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EXIT (ex utero intrapartum treatment) surgery for the management of fetal airway obstruction: A systematic review of the literature☆

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ABSTRACT

Purpose: To provide a comprehensive overview of the perinatal and maternal outcomes of fetuses undergoing EXIT surgery for the management of fetal airway obstruction secondary to cervical or oral tumors.
Methods: A comprehensive search from inception to September 2018 was conducted on databases including MEDLINE, EMBASE, Cochrane Library and LILACS. All studies that reported an EXIT surgery in singleton were considered eligible. A descriptive analysis was performed.
Results: Out of the 250 full-text study reports, 120 articles reporting 235 cases of EXIT surgery were included. EXIT surgery was performed at 35.1 weeks of gestation on average. The most frequent diagnosis was teratoma (46.4%, n = 109/235). There were 13 adverse maternal events, and the most frequent one was postpartum hemorrhage (4.7%, n = 11/235). No maternal death was reported. Fetal and neonatal death occurred in 17% (40/235) of the cases. There were 29 adverse fetal events (12.2%), and the most frequent one was the failure of intubation or tracheostomy (3.4%, n = 8/235).
Conclusion: EXIT surgery could be considered for the management of an oral or cervical tumor that's highly suspicious of blocking the fetal airway. This systematic review reports that EXIT surgery poses substantial risks of maternal and fetal adverse events, including neonatal death.
Level of Evidence: IV case series with no comparison group.

Contents

Advances in prenatal diagnosis, such as high-resolution ultrasound and fetal MRI to detect and assess severe fetal malformations, have facilitated pre-labor planning to avoid potential catastrophic events during delivery. Ex utero intrapartum

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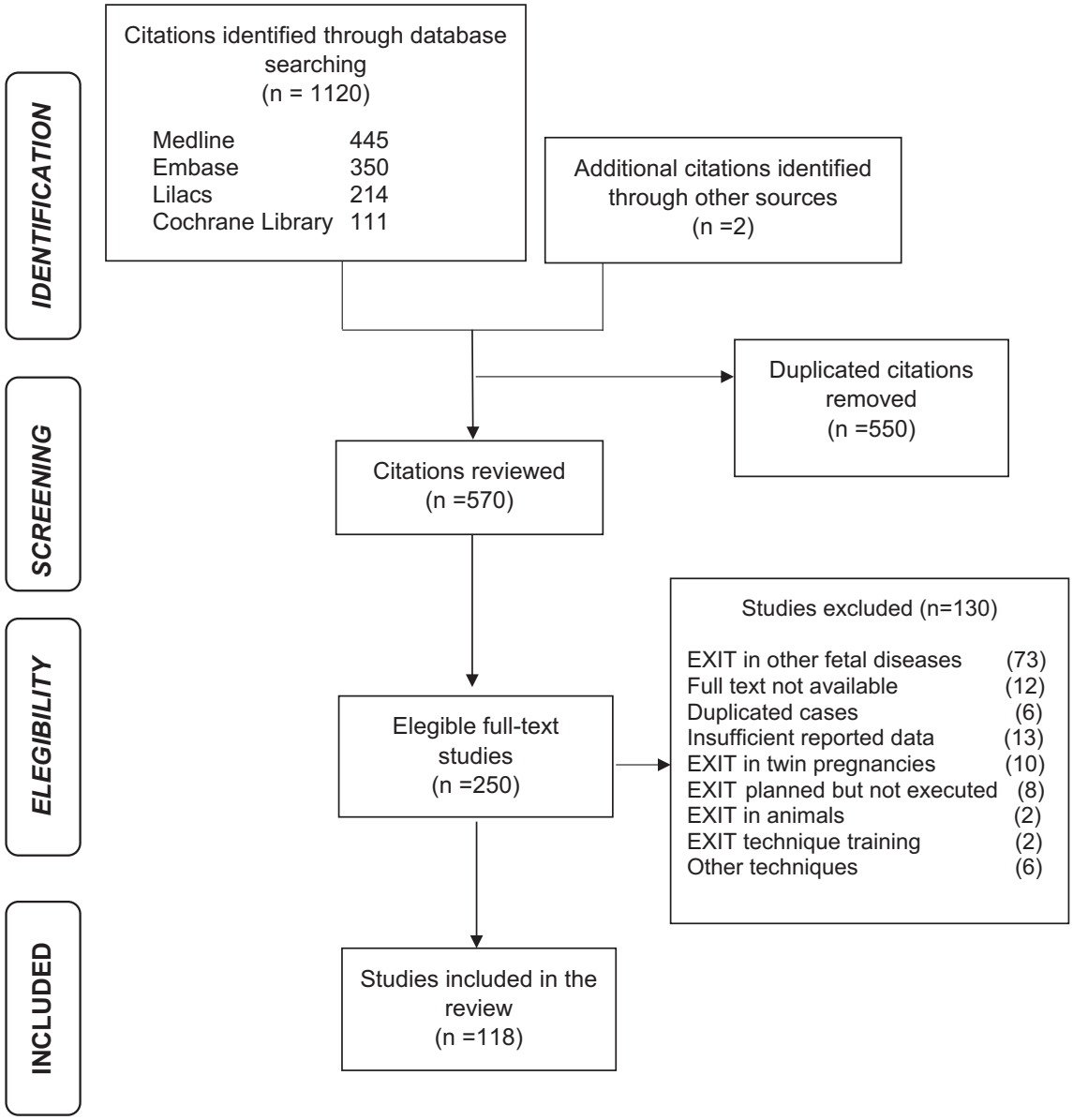

Fig. 1. Flow chart of study selection.

treatment (EXIT) surgery is a complex and meticulously coordinated procedure that is conducted when there is a high suspicion of fetal airway obstruction, such as cervical or oral tumors with a consequent high risk of severe fetal hypoxia or death of the neonate at birth [1]. Initially, EXIT surgery was introduced for clearing the trachea at birth in fetuses previously treated for congenital diaphragmatic hernia using in utero tracheal occlusion. However, current indications include a variety of fetal abnormalities with a risk of severe fetal hypoxia at birth [2].

EXIT surgery is performed under general anesthesia to achieve uterine relaxation and maintain an optimal uteroplacental perfusion. The fetus is partially delivered from the uterus to expose the head, neck and upper part of the thorax while remaining attached to the umbilical cord and placenta. This allows for the maintenance of the uterine volume, thus decreasing the likelihood of uterine contraction and placental abruption. Then, the airway is secured, usually by direct laryngoscopy and guided intubation. However, if it is not achieved by this method, the procedure can evolve to a tracheostomy, bronchoscopy or the partial removal of the tumor. Once the airway is secure, the umbilical cord is cut, and high doses of oxytocin are provided. The fetuses are continuously monitored with fetal echocardiography [3].

EXIT surgery requires a multidisciplinary expert team, including pediatric surgeons, maternal and fetal anesthesiologists, maternal-fetal medicine specialists, and neonatologists, among others. It is preferably performed on a fetus at term and is undoubtedly an effective method to establish an airway in the newborn. However, there are high potential maternal risks involved as compared to standard cesarean section delivery, including severe uterine bleeding and maternal mortality. The risks for the fetus are entirely due to the nature of the obstruction and the impossibility of securing the airway [4].

The available evidence thus far comes from case reports. There is no robust data to support the safety of this procedure. Thus, we aimed to review all the case series reports and provide up-to-date scientific evidence on the maternal and perinatal safety of performing EXIT surgery for the management of fetal airway in the case of cervical or oral tumors.

Table 1
Type of fetal tumor.

Diagnosis	n (%)
Neck masses	186 (100.0)
Teratoma	94 (50.5)
Lynphangioma	60 (32.3)
Cystic higroma	13 (7.0)
Goiter	3 (1.6)
Fetus in fetus	2 (1.1)
Cyst of the branchial cleft	2 (1.1)
Venous malformation	1 (0.5)
Myofibroma	1 (0.5)
Foregut duplication cyst	1 (0.5)
Pyriform sinus fistula	1 (0.5)
Hemangiotelioma	1 (0.5)
Nerve sheath malignant tumor	1 (0.5)
Neck masses without pathologic examination	6 (3.2)
Oral masses	49 (100.0)
Teratoma	15 (30.6)
Epignathus	13 (26.5)
Epulis	6 (12.2)
Ranula	3 (6.1)
Foregut cyst	2 (4.1)
Embryologic remnant cyst	1 (2.0)
Lynphangioma	1 (2.0)
Salivary gland tumor	1 (2.0)
Choristoma	1 (2.0)
Dermoid cyst	1 (2.0)
Congenital granular cell tumor	1 (2.0)
Rhabdomyosarcoma of tongue	1 (2.0)
Lingual foregut duplication	1 (2.0)
Hemangioma	1 (2.0)
Hemangiopericytoma of the tongue	1 (2.0)

EXIT: Ex utero intrapartum treatment.

1. Methods

1.1. Protocol and registration

The protocol for this systematic review was registered in the PROSPERO international prospective register of systematic reviews (Registration ID: CRD42018111889). This research did not receive any specific grants from funding agencies in the public, commercial or not-for-profit sectors. Since our study was concerned with a review, there was no direct patient or public involvement.

Table 2
Main features of EXIT surgery.

Features	n (%)
Type of anesthesia	
General	206 (87.7)
Epidural	3 (1.3)
Not reported	26 (11.0)
Type of surgery	
Scheduled	157 (66.8)
Emergency	63 (26.8)
Not reported	15 (6.4)
Airway access	
Intubation	163 (69.4)
Tracheostomy	50 (21.3)
Retrograde intubation	8 (3.4)
Rigid bronchoscopy	2 (0.8)
Thoracotomy	1 (0.4)
Reported inaccessible	8 (3.4)
Reported unnecessary	3 (1.3)
Additional procedure during EXIT	
Decompression of cyst	16 (6.8)
Total tumor resection	12 (5.1)
Partial tumor resection	3 (1.3)
Surgical decompression of the trachea	1 (0.4)
Thoracotomy and cannulation of large vessels	1 (0.4)
No additional procedure	202 (86.0)

EXIT: Ex utero intrapartum treatment.

1.2. Search strategy

This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Appendix A). We searched for all the case report articles on EXIT surgery, in any language, using the electronic databases MEDLINE, EMBASE, Cochrane Library and LILACS, from its inception to September 30, 2018. MeSH (medical subject heading) terms, keywords and their variants were constructed.

The primary outcome obtained was maternal and fetal death during the EXIT surgery or weeks after the procedure as reported in the article.

A detailed description of the search strategy can be found in the supplementary material (Appendix B). Subsequently, the search was restricted to oral and cervical pathology with potential airway obstruction.

1.3. Inclusion criteria

All studies, including case reports and case series, that reported EXIT surgery as a method of ending the pregnancy term of fetuses with airway obstruction due to oral or cervical tumors were eligible for inclusion. Studies were excluded if the EXIT surgery was carried out in twin pregnancies, if it was described as the OOPS (operation on placental support) technique or simil-EXIT (a similar technique to EXIT for indications other than airway blockage), if cases were previously reported in another study, or if the full article was not available.

1.4. Critical appraisal

Two authors (R.N.R. and W.Q.M.) independently reviewed all the titles and abstracts after eliminating any duplicates. A consensus was reached for the selection of titles and any differences were resolved by a third reviewer (W.V.). Studies that did not meet the selection criteria were excluded. After obtaining the entire text of the relevant articles, a detailed review and extraction of data based on the characteristics of the study and the EXIT surgery were performed. Inconsistencies were discussed and a consensus was reached among the authors. If a case was published in more than one study, the study that contained the most complete information was selected to avoid the duplication of data. Only full-text articles were eligible for inclusion and review. Various databases were searched and the authors of articles unavailable in full text were contacted.

1.5. Data extraction

The characteristics extracted from the relevant articles were as follows: author of the study, year of publication, maternal age, previous delivery, gestational age during the diagnosis of the fetal pathology, fetal indication for the EXIT surgery, type of intervention, duration of the procedure, gestational age at the time of the procedure, type of airway access, surgical intervention performed within or after EXIT surgery, fetal weight, fetal sex, fetal and maternal adverse events, use of magnetic resonance, fetal chromosomal study, type of fetal monitoring within the procedure, type of maternal anesthesia, and survival or cause of death. The main data from the selected studies was extracted and summarized in tables using Microsoft Excel (2013 version, Microsoft Corporation, Redmond, WA, USA).

Quality assessment of the studies was not performed since they were clinical case reports or case series.

Table 3
General characteristics of the cases that underwent EXIT surgery.

Characteristic	Patient (n)	Mean (range)
Maternal age (years)	145	29.4 (17–42)
Gestational age at diagnosis (weeks)	157	25.7 (12–41)
Gestational age at birth (weeks)	229	35.1 (26–41)
Time on placental support (minutes)	150	28.5 (2–157)
Birth weight (grams)	67	2260 (1097–4450)

EXIT: Ex utero intrapartum treatment.
n: number of cases with complete data.

1.6. Statistical analysis

The database was cleaned to eliminate repeated values, assign lost values, and recategorize variables for the final analysis. In the descriptive analysis, the distribution of the absolute, relative, and accumulated frequencies of categorical variables was calculated. For numerical variables, summary measures were applied as averages and ranges. Statistical analysis was performed using Stata Statistical Software 14.0 (Stata Corp. 2015, College Station, TX, USA).

2. Results

We identified 1120 related studies, of which 250 were evaluated in full text to assess the eligibility criteria for their inclusion. Ultimately, 120 studies were included in this review (Fig. 1) [3,5–123]. These articles included 235 cases of EXIT surgery published between 1996 and 2017; 54% (127 cases) were performed in the United States (USA). Laje et al. [78] reported the largest number of cases of EXIT surgery at a single institution (n = 23), from 2012 to 2015.

The general characteristics of the cases that underwent EXIT surgery are described in Table 1. In terms of fetal sex, 25.7% of the fetuses were female and 18.1% were male; 56% of cases were missing data on the fetal sex. The EXIT surgery was performed at 35.1 weeks on average. The time on placental support averaged 28.5 min, and the maximum time reported was 157 min in a case of teratoma resection. The mean fetal weight at birth was 2260 g.

The diagnoses of fetal abnormalities requiring EXIT surgery are presented in Table 2. The most frequent diagnosis in neck and oral masses was teratoma, which occurred in 109 cases (46.4%). There were also reports of rare cases, including epulis, goiter, ranula, pharyngeal cleft cyst, lingual tumor, fetus in fetus, and venous malformation, among others. Six cases of cervical tumors did not report a histopathological diagnosis.

Four intrauterine procedures were performed as part of the management of the fetal disease: the aspiration of cystic fluid before EXIT surgery to achieve a reduction in the size of the fetal tumor was required in two cases, thoraco-amniotic shunting was necessary in one case, and an amniodrainage required in another. Fetal evaluation included an MRI in 71.3% of the cases and karyotyping in 23.6% of them. During the EXIT surgery, fetal monitoring was performed with a continuous assessment of the fetal heartbeat using ultrasound in 195 cases (83%) and a pulse oximeter in 152 (64.7%) cases. Additionally, arterial blood gases were evaluated in 63 (26.8%) of the interventions. ECMO (extra corporeal membrane oxygenation) was required in the EXIT surgery of a fetus with a large cervical mass causing compression and deviation of the airway and major neck vessels. Traditional cardiopulmonary bypass with a cardiotomy venous reservoir (CVR) was utilized in one case, with the fetus undergoing tumor biopsy and partial resection.

A summary of the characteristics of the surgeries is shown in Table 3. Elective surgery was carried out in 157 (66.8%) cases. In 64 (27%) cases, an urgent surgery was performed due to preterm labor or the preterm rupture of membranes (PROM). General anesthesia was reported in 206 EXIT surgeries (87.7%). Epidural and spinal anesthesia was reported in three cases. To provide placental support, various minor procedures and fetal surgeries were performed. This included 16 decompressions of tumor fluid and 16 total or partial tumor resections. In one case, the trachea was surgically decompressed, and in another case, thoracotomy and cannulation of large vessels were performed. Two hundred two fetuses did not require any additional intervention. Access to the fetal airway was achieved using orotracheal intubation in 163 cases (69.4%). Fifty (21.3%) fetuses required tracheostomy. Other procedures that were performed to secure the fetal airway were retrograde intubation in eight fetuses and rigid bronchoscopy in two cases. In eight cases, the fetal airway could not be secured and in six cases, they died immediately. The other two fetuses needed rigid bronchoscopy after EXIT, and they survived. In three cases, the EXIT surgery was performed but there was no need for intubation or any additional procedures as ventilation was spontaneously initiated.

The overall survival rate in the cases reviewed was 83%. The most frequent causes of fetal or neonatal death were reported as cardiorespiratory failure (9), pulmonary hypoplasia (8), intubation or tracheostomy failure (6), hypovolemic shock (3), sepsis (3), and barotrauma (2). Twenty-nine fetal adverse events (12.2%) were reported (Table 4). Other reported events were respiratory distress syndrome, fetal bradycardia and pneumothorax. Among the 40 fetal deaths, 25 (62.5%) were teratomas and 9 (22.5%) were lymphangioma.

Twenty-two adverse maternal events were reported in 13 patients (5%) during the procedure (Table 5). The most frequent event was postpartum hemorrhage. In addition, transient hypotension, placental abruption, and the need for blood transfusion were reported in seven patients. There was no need of hysterectomy in any case. No maternal death was reported.

After EXIT surgery was performed, 170 (72.3%) infants underwent elective tumor resection. Other procedures to treat the tumor included tumor sclerotherapy, laryngotracheoplasty, hemiglosectomy, marsupialization of the cyst, and gastrostomy.

3. Discussion

Table 4
Fetal adverse events during EXIT surgery.

Adverse event	n (%)
Fetal death	40 (17%)
Intubation and tracheostomy failed	8 (3.4)
Acute respiratory distress syndrome	4 (1.7)
Fetal bradycardia	4 (1.7)
Pneumothorax	3 (1.3)
Tracheomalacia	2 (0.9)
Pulmonary hemorrhage	1 (0.4)
Pulmonary hypertension	1 (0.4)
Paresia of right vocal cord	1 (0.4)
Cystic mass rupture	1 (0.4)
Cardiorespiratory arrest	1 (0.4)
Plaquetopenia	1 (0.4)
Tumor bleeding	1 (0.4)
Cardiac shock	1 (0.4)

EXIT: Ex utero intrapartum treatment.

Table 5
Adverse maternal events during EXIT surgery.

Adverse event	n (%)
Maternal death	0 (0%)
Postpartum hemorrhage	11 (4.7)
Blood transfusion	7 (3.0)
Transient hypotension	3 (1.3)
Placental abruption	1 (0.4)

EXIT: Ex utero intrapartum treatment.

This study showed that EXIT surgery performed for oral or cervical tumors involves a substantial risk of maternal and fetal adverse events of about 5% and 13% respectively. The global perinatal survival after the surgery was 83%. There was no maternal death reported thus far.

Interestingly, a majority of fetuses undergoing EXIT surgery were delivered prematurely, at 35 weeks on average. Additionally, about 27% of surgeries were urgently carried out as these cases presented preterm labor or preterm rupture of membranes. Fetuses with an oral or cervical tumor are at high risk of spontaneous onset of preterm labor, mainly due to overdistended uteruses caused by the mass effect of the tumor and polyhydramnios secondary to the impairment of amniotic fluid swallowing. On the other hand, some authors have reported that massive polyhydramnios could indicate an obstruction of the fetal airway due to esophageal compression [124]. However, we believe that there is a need to search for more predictive signs of airway obstruction [125].

Out of the 235 EXIT surgeries reviewed, 79% of them were performed for cervical tumors and 21% for oral tumors. Independent of the tumor localization, the vast majority were teratoma, i.e. solid tumors which are more likely to cause blockage of the fetal airway. Additionally, fetal MRI could play an important role as an adjunctive tool to ultrasound since 71% of cases were assessed by this technology. No data about a specific sign on the fetal MRI (i.e. tracheoesophageal displacement index TEDI) is described in the reports. Therefore, a thorough assessment is warranted for every case before opting for EXIT surgery, and it should be conducted when the potential benefits outweigh the risks.

EXIT surgery is a complex procedure that requires the total relaxation of the uterus while accessing the fetal airway. Although some authors report the use of neuraxial anesthesia, general anesthesia was used to achieve uterus relaxation in most of the surgeries reviewed here [70].

We found that 21% of the fetuses required tracheostomy and other additional procedures during the surgery, and a total removal of the tumor was performed in a few of them. Therefore, the surgical team has to be prepared to perform other complex and risky procedures to secure the fetal airway. Providing proper uterine relaxation and safety for the mother is essential as the procedure could last for over 2 hours, as reported here. We support the idea that EXIT surgery should be done by a multidisciplinary team as additional complex surgical procedures might be required [2].

The overall survival rate for the fetuses reported to have oral or cervical masses and undergone EXIT surgery is 83%. While we were not able to get detailed information about the events post EXIT surgery, according to the data obtained, we believe that the high mortality rate reflects the severity of the tumor, including the type, size, localization, extension, and the secondary effect of obstructing the fetal airway. Therefore, EXIT surgery is a complex procedure with the main goal of securing the fetal airway through oral intubation or tracheal intubation and by performing invasive procedures such as laryngoscopy, tracheostomy or partial removal of the tumor. The parents should be counseled about the serious adverse events that can occur, including cardiorespiratory failure, acute respiratory syndrome, pulmonary hemorrhage, fetal bradycardia, pneumothorax, mass rupture, and hemorrhage, among others. Additionally, despite medical efforts, the intubation and tracheostomy can fail due to the nature of the tumor, as seen here in 3.4% of cases.

It is known that tumors affecting the neck and oral cavity of the fetus, share common features such as rapid growth and invasiveness of adjacent tissues. Thus, the risk of mortality or serious morbidity is not only high at birth due to asphyxia, particularly if standard methods of delivery are carried out, but even also after a successful procedure of securing the fetal airway. Thus, the indication for EXIT surgery should be discussed thoroughly within the team and with parents, since despite all of efforts to perform a technically correct procedure, the mortality for the neonate will still remain high, as we report here. Hence, it is important for EXIT surgery to be done in a referral tertiary center with the capability to provide additional procedures during EXIT, rapid access to a neonatal intensive care unit and a comprehensive further management. Therefore, finding a neck or cervical tumor with high suspicions of fetal airway obstruction should prompt us to provide proper counseling for the parents, and more importantly, an urgent referral for further management.

We did not find any reports of maternal death. Although there were potential risks of massive hemorrhaging, the need for maternal blood transfusion was low (about 3%). We found only one study reporting a case of placental abruption. The EXIT surgery can last from a few minutes to several minutes; however, the risk of placental abruption in the cases reported here was very low (only one case; 0.4%). This low rate of placental abruption can be attributed to the proper anesthetic procedure and relaxation of the uterus as well as the proper surgical technique for ensuring most of the fetal body remained inside the uterus while the intubation was being performed. We did not find any other adverse maternal complications such as sepsis, cardiorespiratory arrest, or hypovolemic shock.

Therefore, EXIT surgery should be performed only when the benefits outweigh the risks for both the mother and fetus. Contraindications to the surgery are fetal distress or serious maternal diseases such as severe thrombocytopenia [2].

The main strength of this review is our inclusion of almost all cases reported thus far, providing a comprehensive overview of the clinical characteristics, diagnoses, and outcomes of fetuses that underwent EXIT surgery. The main limitation of this review is that a majority of the included studies consisted of case-reports or small series originating from single centers in one country (USA). It is unlikely that researchers would carry out a randomized clinical trial in the future since a tumor obstructing the fetal airway is a very rare condition. Additionally, the rationale for securing the fetal airway while the fetus is still connected to the placenta in order to prevent fetal asphyxia is likely to be true.

Furthermore, there is a potential publication bias involved as cases involving a failed surgery or poor outcomes for the mother and fetus are likely to be unpublished. Additionally, we believe that EXIT surgery is a more common procedure in present times and is being performed in many other centers without the results being reported. An international prospective database of EXIT surgery would be of major impact in assessing the actual benefits and risks of this fetal intervention.

4. Conclusion

To conclude, EXIT surgery carries a substantial risk of perinatal adverse events, including neonatal death, and should therefore be considered only when there is a high suspicion of fetal airway obstruction and the assurance of minimal maternal risk.

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