

## Self-Expandable Metal Stents for the Management of Gastric Outlet Obstruction: Experience from A Tertiary-Care Facility in Pakistan

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### Keywords:

Gastric outlet obstruction; Self-expandable metal stents; Technical success; Clinical success; Gastric outlet obstruction score

## 1. Abstract

### 1.1. Aim

Gastric outlet obstruction is commonly considered as advanced malignancies of the stomach, duodenum, pancreas, hepatobiliary, and ampullary regions. Surgical bypass and chemotherapy are the common treatment modalities for gastric obstruction. This study was done to determine the outcomes of self-expandable metal stents in patients with gastric outlet obstruction.

### 1.2. Methods

Forty-seven symptomatic patients with gastric outlet obstruction who underwent self-expandable metal stents in Patel hospital, Karachi-Pakistan from January 2013 till January 2020 were selected for the study. Data on the relief of obstructive symptoms such as; nausea and vomiting and improvement in food intake was the primary clinical success outcome, measured by the gastric outlet obstruction score. Data were statistically analyzed using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

### 1.3. Results

Number of 47 patients received uncovered self-expandable stent (Boston Scientific WallFlex) placements during the study period with n=22 (46.8%) single stents, while n=25 (53.2%) dual stents (enteral and biliary), with a mean  $\pm$ SD age of 60.6 ( $\pm$ 14.1) years. Fifteen (31.9%) participants showed good improvement, n=23 (48.9%) patients showed mild improvements, n=04 (8.5%) reported moderate

improvement, while only n=05 (10.6%) patients showed no improvements at all after placement of the intervention. The median survival time after the intervention was 8.5 weeks (95% CI: 5.469 – 11.674) in the study population.

### 1.4. Conclusion

The endoscopic stenting for malignant gastric outlet obstruction appears to be an effective alternative to surgical palliative bypass.

## 2. Introduction

Gastric outlet obstruction (GOO) is a result of mechanical gastroduodenal obstruction. Moreover, the incursion of upper abdominal carcinomatosis or metastases from advanced extra-abdominal cancer may also incite GOO. GOO is primarily divided into three major categories, which are benign mechanical, malignant mechanical, and motility disorders [1]. The malignant gastric outlet obstruction (MGOO) typically distresses the areas of the distal stomach or proximal duodenum, resulting in poor prognosis due to gastric and pancreatic malignancies [2]. However, malignant infiltration by neoplasms from adjacent organs and compression by malignant regional lymphadenopathy may also contribute to an exacerbation of existing obstruction [3]. Obstruction is an advanced occurrence in GOO manifesting with nausea, vomiting, poor appetite, and an overall reduction in the quality of life of these patients adding to quality-adjusted life years (QALYs) alongside a significant burden on the healthcare resources [4, 6]. In some patients, symptoms including abdominal pain, esoph-

agitis, electrolyte imbalance, poor nutrition, severe dehydration, early satiety, and weight loss are not uncommon due to nutritional deficiencies and other complications [7]. These complications often result in delays in oncologic and other therapeutic interventions and subsequent comorbidities and mortality [8]. Inability to eat and drink not only results in comorbidities and malnutrition, but it also affects the rate of digestion and metabolism since these processes are directly affected by the level of enjoyment experienced while eating and drinking. These experiences in turn cause severe distress and a major factor predisposing these patients to the risk of anxiety and hopelessness [7, 8]. Despite the availability of treatments with varying degrees of effectiveness, the prognosis remains poor due to multiple underlying factors. Some of the promising treatments for managing MGOO include chemotherapy, surgical bypass of the obstruction, decompressive gastrostomy, and endoscopic duodenal stent placement [1, 8]. As for the chemotherapy treatment, there is no standard regimen to ease the cancer symptoms in terminal patients. As a consequence, the mortality rate is substantially high in this specific obstruction sub-type. However, clinical studies and medical researches to improve the operations and success of several targeted therapies are ongoing to achieve more efficient treatments for obstructive biliary cancer as well as gastric carcinoma [9, 10]. Surgical bypass on the other hand has reported success in treating pancreatic cancer; however, a relatively high complication rate and mortality have been documented. Because of high cost, poor outcomes, and prolonged hospital stay, the surgical bypass is not a suitable option for the treatment of advanced cancers such as gastric outlet obstruction disorder, particularly in patients with a compromised state of health [11 -13]. For several years, self-expanding metal stents (SEMSs) have been used to treat malignant gastric outlet obstruction in clinical research settings. In contrast, metal stenting is the most effective option as it allows for the resumption of dietary intake alongside shorter hospital stays. While the cost-effectiveness of this modality is superior to other treatments with success ranging from 75 to a hundred percent [14 -18]. Moreover, this technique is also associated with high technical and clinical success rates, low mortality, morbidity rates, and complication rate, lower incidence of delayed gastric emptying, and faster symptom relief [19 – 22]. Hence, SEMS placement can be considered an effective and safe alternative to managing malignant gastric outflow obstruction in patients with poor general health indicators.

Therefore, a study was conducted at a private, tertiary healthcare facility in Karachi, Pakistan to determine the technical and clinical outcomes of the self-expandable metal stent treatment. It is designed for patients already prone to gastric outlet obstruction as an effective alternative to surgical bypass in Pakistan.

### 3. Materials and Methods

#### 3.1. Patient population

Case series were conducted at the Endoscopy unit of Patel hospital, Karachi Pakistan. Patel hospital is a private, tertiary care facility in

the metropolitan city of Karachi catering to a population of approximately 0.6 million. About 200 individuals reported with inoperable malignant carcinoma causing gastric outlet obstruction, who then underwent uncovered metallic stent placement. Of these, 47 symptomatic patients, including males and females between ages 20 to 90 years were selected and their records were assessed from January 2013 to January 2020. Patients' follow-up was carried out via telephone calls, where a maximum of 05 telephone calls with 5-minute interval time was made to each patient for post-procedure clinical outcomes. Patients who failed to receive the calls in all 05 attempts or those who did not provide verbal consent were excluded from the study. In total 03 patients were excluded based on the above-defined criteria. The process is adapted from the research by JinWonMo. et al. [26] and all to the procedures complied with the ethical guidelines of the World Medical Association Declaration of Helsinki. In addition, formal approval from the Institutional Review Board of Patel Hospital (IRB No: 105) was taken.

#### 3.2. Evaluation of the degree of gastric outlet obstruction

The improvement in oral food intake was the primary outcome for evaluating the improvement in the degree of GOO. Improvement in oral food intake was assessed using the gastric outlet obstruction scoring system (GOOSS) [26]. The scoring specified level of oral intake on the scale of 0-3 as follows: 0= No oral intake, 1= Only Liquid diet, 2= Soft diet, 3= Regular diet.

#### 3.3. Definitions

The information (variables) from the patient database of the endoscopy department and post-procedure follow-ups that evaluated the success of the research included:

1. Technical success,
2. Clinical success (survival rate) of the procedure,
3. Improvement in oral food intake,
4. Duration of stent patency,
5. Information on complications,
6. Re-interventions.

The technical success of the stent placement is defined by adequate deployment and positioning of the stent. Whereas for clinical success, the relief of obstructive symptoms such as nausea and vomiting and improvement of oral intake was taken into account. The Stent patency time was the time interval from SEMS insertion to SEMS restenosis. Complications were graded into major or minor levels. The Minor complications included those that were not life-threatening, such as abdominal pain, nausea, and vomiting. Lastly, aspiration pneumonia, bleeding, perforation, stent migration, sepsis and all related life-threatening complications were considered major complications.

#### 3.4. Data Collection

All patient data including the demographics, procedural and diag-

nostic reports, and characteristics were collected and retrieved from the medical records and endoscopic database of patients from the hospital. The retrospective data included the patient's baseline characteristics, the gastric outlet obstruction score, stent patency time, complications, etc.

### 3.5. Statistical Analysis

Data were statistically analyzed using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA). All continuous variables were expressed as means and standard deviations, and categorical variables as frequencies and percentages. A Chi-square test compared the differences between the groups and the categorical variables. The overall survival after stent insertion was calculated from the date of intervention until death. All patients who were alive at the time of follow-up or did not pick up the call were censored. For the estimation of survival, Kaplan Meier analysis was performed and the difference between the survivals of the two GOOS groups was compared using the Mantel-Cox log-rank test.

## 4. Results

### 4.1. Study Characteristics

Forty-seven symptomatic patients (n=47), underwent uncovered

self-expandable stent placement (n=22 (46.8%) single, while, n=25 (53.2%) dual) in the study, with a mean  $\pm$ SD (median) age in range of 60.6 ( $\pm$ 14.1) years. Among the participants 59.6% (n=28) were female and rest were male (40.4%, n=19). Majority of the GOO presented with pancreatic cancer (25.5%, n=12), and gall bladder cancer (23.4%, n=11), meanwhile 14.9% (n=7) had duodenal cancer, 10.6% (n=5) stomach cancer, 6.4%(n=3) ampullary cancer, 4.3% (n=2) cholangiocarcinoma, 4.3% (n=2) lymphoma and 4.3% (n=2) esophageal cancer. Other (4.3%, n=2) were benign stricture and (2.1%, n=1) were hepatocellular carcinomas. For each etiological finding, the stenting was successfully performed at the respective obstruction site in all participants and none were excluded. The site of obstruction included duodenum (68.1%, n=32), antrum (10.6%, n=5), gastrojejunum (2.1%, n=1) and esophagus (2.1%, n=1).

Thirty-two (n=32) procedures were performed to address duodenal obstruction; of these, 40.6% involved single stent, 59.4% were dual, n=08 were pylorus obstruction with 62.5% managed with a single stent, and 37.5% with dual. Another n=05 were antral obstructions, 40% managed with a single stent, and 60% with dual. One gastrojejunum and oesophageal obstruction were managed with a single stent.

The details are shown in Table 1.

**Table 1:** Demographic and Clinical Characteristics of Patients (n = 47).

Study Characteristics	
Variable	mean $\pm$ SD (median)
Age in years	60.6 $\pm$ 14.1
	<b>N (%)</b>
<b>Gender</b>	
Male	19 (40.4%)
Female	28 (59.6%)
<b>GOO Etiology</b>	
Pancreatic CA	12 (25.5%)
Gall Bladder CA	11 (23.4%)
Duodenal CA	7 (14.9%)
Stomach CA	5 (10.6%)
Ampullary CA	3 (6.4%)
Cholangio CA	2 (4.3%)
Lymphoma CA	2 (4.3%)
Esophagus CA	2 (4.3%)
Benign Stricture	2 (4.3%)
Hepatocellular CA	1 (2.1%)
<b>Stenting</b>	
Single	22 (46.8%)
Dual	25 (53.2%)
<b>Re-stenting</b>	04 (8.5%)
<b>Advise PTC</b>	04 (8.5%)
<b>Site of Obstruction</b>	
Duodenum	32 (68.1%)
Antrum	05 (10.6%)
Gastrojejunal	01 (2.1%)
Esophagus	01 (2.1%)

## 4.2. Clinical and Technical Success

The stenting resulted in 100% technical success and an appreciable clinical success rate (Detail of the outcomes are expressed in Table-2). Stents were successfully placed in all 47 patients without any technical problems during the procedure or the period following the endoscopic procedure. However, as per the improvement outcome results, 5 (10.6%) patients showed no improvements at all after placement of the stents, whereas 15 (31.9%) participants showed good improvement, 23 (48.9%) patients showed mild improvements and 4 (8.5%) reported moderate improvement.

Optimal GOO score was noted in 18 (38.3%) patients who resumed a regular diet (score=3) post treatment, while 22 (46.8%) patients scored 1 on GOOS scale. The remaining 2 (4.3%) patients were on a soft/semi-solid diet (score=2) and 5 (10.6%) patients totally failed to recommence normal eating at all (score=0). One or more than one post-procedure symptoms were presented by patients, where vomiting 53.7% (n=36), jaundice 26.1% (n=12), nausea 13.4% (n=9), abdominal pain 6.0% (n=4), weight loss 3.0% (n=2), hematemesis 3.0% (n=2), melena 1.5% (n=1) and dysphagia 1.5% (n=1) were reported.

## 4.3. Survival after the Intervention

The survival period of terminal patients is expressed in Table 2. According to that, 10.6% (n=5) patients hardly survived for two weeks, 21.3% (n=10) patients survived for 2-4 weeks. The highest ratio of

people surviving after GOO treatment (27.7%, n=13) managed to sustain 5-12 weeks, 23.4% (n=11) of the majority made it to 13-24 weeks. While 17% (n=8) reached less than 24 weeks of survival after the SEMs treatment. Over Forty-one (n=41) patients died during the follow-up period and another 12.8% (n=06) survived at the time of the last follow-up. The median survival was 8.5 weeks (95% CI: 5.469 – 11.674) illustrated by the plot (Figure 1).

Median survival in the patients with GOOS score 0 and 1 was 6.2 weeks (95% CI: 4.983 – 7.874); in those who had GOOS score between 2 and 3 was 21.5 weeks (95% CI: 10.651 – 32.207). A significant improvement in life expectancy after the intervention was recorded in patients with GOOS scores 2 and 3 ( $p < 0.001$ ) as illustrated in the plot (Figure 2).

The demographic characteristics of patients compared with the GOO Score showed no significant association between the GOO Score with age, gender, and the number of stents used in the procedure. The details are given in Table 3.

Restenting was performed in only 04 (8.5%) patients where the primary reasons for restenting constituted regrowth in prepylorus and pylorus region in 02 (50%) patients and tumour extending to duodenal and the common bile duct stricture in another 02 (50%) patients. Only one patient achieved GOO Score 3 after restenting and survived for five months, while the other 03 (75%) showed mild improvement with survival ranging from 45 days to four months.

**Table 2:** Clinical and Technical Success of the GOOS Intervention (n = 47).

<b>Clinical success and Treatment Success</b>	
<b>Outcomes</b>	<b>N (%)</b>
No improvement	05 (10.6%)
Mild improvement	23 (48.9%)
Moderate improvement	04 (8.5%)
Good improvement	15 (31.9%)
<b>GOO Score; mean ±SD (median)</b>	1.7 ±1.1 (1)
<b>GOO Scoring for Food Intake</b>	
0 score (No Oral Intake)	05 (10.6%)
1 score (Liquid Diet)	22 (46.8%)
2 score (Soft Diet)	02 (4.3%)
3 score (Regular Diet)	18 (38.3%)
<b>Mortality</b>	41 (87.2%)
<b>Survival</b>	
< 2 weeks	05 (12.2%)
2 – 4 weeks	10 (24.4%)
5 – 12 weeks	13 (27.7%)
13 – 24 weeks	11 (23.4%)
> 24 weeks	08 (17%)
<b>Symptoms (post-intervention)</b>	
Abdominal pain	04 (6.0%)
Weight loss	02 (3.0%)
Jaundice	12 (26.1%)
Nausea	09 (13.4%)
Vomiting	36 (53.7%)
Hematemesis	02 (3.0%)
Malena	01 (1.5%)
Dysphagia	01 (1.5%)
<b>Technical success</b>	100 (100%)
* All age groups.	
** Few patients presented two or more symptoms concomitantly.	

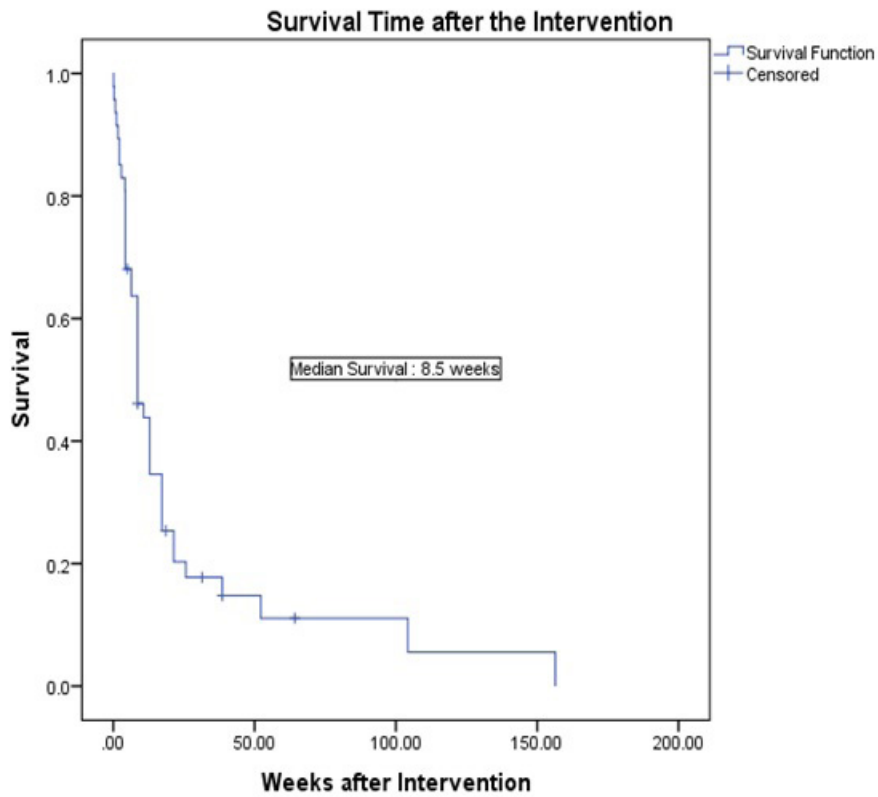


Figure 1: Survival curves of patients with Gastric Obstruction after the intervention ( $n = 47$ ).

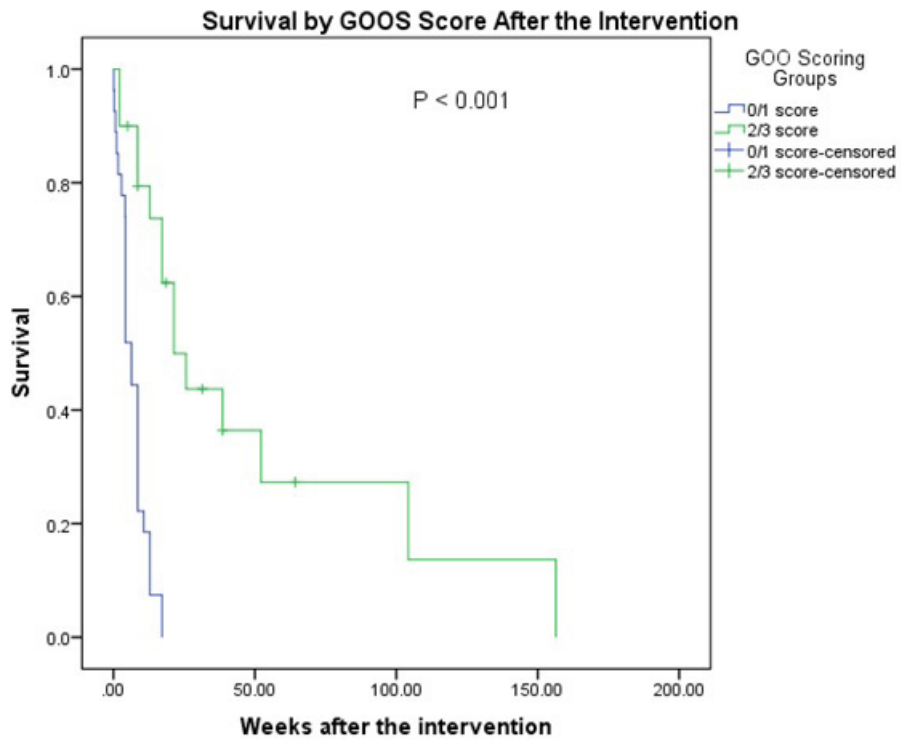


Figure 2: Survival curves of patients with Gastric Obstruction after the intervention by improvement in GOOS score ( $n = 47$ ).

**Table 3:** Describing Gastric Outlet Obstruction Score by age, gender, and stenting (n = 47).

Variable	GOO Score				P - value
	0	1	2	3	
<b>Age</b>					
<50 years	01 (2.1%)	03 (6.4%)	01 (2.1%)	06 (12.8%)	0.441
51-69 years	00 (00%)	07 (14.9%)	00 (00%)	05 (10.6%)	
61 years	04 (8.5%)	12 (25.5%)	01 (2.1%)	07 (14.9%)	
<b>Gender</b>					
Male	03 (6.4%)	09 (19.1%)	01 (2.1%)	06 (12.8%)	0.741
Female	02 (4.3%)	13 (27.7%)	01 (2.1%)	12 (25.5)	
<b>Stenting</b>					
Single	01 (2.1%)	08 (17%)	01 (2.1%)	12 (25.5%)	0.153
Dual	04 (8.5%)	14 (29.8%)	01 (2.1%)	06 (12.8%)	
<b>Restenting</b>					
Yes	01 (2.1%)	02 (4.3%)	00 (0%)	01 (2.1%)	0.742
No	04 (8.5%)	20 (42.6%)	02 (4.3%)	17 (36.2%)	

## 5. Discussion

Relief of obstructive symptoms with optimal improvement in food intake is the fundamental goal of stent palliative treatment in gastric outlet obstruction as dehydration and malnutrition is the fundamental reason for hospitalization in patients with malignant gastric outlet obstruction<sup>[14]</sup>. Also, vomiting and inability to eat and drink are substantial reasons underlying anxiety, distress, and depression in these patients as food is a pleasure of life as these patients face difficulties engaging in these activities and often receive assisted feeding. Self-expandable stents are a safe and efficient method for maintaining the quality of life in these patients alongside increasing the life expectancy [15]. In the present study, our main objective was to observe improvement in terms of oral intake and survival time of the patients that have undergone uncovered self-expandable stents placement. Pancreatic cancer was the most common etiological finding for gastric obstruction in the sampled population in our study, followed by duodenal obstruction. These findings indicate that the epidemiological patterns of gastric malignancies requiring palliative treatment in Pakistan are similar to other populations where pancreatic carcinoma was the leading etiological finding<sup>[16]</sup>. Also highlighted by other studies, the prevalence of gastric obstruction in pancreatic carcinomas is as high as up to 30 percent of the malignant cases [14, 24], however, in the present study, we noted that the prevalence of gastric obstruction was 25 percent. Moreover, the technical success of uncovered stents placement was 100 percent. These findings are in coherence with other researches performed with the same objective in other clinical settings [25, 29] indicating the superiority of self-expandable metal stents over other palliative options for gastric obstruction worldwide. Albeit a high procedural success rate, some limitations of uncovered stents were outlined by Lee, S.M., et al., where the efficacy

of uncovered stents was compromised due to tumor in-growth and migration of the stent [30]. Nonetheless, evidence from other clinical studies supported technical success more feasibility of uncovered stents in the management of gastric outlet obstruction [31] and no such cases of migration have been observed in the procedure employed in the present study. Restenting was performed in less than 10 percent of the study population with the primary indication of regrowth in prepylorus and pylorus, duodenal, and common bile duct stricture. Although these patients had an advanced grade of malignancy, therefore, it cannot be concluded whether this regrowth was due to progressing disease or due to the use of uncovered stent in the palliative procedure.

One of the significances of stent placement in obstructing the gastroduodenal site is the restoration of the patient's ability to take food and liquids orally [14]. Almost half of the patients (46.8%) in the present study resumed liquid diet and another one-third (38.3%) resumed the regular diet after the intervention which is a substantial improvement in terms of success after stent placement. Nonetheless, about 10 percent of the patients failed to resume a regular diet after the intervention. Iruru Maetani et al. regarded tumour dissemination and gastrojejunal anastomosis as the probable reason underlying clinical failure of the endoscopic stent placement procedures [32]. Similar oral intake improvement patterns were observed in studies where clinical success was between 80 to 96 percent [33 -35]. Likewise, approximately half of our study population showed mild improvement, whereas only one-third of the patients showed significant improvement in symptoms following the procedure indicating the superiority of SEMs in the relief of obstructive symptoms in patients with GOO.

Furthermore, the median survival of 8.5 weeks was recorded in the

present study although higher median survival time was reported by other studies where median survival ranged from 12 [36], 13[37] and as high as 14 [38] weeks in other settings. The difference in survival in our study population may be attributable to the advanced disease stage and age of the patients as the life-expectancy of the Pakistani population is relatively less than the populations of other studies from developed countries. Approximately 60 percent of the patients in our study were over 60 years of age, which possibly explains a lower post-survival rate in our study. Prospective data collected from other researches showed the success of chemotherapy in conjugation with SEMs treatment in terms of stent patency and controlling patient performance status [39]. The stent patency time and the overall survival are influenced by factors such as tumor ingrowth and overgrowth [40], disease type, and underlying diseases [33]. Another study also reported malnutrition as a determinant of morbidity and mortality in patients with GOO and recommended enteral feeding to provide nutrition in such patients to benefit their survival [38].

This study also has some limitations, as it was done through a review of records and telephonic follow-up to assess the outcomes of the gastric outlet obstruction management procedure whereas randomized clinical trials are generally more preferred research designs to study treatment outcomes of such procedures [41, 42]. Moreover, the study presents findings from a single-center in a large metropolitan city in Pakistan with a small sample size; therefore, the findings of this study cannot be generalized [43]. The present study was also limited in its scope as details of the metastasis of the primary illness were not included. Details of the metastasis provide prognostic information of the pancreatic adenocarcinoma [44]. Likewise, pain score analysis is another primary prognostic indicator of survival rate in GOO-affected patients [43].

## 6. Conclusion

In conclusion, endoscopic stenting for malignant gastric outlet obstruction appears to be a viable alternative to surgical palliative bypass. However, endoscopic palliation is an attempt to increase the survival time of the patients suffering from an advanced stage of cancer and not a treatment option for the disease.

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