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Retrospective Cohort Study

Time-trends and outcomes of gastrostomy placement in a Swedish national cohort over two decades

Skogar ML *et al.* Gastrostomies: Time-trends and outcomes in Sweden

Abstract

BACKGROUND

Percutaneous endoscopic gastrostomy (PEG) and laparoscopically inserted gastrostomy, have become the gold standard for adult patients and children, respectively, requiring long-term enteral nutrition support. Procedure-related mortality is a rare event, often reported to be zero in smaller studies. National data on 30-d mortality and long-term survival rates after gastrostomy placement are scarce in the literature.

AIM

To study the use of gastrostomies in Sweden during 1998-2019 and to analyze procedure-related mortality, short- (< 30 d) and long-term survival.

METHODS

In this retrospective, population-based cohort study, individuals that had received a gastrostomy between 1998-2019 in Sweden were included. Individuals were identified in the Swedish National Patient Register and survival analysis was possible by cross-referencing the Swedish Death Register. The cohort was divided into three age groups: Children (0-18 years), adults (19-64 years) and elderly (≥ 65 years). Kaplan-Meier with log-rank test and Cox-regression was used for survival analysis.

RESULTS

In total 48682 individuals (52% males, average age 60.9 ± 25.3 years) were identified. The cohort consisted of 12.0% children, 29.5% adults and 58.5% elderly. An increased use of gastrostomies was observed during the study period, from 13.7/100000 to 22.3/100000 individuals ($P < 0.001$). The use of PEG more than doubled (about 800 to 1800/year), with a corresponding decrease in open gastrostomy (about 700 to 340/year). Laparoscopic gastrostomy increased more than 10-fold (about 20 to 240/year). Overall, PEG, open gastrostomy and laparoscopic gastrostomy constituted

70.0% ($n = 34060$), 23.3% ($n = 11336$) and 4.9% ($n = 2404$), respectively. Procedure-related mortality was 0.1% ($n = 44$) overall (PEG 0.05%, open 0.24%, laparoscopic 0.04%). The overall 30-d mortality rate was 10.0% (PEG 9.8%, open 12.4%, laparoscopic 1.7%) and decreased from 11.6% in 1998-2009 *vs* 8.5% in 2010-2019 ($P < 0.001$). One- and 10-year survival rates for children, adults and elderly were 93.7%, 67.5%, 42.1% and 79.9%, 39.2% and 6.8%, respectively. The most common causes of death were malignancies, cardiovascular, and respiratory diseases.

CONCLUSION

The annual use of gastrostomies in Sweden increased during the study period, with a shift towards more minimal invasive procedures. Although procedure-related death was rare, the overall 30-d mortality rate was high (10%). To overcome this, we believe that patient selection should be improved.

Key Words: Gastrostomy; Percutaneous endoscopic gastrostomy; Dysphagia; Enteral nutrition; Long-term; Survival; Complication

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Core Tip: In this large population-based cohort of 48682 individuals, the use of gastrostomies in Sweden increased during the 22-year study period, from 13.7/100000 to 22.3/100000 individuals. Percutaneous endoscopic gastrostomy more than doubled, while a 10-fold increase was seen in laparoscopic gastrostomies. Although the procedure-related mortality was low (0.1%), a 10%-overall 30-d mortality was seen. The latter, however, decreased from 11.6% in 1998-2009 to 8.5% in 2010-2019. One- and 10-year survival rates for children, adults and elderly were 93.7%, 67.5%, 42.1% and 79.9%, 39.2% and 6.8%, respectively. The most common causes of death were malignancies, cardiovascular, and respiratory diseases.

INTRODUCTION

In modern health care, gastrostomies play a crucial role in the management of patients that require long-term enteral nutrition support^[1]. Dysphagia due to stroke, neurodegenerative diseases like Parkinson's or Alzheimer's, and head and neck cancers are among the most common indications^[2]. A gastrostomy may also be placed for stomach decompression to resolve persistent nausea and vomiting *e.g.*, as a palliative procedure in patients with malignant bowel obstruction^[3].

The technique for placing a gastrostomy has evolved significantly over the years, with several approaches available today. In 1980, percutaneous endoscopic gastrostomy (PEG) was introduced as a minimally invasive approach^[4]. The low complication rates associated with PEG has led to widespread acceptance, making PEG the gold standard for enteral access in patients that require long-term enteral nutrition support^[5]. Other available techniques include radiologically inserted gastrostomy (RIG) and insertion by open- or laparoscopic surgery. RIG, percutaneously placed under radiological guidance, is a good alternative when endoscopy is contraindicated *e.g.*, obstructing pharyngeal- or esophageal cancer. Today, open surgical gastrostomy is mostly reserved for specific situations where endoscopic or radiological approaches are not feasible, or during emergent surgery for stomach decompression. Finally, laparoscopically inserted gastrostomy has become standard in children at many institutions because of less complications as compared to PEG in children^[6,7].

Long-term survival and quality of life outcomes following gastrostomy have been the subject of extensive research. In short, gastrostomy has been associated with improved nutritional status, reduced hospitalizations^[8] and enhanced overall quality of life^[9] in patients that require long-term enteral nutrition support. Furthermore, studies have shown that timely gastrostomy placement is associated with improved survival rates and fewer complications when compared to delayed placement^[10-12]. However, in patients with dementia, there is no evidence that enteral tube feeding improves survival or quality of life^[13]. This underlines the importance of choosing the right indication in

order to treat patients who actually benefit from a gastrostomy. In addition, a delayed intervention leads to loss of benefit and greater harm, which is illustrated by higher rates of morbidity and mortality^[2].

This paper aims to provide an overview of the use of gastrostomies in Sweden by studying the trends during the last two decades. In addition, we seek to analyze data pertaining to procedure-related mortality, as well as short- (< 30 d) and long-term survival after a gastrostomy procedure. The purpose is to assist physicians in the risk-benefit assessment of a gastrostomy procedure in the clinical setting.

MATERIALS AND METHODS

This retrospective population-based cohort study included all patients that have had a gastrostomy between 1st of January 1998 to 31st of December 2019 in Sweden, according to the Swedish National Patient Register (NPR). NPR stores gender, age, name of hospital, admission and discharge dates, principal and additional diagnoses on all inpatient care and outpatient visits at hospital-based clinics. Diagnoses and surgical procedures^[14] are coded according to the Swedish version of the International Statistical Classification of Diseases and Related Health Problems (ICD)^[15] with a validity of 85%-95% in general^[16]. Data from NPR were cross-matched with data from the Swedish Death Register which added information about date of death and cause of death. All data was anonymized. The study was conducted in accordance with the ethical standards of the Helsinki Declaration.

Population and type of gastrostomy

Individuals were identified in the NPR by the codes for gastrostomy, *i.e.*, JDB 00 (gastrostomy inserted by open surgery), JDB 01 (laparoscopically inserted gastrostomy) and JDB 10 (PEG). Calculation of annual operative volumes per 100000 inhabitants was performed. For analysis of time-trends, the cohort was halved into an early and a late group, receiving gastrostomy in 1998-2009 and 2010-2019, respectively. The cohort was

further divided into three age groups: Children (0-18 years), adults (19-64 years) and elderly (≥ 65 years).

Indication

The indication for gastrostomy was based on the principal ICD-10 diagnosis, or if not applicable (*e.g.*, dysphagia - R13), indication was searched for in the additional diagnoses, at the time of gastrostomy. Indication was then grouped into four main categories: (1) Malignancy; (2) Neurological diseases; (3) Cerebrovascular lesions (CVL); and (4) Non-malignant gastrointestinal conditions (*e.g.*, gastric-, duodenal- or other bowel perforations, fixation of large hiatal hernias, bowel obstruction without concomitant gastrointestinal malignancies).

Outcome

Procedure-related mortality was defined as having a surgical complication as cause of death (ICD10-code: T80-T88) within 30 d. Short-term mortality was defined as death within 30 d, while long-term survival was analyzed up until 10 years after the insertion of gastrostomy.

Statistics

Independent sample *t* test and χ^2 test were used as univariate analyses for continuous and categorical variables, respectively. Kaplan-Meier with log-rank test was used for survival analyses. Multivariate adjusted survival analyses were performed using Cox-regression, adjusting for differences in gender, age group, type of gastrostomy and time-period, and presented as hazard ratios (HR) with 95% confidence interval (CI). All *P*-values were 2-sided and *P* < 0.05 was considered statistically significant. All analyses were done using IBM SPSS Statistics version 28.

RESULTS

In total 48682 patients had a gastrostomy during the study period, whereof 23500 (48.3%) in the early time-period. The cohort consisted of 52% males and average age was 60.9 ± 25.3 years. A population-based increase in the use of gastrostomies during the study period was observed, from 13.7/100000 to 22.3/100000 individuals ($P < 0.001$).

Age distribution

Children constituted 12.0% ($n = 5828$), adults 29.5% ($n = 14340$) and elderly 58.5% ($n = 28483$) of the cohort. In all three groups, the number of gastrostomies increased during the study period, from 6.1/100000 to 16.3/100000, from 7.1/100000 to 10.7/100000, and from 46.5/100000 to 62.5/100000, respectively. The total number of gastrostomies are demonstrated in Figure 1.

Type of gastrostomy

The technique used for placing the gastrostomy was PEG, open gastrostomy and laparoscopic gastrostomy in 70.0% ($n = 34060$), 23.3% ($n = 11336$) and 4.9% ($n = 2404$), respectively. The remaining 1.8% ($n = 882$) were not specified in the register. During the study period, the use of PEG more than doubled (about 800 to 1800/year), with a corresponding decrease in open gastrostomy (about 700 to 340/year). Laparoscopic gastrostomy increased more than 10-fold (about 20 to 240/year). All changes were statistically significant ($P < 0.001$) (Figure 2).

PEG was the most commonly used technique in all three age-groups, followed by open surgery in adults and elderly. The gradual increase in laparoscopically inserted gastrostomy, made laparoscopic gastrostomy the second most common in children (Figure 3).

Indications

The most common indication for a gastrostomy overall, was various non-malignant gastrointestinal conditions (19.7%), closely followed by CVL (18.9%), malignancies

(18.7%) and neurological disorders (16.7%). The two most common individual diagnoses were stroke and neurodegenerative disorders, including amyotrophic lateral sclerosis (Table 1). As demonstrated in Figure 4, PEG dominated in CVL and neurological diseases, while the opposite was seen in non-malignant gastrointestinal conditions where open gastrostomy placement was predominantly used.

Outcome

30-day mortality: The overall 30-d mortality rate was 10.0% ($n = 4863$), ranging from 0.3% ($n = 17$) in children to 6.2% ($n = 883$) in adults and 13.9% ($n = 3962$) in elderly. For the three different types of gastrostomies, the 30-d mortality was 9.8%, 12.4% and 1.7% for PEG, open and laparoscopic gastrostomy, respectively. The 30-d mortality during the early period was higher than during the late period, 11.6% *vs* 8.5%, $P < 0.001$ (Figure 5).

Adjusted analysis (cox-regression) of differences in gender, time-period, age-group and type of gastrostomy, identified male gender (HR = 1.11, 95%CI: 1.05-1.18), early time-period (HR = 1.33, 95%CI: 1.26-1.41), open gastrostomy (HR = 1.44, 95%CI: 1.35-1.53) and belonging to the adult (HR = 20.9, 95%CI: 12.7-34.4) or elderly age groups (HR = 50.2, 95%CI: 30.7-82.3) as risk factors for 30-d mortality (Supplementary Table 1).

Procedure-related mortality: In 44 patients (16 PEG, 27 open and 1 laparoscopic) the primary cause of death was coded as directly related to a complication of the procedure, giving an overall procedure-related mortality of 0.1% (PEG: 0.05%, open: 0.24%, laparoscopic: 0.04%). The most common procedure-related death was bowel perforation ($n = 16$), followed by acute cardiovascular event ($n = 9$), acute respiratory failure (including aspiration and overdose of sedative drugs, $n = 8$) and gastrointestinal bleeding ($n = 1$). In the remaining 10 cases septicemia was coded as the secondary cause of death.

In an additional 141 patients, a procedure-related complication was judged to have contributed to the cause of death within 30 d. Thus, in 185 patients (0.4%), a procedure-

related complication was either the direct cause of death or a contributing factor. This was more common among those that had undergone an open gastrostomy, 0.9% ($n = 102$), compared to 0.2% for PEG ($n = 74$) and 0.2% for laparoscopic gastrostomy ($n = 6$), $P < 0.001$.

Long-term survival: During the mean observational time of 10.0 ± 6.1 years, 70% ($n = 34055$) of the patients had died after in mean 21.9 ± 35.6 months after receiving the gastrostomy. One-year and 10-year survival rates were 93.7%, 67.5%, 42.1%, and 79.9%, 39.2%, 6.8% in children, adults, and elderly, respectively (Figure 6). The most common stated causes of death were malignancies (C00-D48) 24.4%, cardiovascular diseases (I00-I99) 23.1%, and respiratory conditions (J00-J99) 20.3%.

DISCUSSION

In this nationwide cohort study of 48682 individuals having received a gastrostomy 1998-2019 in Sweden, an increased use of gastrostomies was seen, from 13.7/100000 to 22.3/100000 inhabitants. The increase was found in PEG and laparoscopically inserted gastrostomy, while open gastrostomy was halved. We believe that this mirrors the international shift towards more minimal invasive procedures^[17]. Very few studies examine the number of gastrostomy placements in other countries, but the observed doubling of PEG is similar to the 2.5-fold increase observed in Poland 2010-2020^[18]. The United States experienced an exponential increase in PEG use during 1980-2000, resulting in more than 216.000 annual PEGs^[19]. Based on a population of about 280 million in year 2000, this should correspond to 77/100000 inhabitants. However, the opposite trend has been described in Japan, where a decreased use of PEG has been observed since 2011^[20], especially in patients aged 80 years and over, which has resulted in an increased use of total parenteral nutrition in home care. Stated reasons include changes in the health insurance system, reimbursement-related factors and emotional and ethical barriers.

The overall most common indication for gastrostomy in the present study was various non-malignant gastrointestinal conditions (19.7%), closely followed by CVL (18.9%), malignancies (18.7%) and neurological disorders (16.7%). Neurological dysphagia is otherwise one of the most common indications for PEG tube insertion and the incidence among stroke patients has been reported to be as high as 78%^[21]. In our study, stroke (ischemic or hemorrhagic) was the most common subgroup (17%). In a German, prospectively collected case series of 1041 PEG-patients, the most common indication was neurogenic dysphagia (43%), followed by cancer (37%)^[22]. In the previously mentioned Polish PEG-study^[18], where indication also was based on ICD-10 codes, the most common indication was dysphagia and malnutrition (37.2%), which, as the author states, might have been a consequence of other diseases. The high proportion of non-malignant gastrointestinal conditions in this study is due to perioperative placement of a gastrostomy for stomach decompression in the case of emergency surgery. Examples of such conditions include perforated ulcer, bowel obstruction or incarcerated hiatal hernia.

Although gastrostomy tube placement, especially PEG, is considered a relatively safe surgical procedure, complications are common, which is likely due to greater frailty given an elderly population with multiple comorbidities. About one third of PEG insertion results in minor complications, such as local wound infection, tube dislodgement, or peristomal leakage. Major complications, such as bowel or liver injuries, aspiration pneumonia or major bleedings are rare, affecting 2% to 4% of the patients^[23-26]. In this registry-based study, it was unfortunately not possible to explore the incidence of specific complications. However, in 0.1% (PEG: 0.05%, open: 0.24%, laparoscopic: 0.04%) a procedure-related complication was stated as the primary cause of death and in 0.4% (PEG: 0.2%, open: 0.9%, laparoscopic: 0.2%) of the patients, a procedure-related complication was stated as contributing factor to death within 30 d. Our large number of patients allowed for the detection of this rare event, which is often reported to be zero in smaller studies^[22,26-28]. The fact that the majority of the procedure-

related deaths occurred after an open gastrostomy is no surprise and likely explained by other concomitant surgical procedures as previously mentioned.

The 30-d mortality rates are difficult to compare between studies because of differences in indication, age, comorbidities *etc.* Previous PEG-studies report a 30-d mortality of 3.3% ($n = 302$, Taiwan)^[28], 3.9% ($n = 388$, Japan)^[29], 6.5% ($n = 168$, Brazil, and $n = 787$, Germany)^[26,30], 13% ($n = 277$, Canada)^[27] and 23.5% ($n = 272$, Israel)^[31]. Our 30-d mortality rate of 9.8% in PEG on a national level, is more or less in line with these studies. Interestingly, the overall 30-d mortality decreased from 11.6% in the early time-period (1998-2009) to 8.5% in the late time-period (2010-2019). We believe that the main driving factor was the shift towards more minimal invasive techniques, PEG and laparoscopic gastrostomy. In addition to time-period and open gastrostomy, older age and male gender was associated with an increased 30-d mortality. Due to the registry-based design, we were not able to verify other predictive factors, such as elevated C-reactive protein, anemia, previous intensive care admission, low albumin, high creatinine levels, malignancy, diabetes, heart failure and low body mass index, found in other studies^[23,26,27,29,30].

One of the first publications on laparoscopic gastrostomy in children was published in 1997^[32] and the technique has since then been modified, described by Backman *et al*^[33]. In a meta-analysis from 2018^[6], it was found that PEG was associated with a significantly higher risk of major complication (odds ratio = 3.86, 95%CI: 1.90-7.81) compared to laparoscopic gastrostomy in a pediatric population and therefore it was stated that laparoscopic gastrostomy should be the preferred method in children. The adoption of the new modified technique for laparoscopic gastrostomy is mirrored in this study, where a clear increase was observed from 2010 on. Likely, it explains the ten-fold increase in laparoscopic gastrostomy procedures in Sweden during the study period.

Although procedure-related mortality was a rare event (0.1% overall), an observed 30-d mortality of 10% cannot be ignored. In the case of patient death within 30 d of placement, the gastrostomy may hardly have benefited the patient. We believe these

numbers are important to consider in the risk-benefit analysis when consulting patients before gastrostomy placement, especially in frail patients. However, we acknowledge the difficulties in deciding which patient will benefit from a gastrostomy, both indication, timing of the intervention and ethical aspects are of importance. A recent Cochrane review found no evidence that enteral tube feeding improved survival or quality of life in patients with dementia^[13]. However, in patients with amyotrophic lateral sclerosis, PEG placement was found to prolong survival, if performed before the disease had become too advanced, according to another recent review^[34]. The present one-year survival in elderly of 42.1% is very similar to the 38% reported from a systematic review of patients (> 65 years) receiving a PEG^[35]. Thus, on a national level, our patient selection seems acceptable. In children, however, the situation is completely different, as almost 80% were alive at ten years, in this study.

The cause of death is often related to the underlying diseases^[23], which we could confirm when comparing indication for gastrostomy and cause of death, *e.g.*, malignancies (18.7% *vs* 24.4%) and cardiovascular diseases (17.0% stroke *vs* 23.1% overall cardiovascular death). Respiratory conditions were the third most common cause of death (20.3% of the overall mortality), likely because dysphagia (with the concomitant risk of aspiration pneumonia) was one of the main indications for gastrostomy.

Strengths and limitations

The registry-based nature of this study is both a strength and a limiting factor. The registries made it possible to include all gastrostomies in Sweden with a 100% follow-up on survival-time and cause of death since it is mandatory for physicians to register these data in the Swedish Death Register. However, the major limiting factor of this study where the possibility to find out the indication for the gastrostomy, since it was based on ICD-10 codes. Many patients had symptomatic diagnoses such as dysphagia (R13) as principal diagnosis or a principal diagnosis was missing at the index occasion of gastrostomy. Despite efforts to find the indication among secondary diagnosis or at

the occasion before gastrostomy, 26% of the patients were not possible to categorize into one of the four main categories.

CONCLUSION

During the last two decades in Sweden, there has been a significant increase in the number of PEG and laparoscopically inserted gastrostomies, while open gastrostomy has become less common. Although, procedure-related death was rare, the overall 30-d mortality rate was high (10%). One-year and 10-year survival rates were 93.7%, 67.5%, 42.1%, and 79.9%, 39.2%, 6.8% in children, adults, and elderly, respectively. This study contributes with robust survival data that can assist physicians in a risk-benefit assessment before gastrostomy placement and we believe that the 30-d mortality should be lowered by selecting patients who actually benefit from a gastrostomy.

ARTICLE HIGHLIGHTS

Research background

Placing a gastrostomy in patients requiring long-term nutritional support is standard of care. Since the introduction of percutaneous endoscopic gastrostomy (PEG), there has been a continuous shift towards minimal invasive procedures. However, nation-wide population-based data on the use of different techniques and overall outcome is scarce.

Research motivation

As many patients are frail, the balance between risk and benefit is of particular importance. In the present nation-wide population-based cohort, we could evaluate indication, choice of gastrostomy technique, complications and mortality, as well as time-trends over two decades. The dissemination of such findings can lead to improved care.

Research objectives

Study the use of gastrostomies in clinical praxis concerning number and type of procedures (PEG, open gastrostomy, and laparoscopic gastrostomy), as well as indication (malignancy, neurological diseases, cerebrovascular lesions, and non-malignant gastrointestinal conditions). Analyse time-trends concerning any shift between the three different methods, procedure-related mortality, and short-term mortality (within 30 d). Explore long-term survival up until 10 years after gastrostomy placement.

Research methods

Data on 48682 individuals, having had a gastrostomy between 1998-2019 in Sweden, was collected from the mandatory National Patient Register. Indication, type of gastrostomy and complications were based on registered International Statistical Classification of Diseases and Related Health Problems-diagnoses. Date and cause of death were retrieved by cross-matched data from the Death Register. The cohort was divided into three age groups: Children (0-18 years), adults (19-64 years) and elderly (\geq 65 years), as well as type of gastrostomy: PEG, open gastrostomy and laparoscopic gastrostomy.

Research results

The annual use of gastrostomies in Sweden increased during the study period, from 13.7/100000 to 22.3/100000 individuals. PEG more than doubled, while a 10-fold increase was seen in laparoscopic gastrostomies. Although the procedure-related mortality was low (0.1%), a 10%-overall 30-d mortality was seen. The latter, however, decreased by time. One- and 10-year survival rates for children, adults and elderly was 93.7%, 67.5%, 42.1% and 79.9%, 39.2% and 6.8%, respectively. The most common causes of death were malignancies, cardiovascular conditions, and respiratory diseases.

Research conclusions

More and more gastrostomies are placed in Sweden. The increase is mainly due to the fact that the number of PEGs more than doubled. Although the 30-d mortality rate decreased during the study period, it is still high (10%). The most common causes of death were consistent with the gastrostomy indication, and, as expected, long-term survival was mainly dependent on patient age.

Research perspectives

The present nation-wide population-based results can be used as a reference in future trials and in quality controls at various levels.

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