Comparison of the evolution of patients with gastroschisis treated with the Simil exit technique vs. primary closure: A single-center observational study

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Abstract

Introduction: The surgical treatment of gastroschisis involves closing the abdominal wall after the intra-abdominal organs are reduced. The Simil-exit (SE) method is used to reduce morbidity and mortality. The objective of the present study was to compare the outcomes of patients with gastroschisis who underwent surgery via the SE technique versus those treated with primary closure (PC).

Methods: The present observational study analyzed the records of patients with gastroschisis at the "Dr. Roberto Gilbert Elizalde" Hospital from 2019 to 2022. The SE and CP techniques are compared. The variables included closure success, the start of enteral feeding, the length of hospital stay, and mortality.

Results: A total of 9 patients with ES and 26 patients with PC were included. There were no differences between the start time of enteral feeding (P = 0.13) and the hospitalization time (P = 0.43). Four patients died in the CP technique group (15.4%; P = 0.5), which was significantly related to reoperation (P = 0.002) and complex gastroschisis (P <0.001).

Conclusions: Closure via the SE technique has noninferiority equivalence concerning that via the CP technique.

Keywords:

MeSH: Gastroschisis, Abdominal Wall; Mortality; Feeding; Observational Study.

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Introduction

Gastroschisis is a congenital anomaly of the abdominal wall characterized by herniation of the abdominal organs outside the cavity. It is generally located on the right side of the umbilical cord [1,2]. With a prevalence of 2-5 cases per 10,000 live births [3], the etiology of this disease is unknown; although several theories exist, none have been accepted [4,5]. Gastroschisis can be diagnosed prenatally via ultrasound at the end of the first trimester when the intestinal loops float in the amniotic cavity without membranous covering [1,6]. This contributes to improved delivery planning, although the type of delivery performed and whether or not delivery is induced remain controversial [1,4 5].

The surgical management of gastroschisis consists of reducing the abdominal organs and closing the abdominal wall in a primary or delayed manner before the placement of a silo [2,4 -7]. In 2007, Dr. Svetliza et al. proposed a new closure method called SIMIL-EXIT, which consists of reducing abdominal contents via the EXIT technique (ex utero intrapartum treatment), which maintains the fetoplacental circulation for temporary oxygenation of the newborn while it is being performed the procedure [8] to reduce hospital stays, avoid prolonged fasting, and avoid ventilatory assistance in patients with gastroschisis. At the Latin American level, several comparative studies have been carried out on the outcomes of patients treated with a simile-exit technique vs. primary closure; however, no recorded data exists in Ecuador.

Patients with gastroschisis who underwent surgery via the Simil-Exit technique were suggested to experience significantly more significant clinical improvement than those who underwent primary closure. In this context, the study's objective was to compare the clinical outcomes of patients who underwent surgery via the Simil-Exit technique with those who underwent primary closure.

Materials and methods

Study design

The methodology used corresponds to a descriptive study; the follow-up was cross-sectional, and the source was retrospective.

Stage

This study was carried out at the pediatric surgery service of the Hospital de Niños "Dr. Roberto Gilbert Elizalde" in Guayaquil from January 1, 2019, to December 31, 2021.

Participants

Newborn patients with congenital abnormalities of the abdominal wall who were diagnosed with gastroschisis and who underwent surgical management for resolution were included. Due to the choice of pediatric surgeons, two groups were formed: the first was resolved by primary closure (PC), and the second was resolved by the Simil-Exit (SE) method. Patients who underwent deferred closure were excluded. Incomplete records that did not allow analysis were removed.

Variables

The demographic and clinical variables collected were gestational age at birth and successful or unsuccessful closure, considering the latter surgical reoperations; complexities, stenosis, perforation, and necrosis; and the start of enteral feeding, considering the time elapsed from the closure of the abdominal wall to the beginning of feeding without interruptions until discharge. Referring to other studies, a duration of less than six days is a sign of improved disease progression. Data were also collected on the length of hospital stay, considering a stay of less than 21 days as the best outcome; finally, information was collected on the mortality of the patients.

Data sources/measurements

The source was indirect; an electronic form was used to fill out the data from the institutional medical history of

the patients who entered the hospitalization period. A review of the pediatric surgery unit registry was performed. The information was confidential; no personal data were included to identify the study subjects.

Procedure

The simile exit technique was performed by pediatric surgeons with residents of the "Dr. Roberto Gilbert Elizalde" in conjunction with a multidisciplinary team of anesthesiologists, gynecologists, and neonatologists from the "Alfredo Paulson" Women's Hospital. Once evaluated via ultrasound, a scheduled cesarean section is performed, after which the fetus is extracted and the fetus is placed on the "nest" located on the mother's thighs. The wall defect and protruding organs are observed while the neonatologist inhibits crying, and the gynecologist continuously palpates the heartbeat of the umbilical cord. The viscera are introduced into the abdominal cavity in an orderly manner. First, the stomach, then the colon, is directed toward the left side, and finally, the small intestine is directed toward the right. The umbilical cord is clamped and cut once the beating has stopped or when the reduction of the viscera has been completed. Once this last step has been completed, the patient is transferred to the thermocouple, where the neonatologists evaluate whether the patient will require ventilatory support or nonsupplementary oxygen. At the same time, surgery proceeds to perform the closure of the abdominal wall defect in a single plane with a polyglactin suture.

The primary closure category included patients who underwent abdominal wall reconstruction in the first 24 hours of life without the need to use the silo for prolonged periods, avoiding manipulation of the abdominal contents. This procedure can be done in the operating room or the neonatal care unit. We performed closure with polyglactin sutures for aponeurosis and with polyamide for the skin.

Control of sources of bias.

To avoid bias in the study, the registration of medical records in a Microsoft Excel database, which met the eligibility criteria, was guaranteed.

University and Sample

The universal population included all the patients registered at the institution. The sample size was nonprobabilistic and discretionary since all incident cases in the study period were included.

Quantitative variables

Inferential statistics were calculated. Categorical results are expressed as frequencies and percentages.

Statistical analysis

The categorical variables were compared between the groups with chi-square tests, and odds ratios were obtained with 95% confidence intervals to establish associations. P values less than 0.05 were considered to indicate statistical differences. The statistical package SPSS 25.0 was used for the analysis (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

Results

Participants

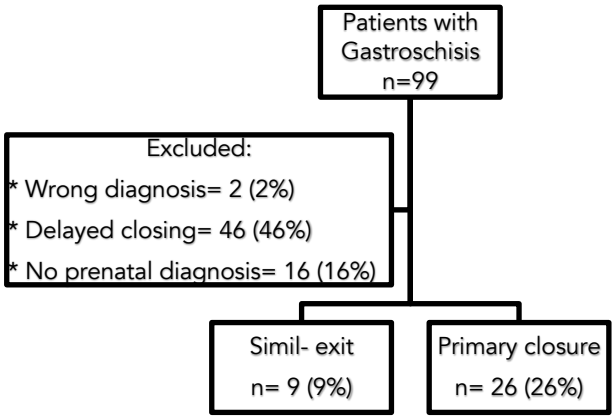
There were 35 patients admitted to the study (Figure 1).

General characteristics of the population

Regarding the days of initiation of feeding, 4 (15.4%) patients were classified as having lost value since the variable was not measurable.

Considering that a duration of less than six days was associated with better progression in the closure group due to Simil-exit, 4 (44.4%) patients died, as did the primary closure group (15.4%). Similarly, among those who started feeding after six days, 5 (55.6%) patients underwent closure due to Simil-exit, and 18 (69.2%) patients underwent primary closure ($P = 0.132$) (Table 1).

Figure 1. Flow diagram.



Regarding the hospital stay, which was less than 21 days, as a sign of good progression, 5 (55.6%) patients were included in the simile-exit group, 9 (34.6%) patients were included in the primary closure group, 4 (44.4%) patients were included in the simile-exit group, and 17 (65.4%) patients were included in the primary closure group (P = 0.43).

Regarding reoperations, 8 (30.8%) patients in the primary closure group underwent reoperation, while in the simile-exit group, only 1 (11.1%) patient required a second surgery (P = 0.24).

Table 1. Type of closure and study variables.

Variables		Clasp type		*P*	OR	IC de 95%	
		Primary	Simil-exit			Lower	Superior
Feeding start days	Not applicable	4 (15.4%)	0 (0.0%)	0.4592	0.556	0.117	2.634
	< 6 días	4 (15.4%)	4 (44.4%)				
	> 6 días	18 (69.2%)	5 (55.6%)				
Hospital stay	< 21 días	9 (34.6%)	5 (55.6%)	0.2752	0.424	0.091	1.982
	> 21 días	17 (65.4%)	4 (44.4%)				
Reoperation	No	18 (69.2%)	8 (88.9%)	0.0729	3.0938	0.901	10.63
	Yes	8 (30.8%)	1(11.1%)				
Complexity	Simple	22 (84.6%)	9 (100%)	0.505	2.829	0.133	60.21
	Stenosis	3 (11.5%)	0 (0.0%)				
	Necrosis	1 (3.8%)	0 (0.0%)				
Mortality	No	22 (84.6%)	9 (100%)	0.386	0.2632	0.013	5.385
	Yes	4 (15.4%)	0 (0.0%)				

When comparing whether the reoperation was related to the presence of complex gastroschisis, it was observed that there was no association with the type of gastroschisis (P = 0.008); instead, it was associated with other complications, such as flanges and adhesions or intra-abdominal compartment syndrome.

In the simile-exit group, there were no deaths, while in the primary closure group, there were 4 (15.4%) patients (P = 0.21). These factors were associated with complex gastroschisis (P = 0.001) and reoperation (P = 0.002).

Discussion

Gastroschisis is one of the most common abdominal wall pathologies in neonates, and the main objective is to close the defect while reducing the number of protruding organs; different methods have been proposed for this purpose. In the present study, gastroschisis was diagnosed prenatally via ultrasound; therefore, the multidisciplinary team must be fully informed and prepared to receive the product. However, letting pregnancy progress naturally or inducing early pregnancy

continues to be a controversial element among professionals [9,10].

Svelitza et al. (2007) used prenatal ultrasound for the termination of pregnancy at 34 weeks of gestation, a sentinel loop dilation of 18-20 mm, and a wall thickening of 2 mm6. The Simil-exit technique aims to maintain the support of the fetal-placental circulation for surgical reduction [11,12], avoiding crying or swallowing air during surgery, which could interfere with reducing the content of the abdominal cavity.

One of the most critical parameters for patients with gastroschisis is the start of enteral nutrition. In this study, 44.4% of patients were closed with a simile-exit technique and started enteral nutrition less than six days after closure, while in the primary closure group, only 14.4% of the patients achieved this outcome (P = 0.13); in this sense, better results were observed than those found in other studies, in which the patients were started on nutrition at 11.88 and 17.4 days, respectively [12,13]. Regarding this aspect, other authors relate gastrointestinal slowing or intestinal dysmotility to the chronic changes produced by the exposure of the loops to the amniotic fluid inside the uterus in the prenatal period [7,10].

Regarding the days of hospitalization, in 55.6% of the simile-exit patients, there were fewer than 21 days, while 34.6% of the patients who underwent primary closure had a stay of less than 21 days (P = 0.43); this could be due to the delay in the start of enteral stimulation in the primary closure group. A comparison of the stays of the patients with similar exits revealed that these patients had fewer days than did the patients in the study carried out by Mostajo et al. [5], in which the average stay was 25 days, and by de Cisneros et al. [7], in which the average hospitalization duration was 35 days.

Although our study does not indicate the consequences of a more extended hospital stay, it would be interesting to know mainly its cost since, in a study carried out by Wong et al. [14], the expenses increased by up to 57% due to the hospital stay in the neonatal intensive care unit (NICU); if we add to the fact that they require subsequent interventions in the operating room, the cost increases by 47%.

Regarding mortality, no patient in a similar group died, compared to the primary closure group, with a mortality of 15.4%. Exposure to the simile-exit technique protected against mortality, with a relative risk of 0.84 and a 95% confidence interval of 0.71-0.99, although these findings were not significant, as the P value was 0.21. Mortality was significantly related to the complexity of gastroschisis (P = 0.001) and the type of reoperation performed due to different causes (P = 0.002).

Despite the reasonable survival rate in this study and the low mortality rate compared to those of individuals with other conditions in our population, it is still essential to consider the usefulness of the similar-exit technique, as this approach emphasizes the importance of maintaining care and careful prenatal care and providing timely care with this technique to improve postnatal outcomes.

The use of the simile-exit technique in Ecuador represents an innovation in medical practice, and an inherent limitation of our research is the availability of a small number of patients who have been treated using this technique. Given that its implementation is novel in our context, the sample is limited and could require a broader evaluation in the future to fully understand its results and benefits, much more so if the study could be carried out prospectively.

Conclusions

The simile-exit technique is positioned as a new technique for the closure of gastroschisis, as it can reduce reoperations and mortality while facilitating the early initiation of enteral feeding and reducing hospital stays. Although the scientific evidence supporting these claims is still limited, adopting this technique may benefit patients. However, it is essential to highlight that its implementation requires efficient multidisciplinary coordination; despite these challenges, the favorable results justify its consideration in clinical practice.

Abbreviations
NICU: Neonatal Intensive Care Unit.

Supplementary information
No supplementary materials are declared.

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Authors' contributions
Mei Chun Lin: Conceptualization, data curation, formal analysis, fundraising, research, writing - original draft.
Daniel Acosta Farina: Methodology, project management, resources, software, supervision, validation, visualization, writing – review, and edition.
Jorge Oliveros Rivero: Methodology, project management, resources, software, supervision, validation, visualization.
Verónica Pólit Guerrero: research, resources, writing - original draft.
Rodrigo Argotti Zumbana: research, resources, writing - original draft.
Jimmy Andrade Montesdeoca: research, resources, writing - original draft.
All the authors read and approved the final version of the manuscript.

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Availability of data and materials
The data were collected from medical files; they are not publicly available due to patient confidentiality but are available through the corresponding author under a justified academic request.

Declarations

Ethics committee approval and consent to participate
The Bioethics Commission of the Faculty of Medical Sciences of the Universidad Católica Santiago de Guayaquil approved the study.

Publication consent
Images, radiographs, and specific patient studies were not available.

Conflicts of interest
The authors declare that they have no conflicts of interest.

Author information
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