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Original article

A PROSPECTIVE NON-RANDOMIZED STUDY OBSTRUCTION OF GASTRIC OUTLET: OUTCOMES OF ANTRODUODENAL STENTING.

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Abstract.

Background:

The advanced stage of gastric cancer is commonly characterized by gastric outlet obstruction (GOO), extrinsic lymph node compression, and pancreaticobiliary malignancy. The patient presents with symptoms of gastric discomfort, postprandial epigastric fullness, and recurrent abdominal pain. The act of emesis can lead to significant consequences such as severe dehydration, malnutrition, and a diminished quality of life (QoL). Endoscopic enteral stent implantation has gained recognition as a viable alternative treatment modality for malignant gastric outlet obstruction (GOO) due to its favorable safety profile, minimal invasiveness, and cost-effectiveness.

Method:

For five years, a prospective, non-randomized study was conducted on Patients who had a gastric outlet obstruction (GOO) and weren't candidates for surgery because of the procedure's high morbidity, refusal, or low nutritional status were suitable if they were over 18. The stent that was utilized was a Wallflex by Boston Scientific Corporation, MA, United States, exposed SEMS with a diameter of 27 mm (22 mm at the mid-body) and lengths of 60, 90, or 120 mm preloaded in a 10 Fr delivery system

Result:

The presence of Gastric Outlet Obstruction Score (GOOS) ≥ was observed in three instances 8 instances (53.33%) of those with laboratory evidence of biliary blockage had biliary drainage (50.00% endoscopic and 50.00% surgical). A favorable response to the intervention of oral diet tolerance was observed, with an average duration of approximately 1 day (19 hours) until the patient could tolerate a liquid diet

Conclusion:

The utilization of self-expandable metal stents (SEMS) in the management of gastroduodenal malignancies is a viable, safe, and effective strategy, especially in individuals with a limited life expectancy or in advanced disease states. This intervention facilitates improvements in both nutritional status and overall quality of life.

Keywords: Vomiting, gastric outlet blockage, cancer of the gallbladder, enteral nutrition, enteral stent, and cancer of the gastric tract., Submitted: 2023-08-29 Accepted: 2023-09-14

1. INTRODUCTION.

Gastric outlet obstruction (GOO) typically arises after the manifestation of pancreaticobiliary cancer, extrinsic lymph nodal compression,

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and gastric cancer in the majority of instances. [1,2] Abdominal pain, postprandial epigastric satiety, and recurrent emesis manifest as clinical indicators linked to profound malnutrition, dehydration, and diminished quality of life (QoL). [1,3] The life expectancy is diminished due to the multifactorial nature of these variables. The mean survival duration of GOO (Gastrointestinal Obstruction) typically ranges from 7 to 20 weeks post-development. [4,5] The primary approach to managing malignant gastrointestinal obstructive obstruction (GOO) typically involves providing supportive care. In these specific patient populations, surgical bypass is widely recognized as a conventional approach for managing gastric outlet obstruction. [6,7] Nevertheless, it is crucial to acknowledge that patients in this population face a significant surgical risk, as supported by the documented mortality rate of up to 2% and a perioperative complication rate ranging from 25% to 35%. [7,8] A viable alternative to surgical intervention entails the utilization of endoscopic enteral stents for implantation purposes. The efficacy of endoscopic therapy has been substantiated in medical literature, showcasing a reduced incidence of morbidity and mortality, a decreased duration of hospitalization, and expedited relief of symptoms.[9]

Gastroduodenal restrictions can result from cancerous conditions of the stomach, pancreas, and duodenum as well as from the widespread effects of lymphoid metastases. About 40% of these gastric lesions and up to 80%-95% of pancreatic lesions may not be amenable to curative resections, highlighting the need for alternate methods to provide palliation and a higher quality of life[10-13].

In the present research, we looked at how well a score for obstruction of the gastric outlet might be used to evaluate the efficacy of duodenal stenting in the treatment of gastroduodenal cancerous obstruction.

2. MATERIALS AND METHODS.

For five years, a prospective, non-randomized study was conducted on Patients who had a gastric outlet obstruction (GOO) and weren't candidates for surgery because of the procedure's high morbidity, refusal, or low nutritional status were suitable if they were over 18. Several lesions with enteral stenosis, probable intestinal ischemia, difficulty passing a guidewire, stomach cancer presenting as linitis plastica, and gastrointestinal endoscopic restrictions were the main criteria for exclusion. Each participant completed a review board-approved waiver of informed permission.

The medical records and demography of the patient were gathered during the baseline visit, and regular interviews were conducted on the day of the treatment, 15 d, 30 d, 90 d, and 180 d afterward, or unscheduled interviews if needed (Table 1). At 180 days or if a patient passed away before then, they were removed from the research.

The stent that was utilized was a Wallflex by Boston Scientific Corporation, MA, United States, exposed SEMS with a diameter of 27 mm (22 mm at the mid-body) and lengths of 60, 90, or 120 mm preloaded in a 10 Fr delivery system. Under sedation or general anesthesia, and using iodine contrast for radiologic guidance, all surgeries were carried out.

3. RESULTS.

A total of 15 patients who were eligible for the study were selected and those who seemed to satisfy the exclusion criteria were eliminated. From 15 our study comprised of 7 males and 8 females, who underwent duodenum stenting procedure. The cohort had a median age of 60 years. As a result of compromised medical conditions, the therapeutic intervention was conducted with sedation in six occurrences and with general anesthesia in nine individuals. The vast majority of patients (94.43%) exhibited a lack of oral intake during the initial assessment and presented with metastatic conditions (65.70%), with seven patients relying on enteral nutrition via a feeding tube. The presence of Gastric Outlet Obstruction Score (GOOS) ≥ was observed in three instances.

8 instances (53.33%) of those with laboratory evidence of biliary blockage had biliary drainage

(50.00% endoscopic and 50.00% surgical), according to the data.

Following the insertion of a stent, a patient presented with symptoms indicative of blockage after one month. This blockage was attributed to the growth of a tumor. The subject under examination underwent a medical intervention involving the insertion of an additional stent within the pre-existing stent, resulting in the absence of reoccurrence of the obstruction. Another patient presented with symptoms of obstruction six months post-tumor growth, however, due to haemorrhage and fragility, the removal of the stent or bridge was not feasible. The patient expired 9 months post-stent implantation.

Stent migration was observed in two separate occurrences. Following the implantation of a stent, the patient in the aforementioned case, who presented with a duodenal metastasis originating from colon cancer, exhibited symptoms indicative of restriction after 8 days. The primary stent was subsequently substituted with two additional stents, however, the patient expired within nine days after the intervention. The subsequent individual exhibited indications of obstruction within three months after the intervention. The patient, a 53-year-old female, presented with a diagnosis of gastric cancer accompanied by liver metastases. Additionally, she exhibited signs of compromised nutritional status. As a result of the patient's elevated nutritional status during the period, the migrated stent was successfully extracted through surgical means without any complications, followed by the implementation of a surgical bypass procedure. A case involving the uncomplicated extraction of a foreign object was successfully conducted on a single patient.

A favorable response to the intervention of oral diet tolerance was observed, with an average duration of approximately 1 day (19 hours) until the patient could tolerate a liquid diet. The time required for the patient to tolerate soft solids and solids, specifically food from a regular diet, was slightly longer, with an average duration of more than 2 days (51 hours) and 2 days and 3 hours (55 hours), respectively. These findings are in opposition to the results of other clinical trials, which showed a more rapid resumption of solid food intake post-surgery, with a return to solid food observed in up to 52% of instances [8]. In the ongoing clinical trial, the patient's attending physicians, predominantly specializing in surgical medicine, issued medical prescriptions on their behalf. If the aqueous substances were adequately tolerated during the initial day, it was advised to transition to a solid dietary regimen on the subsequent day.

At an average duration of 3.1 months, the initial occurrence of inadequate fluid intake (GOOS 1) was observed. At a median follow-up duration of 2.35 months, the initial technical failure, characterized by an inability to sustain the previously attained GOOS (Gastrointestinal Objective Scoring System) score of 2-3 for solid or semi-solid food intake, was observed.

4. DISCUSSION.

Patients diagnosed with gastroduodenal cancers often experience dysphagia, a condition characterized by the inability to swallow semi-solid food. This distressing symptom significantly impacts their overall quality of life, leading to a diminished prognosis and a reduced life expectancy. Consequently, there exists a notable prevalence of insufficient nourishment and dehydration, thereby constraining the available resources to ameliorate this circumstance [13,14]. While surgical intervention has been shown to provide more favorable long-term outcomes, it is contraindicated for patients with compromised clinical conditions due to the associated increased morbidity and mortality rates.

A considerable proportion, specifically less than 40%, of individuals necessitating palliative care exhibit suitability for surgical intervention. Consequently, it becomes evident that an alternative approach, one that is less invasive, poses fewer risks, and demonstrates enhanced efficacy, is imperative to accomplish this objective [10,15,16]. The gastrointestinal tract has been equipped with stents to address this concern, exhibiting the advantages of surgical intervention. However, the long-term durability of these stents is not ideal,

Table 1: **Baseline demographic and clinical features of patients.**

Characteristic	Data (average)
Age (yr)	62.43
Gender	Male (7)/female (8)
Height (m)	2.72
Weight (kg)	55.93
Weight loss (kg)/(mo)	14.53/5.40
Location of the obstruction Tumor extension (cm) Stomach Second and third portion Bulb	5.83 4 6 8
Malignancy Metastatic disease Pancreatic adenocarcinoma Cholangiocarcinoma Gastric adenocarcinoma	3 10 2 4
Previous chemotherapy/ radiation therapy	Yes (6)/no (12)
Previous biliary drainage	Yes (9)/no (8)
Biliary stenosis	Bismuth**I**(3)/Bismuth **II** and **III**(5)
Only local cancer	Yes (6)/no (12)

primarily due to the proliferation of tumoral tissue through the mesh (known as tumor ingrowth) or over the stent (known as tumor overgrowth). This leads to a recurrence of symptoms related to obstruction [17-19].

The assessment of an individual's quality of life and performance status in studies of malignancies often involves the utilization of various scales, such as the World Health Organisation performance status (WHO status), the widely employed Short Form-36 questionnaire, and the scale developed by the European Organisation for Research and Treatment of Cancer. These scales serve as valuable tools in evaluating and measuring the medical and academic aspects of an individual's well-being in the context of malignancy research. The gastrointestinal oncology scoring (GOOS) system is commonly utilized for evaluation purposes. However, in cases of gastrointestinal oncology (GOO) malignancies, the ability to ingest nourishment seems to be the foremost aspect taken into account when assessing the individual's quality of life status [20]. According to a retrospective multicenter study involving 62 patients, it was observed that all patients had resumed oral intake. The study utilized the Glasgow Outcome Scale Extended (GOOS) to evaluate the clinical efficacy of enteral stenting. However, it should be noted that 14.5% of the patients (n = 9) did not show any improvement in their GOOS scores. Before the implementation of stenting, a group of patients exhibited elevated scores, indicating the severity of their condition. Remarkably, in each of these individuals, a notable amelioration of symptoms was observed [21].

The study conducted a prospective analysis of 101 patients diagnosed with incurable cancers of the gastric outlet. The researchers identified three independent indicators of survival: the ability to maintain self-care according to the World Health Organisation (WHO) status, pain score, and the usage of morphinomimetics. Patients exhibiting all three prognostic indicators (World Health Organisation status of 3–4, baseline pain score exceeding 83, and utilization of morphinomimetics more potent than tramadol) demonstrated a 30-day survival rate below 10%. This finding suggests that a less invasive therapeutic approach should be contemplated for this specific patient cohort [10,21].

In a recent randomized experiment, a comparative analysis was conducted to evaluate the financial implications of gastrojejunostomy (GJJ) and stent implantation in cases of gastric outlet obstruction (GOO). Both the direct and indirect costs of the two therapies were considered in the

analysis. The research findings led to the determination that despite GJJ exhibiting higher overall expenses, predominantly due to prolonged hospitalizations, the disparity was negligible and of minimal importance when considering the treatment approach [22].

In a recent randomized prospective study, the group of patients who received covered self-expandable metal stents (SEMS) exhibited a higher rate of stent migration within 8 weeks of stent placement (25.8%) compared to the group who received uncovered SEMS (2.8%). The study included a total of 40 patients diagnosed with gastric cancer in each group. Furthermore, when comparing the group of patients treated with covered self-expandable metal stents (SEMS) to the group of patients treated with uncovered SEMS, it was observed that the rate of restenosis related to tumor ingrowth was significantly higher in the latter group (25.0%) compared to the former group (0.0%). A routine endoscopic procedure was conducted in the aforementioned study irrespective of the presence of obstruction symptoms, potentially contributing to the observed higher rates of migration [23].

Due to the observed correlation exceeding 61% in a significant number of cases, it is imperative to conduct a thorough evaluation of obstructive biliary symptoms in individuals presenting with gastroduodenal malignant obstruction [24,25]. Imaging modalities should be conducted in the presence of jaundice to elucidate its characteristics and exclude alternative aetiologies, such as hepatic insufficiency precipitated by metastatic lesions. Obstructive jaundice can be effectively managed through various therapeutic modalities, including endoscopic interventions, interventional radiology procedures, or surgical interventions. These treatment options have demonstrated comparable clinical outcomes, although surgical interventions are associated with a heightened risk of morbidity and prolonged hospitalization duration. The assessment of the patient's clinical condition and the accurate determination of tumor staging are crucial factors to be taken into account when determining an appropriate treatment plan. Biliary endoscopic drainage can employ either plastic or metallic studs, with the latter demonstrating reduced incidences of cholangitis and occlusion, as well as shorter hospitalization durations. However, it is important to note that the utilization of metallic studs incurs higher costs compared to their plastic counterparts. During the initial trimester, both stents effectively maintain their patency. The utilization of plastic studs has demonstrated efficacy and reliability, while also offering cost advantages, particularly in cases where patients have a constrained life expectancy. However, it is imperative to note that these studs necessitate periodic replacement every 3 to 6 months or in instances of suspected cholangitis [23, 25, 26].

5. CONCLUSION.

In summary, gastroduodenal malignancies are associated with symptoms of gastric outlet obstruction, resulting in a diminished quality of life characterized by dysphagia, intractable emesis, postprandial epigastric tenderness, and abdominal pain. Additionally, these individuals often exhibit suboptimal nutritional and clinical conditions, thereby limiting the available therapeutic interventions. The utilization of self-expandable metal stents (SEMS) in the management of gastroduodenal malignancies is a viable, safe, and effective strategy, especially in individuals with a limited life expectancy or in advanced disease states. This intervention facilitates improvements in both nutritional status and overall quality of life. The installation of self-expandable metallic stents (SEMS) may serve as an interim solution before definitive surgical intervention in patients at high risk, as observed in a single patient within the scope of this study. Following the surgical procedure, it was observed that our cohort promptly resumed their consumption of food via the oral route. The assessment of patency was determined by evaluating the clinical effectiveness of sustaining an oral regimen consisting of solid or semi-solid nourishment. The average duration until the reappearance of obstructive symptoms was found to be 3.1 months. The existing body of literature about the endoscopic management of gastro-

duodenal malignancies predominantly comprises studies with limited sample sizes.

6. RECOMMENDATION.

Consequently, there is a pressing requirement for further investigations to facilitate comparative analyses between this therapeutic modality and surgical interventions, while also appraising the economic implications associated with its implementation.

7. LIMITATION.

The study that is conducted is on limited sample size a more studies on large sample population is required to evaluate the efficacy of the process.

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9. LIST OF ABBREVIATIONS.

GOO- Gastric outlet obstruction
QoL- quality of life
WHO- World Health Organisation
GJJ- gastrojejunostomy
SEMS- self-expandable metal stents

10. Conflict of interest.

There was no conflict of interest.

11. Funding.

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