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Research Article

Evaluating The Safety And Effectiveness Of Gastric Electrical Stimulation (GES) In Patients With Severe Gastroparesis During Pregnancy.

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Abstract

Introduction: Gastroparesis presents a significant challenge in pregnancy, affecting maternal and foetal health. This paper examines the safety and efficacy of Gastric Electrical Stimulation (GES) as a therapeutic modality in pregnant patients with gastroparesis.

Materials & Methods: A retrospective analysis was conducted on pregnant patients with in-situ GES identified from our gastroparesis patient database. We evaluated the safety and efficacy of GES during pregnancy, focusing on Quality of Life (QoL) improvements and symptom control. Key metrics included QoL SF36 scores, and the severity of nausea, vomiting, pain, satiety, and bloating. Hospital stay lengths, admission frequency, and the need for feeding support were also assessed both pre- and post-operatively.

Results: The study included twelve pregnant women with in-situ GES. The median age at surgery was 29 years (Interquartile Range [IQR]: 26-31 years), with 58% of the patients having diabetes-induced gastroparesis. Robotic GES insertion was performed in 75% of cases. Post-operatively, significant improvements were observed in nausea score (reduced from 4 to 1), vomiting score (from 4 to 0), pain score (from 4 to 1), satiety score (from 4 to 0), and bloating score (from 4 to 0). SF36 scores improved significantly, increasing from a median pre-operative score of 261 (IQR: 178-65) to 1,783 (IQR: 765-3,527, $p<0.001$). Additionally, 58% of patients transitioned from assisted to independent feeding.

Conclusion: Gastric Electrical Stimulation appears to be a safe and effective treatment modality for gastroparesis in pregnant patients, significantly improving symptoms and QoL. Further extensive research is warranted to validate these findings and explore the broader implications of GES in the management of pregnancy-associated gastroparesis.

Keywords: pregnancy, gastroparesis, Gastric Electrical Stimulator (GES).

INTRODUCTION

Gastroparesis is a chronic neuromuscular disorder characterised by delayed gastric emptying in the absence of mechanical obstruction. It presents with debilitating gastrointestinal symptoms such as nausea, vomiting, early satiety, bloating, and epigastric discomfort—each of which significantly impairs quality of life and nutritional status[1]. Although gastroparesis affects individuals of all genders, its prevalence is notably higher among women, particularly during their reproductive years[2]. This increased incidence among women of childbearing age renders the intersection of gastroparesis and pregnancy both clinically significant and complex.

Managing gastroparesis during pregnancy presents distinct challenges. Pharmacological options commonly used to treat gastroparesis—such as dopamine receptor antagonists, macrolide antibiotics, and serotonin receptor agonists—are associated with potential teratogenic risks and have not been extensively validated in pregnant populations. Non-pharmacological strategies, including dietary modifications and behavioural interventions, may provide some symptom relief but their efficacy is variable[3]. These limitations are further compounded by the physiological changes of pregnancy, such as altered gastrointestinal motility and hormonal influences, which can exacerbate symptoms and complicate management[4].

Gastric Electrical Stimulation (GES) has emerged as a promising therapeutic option for refractory gastroparesis. It has demonstrated efficacy in improving gastric motility and reducing symptoms such as nausea and vomiting.[5] However,

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the safety and effectiveness of GES in pregnancy remain poorly characterised, with limited data available. A small case series by Soliman and colleagues published in 2023 represents one of the few contributions examining maternal and foetal outcomes in this context[6].

Given the sparse and fragmented nature of existing research, this study aims to retrospectively evaluate the safety and clinical effectiveness of GES in pregnant patients with severe gastroparesis. We explore symptom control, nutritional support requirements, and maternal-foetal outcomes, with the broader objective of informing best clinical practices and guiding future research in this underexplored domain.

MATERIALS & METHODS

Study Design and Population

This retrospective study was conducted on a cohort of pregnant patients (with proven Gastroparesis) who had previously undergone Gastric Electrical Stimulation (GES) implantation. We included patients from December 2000 to June 2021, identified from our comprehensive gastroparesis patient database. The study aimed to evaluate the safety and efficacy of GES during pregnancy, with a specific focus on Quality of Life (QoL) improvements and symptom control.

Data Collection

Prospective data were collected on all patients undergoing GES insertion within the specified timeframe. This included detailed patient demographics, disease aetiology, and a comprehensive record of symptoms such as nausea, vomiting, bloating, early satiety and abdominal pain. The severity of these symptoms was quantitatively assessed using a Likert scale both pre and post GES insertion. Additionally, the SF-36 questionnaire, a standardised tool for measuring health-related quality of life, was completed by patients prior to GES insertion and then at regular intervals of 6 to 18 months post-surgery.

Outcome Measures

The primary outcome measures were changes in the QoL, as reflected in the SF-36 scores, and the severity of gastroparesis-related symptoms. We also meticulously recorded patient weight before and after GES insertion to monitor any significant changes. Hospital records were reviewed to gather data on the number of hospital admissions and the duration of hospital stays attributed to gastroparesis symptoms, both before and after the insertion of the GES device.

Additional Data Analysis

Information regarding the patients' feeding regimes was also collated. This included details on the type of feeding support required, such as enteral feeding or total parenteral nutrition, and any changes in these requirements following GES insertion. The analysis of these data aimed to provide a comprehensive understanding of the impact of GES on the management of gastroparesis in pregnant patients, assessing both the physical health outcomes and the overall improvement in the patients' quality of life.

Statistical Analysis

Different methods were employed for the statistical evaluation of outcomes based on the nature of the data. Parametric data were analysed using the Student's t-test, which is suitable for comparing means of two groups. For non-parametric data, which do not assume a normal distribution, the Wilcoxon test was utilized to assess the differences. This test is particularly useful for comparing the median values of two related samples. In the case of binomial data, mar's test was applied. This test is specifically designed for paired nominal data to determine if there are differences in the proportions between two related groups. All statistical analyses were performed using the latest version of IBM® SPSS® Statistics (v28.0), a comprehensive software package widely used for data management and statistical analysis in social science and medical research.

RESULTS

The cohort for this study comprised twelve women with GES in situ (**Table 1**) who became pregnant (14 pregnancies in 12 patients; n=10 had 1 pregnancy and two patients had two pregnancies each). The median age at the time of GES insertion was 29 years (IQR: 26-31 years). Most of these patients, 58.3%, were diagnosed with diabetic gastroparesis. The operative approach for GES insertion was predominantly robotic, utilised in 75% of the cases.

Table 1. Demographics of patients with a Gastric Electrical Stimulator (GES) in situ for refractor gastroparesis who became pregnant during their treatment.

		n	%
Age at GES insertion	<30 years	7	58.3%
	30+ years	5	41.7%
Gastroparesis Type	Diabetic	7	58.3%
	Idiopathic	5	41.7%
Number of Pregnancies	1	10	83.3%
	2	2	16.7%
Operative Approach	Open	3	25.0%
	Robotic	9	75.0%

Post-surgical evaluations revealed marked improvements across several metrics (**Table 2**). The nausea score experienced a substantial reduction, decreasing from an average of 4 to 0.5 (p=0.004). There was a notable decrease in the vomit-

ing score, which dropped from 3.4 to 1.0 (p=0.011), and the pain score similarly improved from 1.8 to 0.3 (p=0.039). Improvements were also seen in the satiety and bloating scores, with decreases from 2.4 to 0.7 (p=0.026) and from 2.7 to 0.4 (p=0.010), respectively. The number of hospital admissions post GES insertion showed a non-significant reduction from an average (mean or median) of 2.8 to 0.0 (p=0.066). Regarding the SF-36 Quality of Life Score, there was a significant increase, indicating an enhanced quality of life post-surgery; the score rose from a median of 261 pre-operatively to 1783 post-operatively.

Table 2. Comparison in weight and mean symptom scores pre and post surgery (higher symptom scores correlate with worse symptoms).

Mean	Pre GES	Post GES	p
Weight (kg)	64.7	69.7	0.655
Nausea Hours Per Day	15.2	3.7	0.048
Nausea Score	4.0	0.5	0.004
Vomiting Episodes Per Day	4.4	2.8	0.102
Vomiting Score	3.4	1.0	0.011
Pain Score	1.8	0.3	0.039
Satiety Score	2.4	0.7	0.026
Bloating Score	2.7	0.4	0.010
Days in Hospital	21.1	0.0	0.038

The average body weight of the patients saw a non-significant increase from 64.7 kg before GES insertion to 69.7 kg after the procedure (p=0.655). The number of nausea hours per day was significantly reduced from 15.2 to 3.7 (p=0.048). Furthermore, the length of hospital stay due to gastroparesis symptoms showed a significant decline, with patients not requiring hospitalisation post GES insertion compared to an average of 21.1 days before the procedure (p=0.038). Importantly, all the women carried their pregnancies to full term with no complications encountered by the mother or the child.

DISCUSSION

The salient outcomes of our study demonstrate that the use of GES in pregnant patients with gastroparesis is both safe and effective. All pregnancies in the study culminated in live births without any maternal or foetal mortalities, and notably, there were no device-related complications. This suggests that GES can be a viable treatment for managing gastroparesis symptoms during pregnancy, potentially improving the quality of life for expectant mothers suffering from this condition.

The challenge of diagnosing and managing gastroparesis is considerable, compounded by its poor understanding of its pathophysiology and the limited efficacy of existing treatments. The literature on this subject, particularly during pregnancy, is notably scant. Our study enriches the sparse data available, methodically documenting the pregnancy outcomes of women undergoing GES treatment for gastroparesis. This research marks a pioneering step, especially when considered against the backdrop of the only other known case series—a collection of 12 patients from France reported by Soliman[6].

Addressing severe gastroparesis therapeutically is particularly arduous, mainly as resultant of the fact that the pathophysiology of gastroparesis remains poorly understood[2]. Current medical interventions frequently fall short of providing significant relief[1], this is even more acute for pregnant patients. Over the last fifty years, substantial efforts have been directed towards pioneering treatments that can normalise gastric myoelectrical activity. GES, especially the high-frequency/low-energy variant with brief pulses, has shown promise, not only in symptom management but also in enhancing patient well-being[7].

The efficacy of GES is thought to reach beyond the alleviation of symptoms; it may also activate ghrelin secretion[8,9], which plays a critical role in satiety and gastrointestinal motility. This mechanism could elucidate the observed improvements in gastric emptying in some and patient satiety. Comprehensive reviews and extended studies have affirmed GES's significant influence on the gastric emptying of both liquids and solids, with long-term safety and sustained control over symptoms[10–12]. These insights also shed light on the additional advantages of GES, such as enhanced body mass index, serum albumin concentration, and blood sugar regulation[13,14].

Our findings reveal no notable increase in pregnancy-associated maternal complications within the cohort, bolstering the view of GES as a viable treatment during pregnancy. Furthermore, the manifestation of gastrointestinal symptoms frequently mirrored physiological changes in pregnancy, rendering it difficult to distinguish between symptoms caused by gastroparesis and those typically experienced during gestation. Maintaining GES throughout pregnancy has thus been validated as a judicious strategy to manage chronic vomiting symptoms, corroborating its safety for both the mother and the unborn child.

CONCLUSION

In summary despite the retrospective nature of our study and the inherent potential for recall bias, it offers invaluable insights into the management of gastroparesis in the context of pregnancy. It lays the groundwork for future inquiries and reassures the medical community about the applicability of GES for pregnant individuals. To fortify these preliminary findings and refine gastroparesis treatment protocols during pregnancy, further research with more extensive patient groups is imperative.

Ethics

Ethical approval has been obtained from and the study has been registered with the Mid & South Essex NHS Foundation Trust's Research Department Registration number GSURG223

Conflict of Interest

All authors declare no conflict of interests

Author Contributions

The authors have contributed to this study in the following ways:

Study Design: Alan Askari, Priyantha Siriwardana Sritharan Kadirkamanathan

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