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Gastric electrical stimulation is safe during pregnancy and delivery: Results from a French cohort

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Abstract

Background: Gastric electrical stimulation (GES) is an effective therapy in medically refractory chronic nausea and vomiting. GES is assumed to be a contraindication for pregnancy. We examined the safety of GES during pregnancy and its clinical impact on vomiting symptoms.

Methods: A retrospective study was performed in two tertiary centers including all female patients of childbearing age implanted with GES. Patients without pregnancy while on GES were asked about their desire and concerns about pregnancy. Patients who were pregnant while on GES therapy were interviewed about the course of the pregnancy and labor, as well as the health of the children.

Key Results: Among 91 patients implanted at childbearing age, 54 patients without pregnancy answered the questionnaire. Nine patients (16.7%) reported a desire for pregnancy and five patients (7.4%) reported worries about the safety of GES during pregnancy. Sixteen pregnancies were reported in 10 patients. All pregnancies ended in a live birth with premature birth in 12 pregnancies (75.0%). No health concern was currently noted in these children. No severe GES-related complications occurred during pregnancy with only pain at the implantation site reported during 3 pregnancies (18.8%). The severity and frequency of nausea and vomiting significantly increased during the first trimester ($p=0.04$ and $p=0.005$, respectively) and decreased after the delivery, becoming lower than before the pregnancy ($p=0.044$ and $p=0.011$, respectively).

Conclusion & Inferences: Patients are concerned regarding pregnancy while being treated with GES. No serious maternal or fetal complications related to GES were noted in our cohort.

KEYWORDS
chronic vomiting, Enterra therapy, gastric electrical stimulation, gastroparesis, pregnancy

1 | INTRODUCTION

Chronic unexplained nausea and vomiting can be a challenging condition when refractory to medical treatment.[1] This condition is often associated with delayed gastric emptying and dyspeptic symptoms in the context of gastroparesis.[2,3] However, vomiting can also occur in patients with normal gastric emptying.[4] All of the series report a higher prevalence in female patients.[4,5] Severe forms might lead to an altered quality of life and impaired nutritional status, requiring treatment intensification.[1]

Gastric electrical stimulation (GES) has proven to be effective in the treatment of refractory chronic nausea and vomiting.[6] This efficacy has been proven in patients with normal and delayed gastric emptying.[7] In 2019, a multicenter cohort study of 319 gastroparesis patients concluded a significant improvement in nausea and vomiting within 48 weeks after the implantation of GES.[8] In a large prospective randomized controlled trial including 172 patients, GES reduced the frequency of refractory vomiting in patients.[9] Moreover, GES was observed to have maintained a long-term efficacy within 10 years after implantation improving vomiting symptoms along with the quality of life.[10] The battery life is 5 to 10 years, but it can be replaced if necessary.[6] Therefore, many female patients remain with an active GES device for many years.

However, reports about the course of pregnancy and delivery in the presence of GES are missing. To date, only one case report described the course of one pregnancy in a patient with diabetic gastroparesis treated with GES.[11] Interestingly, this patient's gastrointestinal symptoms remained sparse for the first 6 months. Although several episodes of vomiting, abdominal pain attacks, modest nausea, and constipation were noted during the third trimester, spontaneous labor and uncomplicated vaginal delivery occurred.[11] Apart from this case report, GES treatment has been generally considered a contraindication to pregnancy. Therefore, there is a need to assess the course and outcomes of pregnancy in the presence of GES.

The present study aimed to report on the safety of GES during pregnancy, based on the cases reported in our cohort of patients. The secondary outcomes were to evaluate the efficacy of GES during pregnancy and the evolution of digestive symptoms during this period. Also, we aimed to assess the worries about GES and pregnancy in female patients of childbearing age implanted with GES without pregnancy.

Key Points

- Women of childbearing age implanted with gastric electrical stimulation (GES) are concerned about the safety of the device during pregnancy, as reported by 7% of 91 women in our cohort.
- No maternal or fetal complication was observed based on 16 pregnancies with GES. There was only an increased risk of premature birth but which does not seem to be related to the device.
- An increase in the frequency and severity of nausea and vomiting was observed during the pregnancy, especially during the first trimester. Overall, GES should not be considered as an independent contraindication for pregnancy.

2 | METHODS

2.1 | Patient selection

A retrospective bicentric study was conducted in two tertiary centers specialized in the management of chronic nausea and vomiting in France. Female patients treated with GES for gastroparesis or chronic vomiting between 2000 and 2020 were selected. Patients aged 18 to 50 years at the time of implantation were interviewed by phone in September 2021. Two pregnancies were ongoing, and these patients were called a second time in September 2022. All participants gave their consent to participate and the study was approved by the local human research committee (E2020-51) and the Commission Nationale de l'Informatique et des Libertés (CNIL) (n°817.917), in compliance with French regulations. The cohort was declared on clinicaltrial.gov (NCT04918329).

2.2 | Patient evaluation

Patients were asked for pregnancy complications including hyperemesis gravidarum, gestational diabetes, the exacerbation of preexisting diabetes, gestational hypertensive disorders, or the need for hospitalization for any specific reason. Next, gestational age (GA) at birth and the type of delivery were collected (vaginal delivery, instrumentally assisted delivery or cesarean section). Patients were then asked about labor and postpartum complications (need for episiotomy, perineal injury, excessive bleeding, postpartum infection, anemia, or thrombosis). Finally, postnatal complications were collected such as the need for resuscitation, neonatal hypoglycemia, need for phototherapy due to newborn jaundice, neonatal infection, or growth delay. Also, the current health of the child (chronic disease, or no health problems) was recorded.

The second section of the questionnaire aimed to assess gastrointestinal symptoms and GES-related symptoms. Patients were asked if the stimulator remained active during pregnancy or was inactivated. Any GES-related complications (pain, infection, unintentional inactivation, dislocation) that occurred during pregnancy and delivery were inquired about. Finally, patients were asked about the severity of nausea and vomiting as well as the frequency of vomiting. They were asked to score both symptoms retrospectively for the period before the pregnancy, for the first, second,

and third trimesters of the pregnancy and the postpartum period. The severity of nausea and vomiting was scored from 0 to 5, with 0 indicating the absence of nausea, 1 denoting very mild severity, 2 for mild, 3 for moderate, 4 for severe, and 5 for extremely severe symptoms. The frequency of vomiting was also scored from 0 to 4 according to the vomiting score used by Ducrotte et al. with 0 denoting no episodes of vomiting, 1 for less than one per month, 2 for at least one episode per month, 3 for at least one per week, and 4 for several episodes per week.[9]

The second form of the questionnaire was intended for patients who were not pregnant while on GES. Patients were asked about the reasons for not getting pregnant with GES, whether they had a desire for pregnancy, if the GES device or the disease itself had an impact on their pregnancy plans, or if they had worries related to the device. Finally, pregnancies that were terminated before term while on GES therapy were also reported.

2.3 | Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 26.0. (IBM Corp. Released 2019. Armonk, NY: IBM Corp). Data are presented as mean value ± standard deviation (SD) for continuous data and number and percentage for categorical data. The distribution of data was first investigated for normality. Then, intra-individual comparisons of the severity of vomiting and nausea as well as the frequency of vomiting between different time points were analyzed using the paired Student *t*-test or the Wilcoxon test, depending on data distribution. Differences were considered significant for a p-value <0.05.

3 | RESULTS

3.1 | Initial characteristics of the pregnant patients

A total of 91 patients aged between 20 and 50 years at the date of implantation (34.1 ± 9.3 years old) were contacted for the study, of which 64 completed the questionnaires. The flow chart for the selection of patients is depicted in Figure 1. Ten of the total 64 patients reported at least one pregnancy in the presence of GES that ended in a live birth. Two patients had two pregnancies, and one had 5 pregnancies with an active GES. In total, 16 pregnancies were counted.

The characteristics of those patients are summarized in Table 1. Age at the time of implantation ranged from 22 to 39 years (29.0 ± 5.6 years old). Age at the time of the pregnancy ranged from 24 to 42 years old (32.7 ± 5.4 years old). Four women were over 35 years old when giving birth. Eight patients suffered from gastroparesis, of which five had idiopathic gastroparesis, two had underlying type 1 diabetes, and one had postoperative gastroparesis. The other two patients had chronic nausea and vomiting with normal gastric emptying.

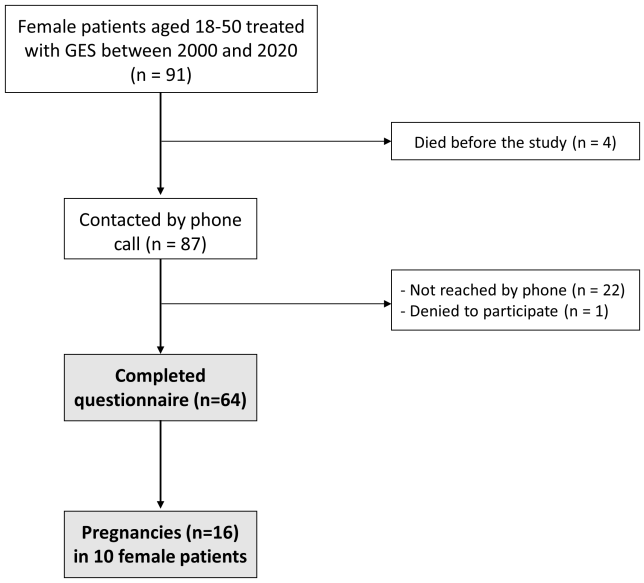

FIGURE 1 Flow chart of the patients' selection.

3.2 | Complications during pregnancies and deliveries

No complication occurred for 6 patients, concerning 8 of the 16 pregnancies (50%). Other complications are summarized in Table 2. One patient was hospitalized 4 times out of her 5 pregnancies due to intrahepatic cholestasis of pregnancy, with a threat of preterm delivery. A second patient was hospitalized during her 2 pregnancies for renal failure, in a patient with pre-existing type 1 diabetes complicated by diabetic nephropathy with kidney transplantation. A third patient aged 41 at the time of the pregnancy was hospitalized for gestational hypertension and preeclampsia. Finally, two patients developed gestational diabetes during three pregnancies.

Ten pregnancies (62.5%) ended in a vaginal delivery, of which two were assisted, while the other six pregnancies (37.5%) ended in a caesarian section (Table 2). Eight births were induced, and four of those inductions were performed in the same woman because of intrahepatic cholestasis of pregnancy. The other causes of induction were large for gestational age (LGA) ($n=1$), preeclampsia ($n=1$), and renal failure ($n=2$). Only 4 pregnancies (25%) ended at term, while the other 12 (75%) ended prematurely, with mild prematurity (above 32 weeks of GA) for all pregnancies except one that ended at 31 weeks of GA. No delivery-related complication occurred (no postpartum bleeding, no thrombosis, no maternal infection).

The age of the children at the time of the interview ranged from 2 months to 15 years (6.4 ± 4.9 years old). Although one of the preterm newborns had health concerns due to immaturity requiring several hospitalizations during the 2 first years of its life, all children were in good health at the time of the interview (Table 2).

TABLE 1 Characteristics of pregnant patients ($n = 10$ patients).

	$n = 10$ patients
Age at implantation (years)	29.0 ± 5.6 [22–39]
Age during pregnancy (years)	32.7 ± 5.4 [24–41]
Duration between implantation and pregnancy (years)	8.5 ± 5.1 [1–17]
Cause of GES implantation	
Diabetic gastroparesis	2 (20%)
Idiopathic gastroparesis	5 (50%)
Postoperative gastroparesis	1 (10%)
Chronic vomiting with normal gastric emptying	2 (20%)
Severity of nausea and vomiting before pregnancy	2.7 ± 0.8
Frequency of nausea and vomiting before pregnancy	2.3 ± 1.1

Note: Data are given as mean ± standard deviation, or number and percentage.
Abbreviation: GES, gastric electrical stimulation.

TABLE 2 Complications during pregnancy, delivery, postpartum and neonatal period among the patients pregnant with GES device.

Complications	*Number of cases n = 16*
Pregnancy-related	
Hospitalization	6 (37.5%) 4/6 in the same patient
Cholestasis of pregnancy	4 (25%) all in the same patient
Preeclampsia	1 (6.25%)
Gestational diabetes	3 (18.8%)
Insulin treatment	2
Renal failure	2 (12.5%) all in the same patient
Delivery-related and postpartum	
Need for birth induction	8 (50%) 4/8 in the same patient
Cesarian-section	6 (37.5%)
Assisted vaginal delivery	2 (12.5%)
Episiotomy	1 (6.3%)
Child health-related	
Preterm	12 (75%)
Late preterm (34–36 weeks of gestation)	10
Moderate preterm (32–34 weeks of gestation)	1
Very preterm (<32 weeks of gestation)	1
Neonatal jaundice	5 (31.3%)
Need for phototherapy	2
Neonatal resuscitation	2 (12.5%)
LGA and newborn hypoglycemia	1
Cystic adenomatoid malformation	1

Note: Data are presented as numbers and percentages.
Abbreviation: GES, gastric electrical stimulation; LGA, large for gestational age.

3.3 | GES-related events and gastrointestinal symptoms

GES remained activated during the entire pregnancy in 12 cases. In four pregnancies, the stimulator was inactivated due to concerns about the impact of GES on pregnancy. It had to be reactivated in one of them due to increased vomiting. Three patients reported pain at the implantation site of the GES only during pregnancy, while one patient reported reduced pain during pregnancy. No other device-related complication was reported.

The severity of nausea and vomiting before the pregnancy, during the first, second, and third trimesters of the pregnancy and after pregnancy was rated as 2.7 ± 0.8, 3.9 ± 0.9, 3.4 ± 1.1, 3.5 ± 1.5, and 2.0 ± 0.9, respectively (Figure 2). There was a significant increase in the severity score in the first trimester compared to before the pregnancy ($p = 0.04$) which persisted during the entire pregnancy

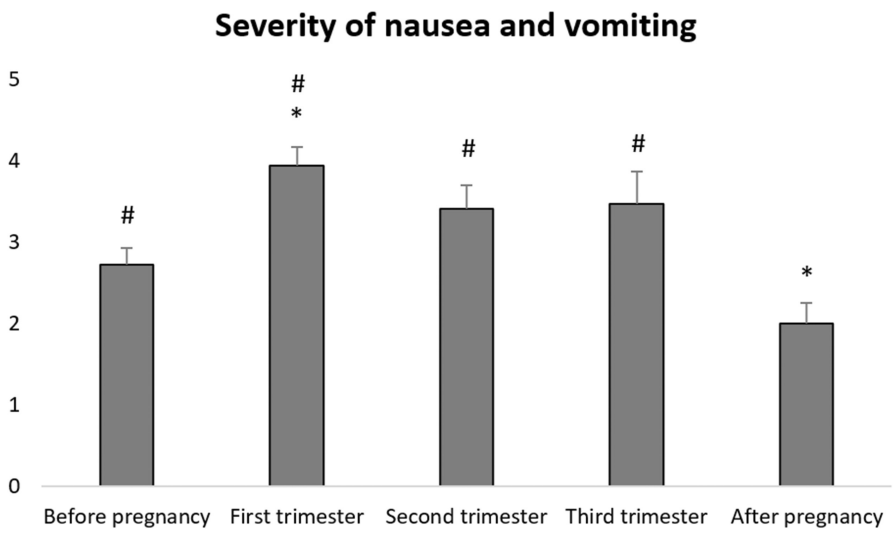

FIGURE 2 Evolution of the severity of nausea and vomiting during the pregnancyData were analyzed using the Wilcoxon test. All data are expressed as mean ± SEM. * $p < 0.05$ vs. before pregnancy. # $p < 0.05$ vs. after pregnancy.

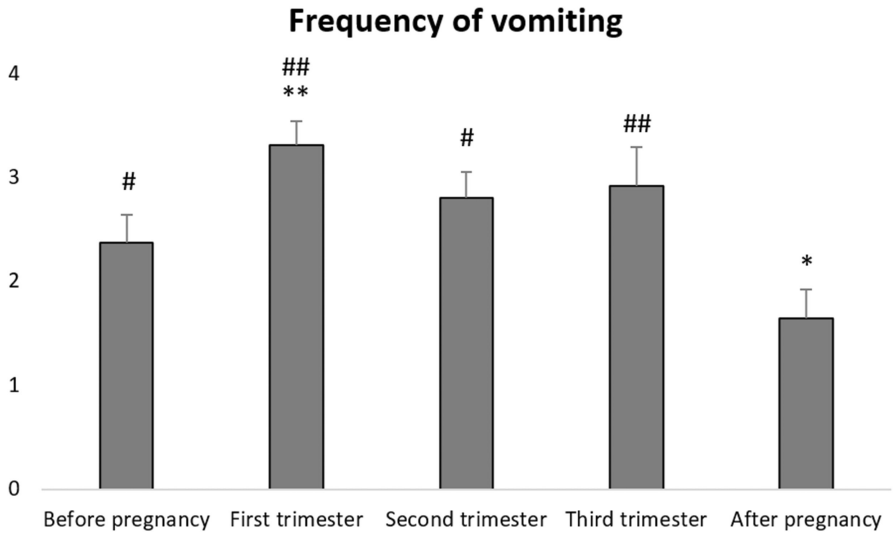

FIGURE 3 Evolution of the frequency of vomiting during the pregnancyData were analyzed using the Wilcoxon test. All data are expressed as mean ± SEM. * $p < 0.05$ versus before pregnancy; ** $p < 0.01$ versus before pregnancy. # $p < 0.05$ versus after pregnancy, ## $p < 0.01$ versus after pregnancy.

(Figure 2). After delivery, there was a significant decrease in severity score compared to before ($p = 0.04$) or during the pregnancy ($p = 0.02$).

The frequency of vomiting before the pregnancy during the first, second, and third trimesters of the pregnancy and after pregnancy was rated as 2.4 ± 1.1, 3.3 ± 0.9, 2.8 ± 1.0, 2.9 ± 1.3, and 1.6 ± 1.0, respectively (Figure 3). In the same way, there was a significant increase in the frequency of vomiting in the first trimester of the pregnancy compared to before the pregnancy ($p = 0.005$) which persisted during the entire pregnancy (Figure 3). In addition, there was a significant decrease in the frequency score after the delivery compared to before ($p = 0.01$) or during the pregnancy ($p = 0.01$).

3.4 | Concerns about GES and pregnancy

Among the initial 64 patients, 54 patients did not report pregnancy under the GES therapy. The main reason for not getting pregnant was that the patients had completed family planning at the time of the implantation ($n = 22$; 40.7%). One-third of the patients reasoned the absence of pregnancy after implantation using severe health concerns ($n = 17$; 31.5%). Nine women (16.7%) reported a current or future desire to have (more) children, of which four patients (7.8%) reported worries about the safety of pregnancy with a GES device. Six patients reported one or more pregnancies in the presence of GES which did not end in a live birth (Table 3). Particularly, one patient performed an abortion due to concerns about the course of pregnancy with GES and gastroparesis. Also, one patient refused to change the battery of her GES device due to the desire to become pregnant.

4 | DISCUSSION

The main findings of this series are that pregnancy and delivery under GES were not associated with device-related complications. All of the pregnancies ended in a live birth, with no fetal or maternal mortality reported. However, a high risk of pregnancy-related

TABLE 3 Results of the questionnaire on the reproductive history of women without any pregnancy while on GES therapy and the reasons for not getting pregnant with GES.

	n = 54 patients
Reason for not getting pregnant while on GES therapy	
Completed family planning before implantation	22 (40.7%)
Health concerns	17 (31.5%)
Infertility	5 (9.3%)
Preference of partner	1 (1.9%)
Desire to have children	**9 (16.7%)**
Worries about safety and fear of complications	4
Pregnancies terminated before the term	**6 (11.1%)**
Ectopic pregnancies	2
Abortion	2
Miscarriage	2

Note: Data are presented as numbers and percentage.
Abbreviation: GES, gastric electrical stimulation.

complications, especially premature birth, was reported in this series, but these complications could be independent of the GES device. Of note, 7.8% of women reported worries regarding GES which may have resulted in their choice against having children.

Reports about pregnancy in patients with gastroparesis are lacking. There are only some case reports in the literature.[12–14] Although the epidemiology of gastroparesis shows that the mean age at the diagnosis is around 50 years old, female predominance is reported in all studies, accounting for 63% to 69% of patients.[5,15] Moreover, this condition is being more frequently diagnosed, with the number of hospitalizations increasing by 160% between 1995 and 2004.[16] Thus, the question of pregnancy in patients with gastroparesis is becoming increasingly crucial. This series included 91 female patients of childbearing age considering only those who were treated by a GES device. The concern about GES and pregnancy could thus be of interest to those patients, as suggested by 16.7% of the patients who had a desire for pregnancy. One patient even performed an abortion due to worries about pregnancy with GES.

GES was shown to be an effective treatment not only for gastroparesis[8] but also for refractory vomiting in patients without delayed gastric emptying.[6,9] This treatment was able to reduce nausea and vomiting symptoms and improve the overall quality of life.[6,17] Therefore, one might ask whether it allows female patients to have uncomplicated pregnancies and deliveries as well as healthy children despite their gastrointestinal disease. To date, there was only one publication reporting a patient's pregnancy and delivery with a GES implanted for type 1 diabetes.[11] Only several episodes of vomiting, abdominal pain attacks, modest nausea, and constipation during the third trimester were reported. Aside from this, the patient had normal pregnancy and delivery suggesting that better control of diabetes and gastroparesis using GES could improve the outcome of pregnancy.[11] In addition, only mild sensation of gastric pacemaker activity was reported during pregnancy.[11] To the best of our knowledge, there is no other report of the course of pregnancy and delivery in patients treated with GES for gastroparesis. Thus, the present study is the very first to systematically report pregnancies in female patients treated with GES for gastroparesis or refractory vomiting.

The rate of complications related to pregnancies in chronic vomiting patients has never been reported. Only one case report in nondiabetic gastroparesis was reported, which was treated by endoscopic jejunostomy; this ended in the delivery of a healthy neonate.[14] In this series, there were three pregnancies (18.8%) with gestational diabetes, which is similar to the overall prevalence of gestational diabetes in pregnancy, reported to be 13%.[18] As the prevalence of gestational diabetes rises with age, it should be noted that the patients in the presented report were 28, 35, and 40 years old at the time of delivery.[18] One case of preeclampsia was reported (6.3%); thus, the frequency was similar to the global prevalence of 4.6%, with a patient aged 41 years old.[19] Intrahepatic cholestasis of pregnancy was reported more often in our cohort (25%) than in the general European population (0.5%–1.5%).[20] However, all of these episodes were reported by the same patient (1 in 10). Thus, this higher prevalence in the present cohort certainly seems to be caused by an associated condition rather than chronic vomiting or GES. In summary, no significant increase in one specific pregnancy-related maternal complication could be observed in our cohort, but further observations will be necessary to confirm this finding.

Regarding delivery and child health, we found that six infants in our cohort were delivered via cesarean section (37.5%), while the rate of cesarean sections in France since 2003 has been very stable, at a level of about 20.4%.[21] This high rate is probably associated with the high level of preterm deliveries in our cohort. In the present report, 12 newborns were born prematurely (75.0%), while only 10% of infants in the general population are preterm.[22] Of particular note, only one patient had two children born before the 34th week of GA. The risk of premature birth might be related to chronic nausea and vomiting, gastroparesis, or underlying disease (diabetes) and patients need to be informed about this possible complication, requiring close monitoring of the pregnancy. Nevertheless, postnatal complications were rather sporadic and short-term. The younger preterm newborn required oxygen after birth while another preterm infant had a cystic adenomatoid malformation of the lung. Aside from these complications, one preterm newborn was LGA (6.2% vs. the 9.9% prevalence of LGA infants in the general French population)[23] and had postnatal hypoglycemia (6.3% vs. the 12.1% prevalence of hypoglycemic infants in the general population).[24] Two of the preterm infants required phototherapy for jaundice (15.4% vs. 2% incidence of phototherapy worldwide).[25] Most importantly, all children, whose ages ranged from 2 months to 15 years at the time of the interview, were in good health. Thus, apart from the risk of premature birth, no risk for the health of the children seemed to be reported in pregnancies with a GES device.

Finally, no severe device-related adverse event was reported, requiring inactivation or specific treatment. Pain sensation could be altered during pregnancy, leading to an increase in the

stimulation sensation in three patients.[26] Interestingly, one patient even reported less pain at the location of the GES. The evolution of gastrointestinal symptoms showed a significant increase in the severity and frequency of nausea and vomiting, mostly in the first trimester. This evolution overlaps with physiological adaptation to pregnancy, followed by a moderate reduction of those symptoms during the second and third trimesters.[27] Therefore, it is difficult to distinguish between pregnancy-related and chronic vomiting-related evolution. Thus, keeping GES activated to limit the contribution of chronic vomiting symptoms appeared to be an interesting strategy. The current strategy confirms the safety of GES for both the mother and the child. Moreover, the device was turned off in one patient due to safety concerns at the beginning of the study, but this resulted in a resurge of vomiting and the device had to be reactivated.

These results are also in line with the safety of other bioelectronic medicine during pregnancy. Indeed, the outcome of vagus nerve stimulation has been reported in 26 pregnancies in women treated for epilepsy.[28] This study did not report any vagus nerve stimulation-related teratogenicity, and maternal complications during pregnancy were related to the underlying disease and seizures during pregnancy.[28] Another review on vagus nerve stimulation including 10 articles and 44 pregnancies confirmed the safety of this device and found two fetuses malformations (4.8%) attributed to the combination of antiepileptic drugs, whose teratogenicity is well known.[29] Finally, the safety of cardiac pacemakers during pregnancy has also been reported in several series and case reports.[30,31] Thus, reports with gastric electrical stimulation were still missing but the current study confirmed there was no device-related adverse event.

There are several limitations to the present study. The questionnaire used was self-designed and not validated before, based on the fact that this is the first study investigating pregnancy and delivery in patients with refractory vomiting, including gastroparesis treated with GES. Since it is a retrospective study based on the reports of the interviewed patients, the present study is prone to recall bias. Only birth dates, implantation dates and gastrointestinal diagnoses were extracted from the hospital documents. Moreover, the number of pregnancies with GES remains small, even if this cohort is the largest to assess this condition during pregnancy.

In conclusion, women implanted with GES were concerned about possible device-related risks in pregnancy and/or delivery that may compromise the birth project. The present study found no significant increase in a specific maternal, fetal, or device-related serious complication in patients implanted with GES. There was a significant increase in the severity and frequency of nausea and vomiting, mostly in the first trimester. An increased risk of premature birth was also observed, although this may be related to the underlying condition, including gastroparesis and/or chronic vomiting. Whether the presence of GES indeed contributes to the successful outcome of pregnancies and deliveries or not warrants further research, including more patients.

AUTHOR CONTRIBUTIONS

HS collected the data, and drafted the manuscript. MAS collected data, performed the analysis, designed the figures and contributed to draft the manuscript. BC contributed with data and provided critical feedback. GG conceived the presented idea and critically reviewed the manuscript. All authors approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare there is no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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