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Prospective randomized comparative study of hemodynamic changes between ultrathin transnasal and conventional transoral esophagogastroduodenoscopy in percutaneous endoscopic gastrostomy placement with modified introducer method under sedation

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| | 作成者: Suzuki, Rei, Hikichi, Takuto, Sato, Masaki, |
| | Takagi, Tadayuki, Ikeda, Tsunehiko, Watanabe, Ko, |
| | Nakamura, Jun, Irisawa, Atsushi, Obara, Katsutoshi, |
| | Ohira, Hiromasa |
| | メールアドレス: |
| | 所属: |
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[Original Article]

PROSPECTIVE RANDOMIZED COMPARATIVE STUDY OF HEMODYNAMIC CHANGES BETWEEN ULTRATHIN TRANSNASAL AND CONVENTIONAL TRANSORAL ESOPHAGOGASTRODUODENOSCOPY IN PERCUTANEOUS ENDOSCOPIC GASTROSTOMY PLACEMENT WITH MODIFIED INTRODUCER METHOD UNDER SEDATION

REI SUZUKI¹, TAKUTO HIKICHI², MASAKI SATO¹, TADAYUKI TAKAGI¹, TSUNEHIKO IKEDA¹, KO WATANABE¹, JUN NAKAMURA¹, ATSUSHI IRISAWA³, KATSUTOSHI OBARA² and HIROMASA OHIRA¹

¹⁾Department of Gastroenterology and Rheumatology, Division of Medicine, School of Medicine Fukushima Medical University, ²⁾Department of Endoscopy, Fukushima Medical University Hospital, ³⁾Department of Gastroenterology, Preparatory office for Aizu Medical Center, Fukushima Medical University

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Abstract : AIM : Percutaneous Endoscopic Gastrostomy (PEG) placement is a useful but invasive method. Recently, the hemodynamic change of ultrathin transnasal esophagogastroduodenoscopy (transnasal EGD) was reported as less than that of conventional transoral EGD (transoral EGD). This study compared hemodynamic changes between transnasal EGD and transoral EGD in the setting of PEG placement using a modified Introducer method under sedation.

METHODS : All 25 patients who were performed PEG in our hospital during the period December 2007 to February 2009 were enrolled in this study. We assigned them randomly to one of two groups, Group A for transoral EGD and Group B transnasal EGD. For both groups, the modified Introducer method was used. Vital signs (systolic blood pressure ; SBP, heart rate ; HR and rate pressure product ; RPP) were monitored before and after scope insertion.

RESULTS : We assigned 13 patients to Group A and 12 patients to Group B. The mean age was 69.4 years old in Group A and 69.8 in Group B. After scope insertion, mean changes of vital signs in Group A and B were, respectively, 17.8 mmHg and 17.3 mmHg in SBP, 12.1 bpm and 5.08 bpm in HR, and 25.9 and 17.5 in RPP.

CONCLUSION : No significant differences of hemodynamic changes were seen between transnasal EGD and transoral EGD for the PEG placement with modified Introducer method under sedation. Results show that both methods are tolerable and feasible for PEG placement.

Key words : Percutaneous Endoscopic Gastrostomy (PEG), modified Introducer method, Hemodynamic change

INTRODUCTION

Percutaneous Endoscopic Gastrostomy (PEG) was first introduced by Ponsky and Gauderer at

1979¹⁾ for maintenance nutrition therapy for pediatric patients. Since then, PEG has become widely available world-wide. It is regarded as a useful method for providing access for hydration or for

鈴木 玲, 引地拓人, 佐藤匡記, 高木忠之, 池田恒彦, 渡辺 晃, 中村 純, 入澤篤志, 小原勝敏, 大平弘正 Corresponding author: Rei Suzuki, MD E-mail address: subaru@fmu.ac.jp http://www.jstage.jst.go.jp/browse/fms http://fmu.ac.jp/home/lib/F-igaku/ delivery of medication, especially for patients with impaired swallowing function and alimentary tract obstruction.

Because those who require PEG placement tend to have poor cardiopulmonary functions, not only PEG placement but also scope insertion itself is invasive for such patients. Therefore, less invasive methods are necessary. Recently, it has been reported that ultrathin transnasal EGD (transnasal EGD) causes less hemodynamic change than conventional transoral EGD (transoral EGD)²⁻⁵⁾. In this study, we compared hemodynamic changes observed for transnasal EGD and transoral EGD in the setting of PEG placement using a modified Introducer method under sedation.

MATERIAL AND METHODS

Between December 2007 and February 2009, all 25 consecutive patients who was performed PEG were enrolled in this study. Written informed consent was obtained from all patients or family before they entered the study. We randomly assigned each to one of two groups : Group A, using a conventional endoscope (GIF-Q260; Olympus Corp., Tokyo, Japan); and Group B, using an ultrathin endoscope (GIF-XP260N; Olympus Corp., Tokyo, Japan). The respective diameters of the insertion part and working channel of GIF-Q260 were, respectively, 9.2 mm and 2.8 mm. Those of GIF-XP260N were 5.5 mm and 2.0 mm. No difference was found between the two scopes with respect to resolution optics, or the tip's capability to bend up, down, left, or right.

All procedures were performed by two or more endoscopists, at least one of whom had experienced over 100 PEG placements. Group A patients received local pharyngeal anesthesia, 40 mg of 8% lidocaine spray (AstraZeneca International plc, Tokyo, Japan), before sedation. Group B patients received nasal anesthesia : a sprayed mixture of 0.4% lidocaine and 0.118% tramazoline hydrochloride. All patients underwent EGD in a recumbent position.

We inserted a scope 5 min after intravenous injection of 15 mg pentazocine hydrochloride and 2.5 mg midazolam hydrochloride. Patients were under cardiopulmonary monitoring with a nasal cannula providing oxygen at a flow rate of 2 L/min. Systolic blood pressure (SBP, mmHg), heart rate (HR, bpm), and rate pressure product (RPP)⁵⁻⁶⁾ were recorded at four points : before sedation, before scope insertion, before needle insertion, and immediately after PEG placement (Figure 1). Vital signs before scope insertion were regarded as baseline data. Changes of vital sign during scope insertion showed the effect of scope insertion and those during PEG placement showed effects of PEG placement.

Blood pressure was measured at the upper right arm. The pulse rate was measured at the left middle finger using pulse oximetry. These parameters were measured and documented on a recording sheet using automatic instruments. The RPP, which is reported as a useful marker of cardiac oxygen demand, was calculated as $HR \times SBP/100^{6.7}$.

The procedure was performed using a modified Introducer method (Direct Ideal PEG kit; Olympus Corp., Tokyo, Japan). No anti-spastic agent was given to any patient. Using this method, the anterior wall of the stomach was sutured (with two nylon sutures) using an endoscope for inserting the PEG catheter easily. The anterior abdominal wall from the rib cage up to the pelvic brim was scrubbed and



draped as for other surgical procedures; 10 ml of 1% lidocaine was injected at the best place into all layers of the abdominal wall. The stomach was punctured using a double lumen gastropexy device (Ideal lifting; Olympus Corp., Tokyo, Japan). The loop of the device was opened; then the first suture was applied. Similarly, the second suture was applied within 2-4 cm of the first suture. An approximately 10 mm incision was made between these two sutures on the anterior abdominal wall. A needle with an outer plastic sheath (18 Fr) was introduced into the stomach under endoscopic control. The needle was removed and the guidewire was replaced. Then a 24 Fr PEG kit attached to the obturator was introduced with the guidance of a guide-wire. Finally, the PEG tube was detached from the obturator (Figure 2).

To all patients, cefazolin sodium 2 g/day was given as prophylactic antibiotic for three days following the procedure. Laboratory data (white blood cell counts and c-reactive protein : CRP values) and chest X-ray images were evaluated the following day.

Categorical parameters including gender and underlying diseases were assessed using a χ^2 -test. Continuous variables including age, mean procedural time (min), and mean vital sign changes of each parameter were assessed using Student's *t*-test. All statistical analyses were performed using software (SPSS, ver. 17.0; SPSS Inc., Chicago, United States) with results considered significant for P < 0.05.

RESULTS

We assigned 13 patients to Group A (8 male, 5 female) and 12 patients to Group B (5 male, 7 female).

Table 1 presents clinical characteristics of patients in each Group. Age and procedural time are shown as mean \pm SD. In Group A, the age was 69.4 ± 14.7 years old and procedural time was



Fig. 2. Scheme of PEG with modified Introducer method (Illustration referred from Olympus CORPORATION)

a) After gastropexy, a puncture is made with an 18 G needle. Then a guide-wire is inserted through the needle.

b) Through the guide-wire, a 27 Fr dilater is inserted to gain sufficient space for PEG.

c) After dilation, a PEG kit attached to obturator is inserted.

d) 24 Fr PEG are placed.

| | Group A (<i>n</i> =13) | Group B (<i>n</i> =12) | P value |
|---------------------------------|-------------------------|----------------------------|---------|
| Age (years) | 69.4 ± 14.7 | 69.8 ± 12.2 | 0.94 |
| Gender (M/F) | 8:5 | 5:7 | 0.32 |
| Underlying disease | | | |
| Neurogenic disease | 11 | 5 | |
| \cdot GI and/or ENT disease | 2 | 7 | |
| Mean (SD) procedural time (min) | 19.7 ± 4.62 | 20.0 ± 3.50 | 0.89 |

Table 1. Patient characteristics

GI, gastrointestinal; ENT, ear, nose, throat

 19.7 ± 4.62 min. In Group B, the age was 69.8 ± 12.2 years old and procedural time was 20.0 ± 3.50 min. No significant difference between the two groups was seen for age, gender and procedural time.

Patients with gastrointestinal (GI) or ear-nosethroat (ENT) disease in Group B (11/13 cases) were more numerous than those in Group A (7/12 cases), but no significant difference was seen.

Baseline vital signs were monitored 5 min after sedation; changes of vital signs over the course of the procedure are presented in Table 2 and Figure 3.

In both groups, each vital sign was elevated, compared with baseline data, after scope insertion and PEG placement. After scope insertion, mean changes of vital signs in Group A and B were, respectively, 17.8 mmHg and 17.3 mmHg in SBP, 12.1 bpm and 5.08 bpm in HR, and 25.9 and 17.5 in RPP. After PEG placement, mean changes of vital signs in Group A and B were, respectively, 11.7 mmHg and 4.8 mmHg in SBP, 12.1 bpm and 5.08 bpm in HR, 24.8 and 22.0 in RPP. No significant

difference was seen between the two groups in the vital sign change in scope insertion and PEG placement. Changes of HR and RPP in Group B were less than those of Group A, but no significant difference between the two groups was seen.

As a complication, pneumonia occurred in one patient of Group A. However, no difference was found in the number or patients with elevated white blood cell counts or CRP values (Table 4).

DISCUSSION

This report is the first directly comparing transnasal EGD and transoral EGD in the setting of PEG with modified Introducer method under sedation. Our results showed no superiority of transnasal EGD in this setting.

Ayada *et al.*²⁾ reported the feasibility and safety of transnasal EGD for PEG placement without sedation compared to transoral EGD, describing that PEG candidates have poor cardiopulmonary function and that sedation can burden them. Although that

Table 2. Baseline vital signs were monitored before scope insertion

| | GroupA (<i>n</i> =13) | Group B (<i>n</i> =12) | P value |
|--------------------|---------------------------|----------------------------|---------|
| SBP (mmHg) | 140 ± 23.8 | 133 ± 26.0 | 0.28 |
| HR (/min) | 82.3 ± 17.9 | 81.7 ± 17.6 | 0.93 |
| RPP (mmHg/min/100) | 116 ± 23.5 | 106 ± 20.9 | 0.28 |



Fig. 3. Mean changes of vital signs during scope insertion and PEG. No significant difference was found between groups for any vital sign.

| | Group A (<i>n</i> =13) | Group B (<i>n</i> =12) | P value |
|-----------------------------------|----------------------------|----------------------------|---------|
| Complication | | | |
| Pneumonia | 1 | 0 | 0.32 |
| Laboratory data (no. of patients) | | | |
| Elevated WBC | 5 | 3 | 0.47 |
| Elevated CRP | 9 | 10 | 0.41 |

Table 3. Complications and laboratory date changes

might be true, data related to whether patients requiring PEG are highly sensitive to sedation have not been reported in the literature. Our study included no patients who were intolerant of sedation. Additionally, we infer that no significant difference was seen in change of vital signs in our study, probably because of sedation use. Considering this result, we infer that, for ethical reasons, sedation should be performed to reduce pain during PEG placement.

In addition, management of complications with ultrathin transnasal EGD is often difficult because of its limitation of available devices and weak suction capability. PEG-related complications occur in about 10% of all cases^{8,9}. In case with rare but life-threatening PEG-related complications such as bleeding or perforation, we occasionally have to change the scopes which enable us to use various devices during PEG placement if we use transnasal EGD. Considering this experience, we recommend to use transoral EGD under the same condition as this study.

In conclusion, this prospective randomized study showed no significant difference between transnasal EGD and transoral EGD in PEG placement under sedation. Each method is tolerable and feasible for patients who require PEG placement. Considering the management of complication during PEG placement, we recommend to select the conventional transoral EGD under the condition with a modified Introducer method under sedation.

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