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Percutaneous endoscopic colostomy

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PRIORITISING SUMMARY

REGISTER ID **S000092**

NAME OF TECHNOLOGY **PERCUTANEOUS ENDOSCOPIC COLOSTOMY**

PURPOSE AND TARGET GROUP **AN ENDOSCOPIC PROCEDURE TO RELIEVE PATIENTS WITH COLONIC DYSFUNCTION WHO HAVE EITHER UNDERGONE CONVENTIONAL TREATMENT WITH NO SUCCESS OR ARE UNSUITABLE FOR OPEN OR LAPAROSCOPIC INTERVENTIONS**

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- ☐ Yet to emerge
- ☑ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☐ Yes
- ☐ No
- ☑ Not applicable

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	**Limited Use**	**Widely Diffused**
Austria	✓		
China	✓		
France	✓		
Germany	✓		
Japan	✓		
Netherlands	✓		
Spain	✓		
Switzerland	✓		
Taiwan	✓		
United Kingdom		✓	
United States		✓	

IMPACT SUMMARY

Percutaneous endoscopic colostomy provides relief in patients with colonic dysfunction disorders, as an alternative procedure to open or laparoscopic fixation or resection surgery. This technology is currently in the experimental stage in Australia.

BACKGROUND

Percutaneous endoscopic colostomy (PEC), a variation of percutaneous endoscopic gastrostomy (PEG), which is an established technique for parenteral gastric feeding, was first described by Ponsky et al in 1986 in patients with acute colonic pseudo-obstruction (Lynch et al 2006). PEC involves the advancement of a flexible, illuminated colonoscope, under laparoscopic control, through the anus into the proximal (upper) sigmoid colon until the loop comes into contact with the abdominal wall, which is determined by transillumination seen through the skin and palpation (Gauderer et al 2002; Rawat et al 2004). A small incision is made at the determined left lower abdominal site and a needle cannula is then inserted through the incision, abdominal and sigmoid walls and into the lumen of the bowel (Gauderer et al 2002). A plastic-covered guide wire is progressed through the cannula and retrieved out of the anus (Gauderer et al 2002). The scope is removed and a PEG-type catheter attached to the guide wire, which is then retracted back through the abdominal incision, securing the sigmoid loop to the abdominal wall (Gauderer et al 2002). The catheter is attached to a drainage bag which is flushed twice daily; the tube may remain *in situ* long- or short-term, depending on the indication for treatment (NICE 2005). Standard bowel preparation and prophylactic antibiotics are administer prior to treatment using PEC. The procedure usually takes place under sedation and local anaesthetic (Rawat et al 2004).

PEC can be used to treat recurrent sigmoid volvulus, colonic pseudo-obstruction, refractory constipation and faecal incontinence. PEC can also be used for the delivery of anti-inflammatory drugs in patients with colitis (NICE 2005). The most common indications for PEC include:

- Sigmoid volvulus, which is the most common volvulus (twisting of an organ causing obstruction) of the gastrointestinal tract, accounting for 5–8% of all intestinal obstructions (in the US) and is most common in elderly people, and individuals with a neurologic condition. Sigmoid volvulus occurs when there is an unusually narrow attachment of the root of the sigmoid mesentery to the posterior abdominal wall. This allows the two limbs of the sigmoid colon to come into contact with one another, which in turn may lead to twisting of the sigmoid colon around its mesenteric axis. Symptoms of this condition include distension, pain, failure to pass flatus or stool and vomiting (Lau et al 2006; Khan 2008), and
- Colonic pseudo-obstruction, which is a syndrome characterised by a clinical picture suggesting mechanical bowel obstruction, without physical evidence of such an obstruction within the intestine. Colonic pseudo-obstruction is a rare condition which can occur in both adults and children. Pseudo-obstruction may be chronic or acute. The symptoms, signs, and radiological findings of patients with colonic pseudo-obstruction are similar to those of patients with acute large bowel obstruction; therefore, symptoms include persistent vomiting, distension and abdominal pain (Shalkow 2006; Cagir 2008; Remy 2008).

PEC is being used as an alternative procedure in patients who have undergone conventional treatments to no avail or in patients that it is inappropriate or unsafe to perform elective open or laparoscopic fixation or resection on, namely the elderly, chronically ill and severely immunocompromised. Conventional treatments are major operations and include sigmoidopexy, sigmoidoplasty, sigmoid colectomy and primary anastomosis (Campbell 2005).

CLINICAL NEED AND BURDEN OF DISEASE

Large bowel volvulus is common in the developing world, where sigmoid volvulus accounts for 50% of all bowel obstructions, compared with the developed world at 5–8% (Lau et al 2006; Khan 2008). The mortality rate associated with sigmoid volvulus is 20–25% (Khan 2008). Colonic pseudo-obstruction is also a rare condition among the developed world; however, the mortality rate associated with it has been reported at 15–50% (Remy 2008).

Gastrointestinal dysfunction impacts greatly on a patient's quality of life as well as impinging on their ability to function socially. The physical and emotional distress suffered by a patient with sigmoid volvulus or colonic pseudo-obstruction is enough to warrant investigation into the progression of interventions available to treat them, particularly for the elderly who are often at greatest risk of developing such conditions and often cannot withstand invasive surgical management.

DIFFUSION

The majority of literature (case series and case reports) published for the use of PEC originates from the United Kingdom and the United States, where the technology appears to be used to a moderate degree. Other studies have been published for various patient populations throughout Asia and Europe, indicating that this technology has diffused quite substantially. In Australia, PEC appears to have emerged but is currently not routinely available.

A Percutaneous Endoscopic Gastrostomy tube was approved by the US Food and Drug Administration (FDA) in 1996. No such device is present within the Australian Register of Therapeutic Goods (ARTG).

COMPARATORS

PEC is an alternative procedure for patients who have undergone conventional therapy for colonic dysfunction without success or for patients where invasive surgery is an unsafe option. Existing surgical techniques are the comparator of PEC, they include:

- Sigmoid colectomy, with or without primary anastomosis.
- Sigmoidopexy, which is the most like PEC but is very rarely used in Australia. It is essentially a historical operation.
- Sigmoidoplasty, which is also rarely used and essentially a historical operation.

SAFETY AND EFFECTIVENESS ISSUES

There were three level IV studies identified as suitable for inclusion (Rawat et al 2004; Baraza et al 2007; Cowlam et al 2007). These case series discussed the safety and

effectiveness outcomes in patients, including children, with lower gastrointestinal disorders including constipation, recurrent sigmoid volvulus and chronic colonic pseudo-obstruction.

In the study by Rawat et al (2004), 15 children (12 boys, 3 girls) underwent the PEC procedure for the treatment of refractory constipation. The median age of the patient population was 5.5 years (range, 2–10 years). All of the patients were faecally incontinent and had undergone conventional therapies for a median of 4.4 years (range, 1.2–10 years) to no avail. The patients were admitted to hospital four days prior to surgery to undergo mechanical bowel preparation and prophylactic antibiotic therapy (intravenously). At 4-months follow-up, the PEC tube was converted into a button device. Each patient's outcomes were measured at 2, 6 and 12 months, and bi-annually thereafter. The median duration of follow-up was 12.5 months (2–51 months).

In the single centre, prospective study by Baraza et al (2007), 33 patients were referred to receive PEC (35 procedures, 50 tubes inserted). Inclusion criteria were recurrent sigmoid volvulus (n=19; median age: 79 years [range, 65–99 years]), severe idiopathic slow-transit constipation (n=10; median age: 51 years [range, 36–77 years]) and recurrent or unremitting pseudo-obstruction (n=4; median age: 75 years [range, 22–77]). Exclusion criteria were non-correctable coagulopathy, failure to give signed, informed consent, anterior abdominal wall sepsis and ischemic colitis. All patients (except those with pseudo-obstruction) received formal bowel preparation and prophylactic antibiotic therapy. The median duration of follow-up was 35 months (range, 21–89 months).

In the single centre, retrospective study by Cowlam et al (2007), 31 patients received PEC tube insertion for either functional constipation (n=11; age: 41 ± 1.4 years [mean ± standard error of mean]), recurrent sigmoid volvulus (n=8; age: 80.4 ± 3.5 years), colonic pseudo-obstruction (n=8; age: 70.2 ± 6.2 years or neurologic constipation (n=7; age: 50 ± 5.4 years). Patients with neurologic constipation attributed their constipation to a neurologic condition including, cerebral palsy, spinal cord injury and multiple sclerosis. Preparation for PEC insertion included full-bowel clearance 24 hours prior to the procedure, along with prophylactic antibiotic administration. The mean duration of follow-up for all patients was not specified.

Safety

One major complication was observed by Rawat et al (2004). This occurred in a female patient who previously underwent a pull-through procedure for Hirschsprung's disease and was found to have macroscopic evidence of enterocolitis. Throughout her postoperative course she experienced sepsis which required the removal of the PEC tube and subsequent colostomy. Other minor complications included granuloma formation in 50% (6/12) of patients, local tract infection in 16.5% (3/12) of patients (all successfully treated with a 5-day course of antibiotics) and abdominal pain associated with enemas in 8% (1/12) of patients.

In the study by Baraza et al (2007), 42% (8/19) of patients undergoing PEC for recurrent sigmoid volvulus died from unrelated causes, generally reflecting the frailty of this cohort. There were no other deaths. Of the total population, 30% (10/33) of patients had

their PEC tube removed between 28 days and 29 months postoperative; 6 with recurrent sigmoid volvulus, 3 with constipation and 1 with pseudo-obstruction. Three patients developed peritonitis due to faecal contamination, one patient required laparotomy, bowel resection and end sigmoid colostomy, another underwent peritoneal washout for minimal contamination and the third patient had their condition managed conservatively due to their high surgical risk, but died 3 days after the complication. Minor complications occurred in 30% (10/33) of patients, they included site infection (n=6), abdominal wall bleeding (n=2) and one patient with buried bumper syndrome, this patient was managed conservatively because she was frail but died four months after the procedure.

Cowlam et al (2007) stated that patients with recurrent sigmoid volvulus and colonic pseudo-obstruction represented a more elderly cohort with many coexisting medical conditions. The World Health Organisation (WHO) score was used to report the performance status of patients in each group. Patients in the recurrent sigmoid volvulus group had a WHO score ≥ 3 (limited self care, resting > 50% of daylight hours) and patients in the colonic pseudo-obstruction group had a score of 4 (minimal or no self care, bed bound). Thirteen per cent (4/31) of patients had their procedures abandoned because a suitable site for PEC insertion could not be found; therefore, in the remaining 27 patients, 28 tubes were inserted into the left side of the colon.

Seven out of 27 (26%) patients died, five of which from unrelated causes. The two remaining deaths were caused by faecal peritonitis immediately following surgery and at one-year follow-up, respectively. Localised peritonism occurred frequently in the immediate postoperative period, with 67% (18/27) of patients affected. The mean duration of peritonism among all of the patients was 1.5 ± 0.3 days (mean ± SEM). There was no significant relationship seen between the duration of peritonitis and the indication for PEC; however, it was noted that patients with hemodynamic compromise were less likely to respond to conservative therapy for peritonitis. Other complications included formation of granulation tissue, buried internal bolster, leakage, painful episodes and infection. Twenty of the patients had ≥ 1 infectious episode throughout follow-up (total 53 infectious episodes). The incidence density of infective episodes in the colonic pseudo-obstruction group was approximately 13.5 per 100 patient-months with PEC tube *in situ*, in the neurological constipation group it was approximately 17.5 per 100 patient-months with PEC tubes *in situ*, in the recurrent sigmoid volvulus group it was approximately 7.5 per 100 patient-months with PEC tubes *in situ* and in the functional constipation group it was approximately 53.5 per 100 patient-months with PEC tubes *in situ*. Therefore, the rate of infection was significantly higher in patients with functional constipation compared with all other patients (P=0.0004). There was no significant relationship seen between the rate of infection between patient groups and the diameter of the PEC tube or the location at which the tube was inserted (P>0.05) (Cowlam et al 2007).

Effectiveness

Rawat et al (2004) reported that distal PEC insertion was successful in 93% (14/15) of patients. In a single patient, PEC was abandoned due to technical difficulties locating the sigmoid/descending colon junction, which was found to be as a result of a massively dilated rectosigmoid colon, requiring surgical resection. This patient subsequently

underwent successful PEC tube placement. Median procedural time and hospital stay were 30 minutes (range, 20–45 minutes) and 4 days (range, 2–27 days), respectively, which was comparable to that of the open technique.

Throughout follow-up a "clean score" of 0–3 was established, where 0 indicated daily soiling, equivalent to the patients' preoperative state and 3 indicated no soiling. At 2-month follow-up 13 children were evaluated and 100% (13/13) reported significant improvement in social continence (clean score > 2). One of these patients developed subsequent faecal impaction, requiring two manual evacuations. At 12-month follow-up 6 children were evaluated, at which time 100% (6/6) were socially clean, two of these re-established normal bowel movements and no longer required the PEC tube, which was removed leaving a small (5 mm) scar. All of the patients that underwent PEC reported greater attendance at school and no significant impedance to daily activities (Rawat et al 2004).

Baraza et al (2007) noted that 74% (26/35) of procedures had satisfactory outcomes. PEC was eventually successful in 75% (18/24) of patients who survived the duration of follow-up. The procedure failed in six patients with slow transit constipation.

In the study by Cowlam et al (2007), the mean duration of the procedure was 30 minutes ± SEM 1.97 minutes. In 9 patients the original tube was removed and replaced with another tube in the existing tract, the majority of these were due to recurrent complications, including infection and faecal leakage. The mean duration of hospital stay for all patients was 15.4 days ± SEM 2.0 days. In 81.5% (22/27) of patients symptoms were reported as improved after PEC tube insertion. Of the 28 tubes inserted, 2 remained *in situ*, 3 were removed electively, 2 were inadvertently dislodged and 16 were removed due to complications. In the remaining 20 patients, 18 no longer had tubes *in situ*, of these 5 continued conservative therapies (including laxatives, enemas, biofeedback training and rectal irrigation), 2 were symptom free and 11 underwent a definitive surgical procedure. Six patients with constipation had their transit time measured before and after PEC insertion. Preoperatively, delayed transit was demonstrated (mean colonic transit time 69.3 minutes ± SEM 1.3 minutes) and (3-month) postoperatively this was significantly reduced by 35.7 hours (P=0.003) (Cowlam et al 2007).

COST IMPACT

No literature investigating the cost effectiveness of PEC was identified.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

No issues were identified from the retrieved material.

SUMMARY OF FINDINGS

The included literature represents conflicting conclusions in regards to the efficacy of PEC, with one study unsupportive of its use (Cowlam et al 2007) and the other two in favour of its introduction to routine clinical practise (Rawat et al 2004; Baraza et al

2007). The study by Cowlam et al (2007) brings into consideration the proportion of patients (13%) who it was not possible to insert the PEC tube in and the high complication rate associated with the procedure, including infection which often necessitated the removal of the device (16 tubes were removed due to complications, 2 under emergency conditions).

All three studies highlighted the importance of patient selection for optimal PEC success, with patients with recurrent sigmoid volvulus and colonic pseudo-obstruction who are unfit for invasive surgery most likely to benefit from the procedure. It is important to note that the evidence available to date is limited to case series studies involving small numbers of patients, which makes it difficult to make an accurate assessment of the associated risks of using PEC.

HEALTHPACT ACTION

Based on the quality of the evidence and the uncertainty of results reported, it is difficult to recommend the use of PEC. However, the procedure has the potential to treat a select group of patients who are unfit for surgery. It is recommended therefore that PEC is monitored for 12 months, with the view of collecting more comprehensive data on its potential utilisation.

NUMBER OF STUDIES INCLUDED

Total number of studies 3
Level IV intervention evidence

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SEARCH CRITERIA TO BE USED

Percutaneous endoscopic colostomy
Sigmoid volvulus
Colonic pseudo-obstruction
Constipation