BMC Pregnancy and Childbirth

RESEARCH

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Sacrococcygeal teratoma - prognosis based on prenatal ultrasound diagnosis, single-center experience and literature review

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Abstract

Introduction Sacrococcygeal teratoma (SCT) is the most common congenital tumor. The incidence of malignant types is rare but increases with late detection or in case of relapse. Prenatal diagnosis is based on ultrasound examination and magnetic resonance imaging (MRI). Since this is a rare congenital anomaly, we should report all cases to improve prenatal diagnosis and postnatal management.

Material and methods Retrospective analysis of sixteen cases of sacrococcygeal teratoma delivered and treated at the University Hospital Brno between 2005 and 2020. The following criteria were evaluated: gestational week of the primary diagnosis, exact description of ultrasound findings, pregnancy management, delivery mode, correlation of prenatal ultrasound with postnatal findings in the newborn, as well as the occurrence of early and late complications in newborns and children.

Results Out of sixteen cases, seven cases (43.8%) were indicated for pregnancy termination based on ultrasound findings, the parent's decision, and an estimation of an adverse pregnancy outcome. In nine cases (56.2%), the pregnancy continued and was ended by delivery. In one case, there was an early postnatal death of a newborn after birth in the 25th week of gestation. In eight cases, live fetuses were born in which the tumor was surgically removed between day 1 and 14 months after birth. There was a strong correlation between the tumor description made by prenatal ultrasound diagnosis and related severe complications in newborns. The incidence of severe early and late complications in ongoing pregnancies was very low—only one case of infection in the surgical wound requiring reoperation (12.5%) was described. In two patients (25%), a transient stoma establishment was necessary for secondary ileus. One case of recurrence of the disease at two years of age occurred, requiring the administration of chemotherapy (12.5%), and one patient has mild persistent urinary incontinence.

Conclusion Sacrococcygeal teratoma is one of the rarest congenital malformations. A detailed prenatal ultrasound examination is essential to estimate the pregnancy prognosis. The most predictive ultrasound predictor of favorable early and late postnatal outcomes and long-term child development is the presence of cystic sacrococcygeal

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formation, the most common tumor type, and the absence of signs of cardiac failure due to fetal anemia. In these cases, with early surgical treatment provided, the incidence of severe complications and long-term consequences in children is very low, and parents should be informed during prenatal counseling. It is necessary to register all the SCT cases due to the rarity of this congenital anomaly for further statistical analysis of the importance of ultrasound markers.

Keywords Sacrococcygeal teratoma, Congenital tumor, Prenatal diagnosis, Ultrasound, Prognosis, Prenatal counseling

Plain Language summary

Sacrococcygeal teratoma (SCT) is a type of tumor that develops at the base of the spine in newborns. It is the most common congenital tumor. While most SCTs are not cancerous, malignant types do exist. The risk of malignancy increases if SCTs are detected late or if there is a relapse. Doctors can identify SCTs before birth using various imaging techniques: ultrasound examination and magnetic resonance imaging (MRI). The primary treatment for SCT is complete surgical removal of the tumor. Early detection and timely intervention are crucial for better outcomes. We analyzed fifteen cases of SCT treated at the Department of Obstetrics and Gynecology and the Department of Pediatrics, University Hospital Brno, between 2005 and 2020. We evaluated factors such as gestational week of diagnosis, ultrasound findings, pregnancy management, delivery mode, and correlations between prenatal and postnatal findings. Complications in newborns and children were also assessed.

Introduction

Sacrococcygeal teratoma (SCT) is the most common congenital tumor, with an incidence of 1/40,000 live births and predominance in female fetuses of 3:1–4:1 [1–5].

In general, teratomas are neoplasms primarily containing derivatives from more than one germinal layer of embryonic structures. Sacrococcygeal teratoma is presented as a mass arising from the region of the distal sacrum and sacral bone. This specific location is given by many pluripotent cells occurring in this area, and the degree of differentiation of these cells indicates the resulting type of tumor [3, 6]. The majority of these tumors are histologically benign, with malignant types being rare (12–14%). However, the risk of malignant transformation increases with the child's age or in cases of disease recurrence [2, 3, 7].

Multiple clinical classifications exist for sacrococcygeal teratomas. As outlined by Altman, the postnatal classification most frequently referenced organizes the extent of tumor invasion into intrapelvic structures [8]. In type I, the tumor is predominantly external (extrapelvic), located outside the fetus (45%). Type II – relatively large portion extends into the small pelvis (intrapelvic component) (35%); type III: A significant part of the tumor infiltrates the small pelvis and the abdominal cavity (10%), and type IV: The tumor is presacral, affecting only the small pelvis and abdominal cavity (10%) [9]. About 2% of sacrococcygeal teratomas extend into the spinal canal [10]. The diagnosis is based on the prenatal ultrasound examination, focusing primarily on estimating tumor size and morphology. According to the literature, fetal growth restriction, fetal anemia, abnormalities in amniotic fluid levels, or related anomalies are described by [3]. Key ultrasound (US) markers linked to a higher mortality risk include solid, fast-growing, and highly vascularized teratomas [4]. Nevertheless, the importance of individual US markers in estimating the adverse outcome for newborns remains unclear - due to the low incidence of this congenital anomaly, the size of the studied groups is minimal, with a predominance of case reports [4, 5, 11–22].

Published mortality associated with prenatally diagnosed SCT varies widely from 25 to 50% and is mainly related to tumor morphology [13, 15, 23]. The incidence of described complications in newborns and children ranges from 15 to 33% [2, 7, 24]. The most common complications include bowel or urinary tract obstruction, pelvic muscle hypoplasia, and postoperative surgical wound infections. Long-term complications primarily involve functional issues, such as stool incontinence, constipation due to rectal or colon obstruction, urinary incontinence, disease recurrence, or aesthetic concerns [7, 24–26].

Materials and methods

Retrospective analysis of sixteen cases of SCT delivered and treated at the Department of Obstetrics and Gynecology and the Pediatric Clinic at the University Hospital Brno in the period 2005–2020. Together, both departments form a tertiary center with more than

six thousand births annually, focusing on pathologies from the region with more than twelve thousand births annually. We gathered information from all patients with SCT who underwent surgical treatment. All pregnancies with detected SCT were monitored by prenatal medicine specialists, with ultrasound examinations focusing on tumor characteristics, including tumor size, the predominance of solid or cystic components, vascularization assessed by Doppler flow (Fig. 1), fetal anemia, hydrops development, amniotic fluid volume, fetal growth abnormalities, and other ultrasound markers such as cardiomegaly and placentomegaly. Another assessment concerned the week of the primary tumor detection, the proportion of terminated pregnancies, and the mode and timing of labor and perinatal results in the delivery.

All newborns were transported to the Neonatology Intensive Care Unit (NICU), and magnetic resonance imaging (MRI) or computed tomography (CT) was followed by surgical treatment at the Pediatric Surgery Department. Perioperative findings were described, as well as early and late complications in newborns and children (infection in the surgical wound, gastrointestinal or urinary tract obstruction leading to functional problems, and further long-term complications). The histological subtype of the tumor (malignant vs. benign, mature, or immature teratoma) was determined through histopathological examination and assessed postoperatively. All children are monitored every 6–12 months in the Department of Pediatric Oncology outpatient clinic. The information was drawn from the institutional data systems, the Electronic Delivery Book application, and image documentation within the PACS (picture archiving and communicating system). The Ethical Committee of Faculty Hospital Brno approved this study.

The primary objective was to determine the correlation between risk estimation according to prenatal ultrasound findings in the fetus, postnatal findings, and related early severe complications in

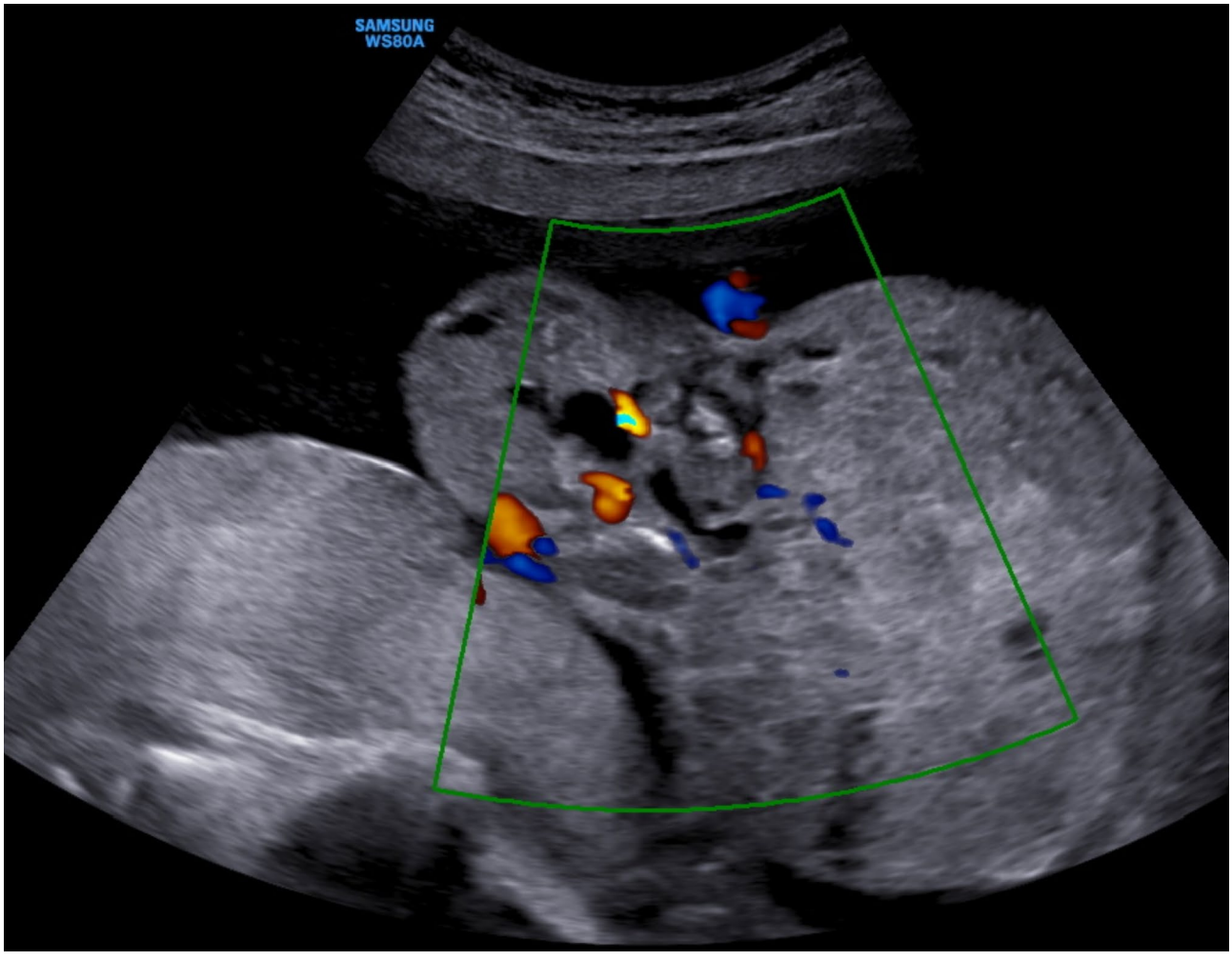

Fig. 1 Doppler imaging of the tumor vascularization (case 1, terminated pregnancy)

the newborns. The secondary goal was to evaluate the incidence of late complications in children.

Results

From 2005 to 2020, sixteen cases of SCT were delivered and treated at the Department of Obstetrics and Gynecology and Department of Pediatrics, University Hospital Brno. Three cases (18.8%) of SCT were detected by ultrasound examination early—in the 13th, 14th, and 16th weeks of pregnancy; nine more during the second-trimester screening (56.2%); two after the 30th week of gestation (12.5%); and two cases postnatally (12.5%).

In seven cases (43.8%), pregnancy termination was requested by the parents and performed before the 24th week of gestation. In one of these cases (14.3%), the tumor was detected at 14 weeks of gestation, while in the remaining six cases (85.7%), it was diagnosed between the 20th and 23rd week. Severe complications were identified via ultrasound in four patients (57.1%), including a predominant solid component, hydronephrosis, hydrops, polyhydramnios, clubfoot, cardiomegaly, placentomegaly, and urinary bladder displacement (Table 1). These findings were subsequently confirmed by autopsy. In the remaining nine cases, the pregnancy continued with parental consent.

Among the seven prenatally detected, monitored, and delivered newborns in six patients (85.7%), a cystic formation between 9 and 18 cm was described by prenatal ultrasound examination. A predominantly solid appearance was described in one case (14.3%). (Table 2)

All live newborns underwent postnatal MRI or CT imaging, which strongly correlated with prenatal ultrasound findings in all prenatally diagnosed cases. Additionally, MRI identified a 10 mm meningocele in the neck region of one patient.

Two cases of SCT (12.5%) were diagnosed postnatally. Histological examination confirmed that both postnatally detected tumors were malignant, specifically malignant Yolk Sac Tumors.

Among the nine delivered fetuses (including two cases not detected prenatally), eight patients (88.9%) underwent cesarean section, while one case (11.1%) resulted in spontaneous precipitous vaginal delivery. Deliveries occurred between the 25th and 40th weeks of gestation, with a median of 35 weeks. In the case of spontaneous precipitous labor, the newborn died shortly after birth due to complications from a large tumor with an extensive extra-abdominal component. (Table 3). Eight live fetuses were born, and the tumors were surgically removed. In the six prenatally detected SCTs, the surgery was performed between the 1st and 5th postpartum days. In the remaining two cases diagnosed postnatally, the operation was performed on the 43rd day and the 14th month after birth. In the first postnatally detected case, additional excision of residual tissue was required, while in the second case, a temporary sigmoidectomy was performed for five months, followed by a necessary reoperation. Of the early perinatal complications, there was one case of early neonatal asphyxia (i.e., arterial pH below 7.0 or Apgar score below 5 in the fifth minute) in case of early neonatal death after the abrupt onset of labor in the 25th week of gestation. From the eight delivered newborns, only one case of infection in the surgical wound requiring reoperation was described (12.5%). From late complications, in two patients (25%), a

Table 1 The list of ultrasound parameters, histology characteristics, and complications of terminated cases

Case	Size (cm)	Main structure	Amniotic fluid amount	Vascularisation	Prenatal diagnosis (weeks)	FGR	Signs of fetal anemia	Histology	Another US findings
1	10	Solid	Normal	High	Yes (20)	No	Yes (severe)	Benign immature	Hydrops, placentomegaly, cardiomegaly, severe anemia
2	1	Solid	-	-	Yes (14)	No	-	Benign immature	Parents want immediate termination
3	-	-	-	-	Yes (22)	No	-	Benign immature	-
4	7	Solid	Normal	High	Yes (21)	No	-	Benign immature	Club foot, dislocation of the urinary bladder
5	9	-	Polyhydramnios	-	Yes (22)	No	Yes	Benign immature	Megavesica, hydronephrosis, cardiomegaly, hydrops
6	6	Solid	-	-	Yes (24)	No	-	Benign immature	-
7	3	Cystic	Normal	-	Yes (20)	No	-	Benign immature	-

FGR: fetal growth restriction (i.e., growth below 10th centile), SCT: sacrococcygeal teratoma, YST: yolk sac tumor, -: not specified

Table 2 The list of ultrasound parameters, histology characteristics, early outcome, and neonatal severe complications in prenatally diagnosed cases followed by delivery

Case	Size (cm)	Main structure	Amniotic fluid amount	Vascularisation	Prenatal diagnosis (weeks)	FGR	Signs of fetal anemia	Histology	Early neonatal outcome	Serious neonatal complications
1	12	Solid	Normal	Minimal	Yes (13)	No	No	Benign immature teratoma	Neonatal death, precipitous delivery	YES
2	18	Cystic	Polyhydramnios	Minimal	Yes (20)	No	No	Benign mature teratoma	Complete resection of SCT	NO
3	9	Cystic	Normal	Minimal	Yes (32)	No	No	Benign mature teratoma	Complete resection of SCT	NO
4	9	Cystic	Normal	Minimal	Yes (16)	No	No	Benign immature teratoma	Residuum resection, relapse malignant YST chemotherapy, transient hearing impairment	NO
5	12	Cystic	Normal	Minimal	Yes (30)	No	No	Benign mature teratoma	Temporary ileostomy, detrusor hyperreactivity, urine incontinency	NO
6	9	Cystic	Normal	Minimal	Yes (20)	No	No	Benign mature teratoma	Complete resection of SCT	NO
7	9	Cystic	Normal	Minimal	Yes (21)	No	No	Benign immature teratoma	Complete resection of SCT, infection in operation wound	NO

FGR: fetal growth restriction (i.e., growth below 10th centile), SCT: sacrococcygeal teratoma, YST: yolk sac tumor

transient establishment of the stoma was necessary for secondary ileus, and one case of recurrence of the disease at two years of age occurred, requiring the administration of chemotherapy (12.5%). In the other five cases (62.5%), subsequent long-term development was without serious complications (Table 3). One case of urinary incontinence and no case of stool incontinence were recorded. All children are dispensed at the Clinic of Pediatric Oncology, University Hospital Brno.

Discussion

Sacrococcygeal teratomas are rare congenital anomalies with an incidence of 1/40,000 of live births [2–5]. Between 2005 and 2020, 44 cases of SCT were reported In the Czech Republic, of which in 34 cases (77.3%) the pregnancy was terminated (data provided by the Institute of Health Information and Statistics of the Czech Republic).

In our group, seven pregnancies out of fourteen prenatally diagnosed were terminated at parents' request (50%). Compared to the national reported average in the Czech Republic, our department's incidence of terminations was significantly lower (50% versus 77.3%).

Ultrasound examination is the primary modality for diagnosing SCT. The sacrococcygeal teratoma is mainly presented as a heterogeneous, well-defined mass arising from the sacrum region; most SCTs are prenatally diagnosed by ultrasound examination [3]. Therefore, focusing on the sacral area is essential, especially during the ultrasound scan in the second trimester of pregnancy. In our group, 87.5% of SCTs were diagnosed by ultrasound scan.

Ultrasound examination allows for assessing tumor structure (morphology), including its components, size, and intrapelvic extensions. The ratio and characteristics of these components—such as cystic and solid elements, tumor necrosis, cystic degeneration, calcification, or bleeding—are clinically significant [3, 6, 23, 25]. Previous studies have demonstrated that tumors with a predominant cystic component are more commonly associated with histologically benign findings and have a significantly better prognosis. On the contrary, necrosis and hemorrhage are more common in malignant forms [2–5]. In our study group, cystic formations were observed in the majority of congenital and prenatally monitored fetuses (six cases, 85.7%). All

Table 3 Timing of surgical procedure and overview of complications in cases that led to delivery. Case no. 8 and 9 were diagnosed postnatally due to small size and intrapelvic localization

Case	Delivery time (weeks), mode of delivery	Age of surgery	Residuum	Scar defect	Urine/stool incontinency	Postnatal development	Long-term outcome	Developmental milestones
1	25, spontaneous	-	-	-	-	Neonatal death, precipitous delivery	-	-
2	34, CS	day 1	No	No	No/no	Complete resection	13 yrs, elementary school, muscular dystrophy	Normal
3	34, CS	day 5	No	No	No/no	Complete resection	12 yrs, judo	Mild ADHD
4	33, CS	day 3	Yes	No	No/no	Residuum resection, relapse-malignant YST chemotherapy, transient hearing impairment	7 yrs, elementary school, transient psychogenic obstipation	Normal
5	38, CS	day 3	NO	mild hernia	YES/NO	Temporary ileostomy, detrusor hyperreactivity	5 yrs, preschool, urine incontinence, detrusor hyperreactivity	Normal
6	37, CS	day 2	NO	NO	NO/NO	Complete resection	4 yrs, preschool	Normal
7	31, CS	day 2	NO	NO	NO/NO	Complete resection, infection in operation wound	3 yrs, preschool	Normal
8	40, CS	day 43	YES	NO	NO/NO	Reoperation for residuum (2 months), further course without complications	17 yrs, university student	Normal
9	39, CS	14. month	YES	NO	NO/NO	Temporary ileostomy, reoperation for residuum (3 months)	12 yrs, elementary school, football player	Normal

CS: caesarean section, ADHD: attention deficit hyperactivity disorder, -: not specified

these cases were diagnosed as mature teratomas with a favorable prognosis, and the postnatal course was free of severe long-term complications. In one case (14.3%), a predominant solid component was identified, which was associated with a poor prognosis, resulting in neonatal death immediately after spontaneous preterm birth at 25 weeks of gestation. The incidence of malignant types is generally rare and increases with late detection or relapse [3]. In our study group, both cases of malignant SCT (100%) were diagnosed postnatally, with none detected during the prenatal period. Imaging techniques, primarily postnatal MRI, were performed in both cases. In the first case, a polycystic-solid formation in the gluteal and sacrococcygeal region was described; in the second case, a predominantly cystic formation with numerous hypodense parts with infiltration of gluteal muscles and calcifications of the sacrum was observed. Surgical intervention was performed at two and fourteen months of age, considerably later than in prenatally diagnosed benign cases. Both children required reoperations, and in one case, a temporary sigmoidectomy was also necessary. (Table 3)

The associated complications mainly relate to the tumor blood supply and anatomy of the feeding vessels. SCT creates a low-resistance arterio-venous shunt, gradually increasing cardiac preload and afterload in the fetus, leading to intravascular volume overload, dilatation of the chambers, hypertrophy, and, subsequently, heart failure [6, 13]. In prenatal diagnosis, it is crucial to assess potential fetal cardiac dysfunction, as it precedes the onset of severe complications such as anemia, hydrops, placentomegaly, and fetal heart failure.

With the progression of heart failure based on circulatory overload and stealing phenomenon, intrauterine fetal death may occur. Therefore, these pregnancies are prognostically unfavorable, and it is appropriate to consider termination of pregnancy [6, 15, 23]. In our group, severe hydrops were described in two cases (12.5%) in combination with progressive anemia of the fetus, and these pregnancies were terminated at 20 and 22 weeks of gestation. Histopathological examination confirmed signs of cardiac failure. (Table 1)

Elevated cardiac output contributes to the development of polyhydramnios, which can lead to preterm birth due to uterine wall distension, thereby increasing neonatal morbidity [23]. In our group of sixteen SCTs, an increased amount of amniotic fluid was described in two cases (12.5%)– the pregnancy was terminated in one case due to poor prognosis and associated complications (cardiomegaly, hydronephrosis, mega vesica). In the second case, delivery occurred at 35 weeks with an uncomplicated postnatal course. However, no other ultrasound markers of heart failure were present. The literature also describes cases of oligohydramnios,

which usually arise due to urinary tract obstruction [4, 23]. In our group, no significant oligohydramnios was detected.

Neonatal morbidity, both early and late, is primarily influenced by the anatomical location of the tumor. The most frequent complications include rectal or colonic obstruction, constipation, altered stool frequency, and urinary tract obstruction. Commonly associated issues include obstructive hydronephrosis, anorectal displacement, bowel distension, pelvic muscle hypoplasia, and hip dislocation. These complications are more prevalent in tumors with a more prominent intrapelvic component [3, 24]. In our group of terminated pregnancies, we identified one predominantly intrapelvic tumor with urinary bladder displacement, which was confirmed by autopsy. However, we did not systematically assess the exact ratio of intra– and extrapelvic tumor components using prenatal ultrasound. Other congenital malformations associated with sacrococcygeal teratoma are uncommon, with reported incidences ranging widely from 5 to 40%. Defects predominantly occur in the anorectal region and include hip dysplasia [3, 6]. Our group observed only one case of associated meningomyelocele and one case of clubfoot (12.5%) (Tables 1 and 3).

Based on the published data, the description of tumor morphology is one of the strongest ultrasound markers predicting postnatal development. An adverse outcome can be expected for solid, fast-growing, and highly vascularized teratomas. The most significant negative prognostic factor is the development of anemia and hydrops, which indicate an increased risk of cardiac failure due to the tumor's vascularization, especially in cases with a predominant solid component [3, 6, 17, 23, 25]. Other ultrasound markers predicting poor long-term prognosis are associated with complications due to intrapelvic organ obstruction - hydronephrosis with ureter dilatation, mega vesica, hydronephrosis, or polyhydramnios. Two or more of these adverse factors were present in our group of terminated pregnancies (4/7–57.1%) confirmed by histopathological examination.

During the prenatal period, magnetic resonance imaging (MRI) is an additional diagnostic tool, particularly valuable in cases where the tumor has a predominant solid component. MRI offers several advantages compared to ultrasound, including a broader imaging range, greater sensitivity for soft tissues, improved assessment of anatomical relationships between intrapelvic structures, higher accuracy, and the ability to evaluate tumor volume, bone destruction, or the presence of distant metastases. All this can be of great importance in the planning of postnatal intervention. In our group, prenatal MRI was indicated in two cases (Figs. 1 and 2).

The primary therapeutic modality of SCT is complete, urgent surgical resection of the tumor. Coccyx removal is indicated as part of the surgical treatment, which prevents local recurrence [2, 25, 27]. This approach was applied to all operated newborns in our group.

Another treatment option is fetal therapy, which should be considered on a strictly individual basis only when the potential benefits outweigh the associated risks. This approach is primarily applicable to fetuses at high risk of cardiac failure due to progressive hydrops or anemia. To determine the need for prenatal intervention, a comprehensive ultrasound examination should be conducted, followed by MRI and fetal echocardiography. The optimal gestational age for performing an invasive procedure typically falls between the 20th and 30th weeks of pregnancy [13, 26].

Fetal therapy is performed by laser ablation of the tumor's supply vessels with a reported survival rate of around 40% [13]. Other invasive techniques include drainage of the urinary tract in the case of obstructive uropathy or pleural effusion. Cases of cystic tumor component aspiration have also been reported. Drainage may be considered just before delivery to reduce trauma to both the fetus and the mother [3, 4, 23, 25]. In our group, we found only one case possibly suitable for prenatal intervention but not convenient because of severe fetal anemia and hydrops with a poor prognosis. This pregnancy was terminated at the 22nd week of gestation.

The mode of delivery is selected individually. For more extensive findings (> 5–10 cm in diameter) and highly vascularized tumors, vaginal birth is not recommended due to a higher risk of complications (rupture, bleeding) [12]. In our study group, one fetus was delivered vaginally due to the sudden onset of labor at 25 weeks of gestation, resulting in early neonatal death. The remaining eight fetuses were delivered via cesarean section.

One of the key strengths of this study is its centralization—all cases were managed in a tertiary center with direct collaboration across multiple specialties, including pediatric surgery, pediatric oncology, and histopathology.

However, the study has certain limitations, primarily the small sample size due to the rarity of this diagnosis, which prevents meaningful statistical analysis. Additionally, a longer follow-up period would be necessary to assess long-term complications.

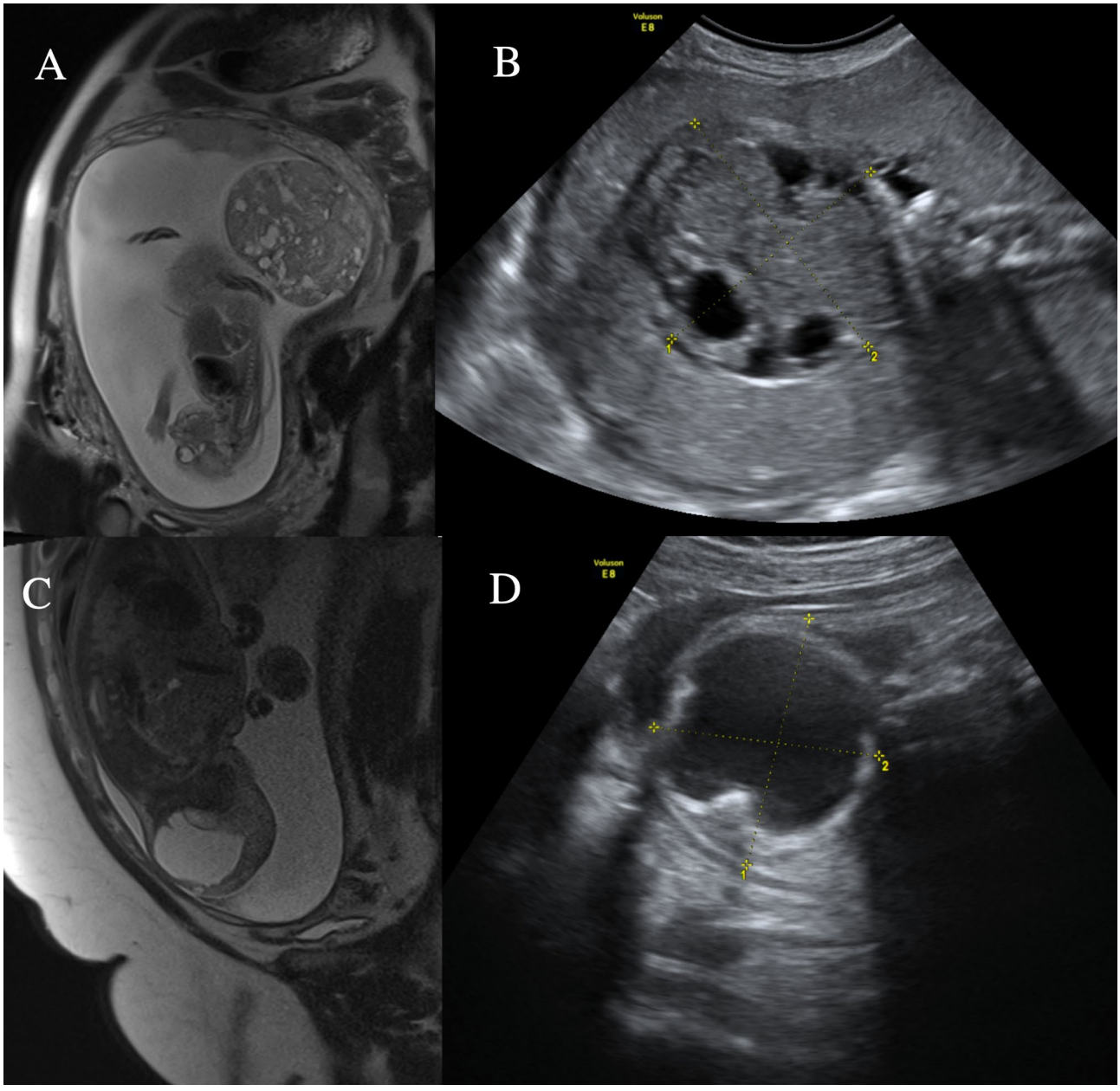

Fig. 2 **A**. Fetal magnetic resonance imaging in the fetus, 23rd weeks of gestation (case 1, terminated pregnancy). **B**. Ultrasound finding in the fetus, 22nd weeks of gestation (case 1, terminated pregnancy). We described a solid teratoma 10 cm in size. **C**. Fetal magnetic resonance of the SCT, 28th weeks of gestation (case 3). **D**. Ultrasound imaging of the SCT, 21st weeks of gestation (case 3)

Conclusion

Sacrococcygeal teratoma is one of the rarest congenital malformations. A detailed prenatal ultrasound examination is essential to estimate the pregnancy prognosis. The most predictive ultrasound predictor of favorable early and late postnatal outcomes and long-term child development is the presence of cystic sacrococcygeal formation, the most common tumor type, and the absence of cardiac failure signs related to fetal anemia. In these cases, with early surgical treatment provided, the incidence of severe complications and long-term consequences in children is very low, and parents should be informed during prenatal counseling.

It is necessary to register all the SCT cases due to the rarity of this congenital anomaly for further statistical analysis of the importance of ultrasound markers.

Acknowledgements
Permission has been obtained from the patients for publication.

Author contributions
A.J. and L.H. prepared and wrote the main manuscript; A.J. completed all the figures, pictures and tables, with L.H. responsible for methodology and conceptualization. A.J., R.G., and L.H. performed the ultrasound examination.

Contributions to the original draft included A.J. and R.G. for prenatal diagnosis, M.J.1 for neonatology, and J.T. for surgical management. M.J.2 performed, collected, and analyzed the pathological-anatomical examination. L.H., M.J.1, and P.J. reviewed and edited the main manuscript, while L.H. and P.J. supervised the work. All authors reviewed the manuscript.

Funding
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Data availability
The article includes a list (Tables) of all cases presenting data used to support this study's findings.

Declarations

Ethics approval and consent to participate
This study was approved by our university's ethics committee and strictly adhered to the tenets of the Declaration of Helsinki. In addition, all patients signed an Informed Consent.

Consent for publication
Not Applicable.

Competing interests
The authors declare no competing interests.

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Received: 11 June 2024 / Accepted: 19 March 2025
Published online: 23 April 2025

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