible at fluoroscopy or use intra-procedural ultrasound.

Some operators advocate the use of pre-procedural oral antibiotics and others the use of topical anti-MRSA prophylaxis to try and reduce the risk of superficial and deep infection which is a recognised complication, in line with guidelines for tunnelled central line insertion (4,5). MRSA prophylaxis involves the use of 2% nasal mupirocin ('Bactroban', GlaxoSmith-Kline, Uxbridge UK) and 4% chlorhexidine gluconate skin wash (Hibiscrub, Mölnlycke, Dunstable, UK) prior to the procedure.

Adequate gastric distention is a prerequisite for gastrostomy and is achieved by inflation of air either via a nasogastric tube placed prior to the procedure, or through a radiological catheter, such as a biliary manipulation catheter (Cook, Bjaeverskov, Denmark) or vascular headhunter catheter (Cordis/Johnson and Johnson, South Ascot, UK) passed per-orally into the stomach at the beginning of the procedure. Gastric distension is improved by intravenous administration of a smooth muscle relaxant, such as 20mg hyoscine bromide (Buscopan, Boehringer Ingelheim, Bracknell, UK). The puncture site is chosen under fluoroscopic guidance avoiding the costal margins, adjacent viscera, in particular the position of the transverse colon (Figure 1a) and the anterior abdominal wall down to the peritoneal reflection is liberally infiltrated with local anaesthetic.

Three T-fastener kits for gastropexy are currently available in the UK. The Cope sutures (Cook, Bjaeverskov, Denmark) consist of two T-fasteners, which are passed through a puncture needle into the stomach. The metal T-bars are attached to a green suture, with a straight surgical needle attached to the other end (Fig. 1a). Skin fixation is performed by suturing the external length into the skin, although the instructions for use do not give specific guidance how this should be performed.

The most commonly used Mueller-Brown sutures (Boston-Scientific) were discontinued in 2008 and replaced by the identical Harpon kit (Pyramed, Basingstoke, UK) containing 3 T-bars attached to polypropylene sutures (Fig. 1b). These are inserted into the tip of a slotted needle (Figure 1c) and after gastric puncture also displaced into the stomach with the help of

a guide wire. External fixation is by crimping small metal tubes onto the suture, although no dedicated tools are available for this.

A dedicated insertion system for balloon-retained gastrostomies was introduced by Vygon (Cirencester, UK) in 2009. Besides guide wire and a telescopic dilator with integrated peel-away sheath the set contains four pre-loaded T-fasteners on a resorbable surgical suture. These are contained in individual puncture needles and released by depressing the Luer-type hub (Fig. 1d). External fixation is by closing a lever on the button mounted on the distal end of the suture with the enclosed forceps. The advantage of this system is the availability of dedicated systems for different tube sizes, the easy external fixation and the resorbable suture, the disadvantage is the relatively high cost.

Once the stomach is distended and fixed, puncture is performed with an 18G needle (figure 2a) and intra-gastric position confirmed by injection of water soluble contrast (Figure 2b). After insertion of a guide wire, tack dilation either with fascial dilators or angioplasty balloons and insertion of a peel away sheath is performed as appropriate (figure 2c-e). Some operators perform direct puncture of the stomach without the use of gastropexy. This is controversial.

Following insertion of the feeding tube, some operators advocate a 'trial of gastrostomy' before the tube is used for feeding. This involves either the infusion of sterile water or a test feed at a reduced rate (eg 50mls/hour for 4 hours) under observation in hospital. The patient requires training and supply with consumables and a feeding pump prior to discharge unless home support is immediately available.

## **Results:**

### **Demographics**

Data from 684 patients in 17 UK centres was collected from 45 radiologists between October 2008 and August 2010. 65% of patients were male, 35% female. Median age was 69 years (age range 16- 95 years). 68% (454/670) had oropharyngeal malignancy, 13%(88/670) neurodegenerative conditions, and 19%(128/670) a variety of other conditions, including oesophageal stricture, advanced malignancy, head injury, cystic fibrosis or other chronic lung conditions and various syndromes (figure 3). The patient's procedural risk was assessed prior to the procedure using a modified American Society of Anesthesiologists scoring system (ASA score)(6,7). Patient's ASA score was generally poor, with over 55% of patients with severe systemic disease, and a further 9% with life threatening disease (figure 4).

### **Life expectancy and mortality**

The overall 30 day mortality for RIG was 1%(5/643). A further 4% of patients(24/643) died during follow up. (median survival 4 months, range 1 month to 18 months) from causes unrelated to RIG placement, and often from the underlying condition (malignant disease progression, neurodegenerative diseases). In order to try to establish whether patient deaths were predictable or not, the life expectancy of patients was estimated prior to the procedure. This estimate was derived following an assessment of the overall clinical condition of the patient, their underlying condition and their clinical progress. Although nearly 20%(111/463) of patients were estimated to have a life expectancy of less than 6 months and 1%(9/643) less than 30 days, four of the five deaths that occurred within 30 days were not predicted and were directly attributable to RIG placement. (ie most deaths occurred in patients with a life expectancy of over 30 days). There were five deaths within 30 days, resulting in a 30-day mortality rate of 1%. Three patients' deaths were secondary to pneumonia between day 13 and 19; one was due to multi-organ failure associated with pneumoperitoneum and sepsis; and one was secondary to a perforated duodenal ulcer. All

procedure-related deaths within 30 days occurred in patients with an ASA score of 3 or above (figure 5). None of the 242 patients with ASA scores of 1 or 2 died within 30 days of the procedure. Neither life expectancy nor the ASA score significantly correlated with any other complication observed, for example post-procedure pain or wound infection ( $P>0.05$ ).

A further 24(4%) deaths were reported during follow up as long as 18 months post-procedure (often from the underlying conditions and not directly related to RIG tube placement. The use of gastropexy did not affect the 30 day mortality but the incidence of death was so low no conclusion can safely be drawn from this observation). Two patients who died had misplacement of the feeding catheter into the peritoneal cavity during the procedure despite the use of gastropexy. In both cases the documented cause of death was recorded as aspiration pneumonia, so the significance of the tube misplacement is uncertain.

### **Operator experience and technique**

Operators were generally experienced with 78% (35/45) having performed more than 30 cases and 55%(5/45) more than 50 cases.

30% of cases were performed after an ultrasound scan prior to the procedure in order to establish the position of the liver, spleen and transverse colon prior to gastric puncture. Only 17% of cases were performed following oral contrast the day prior to the procedure to outline the transverse colon. Presumably because the majority of operators feel the transverse colon is adequately seen with ultrasound, fluoroscopy or a combination of these, without the need for luminal contrast (Figure 6).

28% of procedures were performed using local anaesthesia only. Where intravenous analgesia was used, the commonest agent administered was fentanyl (median dose 50 mcg, range 10-100 mcg). The majority of patients who were given iv analgesia received between

25mcg and 50 mcg. Patients who were given fentanyl experienced a lower incidence of post-procedural pain compared with those who did not receive fentanyl ( $X^2$ ,  $p < 0.001$ ).

37% of procedures were performed without any antibiotic cover. 40% of patients received pre-procedural antibiotics. There was a very wide variation in the type and dosage of antibiotics prescribed. The commonest antibiotic used was coamoxyclav 1.2g (50%), but cefotaxime 1g, amoxicillin 1g, gentamycin 120mg, ceftriaxone 1g, cefuroxime 750mg, flucloxacillin 1g or combinations of these were also used. There was no significant difference in the development of wound infection in patients who received antibiotics (2.6%, 11/432) versus patients who did not (2.8%, 7/252). ( $X^2$ ,  $P > 0.05$ ).

14% (86/620) of patients received anti-MRSA prophylaxis with nasal mupirocin cream and /or chlorhexidine skin wash prior to the procedure. The rate of wound infection was not altered by the use of anti-MRSA prophylaxis. The rate of wound infection was identical in patients who had received MRSA prophylaxis (2.3%, 2/86) and those who had not (2.2%, 12/534). ( $X^2$ ,  $P > 0.05$ ).

Peritonitis was a rare complication occurring in 2.3% (16/684). There was no significant difference in incidence between patients who had received prophylactic antibiotics (1.2%, 3/252) and those that had not (3%, 13/432). ( $X^2$ ,  $P > 0.05$ ).

The use of sutures or adhesive dressings to help maintain the position of the feeding tube varied between operators. No fixation dressing or skin sutures were used in 234/658, 36% of patients. Adhesive dressing or suture retention of feeding tubes was used in 423/658, 64% of patients. The use of skin fixation significantly decreased the amount of pain experienced by the patient from 95% (223/234) to 40% (163/242) [Chi square,  $X^2 = 188.7$ ,  $P < 0.001$ ]. The rate of wound infection was the same whether sutures or other adhesive dressings were used or not.



The length of time that skin sutures remained in situ varied between 7 to 14 days but this did not affect the rate of wound infection (Mann Whitney U,  $P>0.05$ ). The use of sutures did not affect the rate of tube displacement (14/654, 3% versus 2/235, 1%,  $P>0.05$ ).

96% of patients (577/601) underwent a trial of gastrostomy before the tube was used for feeding. No data was collected about variations in the length of the trial or how this is done at each centre.

### **Early complications**

Early complications were defined as those occurring in the first 24 hours following the procedure.

The commonest early complication was pain. For the purposes of this study, pain was defined as mild if the patient was adequately treated with oral analgesia, moderate if intravenous analgesia was required, and severe if the pain persisted 30 minutes following titrated intravenous analgesia.

60% of patients experienced pain requiring medication during and after the procedure. Mild pain was seen in 31% (204/655). A further 28% (182/655) had moderate pain and 1% (6/665) reported severe pain.

Peritonism, in the first 24 hours, was seen in 11 patients (1.7%). Peritonism was localised or minor in 8 and diffuse in 3 patients. This settled in 3 patients by 24 hours and persisted in 8 patients. No recognisable factors or trends to explain this are identified. (e.g. use of gastropexy, prophylactic antibiotics, recognised procedural complication or operator experience).

There was evidence of superficial wound infection in 2% (18/620). One case was associated with a superficial abdominal wall haematoma. There was no difference in incidence between patients who had received pre-procedural antibiotics or prophylactic anti-MRSA eradication treatment and those that had not ( $X^2$ ,  $P>0.05$ ). Of the known cases of wound infection, all

17 occurred in patients in whom gastropexy sutures were placed, but this was not a significant association because of the low incidence of this complication. Some patients received topical antibiotic treatment and others required oral antibiotics. No cases of deep seated peritonitis or intraperitoneal collections requiring surgical or percutaneous drainage were recorded.

0.75% of feeding tubes (5/665) were inadvertently inserted into the peritoneal cavity during the procedure. All cases were recognised peri-operatively. In all cases gastropexy sutures were being used. Tube misplacement was associated with pneumoperitonism and post-procedural pain in 4 out of 5 patients. Cases where tube misplacement occurred were all treated with covering antibiotics for up to three days. Two of the patients (40%) who had misplacement of the feeding catheter into the peritoneal cavity during the procedure died at 14 and 19 days. In both cases, the cause of death was recorded as aspiration pneumonia, so the significance of the tube misplacement is uncertain. There were no other complications associated with this group of patients.

### **Gastropexy**

6.6%(44/668) of procedures were performed without gastropexy and 93%(624/668) the stomach was fixed with sutures. The number of 'T' fasteners used varied between 1 and 4. (figure 7).

The use of gastropexy sutures was associated with complications in 5%. Complications included suture-related pain, balloon rupture, suture rupture, superficial wound infection or a combination of these, all with an approximately 1% incidence (see table 1). The use of 'T' fasteners did not decrease the risk of procedure-related death (1% in each group, Fisher's exact test,  $P>0.05$ ), or wound infection; 3%(17/624) in the gastropexy group and 0%(0/44) in the non-gastropexy group (Fisher's exact test,  $P>0.05$ ). However, all 17 reported cases of wound infection occurred in patients in whom gastropexy had been used. Infections were

usually superficial requiring topical treatment, with occasional use of oral antibiotics. One patient had an associated abdominal wall haematoma.

Patients in whom gastropexy was performed were significantly less likely to complain of pain post-procedure (58%, 349/602) compared with 88% (38/43) without gastropexy,  $\chi^2 = 15.453$ ,  $P < 0.001$ ). However, when looking at the severity of pain in each group, there were significant differences; most patients without gastropexy had only mild pain controlled with oral analgesia alone (92%, 35/38), with 8% of patients suffering moderate or severe pain requiring intravenous analgesia.

Of the patients with gastropexy, 47% (163/349) reported mild pain but 53% moderate or severe pain. This was statistically significant. (Mann Whitney,  $U = 3608.5$ ,  $z = -5.281$ ,  $P < 0.001$ ). After 24 hours, the number of patients experiencing pain was lower if gastropexy was used (36%, 190/524), versus 63% (26/33) without gastropexy,  $\chi^2 = 23.651$ ,  $P < 0.001$ ,

The severity of pain after 24 hours was much reduced in both groups with over 90% of patients requiring oral analgesia only in both groups controlled with oral analgesia alone. At that point the severity of pain was no longer different in patients with and without gastropexy ( $P > 0.05$ ).

Balanced against this observation however, is that the incidence of pain reported in the first 24 hours increased significantly with the number of gastropexy sutures used, from 22% of patients with 1 'T' fastener compared to 85% with 3 (Mann Whitney,  $U = 24145$ ,  $z = -10.428$ ,  $P < 0.001$ ) [table 2]. This observation is continued after the first 24 hours with pain reported in 11% of patients with one suture rising to 63% of patients with 3 sutures (Mann Whitney,  $U = 17710$ ,  $z = -9.008$ ,  $P < 0.001$ ).

Bleeding was observed in 2% (13/668) of patients. All 13 cases were in patients in whom gastropexy had been used, although there was not a significant difference compared to the non-gastropexy group (Fisher's exact test,  $P > 0.05$ ). Bleeding was minor and treated conservatively in all cases. No cases of haemorrhage requiring transfusion or other more

invasive intervention was reported. GI bleeding was reported in two of the patients that died. In one case the patient was diagnosed with a perforated duodenal ulcer, the other patient also developed aspiration pneumonia.

### **Type and size of tube**

Several types of gastrostomy catheters were used in this series. For the purposes of this study, tubes were classified as either balloon- or loop- retained devices. The incidence of pain in the first 24 hours was significantly associated with the use of balloon retention catheters. 67%(264/392) of patients with balloon-retained gastrostomy tubes reported pain compared to 21%(82/392) of patients with loop-retained tubes or any other type ( $X^2=141.44$ ,  $P<0.001$ ). Furthermore, the severity of pain experienced by patients with balloon-retained tubes was higher with 155/264 (59%) reporting moderate pain and 6/264 (2%) severe pain, compared with 11/82(13%) moderate pain and 2/82 (2%) severe pain in patients with loop retained tubes (Mann Whitney,  $U=6061$ ,  $z=-6.875$ ,  $P=<0.001$ ). This difference was also not explained on the basis of larger tube size use by operators favouring balloon retention devices (ie the difference was still observed when each tube size was considered separately).

Pain reported after 24 hours was generally mild in nature and there was no statistically significant difference between the loop-retained or balloon-retained catheter.

The use of balloon- or loop-retained catheter did not result in statistically significant differences in the rates of wound infection, bleeding or mortality ( $P>0.05$ ).

The size of tube inserted varied from 8Fr to 20Fr. There was a statistically significant association between tube size and pain. 60% (30/50) of patients with 8Fr tubes reported pain compared with 81% (35/43) of patients with a 16Fr tube. (Mann Whitney.  $U=40288$ ,  $z = -4.8$ ,  $P<0.001$ ).

There was no statistically significant association between size of tube inserted and the rate of peritonism or 30 day mortality observed ( $P>0.05$ ).

### **Late complications**

Late complications were defined as those occurring between day 2 and day 30 inclusive.

Again, the commonest complication was pain, which was seen in 35% of patients (200/563). This was mild, defined as requiring oral analgesia only, in the majority (200/217, 92%), with a further 8% of patients requiring intravenous analgesia to control pain. One patient's pain could not be controlled with intravenous analgesia after 30 minutes. This was related to gastropexy suture placement and was relieved when the suture was cut.

Peritonism settled in three patients but persisted in eight beyond 24 hours. This was localised in four patients and symptomatic in four patients. It was related to wound haematoma and subsequent wound infection in one, suture rupture and catheter balloon rupture and subsequent tube displacement in one and a catheter misplacement into the peritoneal cavity (recognised during procedure) in one patient.

Minor bleeding, defined as not requiring transfusion or other intervention was seen between day 2 and 30 in five patients (1%).

Late complications related to the use of T-fasteners was seen in 4%(23/624) of patients. These included suture related pain, often relieved by cutting the sutures, minor superficial wound infection sometimes requiring oral antibiotics., suture rupture or combinations of these complications.

Tubes fell out inadvertently within 30 days in 14 patients (2%). 12 of these were loop retained catheters. 1 was a balloon retained device. Another had no catheter type recorded. Some patients required multiple tube reinsertions within the first 30 days.

There was one reported case of metastases developing in the tube tract in a patient with head and neck cancer. In this case there were technical difficulties during the procedure with misplacement of the tube in the peritoneal cavity and subsequently post procedure there was balloon rupture and misplacement of the catheter in the peritoneal cavity.

## **Dose**

Accurate Dose area product (DAP) information was available from 106 procedures. The median dose was 430 cGy.cm<sup>2</sup>. There was a wide variation in exposures depending on the exact technique used by the operator, patient and machine factors as well as the technical difficulty of the case (range 52 – 8840 cGy.cm<sup>2</sup>). The standard deviation was therefore wide.(1514 cGy.cm<sup>2</sup>). .See Figure 8.

## **Conclusions**

Radiologically-placed gastrostomy is a commonly performed procedure. Clinical practice and techniques currently vary widely in the UK. Most patients referred for this procedure by definition are malnourished or at risk thereof. The majority have head and neck cancer and are undergoing extensive surgery and /or radical chemo-radiotherapy or they are debilitated with a short life expectancy. Despite patient frailty, radiologically-inserted gastrostomy is a relatively safe procedure with a mortality of 1% which compares to a 43% 1 week mortality after PEG for stroke disease and other causes of dysphagia (8).

Pain is the commonest complication and this survey provides compelling evidence that the use of gastropexy, fixation dressing or skin sutures, smaller tube sizes can reduce the incidence of this pain significantly. Loop-retained catheters were also associated with a lower incidence of pain but that may be a consequence of small tube sizes compared to balloon retained devices. Loop retained catheters have however been shown to be associated with a higher complication and failure rate in several studies (9-11).

93% of known cases in the survey were performed using gastropexy sutures to secure the stomach to the anterior abdominal wall. The use of gastropexy is however not without complication. Our results show that immediate post-procedure pain is more severe and increases with the numbers of sutures used, but tends to improve within the first 24 hours. Sutures are easily fashioned too tightly, in particular if smooth muscle relaxants have been administered to paralyse the stomach and this has been well distended with air. When the stomach deflates after insertion of the tube and muscle tone returns, the tension on the T-fasteners can increase dramatically. It is important that operators rely more on gastric distension by air for successful tube insertion than on the traction provided by the retention sutures.

Severe post-procedure pain may often be immediately relieved by cutting the tightest or the most painful suture. A previous study into pain following interventional procedures identified the peak after gastrostomy to be at 6 hours (12). At that point, patients may still be drowsy from sedation, unable to communicate because of the underlying disease or in transit back to the referring hospital. This illustrates the need for a reliable protocol for post-procedure analgesia, particularly if patients are unable to swallow. One simple solution applied by some operators routinely is the administration of liquid preparations of analgesics (e.g. ibuprofen syrup) through the tube at the end of the procedure

Suture rupture and balloon rupture are also associated with the use of gastropexy. The risk of wound infection is increased, if non-resorbable sutures are used and not removed, giving

an overall known gastropexy complication rate of 5%. The difference in stoma infections in this survey was not significant, however all known cases of wound infection were seen in patients who had gastropexy. All cases (2%) of minor bleeding, including one abdominal wall haematoma also occurred in patients with gastropexy, but again the difference was not significant. Localised peritonism was seen in 11 patients (2%). Some of these may be due to the unavoidable leak of small amount of gastric content, but all settled spontaneously.

The overall mortality was 1% which was the same whether gastropexy was used or not. Interestingly, neither the use of pre-procedural antibiotics nor anti-MRSA prophylaxis affected the rate of wound infection. This is in contrast to guidelines for endoscopically placed gastrostomy, which suggested a prolonged routine antibiotic regime prophylaxis (13). RIG however is a much cleaner technique, as the tube avoids contamination by oral bacterial flora in patients with poor oral hygiene. Our results suggest that routine antibiotic prophylaxis is not beneficial.

Stoma metastases are well described after PEG from a variety of different upper GI-tumours (14-16) and assumed to be a result of direct implantation of tumour cells into the gastrostomy track. One case has been reported after direct percutaneous tube insertion, raising the possibility of haematogenous dissemination (17). We also observed one case of stoma metastasis in a patient, who had a complicated insertion of a RIG. This would indeed suggest that haematogenous spread to an area of inflammation and hyperaemia is possible.

In summary, RIG is a well-established procedure in the UK, which has a high success and a low complication rate in high-risk patients, most of which are unsuitable to endoscopic gastrostomy. In contrast to previous comparative studies our results do not confirm a clear benefit from using one tube over another or the application of gastropexy. This may be due to the large number of different centres included and the great variation in practice.

Pain is common after the procedure and this needs to be expected and treated preemptively. The incidence of pain is reduced through the use of gastropexy, but when it



occurs it may be more severe. Pain is aggravated with increased number of T-fasteners and larger tube size. This illustrates the need for careful application of T-fasteners and early review by the specialist team.

This was the first national audit performed through the British Society of Gastro-Intestinal and Abdominal Radiology, resulting in one of the largest published series in gastrostomy. The authors would like to thank the officers of BSGAR involved in the study and the centres who have taken the time and effort to contribute.

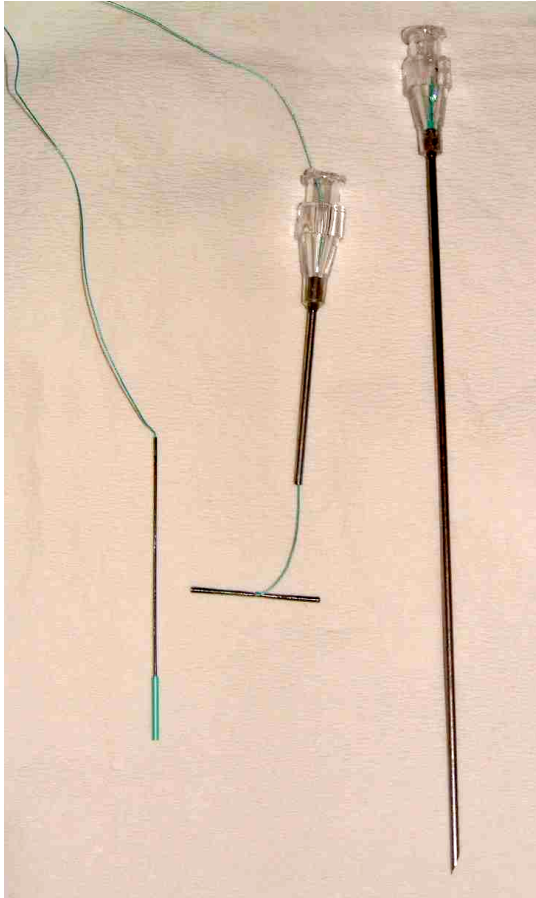
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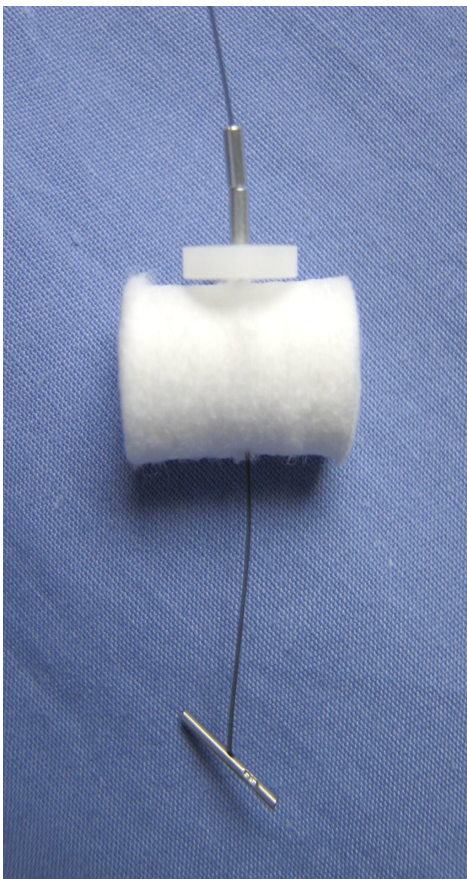
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Figure 1. Types of Gastropexy suture.

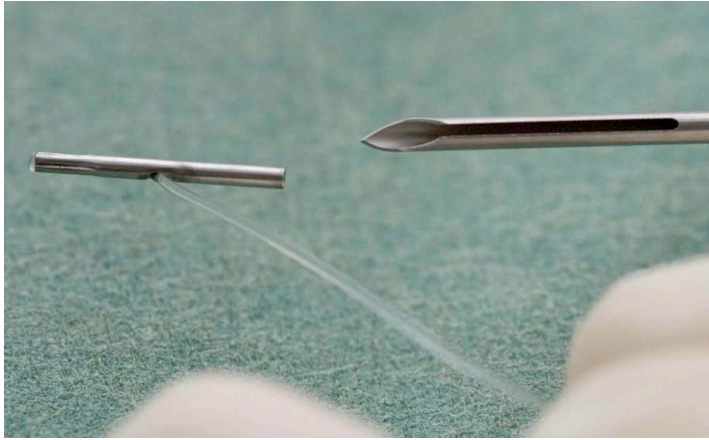
(a) Cook T fastener kit



(b) Pyramed 'harpoon' gastropexy 'T fastener'



(c)



(d)

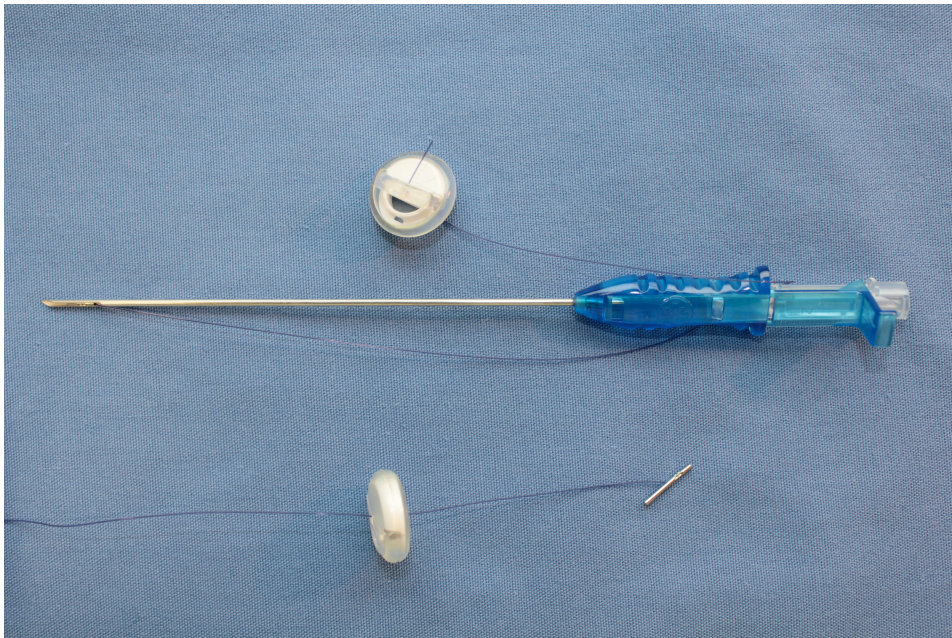
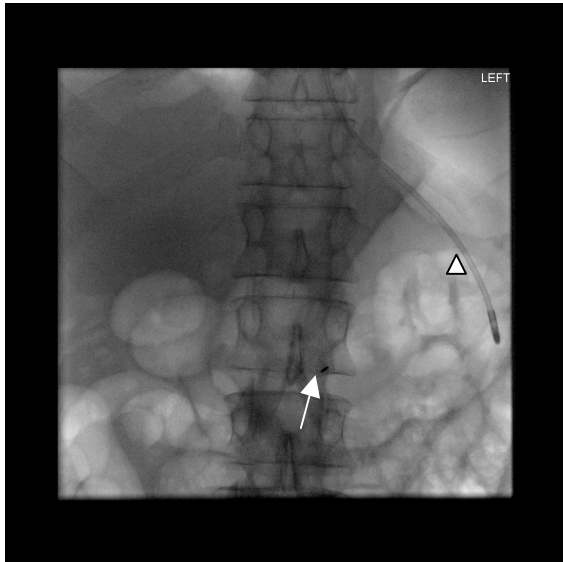
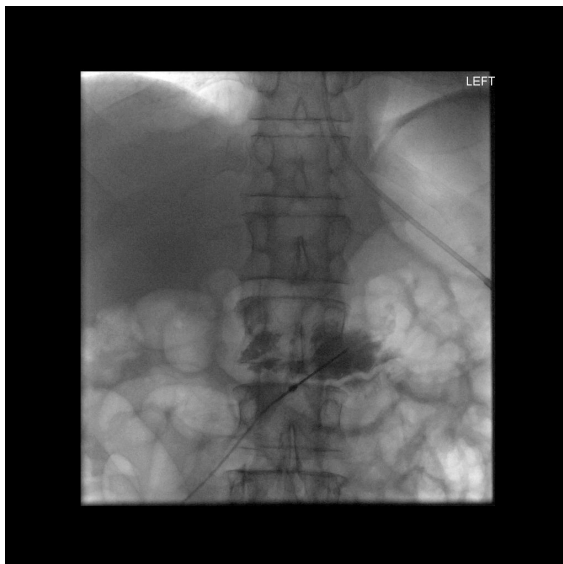


Figure2. Fluoroscopic guided placement of a radiologically- Inserted Gastrostomy Feeding tube.

(a) Identification of a suitable site for gastric puncture( needle at arrow) after insufflation of the stomach with room air via nasogastric tube (arrowhead)

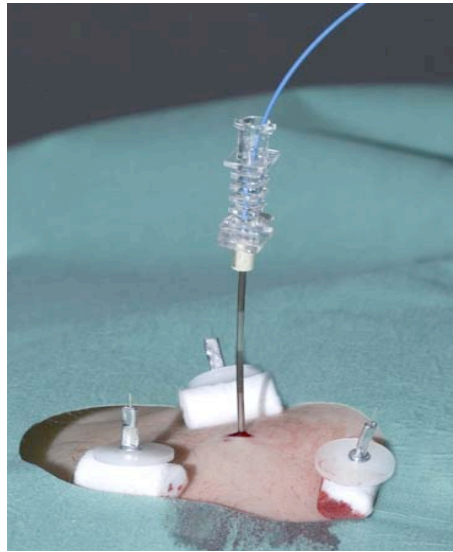


(b) Confirming intragastric position by injection of water soluble contrast

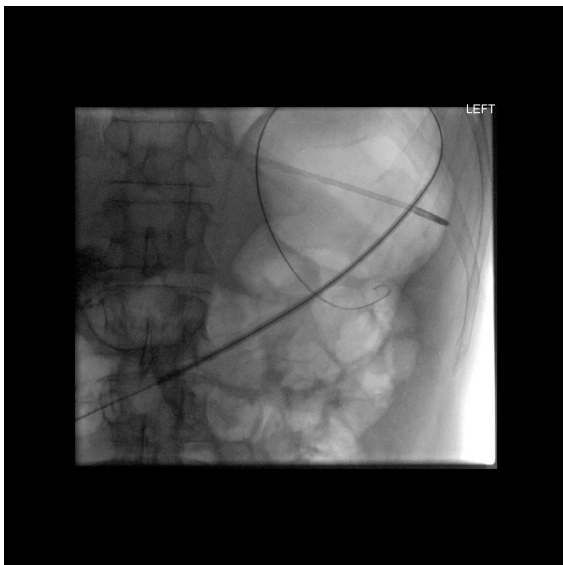




(c and d) Use of gastropexy suture to help secure the stomach to the anterior abdominal wall prior to placement of the feeding tube



(e) placement of an 0.035 wire to guide the placement of the feeding tube following tract dilation with fascial dilator or angioplasty balloon



(f) confirmation of correct gastric tube placement by injection of water soluble contrast

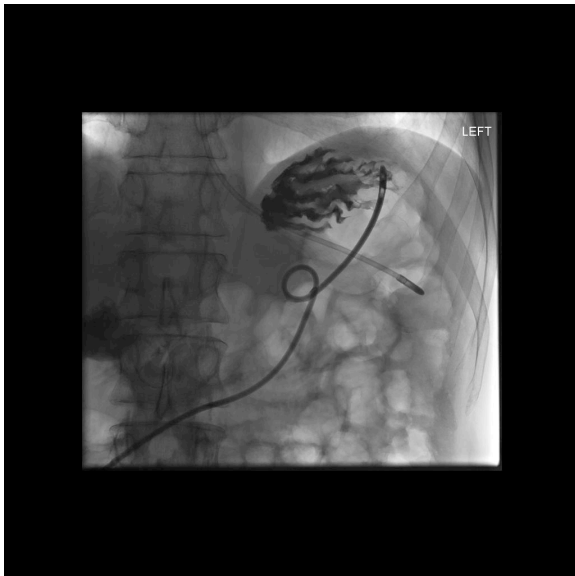




Figure 3. Underlying diagnoses of patients referred for Radiologically Inserted Gastrostomy (RIG) (n=685). 'Other' category includes post trauma, oesophageal stricture, cystic fibrosis and other chronic lung conditions and advanced malignancy.

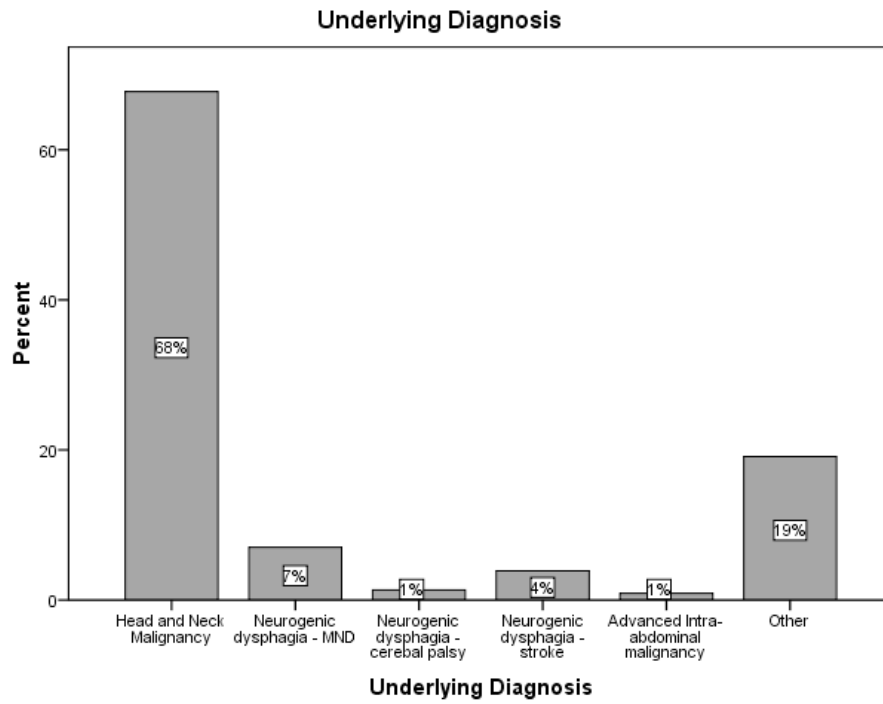
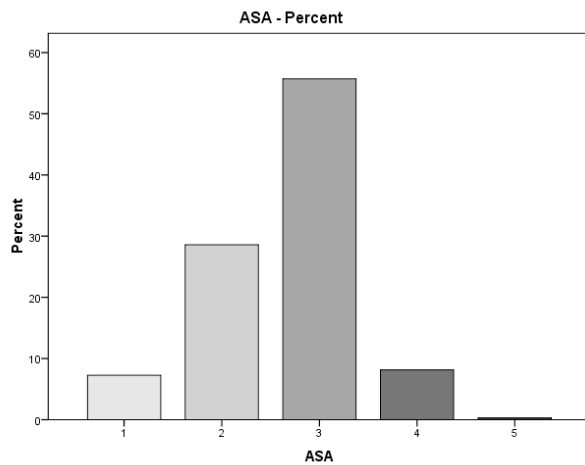


Figure 4. Distribution of patient ASA scores (from American Society of Anaesthesiologists, 1963) n=670



ASA score 1. A normal healthy patient. 2. A patient with mild systemic disease. 3. A patient with severe systemic disease. 4. A patient with severe systemic disease that is a constant threat to life. 5. A moribund patient who is not expected to survive without the operation.

Figure 5. Deaths occurring within 30 days directly attributable to RIG placement by ASA score of patient (n=675).

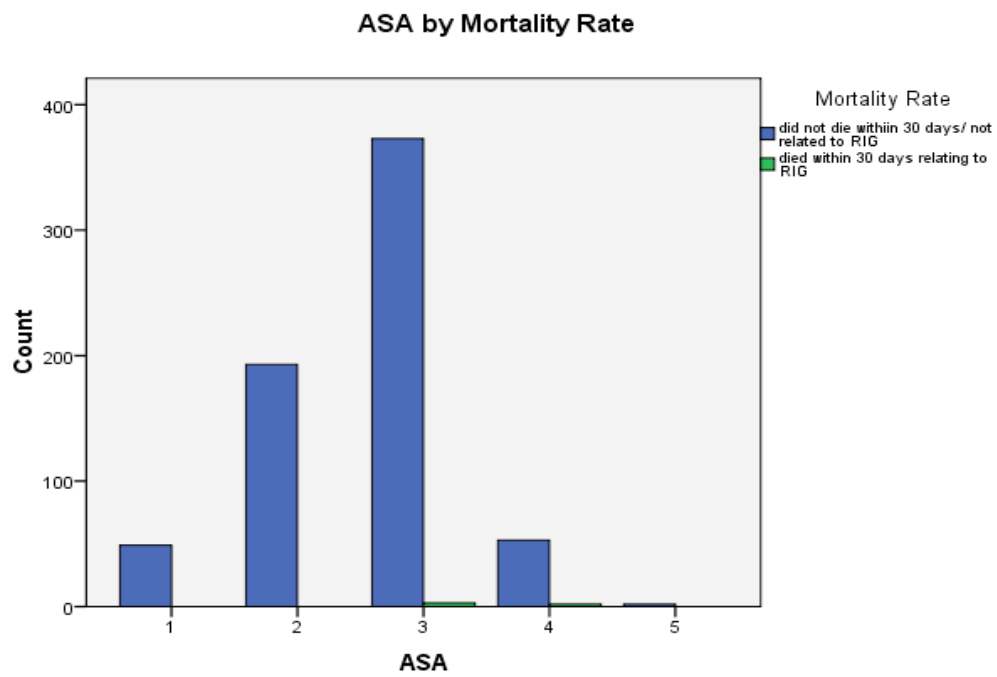


Figure 6. Pre-procedural preparation of patients for radiologically placed gastrostomy (n=599).

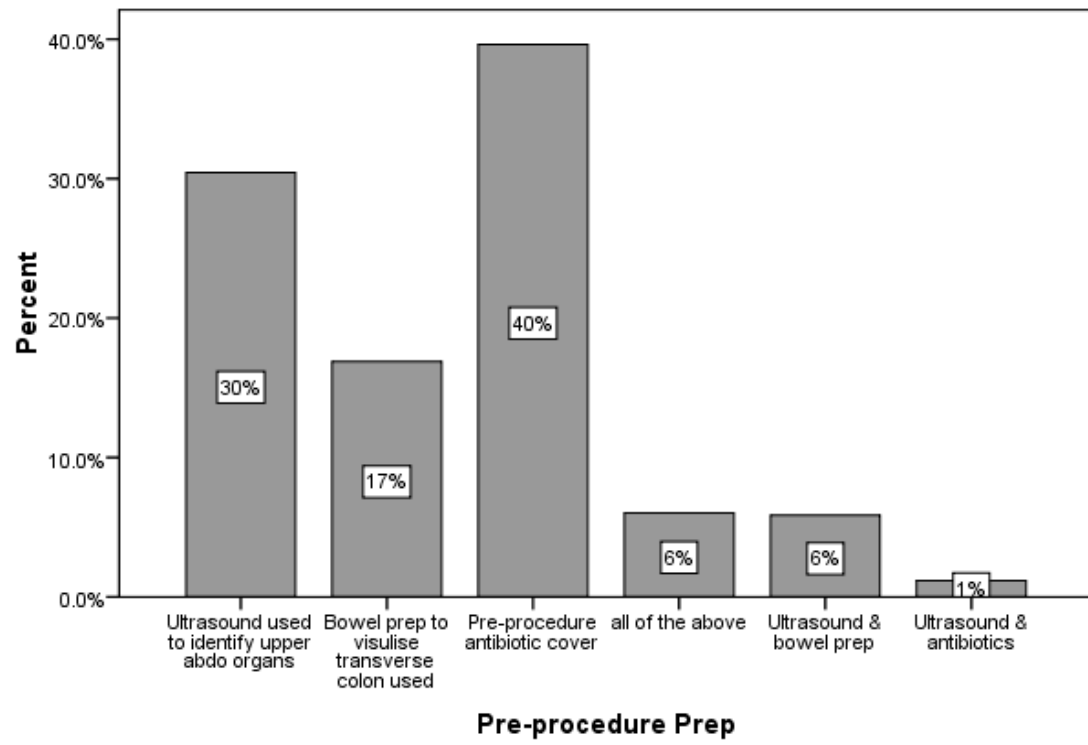


Figure 7. The number of 'T' fasteners used per procedure (n=624).

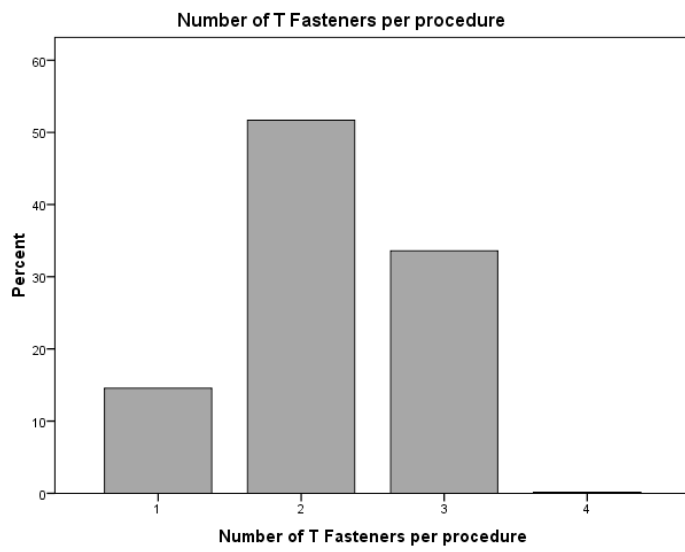


Table 1. Complications associated with the use of T-fastener gastropexy sutures

Complication	N	Percent
None	568	95%
Suture pain	7	1%
Balloon rupture	3	1% (3/351)
Suture rupture	3	1%
Other	19	3%
TOTAL complications	32	5%
TOTAL patients	600	100%

Table 2. Relationship between the incidence of pain post procedure and the number of gastropexy sutures used. Mann Whitney ,U=24145, z= -10.428, P<0.001

Number of T-fasteners	No pain	pain
1	68	19 (22%)
2	150	158(51%)
3	32	174 (85%)

Figure 8. Spread of Dose in  $\text{cGycm}^2$  across patients undergoing Radiologically placed gastrostomy. Mean = 954.68, Median 430.5 , s.d = 1521.5 ( N= 106).

