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ORIGINAL ARTICLE

Fetal Surgery in the Era of SARS-CoV-2 Pandemic: A Single-Institution Review

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Abstract

Objective: To cope with the changing health care services in the era of SARS-CoV-2 pandemic. We share the institutional framework for the management of anomalous fetuses requiring fetal intervention at Mayo Clinic, Rochester, Minnesota. To assess the success of our program during this time, we compare intraoperative outcomes of fetal interventions performed during the pandemic with the previous year.

Patients: We implemented our testing protocol on patients undergoing fetal intervention at our institution between March 1, and May 15, 2020, and we compared it with same period a year before. A total of 17 pregnant patients with anomalous fetuses who met criteria for fetal intervention were included: 8 from 2019 and 9 from 2020.

Methods: Our testing protocol was designed based on our institutional perinatal guidelines, surgical requirements from the infection prevention and control (IPAC) committee, and input from our fetal surgery team, with focus on urgency of procedure and maternal SARS-CoV-2 screening status. We compared the indications, types of procedures, maternal age, gestational age at procedure, type of anesthesia used, and duration of procedure for cases performed at our institution between March 1, 2020, and May 15, 2020, and for the same period in 2019.

Results: There were no statistically significant differences among the number of cases, indications, types of procedures, maternal age, gestational age, types of anesthesia, and duration of procedures (P values were all $>.05$) between the pre−SARS-CoV-2 pandemic in 2019 and the SARS-CoV-2 pandemic in 2020.

Conclusions: Adoption of new institutional protocols during SARS-CoV-2 pandemic, with appropriate screening and case selection, allows provision of necessary fetal intervention with maximal benefit to mother, fetus, and health care provider.

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The advancement of prenatal diagnostic imaging has led to early and more accurate detection of congenital malformations in the antenatal period as well as in the development of new and safe in utero interventions.[1,2]

Several prenatal congenital malformations, such as twin-to-twin transfusion syndrome (TTTS),[3] twin anemia polycythemia syndrome (TAPS),[3] lower urinary tract obstruction (LUTO),[4,5] congenital diaphragmatic hernia (CDH),[6-9] and myelomeningocele,[10,11] carry varying degrees of perinatal morbidity and mortality. Fetal intervention to modify outcome is potentially available, and the decision to perform these procedures and timing of intervention can significantly affect maternal and fetal outcomes.[12] These interventions can be minimally invasive, such as ultrasound-guided or fetoscopic procedures, or more invasive procedures requiring laparotomy and uterine incisions.[13] Fetal interventions are usually performed in the OR, and the type and timing of procedure and choice of anesthesia is dependent on multiple factors including diagnosis, indications, maternal comorbidities, gestational age, and placental location.

On March 11, 2020, the World Health Organization (WHO) declared a global pandemic of the SARs-CoV-2 virus,[14] the etiologic agent of

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COVID-19.[15] The pandemic has demanded significant adjustments in health care systems worldwide, including delivery of prenatal care, labor and delivery care, and medically indicated fetal interventions for anomalous fetuses. Different perinatal societies, including the American College of Obstetrics and Gynecology (ACOG),[16] Society for Maternal Fetal Medicine (SMFM),[17,18] and Royal College of Obstetrics and Gynecology (RCOG),[19] have published individual recommendations to guide patients, health care workers, and health care institutions on prenatal and labor and delivery care.[20] Fetal intervention societies, including North American Fetal Therapy Network (NAFTNet)[21] and International Fetal Medicine and Surgery Society (IFMMS),[22] have published guidelines specific to fetal interventions. These recommendations need to be adopted and adjusted to fit the infrastructure, resources, and demands of each health care institution and the patient population they serve. The current study aims to report our experience with managing fetal surgeries in our institute during the SARs-CoV-2 pandemic to evaluate the impact of the pandemic in our program.

METHODS

The current study is a retrospective chart review comparing the intraoperative outcomes of fetal interventions performed at Mayo Clinic, Rochester, Minnesota, Maternal-Fetal Medicine Center, during the SARS-CoV-2 pandemic, between March 1, and May 15, 2020, compared with the same time period, between March 1, and May 15, in 2019 (pre-SARS-CoV-2 pandemic).

In March 2020, significant institutional changes occurred, limiting the type and number of surgical cases able to be performed. With the establishment of in-house SARS-CoV-2 screening, our institution was quick to adopt universal testing for patients admitted to Labor and Delivery, beginning March 15, 2020. The addition of screening for those undergoing planned surgical interventions began on April 1, 2020. Fetal intervention cases can be urgent or limited to narrow timeframes for benefit. Patients requiring these interventions intersected both the Labor and Delivery and surgical-practice policies, and therefore a protocol was adopted specifically for these cases, as summarized in the Figure.

Our fetal surgery team developed the Fetal Surgery During SARS-CoV-2 Pandemic Protocol, adopted from our institutional guidelines, including Mayo Clinic perinatal committee guidelines and surgical requirements outlined by our Infection prevention and control (IPAC) committee.

The SARS-CoV-2 screening test is done via nasopharyngeal (NP) swabbing and sent for quantitative real-time polymerase chain reaction (qRT-PCR). Serum antibody testing for SARS-CoV-2 was added to the routine screening protocol starting April 21, 2020; turnaround time for both these tests is between 24 and 48 hours. In the setting of emergencies, procedures are performed, even if results have not returned. If patients are symptomatic, or test results are positive for SARS-CoV-2, a multidisciplinary discussion is required to review risks vs benefits of proceeding. Although testing is obtained to inform all teams and the patient regarding the risks of the procedure, all surgical patients are treated as suspected SASR-CoV-2 carriers. Patients are also usually allowed 1 asymptomatic healthy visitor to accompany them on the day of the procedure; routine NP swab for SARS-CoV-2 is not performed per visitor policy, but they are screened to ensure no recent exposures or concern or infections. Visitors have to wear masks at all times within the hospital. Table 1 summarizes the type of personal protective equipment (PPE) used in different scenarios.

Although our protocol was specifically tailored to fit our institution requirements, and has only been used at our institution, it is compliant with recommendations put forth by ACOG,[16] SMFM,[17,18] NAFTNet,[21] IFMMS,[22] and Deprest et al.[23]

This protocol was implemented on April 1, 2020, and to assess its efficacy objectively, we performed a retrospective chart review of all fetal intervention cases performed at our institutional fetal surgery program between March 1, and May 15, 2019, and March 1, and May 15, 2020. This period was chosen to reflect the start of the pandemic to present and to allow us to include as many patients as possible. Institutional review board approval (ID-19-008729) was obtained before chart review. Patients who met candidacy and underwent fetal intervention within the specified time frame were included. Those who were evaluated but did not undergo intervention were excluded. Data abstracted

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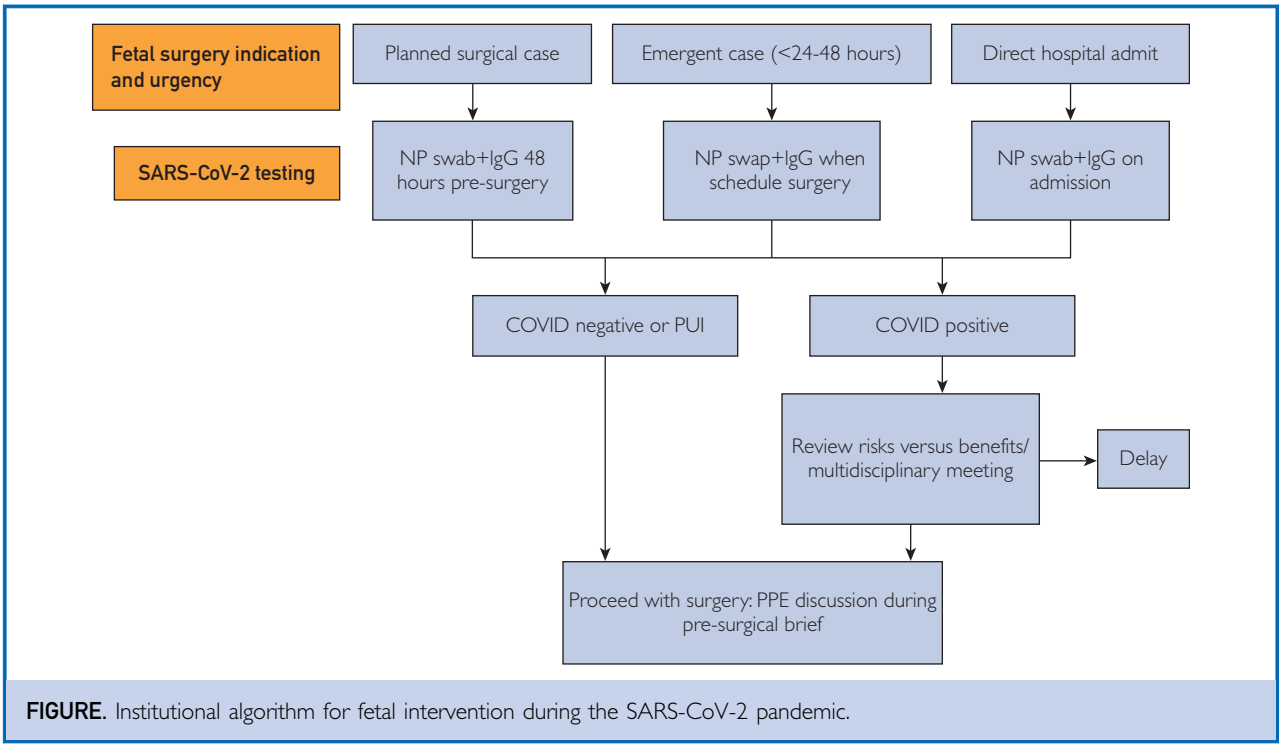

FIGURE. Institutional algorithm for fetal intervention during the SARS-CoV-2 pandemic.

included number of patients who presented for consultation; number of patients who underwent intervention; diagnoses and indications for intervention; type of procedure performed; maternal age at presentation; gestational age at intervention; type of anesthesia (local, regional, or general); total intraoperative preparation; time, defined as anesthesia start time to surgery start time, stratified by type of anesthesia (monitored anesthesia care [MAC], or general anesthesia [GA]); and total procedure time, defined as anesthesia start time to anesthesia stop time, also stratified by type of anesthesia: MAC or GA.

The total intraoperative preparation time (anesthesia start to procedure start) and total procedure times (anesthesia start to anesthesia stop) were defined as our primary outcome.

Statistical analysis was performed using the Fisher exact test, χ^2 test, and Mann-Whitney U test, based on the distribution of the variables (MedCalc Software Ltd, version 19.3, Ostend, Belgium). Statistical significance was considered when P values were $<.05$.

RESULTS

A total number of 37 patients were referred for evaluation during the study period: 15 patients in 2019, pre–SARS-CoV-2 pandemic and 22 patients in 2020, during the SARS-CoV-2 pandemic. Table 2 summarizes our experience with the patients who underwent interventions in our fetal surgery program.

In 2019, a total of 8 cases met criteria for intervention. These included 2 (25%) cases of Quintero Type II TTTS, 1 (12.5%) case of TAPS, 2 (25%) cases of myelomeningocele, 2 (25%) cases of LUTO, and 1 (12.5%) case of bilateral hydrothorax. Procedures performed include 3 (37.5%) cases of fetoscopic laser ablation of placental anastomoses for TTTS and TAPS, 1(12.5%) open and 1 (12.5%) fetoscopic in utero repair of myelomeningocele, 2 (25%) vesicoamniotic shunts for LUTO, and 1 (12.5%) case of bilateral thoracoamniotic shunt placement for the bilateral hydrothorax. Mean maternal age was 27 (range: 17 to 32 years). Mean gestational age at procedure was 21/6 (range, 14/0 to 27/1) weeks. Types of anesthesia used were MAC in 5 (62.5%) cases and GA with epidural block in 3 (37.5%) cases. Mean intraoperative preparation time for MAC was 40 minutes (range: 22 to 61 minutes) and for GA was 42 minutes (minimum to maximum: 25 to 54 minutes). Mean total procedure time for MAC was 123 minutes (range: 60 to 236 minutes) and for

TABLE 1. Summary of Terms and Abbreviations Used in the Protocol for Fetal Intervention During the SARS-CoV-2 Pandemic

Term	Definition	Equipment
PPE	Personal protective equipment	Examples: masks, gloves, gowns
Respirators	Tight fitting mask that is protective against airborne particles and droplets	N95 or PAPR (powered air-purifying respirators)
Eye protection	Protective against droplets	Safety glasses or face shields (shields may also help protect respirators to allow longer use)
Aerosol-generating procedure (AGP)	Procedures that generate aerosols and droplets such as intubation/extubation, suction, sputum induction	N95 with eye protection or PAPR with gown and gloves
Modified droplet precautions (MDP)	PPE to use with patients who are COVID-19 positive, symptomatic, or undergoing COVID screening but not having AGPs	Surgical mask with eye protection, gown and gloves
Standard precautions (SP)	PPE to be worn with all patients who are asymptomatic and have negative screen	Mask with eye protection. Gown and gloves should be used with routine indications
Person under investigation (PUI)	Symptomatic or asymptomatic patients who have pending COVID testing	MDP

AGP = aerosal generating procedure; MDP = modified droplet precaution; PUI = person under investigation; SP = standard precautions.

GA was 211 minutes (range: 59 to 314 minutes).

In 2020, a total of 9 cases met criteria for undergoing intervention. These included 5 (55.6%) cases of TTTS (3 Type II and 2 Type III), 1 (11.1%) case of TAPS, and 3 (33.3%) cases of myelomeningocele. Procedures performed included 6 (66.7%) fetoscopic laser ablations of placental anastomoses for TTTS and TAPS and 3 (33.3%) open in utero repair of myelomeningocele. Mean maternal age was 30 (range 21 to 35 years). Mean gestational age at which the procedures were performed was 21/0 weeks (range 16/2 to 25/1 weeks). Monitored anesthesia care was used in 6 (66.7%) of cases, and GA with epidural block was used in 3 (33.3%) of cases. Mean intraoperative preparation time for MAC and GA was 40 minutes (range: 33 to 52 minutes) and 52 minutes (range: 38 to 59 minutes), respectively. Mean total procedure time (anesthesia start to anesthesia stop time) for MAC was 104 minutes (range: 91 to 121 minutes) and for GA was 241 minutes (range: 211 to 296 minutes).

No cases had positive qRT-PCR or serum antibodies for SARS-CoV-2. Overall, there were no differences between 2019 and 2020 in the number of procedures performed, maternal age, gestational age at procedure, type of anesthesia, intraoperative preparation time, and total procedure time. Of note, we performed more fetoscopic laser ablations of the placental anastomoses for severe TTTS during the SARs-Cov-2 pandemic.

DISCUSSION

Principal Findings

The current study demonstrated that there were no significant differences between the total number of fetal intervention cases performed and evaluated in our institution during and before the SARs-CoV-2 pandemic. Although not statistically significant, procedures performed in 2019 had greater variety, including emergent, urgent, and nonurgent cases, such as placental laser ablation for TTTS, vesicoamniotic shunt placement for LUTO, fetsoscopic and open repairs for myelomeningocele, and bilateral thoracoamniotic shunt placement. In 2020, 6 of 9 (66.6%) cases performed were emergent placental laser ablation for TTTS because deference could result in 1 or both fetal death. The other 3 cases were open myelomeningocele repairs. None of our patients had a positive PCR test. Despite implementing SARs-CoV-2 precautions and following the institutional protocols, we did not observe increased surgical time.

Literature Review and Comparison

Patients who were referred to the Fetal Center at Mayo Clinic for evaluation of potential fetal intervention underwent advanced level

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TABLE 2. Comparison of Outcomes for Fetal Interventions Performed Between March 1 and May 15, 2019, and March 1 and May 15, 2020

Fetal intervention data	March 1 to May 5, 2019	March 1 to May 15, 2020	*P* values
Total number of cases	8	9	
Diagnoses/indication for intervention n (%)			1.00
TTTS (I, II, III, IV, or V)	2 (25) (Type II-2)	5 (55.6) (Type II-3, Type III, 2)	
SIUGR (Types 1, 2, or 3)	0 (0)	0 (0)	
TAPS	1(12.5)	1 (11.1)	
TRAP	0 (0)	0 (0)	
Spina bifida	2 (25)	3 (33.3)	
CDH	0 (0)	0 (0)	
LUTO	2 (25)	0 (0)	
Others (bilateral hydrothorax)	1 (12.5)	0 (0)	
Procedure performed n(%)			1.00
Fetoscopic laser ablation of placental anastomoses	3 (37.5)	6 (66.7)	
In utero repair of spina bifida	2(25) (1 open, 1 fetoscopic)	3 (33.3) (3 open)	
Selective termination of pregnancy	0 (0)	0 (0)	
Vesicoamniotic shunt	2 (25)	0 (0)	
Fetal cystoscopy	0 (0)	0 (0)	
Others (bilateral thoracoamniotic shunt)	1 (12.5)	0 (0)	
Maternal age in years(median [minimum—maximum])	27 (17-32)	30 (21-35)	.15
Gestational age at procedure in weeks (median [minimum— maximum])	21/6 (14/0-27/1)	21/0 (16/2- 25/1)	.67
Type of anesthesia			1.00
MAC	5 (62.5)	6 (66.7)	
GA with epidural block	3 (37.5)	3 (33.3)	
Duration of procedure in minutes (median [minimum—maximum])			.84
Anesthesia start to surgery start			.84
MAC	40 (22-61)	39 (33-52)	
GA with epidural block	42 (25-54)	52 (38-59)	
Anesthesia start to anesthesia stop			
MAC	122 (60-236)	103 (91-121)	
GA with epidural block	211 (59-314)	241 (211-296)	

CDH = congenital diaphragmatic hernia; GA = general anesthesia; LUTO = lower urinary tract obstructions; MAC = monitored anesthesia care; SIUGR = selective intrauterine fetal growth restriction; TAPS = twin anemia polycythemia sequence; TRAP = twin reverse arterial perfusion; TTTS = twin-to-twin transfusion syndrome.

ultrasound followed by a consultation with a fetal interventionist, neonatologist (if pregnancy is viable, >23 weeks' gestation), anesthesiologist, and additional pediatric subspecialist specific to individual diagnosis. Our institution adopts a multidisciplinary approach to our fetal-intervention cases.

Cases such as laser ablation of placental anastomoses for TTTS or TAPS and percutaneous blood sampling (PUBS) and transfusion for fetal anemia can prevent fetal death; however, others, such as myelomeningocele repair[24] and FETO for CDH,[25] are performed to decrease neonatal morbidity and mortality. In these situations, the mother is typically asymptomatic and carries very minimal personal risk of morbidity or mortality. In cases of transfusion or laser ablation, delays of hours can result in fetal death and thus are considered emergent cases, although other procedures need to be performed in a timely fashion at a certain gestational age to have maximal neonatal benefit. They are considered urgent and cannot be significantly delayed,

given the short period when fetal intervention can change the natural history of the congenital anomaly.

If any patients in our cohort did have positive results of SARS-CoV-2 tests, we could choose to delay some of the urgent and nonurgent procedures, such as myelomeningocele repair or FETO for CDH, as long as the new procedure date still fell within the acceptable gestational age range for performing interventions.

Careful selection of candidates for fetal intervention is critical to minimize the risks of SARS-CoV-2 infection exposure to the mother, fetus, and health care workers. In addition, this favors judicious use of PPE,[22] while keeping in compliance with recommendations for care of pregnant women during the COVID-19 pandemic put forth by various perinatal societies,[20] including ACOG,[16] SMFM,[17,18] RCOG,[19] NAFTNet,[21] and IFMSS.[22]

Because of the poor negative predictive value (NPV) and high variability in sensitivity[26] of the SARS-CoV-2 screening test, the American Society of Anesthesiology (ASA)[27] and the American Patient Safety Foundation (APSF)[28] have determined that preprocedural testing cannot rule out infection. Therefore, these organizations recommend that all high-risk aerosol-generating procedures (AGPs) (intubation, extubation, bag-mask ventilation, and open tracheal suctioning) be performed with modified droplet precautions with respiratory protection, using N95 or powered air purifying respirator (PAPR) equivalent, as is done at our institution.

Although most data currently suggest minimal-to-no risk of vertical transmission,[29-31] the risk is real, and avoidance of unnecessary fetal interventions are still imperative. Beyond patient selection and screening for infection, modifications to the OR workflow and etiquette can also minimize the risks of unnecessary exposure to all involved personnel. Per our protocol, before each case, we conduct a surgical briefing including all essential personnel who will be participating in the case. This is a critical component of our care to ensure that everyone understands the nature of the procedure (minimally invasive vs open), type of anesthesia that will be used, expected length of procedure, and each person's role in the case. In addition, the team can develop a plan if the case needs to be paused for an AGP and whether PPE worn at the start of the case should be altered, based on the likelihood of conversion.

Of note, none of the providers involved in the care of fetal interventions became ill during this study period. If there was any concern of provider exposure to COVID-19, they were advised to self-quarantine and not present to work, per institutional policy put forth by IPAC.

Clinical Implications

Our Fetal Surgery During SARS-CoV-2 Pandemic Protocol is up to date at the time of submission; however, it continues to evolve and should only be used as a template for other institutions rather than a prescriptive copy. It is also important to continue to modify and update the protocols to keep up with changing policies, emerging evidence, and community disease activity.

Fetal intervention poses unique challenges in this current era of the SARS-CoV-2 pandemic. Beyond consideration of maternal, fetal, and neonatal outcomes, it is also important to recognize the potential risks of vertical transmission, health care resource availability, and health care worker exposures, as well as psychosocial impact to maternal well being if treatment is indicated and cannot be offered.

Our study suggests that fetal interventions can still be offered successfully and performed during the SARS-CoV-2 pandemic, with the following caveats: The indication and timing of procedure should be triaged based on urgency of the diagnoses, which is determined by type of congenital anomaly, sonographic findings, maternal comorbidities, associated morbidity and mortality, SARS-CoV-2 screening ability, and availability of resources.[21-23] Consultations for fetal interventions are sensitive and require sonographic evidence to guide management: thus, the need for face-to face encounters. Different institutions may have varying protocols on which patients are evaluated using telemedicine vs in-person meetings, but, if fetal intervention is an option, patients with anomalies should be prioritized for in-person visits.

To preserve N95 or PAPR resources,[32,33] efforts to reduce high risk AGPs could include local or regional anesthesia.[33] However,

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because of adequate N95 and PAPR supplies and reuse and recycle protocols at our institution, we did not need to modify our anesthetic plans as a result of the pandemic. Institutions with high disease burden or limited PPE could consider delaying nonemergent procedures if safely feasible and perform certain procedures, such as myelomeningocele repair, under regional anesthesia or laser ablation of placental anastomoses for TTTS and TAPS cases under local anesthesia.

Research Implications

Congenital malformations account for approximately 3% of all pregnancies,[34] and, at present, few centers around the United States have the ability to offer fetal interventions. However, anomalous fetuses represent a highly important subset of patients in which life-changing treatment options could be offered. Further investigation comparing multi-institution protocols to evaluate the impact of SARS-CoV-2 pandemic on the ability to perform these interventions and their outcomes are critical to the care of these patients. In addition, multicenter studies are necessary to evaluate the impact of SARs-CoV-2 infection to those patients who have undergone or will undergo in utero interventions.

Strengths and Limitations

Several factors highlight the strength of our study. The availability of health care resources and personnel, along with ease in collaboration at our institution, allowed us to design and implement this important protocol rapidly. This, in conjunction with our in-house SARS-CoV-2 screening abilities, has made it possible for us to continue to offer fetal interventions to our patients during the pandemic. The teams involved in patient counseling, selection, and performing the surgery were the same for 2019 and 2020; this eliminates design, selection, and procedural bias, while giving us the advantage of being able to directly compare the outcomes of cases performed during the SARS-CoV-2 pandemic with last year.

Our study is limited by the small sample size, as fetal surgeries account for only a small subset of surgeries performed annually. Our data are also limited by representing only a single-institution protocol. The majority of our patients are from the Midwest area, with low community prevalence of SARS-CoV-2. As of June 3, 2020, there were a total of 25,870 cases of patients who tested positive for SARS-CoV-2 in the state of Minnesota, with only 654 (2.5%) within Olmsted County, where our institution is located.[35] Our findings may not translate to communities with higher case prevalence and higher disease burden.

CONCLUSIONS

Our study demonstrates that the SARs-CoV-2 pandemic has had minimal impact on our institution's surgical outcomes (without statistical significance) and our capacity to offer complex fetal surgeries. Our program has established specific protocols based on institutional guidelines and national societies that have enabled us to proceed safely with fetal interventions during the SARs-CoV-2 pandemic.

Abbreviations and Acronyms: **ACOG** = American College of Obstetrics and Gynecology; **AGP** = aerosol-generating procedures; **AFPS** = American Foundation for Patient Safety; **ASA** = American Society of Anesthesiology; **CDH** = congenital diaphragmatic hernia; **COVID-19** = coronavirus-2019; **FETO** = fetoscopic endoluminal tracheal occlusion; **GA** = general anesthesia; **IFMSS** = International Fetal Medicine and Surgery Society; **LUTO** = lower urinary tract obstruction; **MAC** = monitored anesthesia care; **NAFTNet** = North American Fetal Therapy Network; **qRT-PCR** = quantitative real time polymerase chain reaction; **SMFM** = Society for Maternal and Fetal Medicine; **TAPS** = twin anemia polycythemia sequence; **TTTS** = twin-to-twin transfusion syndrome; **WHO** = World Health Organization

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