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Elective paraesophageal hernia repair in elderly patients: an analysis of ACS-NSQIP database for contemporary morbidity and mortality

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Abstract

Background Elective paraesophageal hernia (PEH) repair in asymptomatic or minimally symptomatic patients ≥ 65 years of age remains controversial. The widely cited Markov Monte Carlo decision analytic model recommends watchful waiting in this group, unless the mortality rate for elective repair was to reach ≤ 0.5%; at which point, surgery would become the optimal treatment. We hypothesized that with advances in minimally invasive surgery, perioperative care, and practice specialization, that mortality threshold has been reached in the contemporary era. However, the safety net would decrease as age increases, particularly in octogenarians.

Methods We identified 12,422 patients from the 2015–2017 ACS-NSQIP database, who underwent elective minimally invasive PEH repair, of whom 5476 (44.1%) were with age ≥ 65. Primary outcome was 30-day mortality. Secondary outcomes were length of stay (LOS), operative time, pneumonia, pulmonary embolism, unplanned intubation, sepsis, bleeding requiring transfusion, readmission, and return to OR.

Results Patients age ≥ 65 had a higher 30-day mortality (0.5% vs 0.2%; $p < 0.001$). Subset analysis of patients age 65–80 and > 80 showed a 30-day mortality of 0.4% vs. 1.8%, respectively ($p < 0.001$). Independent predictors of mortality in patients ≥ 65 years were age > 80 (OR 5.23, $p < 0.001$) and COPD (OR 2.59, $p = 0.04$). Patients ≥ 65 had a slightly higher incidence of pneumonia (2% vs 1.2%; $p < 0.001$), unplanned intubation (0.8% vs 0.5%; $p < 0.05$), pulmonary embolism (0.7% vs 0.3%; $p = 0.001$), bleeding requiring transfusion (1% vs 0.5%; $p < 0.05$), and LOS (2.38 vs 1.86 days, $p < 0.001$) with no difference in sepsis, return to OR or readmission.

Conclusion This is the largest series evaluating elective PEH repair in the recent era. While morbidity and mortality do increase with age, the mortality remains below 0.5% until age 80. Our results support consideration for a paradigm shift in the management of patients < 80 years toward elective repair of PEH.

Keywords Paraesophageal hernia · Elective repair · Elderly

Paraesophageal hernias (PEH) account for 5 to 10% of all hiatal hernias but are increasingly common with advancing age, with over 90% of them being type III hernias [1]. It is believed that with aging, there is progressive attenuation and stretching of the phrenoesophageal membrane along with weakening and enlargement of the diaphragmatic hiatus [1–3]. While patients with PEH may present with typical reflux symptoms of heartburn and regurgitation, it is the symptoms of postprandial epigastric discomfort, chest pain, dysphagia, exertional dyspnea, anemia, and early satiety that are more common and require careful questioning.

Elective repair of asymptomatic or minimally symptomatic PEH in patients ≥ 65 continues to be controversial. Recent European expert consensus with 19 experts from 10 countries were divided on offering surgery to asymptomatic patients based on advancing age [4]. With the advent of minimally invasive approaches resulting in shorter hospitalizations and lower complication rates after a PEH repair in older patients [2, 5], many surgeons advocate elective repair due to the risk of acute gastric volvulus requiring an emergency operation. Elective minimally invasive hernia repair is shown to be associated

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with a much lower mortality and morbidity than emergency surgery [6, 7]. Also the likelihood of developing major complications following an emergency operation increases with the age of the patient [6, 8, 9]. Additionally the operative procedure during emergency surgery is often different and not a definitive repair, and entails reduction of the herniated stomach with a gastropexy or gastrostomy alone without a definitive hernia sac reduction, closure of the diaphragmatic hiatus with mesh reinforcement, esophageal lengthening if indicated, and an antireflux procedure.

Proponents of watchful waiting approach in this population cite a much lower mortality rate of emergency PEH repair in the range of 5.4–17%, rather than upwards of 40% as has been reported in some other studies [10, 11]. Additionally the risk of developing life-threatening symptoms of acute gastric volvulus has been reported to be lower than previously believed, about 1.1%/year, with the lifetime risk of 18% for a 65-year-old patient [12]. A high anatomic recurrence rate after PEH repair has also been cited as a reason against operative management of these patients, with failure rates ranging from 7 to 42% reported in literature [13–15].

As the life expectancy in the United States continues to increase, it is projected that the elderly in North America will represent 20% of the entire population by 2030. This increase in aging population, combined with significantly increased utilization of radiography and CT imaging in the last two decades [16], will lead to identification of many more older patients with large asymptomatic or minimally symptomatic paraesophageal hernias. A Markov Monte Carlo decision analytic model developed to track a hypothetical cohort of patients ≥ 65 with asymptomatic or minimally symptomatic paraesophageal hernias using mortality rates of elective and emergency surgery concluded that watchful waiting is the preferred approach for these patients. However, should the mortality rate of elective repair be less than 0.5%, then it would supersede watchful waiting as the optimal treatment option [12]. Previous studies have shown that the increase in mortality in PEH patients is explained by pulmonary complications, venous thromboembolism, and hemorrhage [17]. Our hypothesis was that with advances in minimally invasive surgery, perioperative care, and practice specialization, that mortality threshold has been reached; however, the safety net would decrease with increasing age, particularly in octogenarians. The primary aim of this study was to determine 30-day mortality of patients ≥ 65 undergoing elective minimally invasive paraesophageal hernia repair in the contemporary era.

Materials and methods

Study cohort

A retrospective analysis from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database was performed after signed Data Use Agreement for the ACS-NSQIP. This is a nationally validated, risk-adjusted, outcomes-based program to measure and improve quality and surgical outcomes by collecting data on 30-day morbidity and mortality at over 450 hospitals. We queried the ACS-NSQIP database from 2015 to 2017 for all patients over the age of 18 years of age undergoing elective minimally invasive PEH hernia using Current Procedural terminology (CPT) codes 43281 and 43282. These patients were stratified into cohort by age (< 65 years vs ≥ 65 years) and compared. A subset analysis was performed for patients ≥ 65 years, with breakdown into groups of 65–80 and > 80.

The study was determined to be exempt from the Institutional Review Board at NYU Grossman School of Medicine.

Demographic and clinical variables

Patient demographics, including age, sex, body mass index (BMI), inpatient status, smoking history, co-morbidities (diabetes, HTN, COPD, CHF, renal failure on hemodialysis), significant weight loss (defined as weight loss > 10% in past 6 months), independence status, and steroid use, were collected. Each patient was assigned a frailty index based on a previously validated 5-point scale [18]. Points were assigned for each of the following: COPD or recent pneumonia, CHF, non-independent functional status, hypertension (HTN) requiring medication, and diabetes. Groups were classified into 2 categories (frailty index < 2 or ≥ 2).

Outcomes variables

Primary outcome variable of interest was 30-day mortality. Secondary outcomes of interest included length of stay (LOS), operative time, pneumonia, unplanned intubation, pulmonary embolism, sepsis, bleeding requiring transfusion, return to OR, and readmission. Univariate analysis was performed comparing demographics and postoperative outcomes between patients < 65 and ≥ 65 years. Binary logistic regression was conducted to identify independent predictors of mortality controlling for age, gender, COPD, smoking status, HTN, and malnutrition. Secondary analyses were performed using frailty index as a covariate score and looking at patients 65–80 and > 80 years to identify predictors of mortality in this older cohort.

Statistical analysis

Statistical analysis was performed using the SPSS statistical analysis software package (International Business Machines, Chicago, IL). Descriptive statistics are recorded between age groups. Categorical data were compared by Chi-square or Fishers exact test, and continuous variables by Mann–Whitney *U* or Student's *t*-test as appropriate, with significance set as $p \leq 0.05$. Parametric data are represented as mean ± SD and non-parametric data as median (interquartile range). Binary logistic regression models were used to identify independent predictors of mortality. Significance was set at $p \leq 0.05$.

Results

Study cohort

Within the primary ACS-NSQIP data set, a total of 13,523 patients underwent minimally invasive PEH hernia repair from 2015 to 2017. After eliminating those with emergent or unknown status, 12,422 of these procedures were elective, of which 5476 (44.1%) of patients were ≥ 65 years. Number of patients ≥ 65 by frailty index are indicated in Table 1.

Table 1 Frailty index frequency and percent in patients ≥ 65

Frailty index	Frequency	Percent
0	1777	32.5
1	2863	52.3
2	773	14.1
3	51	1.1
4	2	0.0
5	0	0.0

Demographic and clinical data

Patients ≥ 65 years were significantly more likely to be female, have an inpatient procedure, and have the following comorbidities: COPD, CHF, chronic steroid use, malnutrition, and HTN on medication. Patients ≥ 65 were also more likely to have a frailty index ≥ 2 (15.3% vs 7.6%, $p < 0.001$). Younger patients (< 65) were more likely to smoke and have BMI > 30 (Table 2).

On univariate analysis, patients ≥ 65 years had a significantly longer LOS (2.38 ± 3.93 days vs 1.86 ± 2.38 days, $p < 0.001$) and operative time (142.76 ± 68.60 min vs 134.85 ± 72.88 min, $p < 0.001$), as well as a higher incidence of pneumonia (2.0% vs 1.2%, $p < 0.001$), unplanned intubation (0.8% vs 0.5%; $p < 0.05$), pulmonary embolism (0.7% vs 0.3%; $p = 0.001$), bleeding requiring transfusion (1% vs 0.5%; $p < 0.05$), and 30-day mortality (0.5% vs

Table 3 Univariate analysis of outcome variables between age < 65 and age ≥ 65

Variable	Age < 65	Age ≥ 65	*p* value
LOS (days)	1.86 ± 2.38	2.38 ± 3.93	**< 0.001**
Operative time (min)	134.85 ± 72.88	142.76 ± 68.60	**< 0.001**
Pneumonia	81 (1.2%)	108 (2.0%)	**< 0.001**
Unplanned intubation	35 (0.5%)	45 (0.8%)	**0.031**
Pulmonary embolism	20 (0.3%)	38 (0.7%)	**0.001**
Sepsis	37 (0.5%)	29 (0.5%)	0.998
Return to OR	172 (2.5%)	149 (2.7%)	0.394
Readmission	379 (5.5%)	292 (5.3%)	0.779
Mortality at 30 days	14 (0.2%)	29 (0.5%)	**< 0.001**
Bleeding occurrences	44 (0.6%)	57 (1%)	**0.015**

Table 2 Comparing demographics between Age < 65 and Age ≥ 65

Variable	Age < 65 *n* = 6946	Age ≥ 65 *n* = 5476	*p* value
Female gender	4868 (70.1%)	4162 (76.0%)	**< 0.001**
Inpatient procedure	4100 (59%)	3771 (68.9%)	**< 0.001**
COPD	229 (3.3%)	399 (7.3%)	**< 0.001**
CHF	20 (0.3%)	38 (0.7%)	**< 0.001**
Smoker	924 (13.3%)	213 (3.9%)	**< 0.001**
On HD	8 (0.1%)	7 (0.1%0	1
Disseminated cancer	7 (0.1%)	4 (0.1%)	0.765
Steroid use for chronic condition	240 (3.5%)	259 (4.7%)	**< 0.001**
> 10% wt loss in 6 mo	68 (1.0%)	106 (1.9%)	**< 0.001**
HTN on meds	2533 (36.5%)	3460 (63.2%)	**< 0.001**
BMI > 30	4172 (60.1%)	2253 (41.1%)	**< 0.001**
Frailty Score ≥ 2	525 (7.6%)	836 (15.4%)	**< 0.001**

0.2%, $p < 0.001$) (Table 3). There was no statistically significant difference in incidence of sepsis, return to OR, and readmission between the two groups. When comparing patients > 80 years to 65–80 years, the older patients (> 80 years) had an even higher mortality (1.8% vs 0.4%, < 0.001). Patients with a frailty score ≥ 2 did not have a significantly higher mortality on univariate analysis (0.6% vs 0.3%, p = NS).

On multivariate analysis of the entire cohort controlling for age, gender, COPD, smoking, HTN, malnutrition, and BMI > 30, gender [OR 1.99 (95% CI 1.08–3.70, $p = 0.028$)], age [OR 2.27 (95% CI 1.13–4.53, $p = 0.020$)], and COPD [OR 2.98 (95% CI 1.29–6.89, $p = 0.010$)] remained independent predictors of 30-day mortality (Table 4). Looking at patients ≥ 65 years, controlling for the same co-variates as above, independent predictors of 30-day mortality included age > 80 [OR 5.32 (95% CI 2.46–11.49, $p < 0.001$)] and COPD [OR 2.59 (95% CI 1.02–6.58, $p = 0.04$)]. Gender was no longer significant in patients ≥ 65 years. (Table 5).

A second set of regressions was run controlling for age, gender, and frailty index ≥ 2. Frailty index ≥ 2 was not found to be an independent predictor of mortality for the entire cohort. In the cohort of patients ≥ 65, controlling for the same co-variates, interestingly frailty index ≥ 2 was again not noted to be a significant predictor of 30-day mortality [OR 1.09 (95% CI 0.41–2.88, p 0.86)] (Table 6).

Discussion

Early data showing high rates of morbidity and mortality for laparoscopic PEH repair are used for hypothetical cohort studies evaluating favored treatment strategy and continue to drive patient selection for surgery today [12, 19]. Patients with age > 65 who tend to have multiple comorbidities are historically deemed at an increased operative risk and mortality, and elective surgical repair of paraesophageal hernia is often discouraged. Large population-based studies have shown pulmonary complications, thromboembolic events, and hemorrhage as the primary drivers of the increased mortality in patients undergoing paraesophageal hernia repairs compared to routine antireflux surgery [17]. We found a very low incidence of bleeding requiring transfusions, pneumonia, pulmonary embolism, unplanned intubation, and sepsis in patients ≥ 65 undergoing elective PEH, and the mortality in this group remained low at 0.5%.

Considerable advancements have been made in minimally invasive surgery and perioperative optimization and management since the initial adoption of laparoscopic repair of paraesophageal hernias in the 1990s. Increasingly sophisticated robotic platforms allow for enhanced visualization, dexterity, and precision. A recent large series of robotic paraesophageal hernia repairs of 233 patients reported zero conversions, mean estimated blood loss of 33 cc, and a less than 2% incidence of pneumonia and thromboembolic complications [20]. Surgeon expertise and practice specialization in foregut surgery [21] as well as regionalization of care to high-volume centers [22] have also shown to result in a significantly lower incidence of major complications after PEH repair, such as esophageal perforation, septic shock, and respiratory failure, as well as lower need for reoperation and improved perioperative outcomes at high-volume surgical centers versus centers in which PEH repair is performed infrequently [23–25].

The risk of developing an acute incarceration of paraesophageal hernia leading to emergency surgery is reported at 1.1%/year with a lifetime risk of 18% for a 65-year-old patient [12]. Considering the longevity of current patients, with 85% of patients of advanced age alive at 5 years and 70% at 10 years, it leaves the patients susceptible to complications of a watchful waiting approach for considerably longer times [6]. It is likely that these rates of progression

Table 4 Multivariate analysis of factors associated with 30-day mortality

Variable in equation	Adjusted OR (95% CI)	p value
Gender	1.99 (1.08–3.70)	**0.02**
BMI > 30	0.81 (0.43–1.52)	0.51
Age > 65	2.28 (1.14–4.53)	**0.02**
Current Smoker (w/in 1 yr)	1.13 (0.39–3.26)	0.83
Hx COPD	2.99 (1.29–6.87)	**0.010**
> 10 lb wt loss (w/in 6mo)	2.79 (0.66–11.79)	0.16
HTN requiring medication	1.30 (0.69–2.46)	0.42

Table 5 Multivariate analysis of factors associated with 30-day mortality in patients ≥ 65 years old

Variable in equation	Adjusted OR (95% CI)	p value
Gender	2.06 (0.97–4.35)	0.58
Age > 80	5.32 (2.46–11.49)	**< 0.001**
Current Smoker (w/in 1 yr)	2.89 (0.82–10.12)	0.10
Hx COPD	2.58 (1.01–6.57)	**0.04**
HTN requiring medication	0.75 (0.35–1.58)	0.44
> 10 lb wt loss (w/in 6mo)	0.44 (0.10–1.93)	0.27

Table 6 Multivariate analysis of factors associated with 30-day mortality with frailty index in those ≥ 65 years

Variable	Adjusted OR (95% CI)	p value
Age > = 80	5.23 (2.49–11.02)	**< 0.001**
Male gender	2.20 (1.04–4.62)	**0.04**
Frailty index ≥ 2	1.09 (0.41–2.88)	0.86

to emergency are overestimates, since these were derived from older studies which predate the widespread use of CT scanning and many asymptomatic or minimally symptomatic patients with PEH were not recognized. Conducting large longitudinal studies to follow asymptomatic or minimally symptomatic patients to assess the annual probability of progression to an emergency in the contemporary era would likely not be practical, and hypothetical cohorts may be needed to estimate the current incidence of progression. Previous studies have shown emergent presentation to be an independent predictor of mortality, major complications, readmission to the ICU, and return to the operating room, with a range of 7- to 20-fold increase in mortality after emergent surgery in elderly patients [6, 8]. The Markov Monte Carlo decision model used the lowest value for the mortality rate of emergency surgery (6%), based upon which elective PEH repair would be the preferred treatment option, should the mortality rate for it not exceed 0.5% [12]. Some recent studies have challenged even the 6% mortality rate, showing lower mortality rates of 3–5.5% after emergent surgery [7, 26], while others have shown no difference in mortality compared to elective surgery after risk-adjusted analysis [27, 28]. A lower contemporary mortality for emergent surgery could alter the mortality threshold requirement for elective surgery in the elderly. Pooled analysis of recent large published studies evaluating the mortality of patients ≥ 65 after emergent surgery would be needed to derive this number. Currently there are only a few such studies, with wide variation in reported rates.

In our study of more than 12,000 patients undergoing elective minimally invasive PEH repair, 30-day mortality rates remained at less than 0.5% for patients up to age 80. Based on these results, this procedure ranks between laparoscopic cholecystectomy and laparoscopic colectomy in terms of 30-day mortality (0.3% and 0.9%, respectively) [29, 30]. The 30-day mortality rate increased to 1.8% in patients > 80, with age and COPD being independent predictors of mortality in older patients, but not frailty index ≥ 2. The principal demographic difference in our study was that patients greater than 65 were more likely to be female, had a significantly higher incidence of cardiac, pulmonary, and renal comorbidities, as well as frailty score ≥ 2. This is to be expected as with increasing age, there is also an increase in comorbidities as measurable through the American Society of Anesthesiologists (ASA) scores. Other series studying PEH patients have also shown women making up the majority of the cohort [2, 15, 17]. Published studies across multiple specialties have demonstrated that women tend to live longer than men due to vascular, hormonal, and genetic differences [31].

Thirty-day mortality less than 1% for elective minimally invasive PEH repair in elderly patients has been shown in other large studies despite an increasing number of comorbidities in this population [5, 25]. A recent NSQIP analysis of 2681 patients found only an increase in minor morbidity in older patients undergoing laparoscopic paraesophageal hernia repair with no significant difference between mortality and serious morbidity [5]. We did find a slightly higher incidence of bleeding requiring transfusions, pneumonia, pulmonary embolism, and unplanned intubation in patients ≥ 65, with no difference in sepsis, return to OR, and readmission. While the operative time and LOS were also longer in the older age group in our analysis, they were only increased by a median of 8 min and 0.5 days, respectively. Previous studies have also reported similar results in length of stay with only a slight increase comparing patients > 75 to younger patients (2.8 days vs 1.9 days) after laparoscopic paraesophageal hernia repair [2].

With an aging population coupled with the increased incidence of paraesophageal hernias in the elderly, frailty as an assessment of patient's physiologic reserve and resistance to stressors becomes increasingly important in older patients. We sought to evaluate the condensed 5-item frailty index [18] as a predictor of postoperative mortality in patients ≥ 65 as opposed to previously described modified frailty index (mFI) based on 11 clinical variables in NSQIP, which would lead to exclusion of a relatively high number of patients who were missing one or more variables used to calculate the MFI [32]. We used the cutoff for frailty index as ≤ 2. We would have liked to set the bar even higher since a low number runs the risk that patients who are not actually frail are assessed as such, but our numbers would be very low beyond that index cutoff to make any meaningful conclusions (Table 1). On multivariate analysis, frailty index ≤ 2 was not an independent predictor of postoperative mortality in patients ≥ 65. Only age > 80 and COPD were identified as independent predictors of postoperative mortality in this cohort. Frailty index has been shown by others to be a valid predictor of major postoperative morbidity and discharge to a facility other than home, with a trend toward increased mortality and readmission with increasing frailty scores [32]. With an aging US population, it is of paramount importance to identify frail patients at high risk for not just higher postoperative mortality, but postoperative and long-term morbidity as well as worse quality of life due to discharge to a facility other than home, which were not measured in our study. Further studies are necessary to validate other frailty index scales to allow real-time decision making in elderly patients.

As more published studies continue to show very low mortality rates after elective paraesophageal hernia repair in older patients supporting operative repair in patients, there is discussion about greater quality-adjusted life expectancy in patients undergoing watchful waiting for asymptomatic or mildly symptomatic paraesophageal hernias. These studies use two assumptions in their model impacting the analysis, first an annual recurrence rate of 15.9% and second that 55% of recurrent hernias are symptomatic, both of which are subject to controversy [19]. Recurrence rates show wide variation between studies due to a lack of standardization in repair of large paraesophageal hernias, especially esophageal lengthening and use of mesh for hiatal reinforcement. Also there is varying lengths of follow-up and discrepancy between radiological and symptomatic recurrences. Radiologic recurrence rates in some studies have been reported to be as high as 30–50% [13, 33], with a meta-analysis reporting a recurrence rate of 25.5% [34]. However, recent studies performed with the same experienced surgical team in a high-volume center have shown anatomic recurrence rates of 8 to 9%, much lower than previously reported [20, 35]. Previous studies have shown little to no impact on quality of life (QOL) scores from the majority of anatomic recurrences of hiatal hernia, which are small 2 to 3 cm sliding hiatal hernias [36, 37]. While hernia recurrences have been reported as late as 64 months post-surgery [13], the majority of recurrences are detected within the first postoperative year as has been shown on structured follow-up studies by Morino, with some authors reporting all anatomic recurrences on follow-up in the first year [33, 38]. Thus, an annual recurrence rate calculation year after year does not seem applicable to QOL analysis.

Our study has several limitations, mainly related to limitations of the NSQIP database. It is limited by the nature of database-driven research and the possibility for selection bias in patient and technique selection. Furthermore, while the CPT codes 43281 and 43282 are used for laparoscopic and robotic paraesophageal hernia repairs with and without mesh, it is possible that patients who had sliding hiatal hernias were also placed under these CPT codes. We have no radiologic and anatomic descriptions in the database; therefore, the definition of paraesophageal hernia was based purely on CPT coding. Also the database excludes patients whose procedures were converted from laparoscopic or robotic to open, and patient deaths occurring beyond 30 days after surgery are not captured. The results from this study may not generalize to the broader population and smaller community practices, since hospitals that participate in NSQIP are likely to be larger hospitals and the participation is voluntary. It is also possible that our study underestimates the 30-day mortality in older patients due to selection bias. A large majority of patients greater than 65 years old in our study database had a frailty index of ≤ 2 on the 5-point scale, suggesting that surgeons may have been more inclined to apply watchful waiting in patients deemed to be of a higher perioperative risk.

This is the largest series evaluating elective PEH repair in the modern era with advances in minimally invasive surgery, perioperative optimization, and practice specialization. Patients ≥ 65 years of age had a 30-day mortality of 0.5% with only a slight increase in morbidity, operative time, and length of stay compared to the younger cohort. Independent predictors of mortality in this group were age > 80 and COPD, and special consideration should be given to this subset when evaluating elective repair. Based on the Markov Monte Carlo decision analytic model, we have reached the mortality threshold where surgery would be the favored treatment strategy for asymptomatic and minimally symptomatic PEH in patients ≥ 65. Our results support consideration for a paradigm shift in the management of patients < 80 years toward elective repair of PEH.

Compliance with ethical standards

Disclosures Dr. Tanuja Damani is a speaker, proctor, and consultant for Intuitive Surgical. Dr. Paresh Shah is a speaker for Intuitive Surgical, consultant for Stryker, and co-founder of Care Centra. Drs. Juliet Ray and Mahmoud Farag have no conflicts of interest or financial ties to disclose.

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