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BRIEF ARTICLE

Effectiveness of outpatient percutaneous endoscopic gastrostomy replacement using esophagogastroduodenoscopy and propofol sedation

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Abstract

AIM: To evaluate the effectiveness of outpatient percutaneous endoscopic gastrostomy (PEG) replacement using esophagogastroduodenoscopy (EGD) and propofol sedation.

METHODS: We retrospectively assessed the outcome and complications of consecutive patients referred for PEG replacement which was performed using EGD under propofol sedation in the outpatient setting. The success rate, the mean dose of propofol, procedure time, EGD findings, discharge time from endoscopy unit, respiratory depression, and complications within 72 h of the procedure were evaluated. In a subset of these patients, the blood concentrations of propofol were measured.

RESULTS: All 221 patients underwent successful PEG replacement. The mean dose of propofol was 34 mg (range, 20-60 mg) with a mean procedure time of 5.9 min (range, 3-8 min). Reflux esophagitis (12 patients), gastric ulcer (5), gastric neoplasm (2), and duodenal ulcer (1) were newly diagnosed at replacement. Discharge from endoscopy unit was possible in 100% of patients 45 min after the procedure. Only 3.6% (8) required transient supplemental oxygen. No complications occurred within 72 h of the procedure. During EGD the level of sedation and propofol blood concentrations after administration of propofol (30 mg) in these PEG patients corresponded to those of propofol (60 mg) in middle aged subjects (control).

CONCLUSION: PEG replacement using EGD and propofol sedationin the outpatient setting was safe and practical.

Key words: Esophagogastroduodenoscopy; Gastrostomy; PEG; Propofol

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INTRODUCTION

The number of patients receiving percutaneous endoscopic gastrostomy (PEG) placement has dramatically increased[1,2]. The two commonly used methods of PEG replacement in Japan are replacement using esophagogastroduodenoscopy (EGD) or fluoroscopy in the outpatient setting in a hospital and replacement without EGD or fluoroscopy at the patient's home or nursing home. PEG replacement in the hospital is thought to be safer, but is more expensive than that at the patient's home or nursing home. Propofol is a good sedative agent for endoscopic procedures, in that it is superior to benzodiazepines with regard to rapidity of induction of sedation and is associated with a faster recovery[3-6]. Propofol sedation in high risk and elderly patients undergoing endoscopic procedures has been reported to be both safe and effective[7-15]. The aim of this study was to evaluate the effectiveness of PEG replacement using EGD and low-dose propofol sedation in the outpatient setting.

MATERIALS AND METHODS

Patients

PEG procedures were performed in 251 patients between January 2008 and December 2010 at Showa Inan General Hospital. We retrospectively enrolled patients who underwent PEG replacement at our hospital over a three-year period. Inclusion criteria included patients whose catheters were clogged and whose catheters had not been replaced in the previous 4 mo. Exclusion criteria included patients who received prior gastric surgery (21 patients) and those who were assigned to American Society of Anesthesiologists (ASA) class IV (9 patients) as well as those allergic to the drugs used or its components (soybean or egg).The endoscopic team consisted of a nurse administering the drugs and responsible for the patient, the endoscopist, the physician who performed PEG replacement and a second nurse to assist the endoscopist and the other nurse. Both the nurses and physicians had advanced cardiac life support certification. Written informed consent for PEG replacement was obtained before PEG replacement. For patients unable to give consent, consent was obtained from family members. This retrospective study was approved by the ethics committee at Showa Inan General Hospital.

PEG replacement using this method

PEG replacement was performed using a bumper-tube-type catheter (Ponsky NBR catheter, Medicon, Osaka, Japan) or a bumper-button-type catheter (Ideal Button, Olympus, Tokyo, Japan). The catheter used was chosen according to patients or their family members' requests. Under propofol sedation, conventional EGD was performed in the supine position using the standard endoscope and then PEG replacement was performed endoscopically.

Propofol sedation

As we previously reported[6,15], a butterfly needle for the bolus injection of propofol was placed in the patient's forearm shortly before the start of EGD and removed after completion of the procedure. Propofol (Diprivan, Astra Zeneca, Japan) was given by bolus injection with a standard protocol of 40 mg for patients < 70 years old, 30 mg for patients aged 70 to 89 years, and 20 mg for those 90 years or older. Adequate sedation was achieved when the patient passed through the following sequence: eyes closing, one or two yawns, and cessation of body movements. The target level of sedation was moderate conscious sedation with the patient still able to respond purposefully to verbal commands. When the target level was not obtained or the patients were undersedated, an additional injection of 10-20 mg of propofol was given.

When the peripheral oxygen saturation (SpO_2) was less than 90%, a standard chin lift maneuver was promptly performed by the nurse. If oxygen desaturation continued for more than 20 s, supplemental oxygen was given. Vital signs were frequently assessed. In addition to the monitoring of vital signs, the patients' condition was also assessed more globally by visual inspection. Monitoring and complications were recorded by a registered nurse. SpO_2 was routinely captured by visual inspection of the monitor and the value was recorded on the vital sign sheet.

After the procedure,patients were moved to the waiting room and were discharged after they were awake. The patient's conscious condition was assessed every 15 min starting 30 min after the procedure. The nurses reconfirmed the absence of reemerging sedative effects and finally permitted patients to leave the endoscopic unit.

Study design

The success rate, procedure time, EGD findings, discharge time from endoscopy unit and complications within 72 h after the procedure were retrospectively evaluated. The complications were defined as aspiration pneumonia, bleeding, perforation and peritonitis. During a 3-day period after the procedure, patients' conditions were followed up and recorded using information from health care providers. The patients returned to our hospital if problems occurred or to change the catheter. It was recommended to the families that the catheter be changed about six months after the initial PEG placement to prevent catheter deterioration. The actual decision to replace a catheter was made based on signs of tube blockage confirmed by health care providers. Tube blockage was defined as loss of patency for nutrient flow through the PEG lumen. Exchange systems consisted of the ideal button or the Ponsky gastrostomy catheter depending on the wishes of the caregiver.

Other parameters recorded during chart review included demographic data (i.e., age, sex, indications for the procedure, time to replacement, number of replacements and type of PEG catheter used).

Table 1 Demographic and baseline characteristics of 221 patients

Gender (male/female)	127/94
Age (yr) (mean ± SD)	81 ± 14
Indication for PEG	
CVA/CNSD/tumor	136/77/8
Number of replacement	
1	127 (57%)
2	58 (26%)
3 and more	36 (16%)
Time to replacement (d) (mean ± SD)	271 ± 53
Type of catheter used previously	
Bumper-tube-type	106
Bumper-button-type	103
Balloon-tube-type	4
Balloon-button-type	8

Values are numbers of patients except for age and time to replacement. PEG: Percutaneous endoscopic gastrostomy; CVA: Cerebrovascular accident; CNSD: Central nervous system disorders.

Blood concentrations of propofol

Blood levels of propofol were measured before and 30, 60 and 120 min after the completion of drug administration. The measurement of propofolblood concentration was performed according to previously described methods[16]. For the measurement of propofol, acetnitrile and internal standardwere added to a plasma sample and vortexed for 1 min. Following centrifugation at 13 000 rpm for 5 min, 50 μL aliquots of the supernatant were directly injected into the HPLC systemconsisting of a C18 reversed-phase column. Propofol and the internal standard (thymol) were quantified using coulometric electrochemical detection.

Statistical analysis

Data are presented as means and standard deviations. The Chi-square test, with Yates' correction for continuity where appropriate, was used for comparison of categorical data. Fisher's exact test was used when the numbers were small. For parametric data, the Student's *t* -test was used when 2 means were compared. A value of $P < 0.05$ was regarded as significant. All statistical evaluations were performed using SPSS version 12.0 J software (SPSS Japan Inc., Tokyo, Japan).

RESULTS

Two hundred and twenty-onepatients were enrolled in this retrospective study. The demographic and baseline characteristics of these patients are shown in Table 1. All were elderly with a mean age of 81 years. In 57% of patients this was the first PEG replacement. A bumper-type catheter was present in 95% (209/221) of patients and the time to replacement averaged 271 ± 53 d. As shown in Table 2, all PEG replacements were successful. The mean dose of propofol administered was 34 mg (range, 20-60 mg). Mean procedure time was 5.9 min (range, 3-8 min). As a result of conventional EGD before and after replacement, reflux esophagitis (12 patients), gastric ulcer (5), gastric neoplasm (2), and duodenal ulcer (1) were newly diagnosed. Discharge from the endoscopy unit was possible in 100% of patients 45 min after the procedure. Eight patients (3.6%) required transient supplemental oxygen; neither mask ventilation nor endotracheal intubation was required. No complications occurred within 72 h of the procedure (Table 2).

Table 2 Outcomes and complications of this percutaneous endoscopic gastrostomy replacement method

Successful procedure	221 (100%)
Propofol dose (mg) (mean ± SD)(range)	34 ± 11 (20-60)
Mean procedure time (range)(min)	5.9 (3-8)
EGD findings newly recognized (%)	
Reflux esophagitis	12 (5.4)
Gastric ulcer	5 (2.3)
Gastric neoplasm	2 (0.9)
Duodenal ulcer	1 (0.5)
Type of new catheters chosen	
Bumper-tube-type	112
Bumper-button-type	109
Oxygen administered	8 (3.6%)
Mask ventilation required	0
Heart rate < 50 beats/min	0
Blood pressure < 70 mmHg	0
Discharge within 45 min after the procedure	221 (100%)
Complications within 72 h of the procedure	
Aspiration pneumonia	0
Bleeding	0
Perforation	0
Peritonitis	0

Values are numbers of patients except for procedure time and propofol dose. EGD: Esophagogastroduodenoscopy.

When propofol was administered to these patients undergoing outpatient PEG replacement, blood concentrations of propofol dramatically decreased from 130 ± 36 ng/mL at 30 min to 37 ± 11 ng/mL at 120 min. Although the total dose of propofol used in these patients was only 50% of the total dose used in middle aged patients (30 mg *vs* 60 mg), similar sedation level and propofol blood concentrations were obtained (Table 3).

DISCUSSION

Although PEG replacement is generally considered safe, the procedure can be associated with complications[17,18]. In Japan, PEG replacement is often performed in the patient's home or nursing home without EGDor fluoroscopy. Non-endoscopic methods to determine correct catheter placement include insufflation of air, indigocarmine solutions, or ultrasound[19-21]. Suzuki *et al*[20] reported that PEG catheter misplacement was detected at a frequency of 0.4% in 961 patients using indigocarmine solution. Therefore, PEG replacement using EGD would improve the safety of PEG replacement, independent of the technical difficulty.

Although the dose of propofol required for endoscopy sedation is thought to be correlated to body

Table 3 Comparison of blood concentrations of propofol between PEG replacement patients and middle aged subjects who underwent esophagogastroduodenoscopy

	PEG replacement (n = 20)	Middle age (n = 20)	P value
Gender (M/F)	10/10	10/10	
Age (yr)	78 ± 2	52 ± 6	< 0.0001
Body weight (kg)	54 ± 9	57 ± 6	0.41
Dose used (mg)	30	60	
Sedation level (moderate)	20	20	
Blood propofol concentrations (ng/mL)			
30 min after injection	130 ± 36	125 ± 35	0.55
60 min	60 ± 22	55 ± 19	0.47
120 min	37 ± 11	29 ± 14	0.45

Values are mean ± SD except for gender and sedation level (numbers of patients). PEG: Percutaneous endoscopic gastrostomy.

weight, our previous study demonstrated that low-dose sedation (20-40 mg) for elderly patients was sufficient to provide adequate sedation and patient comfort[6,15]. The protocol adopted in our study was strongly focused on safety, and the initial dose of 20-40 mg of propofol was designed to minimize hypoxemia during PEG replacement. In this study, low-dose of propofol was associated with a low frequency of respiratory depression except for critically ill patients (ASA class Ⅳ). Therefore, even in elderly and class ASA Ⅲ patents undergoing PEG placement, the use of propofolallows fast recovery and may contribute to the low risk of respiratory depression or aspiration.

In Japan, benzodiazepines are widely used for sedation during EGD. However, the action of these drugs continues for a long time and prolonged monitoring may be necessary to ensure recovery before allowing the patient to return home. As complications including aspiration pneumonia did not develop within 72 h of the procedure (Table 2), this study showed that PEG replacement using propofol sedation was safe even in the outpatient setting. From these results, we suggest that propofol should be used as the drug of choice for endoscopic PEG replacement in the outpatient setting.

In this study, the dosage of propofol used averaged 34 mg (0.6 mg/kg). This dose was only 50% of the total dose used in middle aged patients and enabled these PEG patients to obtain a similar sedation level and propofol blood concentrations (Table 3), resulting in early discharge from the endoscopy unit after the procedure. One additional advantage of EGD before or after replacement is that it identified new and potentially treatable problems in 20 patients (9%) (Table 2). Therefore, EGD under low-dose propofol sedation may improve acceptability and quality of PEG replacement in the outpatient setting.

When the bumper-type catheter was used, the mean time to replacement was approximately 9 mo and the annual cost would be approximately 525 US dollars /patient with an average of approximately 1.5 replacements per year (Table 1). Therefore, even if the charge required to transport the patient to and from the hospital was added, the annual cost using this method would be less than that of replacement at the patient's home or nursing home which requires more frequent replacements of the balloon-type catheter.

The present study has some limitations in relation to the dose and cost of propofolduring the procedure. Usually, the dose of propofol as well as other sedatives used for endoscopy is adjusted according to the age and weight of the subject. However, in this study, the dose was adjusted only according to the age of the subject. For elderly PEG patients,weight was not considered important for adjusting the dose of propofol. One of the reasons for this may be that the procedure time was very short (average, 5.9 min).

In addition, although the manufacturer recommends that the balloon type of PEG cathetershould be replaced once per month,this is frequently not followed, balloon type catheters generally need to be changed more frequently than bumper type catheters. On the other hand, the bumper type of PEG catheter requires to be changed one or two times per year, and without EGD or fluoroscopy the catheter may be misplaced. Although the procedure identified new treatable problems in some patients and was safely performed in the outpatient setting in this study, four items were needed to perform our procedure. Therefore, the total cost related to the procedure would increase even if the cost was much lower than that of the procedure which required hospitalization.

In conclusion, EGD using low-dose propofol sedation allowed safe and practical PEG replacement in the outpatient setting.

COMMENTS

Background

The number of patients receiving percutaneous endoscopic gastrostomy (PEG) placement has dramatically increased. The two commonly used methods of PEG replacement in Japan are replacement using esophagogastroduodenoscopy (EGD) or fluoroscopy in the outpatient setting in a hospital and replacement without using EGD or fluoroscopy at the patient's home or nursing home. PEG replacement in the hospital is thought to be safer, but is more expensive than that at the patient's home or nursing home.

Propofol is a good sedative agent for endoscopic procedures as it is superior to benzodiazepines with regard to rapidity of induction of sedation and is associated with a faster recovery. Propofol sedation in high risk and elderly patients undergoing endoscopic procedures has been reported to be both safe and effective.

Research frontiers

This study reported on the effectiveness of PEG replacement using EGD and low-dose propofol sedation in the outpatient setting.

Innovations and breakthroughs

In this study,all patients underwent successful PEG replacement. The mean dose of propofol was 34 mg (range, 20-60 mg) with a mean procedure time of 5.9 min (range, 3-8 min). Reflux esophagitis, gastric ulcer, gastric neoplasm, and duodenal ulcer were newly diagnosed at replacement. Discharge from the endoscopy unit was possible in 100% of patients 45 min after the procedure. No complications occurred within 72 h of the procedure. During EGD, the level of sedation and propofol blood concentrations after administration of propofol

(30mg) in these PEG patients corresponded to those of propofol (60 mg) in middle aged subjects (control). In conclusion,PEG replacement using EGD and propofol sedationin the outpatient setting was safe and practical.

Applications

PEG replacement using EGD and propofol sedationin the outpatient setting would be promising worldwide.

Peer review

The present paper is a retrospective study. The article is well written.

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