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Comparison of Insertion Difficulties and Performance of Thoracoamniotic Shunts for Fetal Hydrothorax

Success and Failure Rates in Different Shunt Types for Fetal Hydrothorax

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ABSTRACT

Objective: This study compared insertion difficulties, shunt failure, reintervention rates, maternal adverse events, and neonatal outcomes among different shunt types used in fetal hydrothorax.

Method: A retrospective multicenter cohort study (2012–2022) was conducted across 12 international centers. The primary outcome was the occurrence of complications, classified as insertion difficulties and shunt failure (dislocation, occlusion, or unexplained shunt failure). Secondary outcomes included reintervention rates, maternal complications, and neonatal survival.

Results: Among 349 cases, 345 were included in the analysis of the outcome measures. Rodeck shunts had significantly fewer complications (19.5%) compared to Somatex (38.3%, OR 2.53, $p = 0.016$) and Harrison shunts (50.0%, OR 3.82, $p < 0.001$). Somatex shunts had the highest rate of incorrect positioning (16%), while dislocation was most frequent with Harrison shunts (31.1%). Reintervention rates were lowest for Rodeck (12.1%) and highest for Harrison (32.2%). Maternal body mass index, fetal hydrops, laterality and year of shunt placement did not significantly influence complication rates. No significant differences in live birth rates or gestational age at delivery were observed.

Conclusions: The Rodeck shunt was associated with fewer insertion difficulties, better shunt performance and lower reintervention rates. There was no difference in perinatal survival among the three shunt types.

The last two authors share senior authorship.

Key Points

- What is already known about this topic?
  - Previous non-comparative studies suggest that shunt complication rates vary by shunt type, but a comparative study is missing.
- What does this study add?
  - Being the first international comparative study, we show that the Rodeck shunt is associated with significantly fewer complications and reinterventions compared with other available shunts.

1 | Introduction

Fetal pleural effusion (PE), or fetal hydrothorax, is a rare condition characterized by fluid accumulation in the pleural cavity, occurring in 1 in 10,000 to 15,000 pregnancies [1]. It can occur uni- or bilaterally and is classified into primary and secondary hydrothorax. Primary hydrothorax typically results from chylous leakage through lymphatic malformations, while secondary hydrothorax results from structural abnormalities or is considered to be part of fetal hydrops [1–3]. Spontaneous regression is reported in 9%–22% of cases with primary hydrothorax [4, 5], but progressive hydrothorax may cause cardiac failure and fetal hydrops, with fetal mortality rates as high as 69%, if left untreated [4, 6]. Thoracoamniotic shunt (TAS) placement is an intervention, which can alleviate the PE, ameliorate cardiac compromise and enhance lung development. Survival rates for hydropic fetuses with primary hydrothorax have been reported to increase from 30% to 72%–88.5% after TAS placement [7–9]. However, the procedure is not devoid of insertion difficulties, shunt failure, such as shunt displacement or occlusion, and pregnancy complications, including premature preterm rupture of membranes and preterm labor [10].

Since its introduction by Seeds and Bowes in 1986 [11], various TAS devices have emerged, including the Rodeck/Rocket (Rocket Medical plc., Watford, UK), the Harrison/Cook shunts (Cook Medical LLC, Bloomington USA, ref J-HFBS-503540), the Somatex (Somatex Medical Technologies GmbH, Berlin Germany, ref 410060), and the Double Basket shunt (Hakko Co., Nagano, Japan) (Table 1).

These devices differ in design, material, thickness, and flexibility. Understanding whether these differences impact surgical and shunt performance is crucial for optimizing clinical decisions. However, the availability of specific shunts varies across regions and time. For example, the Rodeck shunt was withdrawn from the market in 2021 due to unfulfilled manufacturing requirements, leading to a shift to alternative shunts worldwide.

Several smaller studies on Rodeck shunt performance show complication (occlusion and/or dislocation) rates varying between 8.5% and 22% [12, 13]. Another study, comparing Harrison and Somatex shunts, showed significantly higher complication rates with Harrison (73%) compared to Somatex (46.2%) [14]. While previous studies have suggested that shunt performance varies depending on the shunt type, a comprehensive multicenter comparison across different shunt types is lacking. The present study aims to provide a thorough and evidence-based understanding of the insertion difficulties and shunt performance associated with various shunt types worldwide.

2 | Materials and Methods

2.1 | Study Design and Participants

To investigate the insertion difficulties and shunt performance in patients with fetal hydrothorax who underwent TAS, a retrospective, international, multicenter cohort study was conducted, initiated by the Leiden University Medical Center (LUMC) and in collaboration with 11 international fetal surgery centers, including institutions from Europe ($n = 5$), North America ($n = 3$), United Kingdom ($n = 3$) and South East Asia ($n = 1$). The study protocol was approved by the LUMC ethical committee (study number nWMO-22–019) and data sharing agreements with the contributing centers were in place.

2.2 | In- and Exclusion Criteria

Data were gathered on pregnant women whose fetus underwent ultrasound-guided placement of a TAS for fetal hydrothorax, between 2012 and 2022 in 12 participating centers. No exclusion criteria were applied.

2.3 | Data Collection

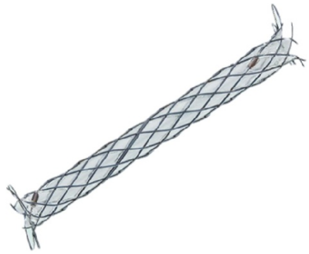
We collected data on antenatal ultrasound images, genetic diagnoses, shunt placement, pregnancy follow-up, birth outcomes and maternal adverse events.

Data were entered into an electronic case report form (Castor-EDC), and stored securely, in compliance with local data protection regulations. The data for this study were collected from 12 fetal therapy centers. While some participating centers have previously published studies that included partially overlapping cases, those publications had different primary objectives and mainly focused on short-term neonatal outcomes. In contrast, our study specifically focusses on technical aspects of fetal surgery, with insertion difficulties and shunt failure as the primary outcome measures. We therefore consider the use of these data appropriate within this context [9, 12, 13, 15, 16].

2.4 | Shunting Procedure

Data were collected on the indication for TAS placement, shunt types (Rodeck, Somatex, Harrison, or Double Basket shunt) and the TAS procedure in fetuses presenting with hydrothorax, either as a single finding or in combination with ascites or skin edema. Data were also collected on fetal structural ultrasound findings other than fetal hydrothorax, if a genetic diagnosis had been made, and any needle procedures prior to placement of the TAS. The choice of shunt was dependent on regional availability. Whenever multiple shunts were available, the decision

TABLE 1 | Comparison of Rodeck, Somatex, and Harrison shunts.

	Rodeck	Somatex	Harrison cook
			
Introducer diameter, mm	3	1.2	2.3
Shunt outer diameter, mm	2.1	2.6	1.67
Shunt length	15 (120 mm including pigtail ends)	25	15 (120 mm including pigtail ends)
Material	Plastic silicone	Nitinol wire mesh, internal silicone membrane	Plastic

was based on the preference or clinical judgment of the fetal surgeon.

2.5 | Follow Up

All centers had comparable protocols to monitor fetal condition after the procedure, which assessed fetal growth, presence and distribution of hydrops and shunt position. Doppler evaluation of peak systolic velocity in the middle cerebral artery, ductus venosus, and umbilical artery, cardiac function, amniotic fluid levels and extent of fluid accumulation were monitored.

2.6 | Outcomes

The aim of the present study was to analyze differences in the occurrence of insertion difficulties and shunt performance across various thoracic shunts in fetal hydrothorax. The primary outcome was the occurrence of complications, which we classified into four categories: insertion difficulties, dislocation, occlusion and unexplained shunt failure (Figure 1).

Cases with visible incorrect positioning at insertion and/or the absence of immediate drainage after the initial insertion were categorized under the 'insertion difficulty' group. Cases that showed dislocation (inward or outward) with reaccumulation of the pleural fluid, after initial correct position with decompression of the hydrothorax, were allocated to the 'dislocation' group. The 'occlusion' group consisted of cases with fluid reaccumulation after initial decompression of the fetal pleural fluid but with ultrasonographic evidence of good shunt positioning. Cases in which the origin of the shunt failure could not clearly be established were allocated to the group 'unexplained shunt failure'. Dislocation, occlusion, and unexplained shunt failure are collectively referred to as 'shunt failure'.

Secondary outcomes were reintervention rates, the number of shunts used on one side of the thorax, maternal adverse events, gestational age at birth and neonatal survival (see Supporting Information S2: Appendix 1 for definitions). Fetal hydrops was defined as an accumulation of fluid in 2 or more body compartments.

2.7 | Statistical Analysis

For the final analysis, the data pertaining to the first-placed shunt and its performance were included. This approach was chosen to minimize the impact of maternal and fetal characteristics in cases where bilateral shunts were used. In cases with bilateral shunts placed within 48 h, one shunt (right or left) was randomly selected. The early second shunt placement at the contralateral side likely reflects suboptimal fetal positioning during the initial procedure, necessitating a temporizing second placement. If bilateral shunts were placed > 48 h apart, the first shunt inserted was included in the analysis.

Statistical analysis was performed using SPSS version 29. Continuous variables are presented as means and standard deviation (std) or medians and interquartile range [IQR] and categorical variables as *n* (%). One way ANOVA, chi square, and Kruskal Wallis tests were used to compare groups. To assess the relationship between shunt type and an eventful course with the occurrence of insertion difficulties or shunt failure, a multivariable logistic regression was used. We considered maternal body mass index (BMI), laterality, presence of fetal hydrops at the time of shunt placement, year of shunt placement and known underlying genetic abnormality as possible confounders.

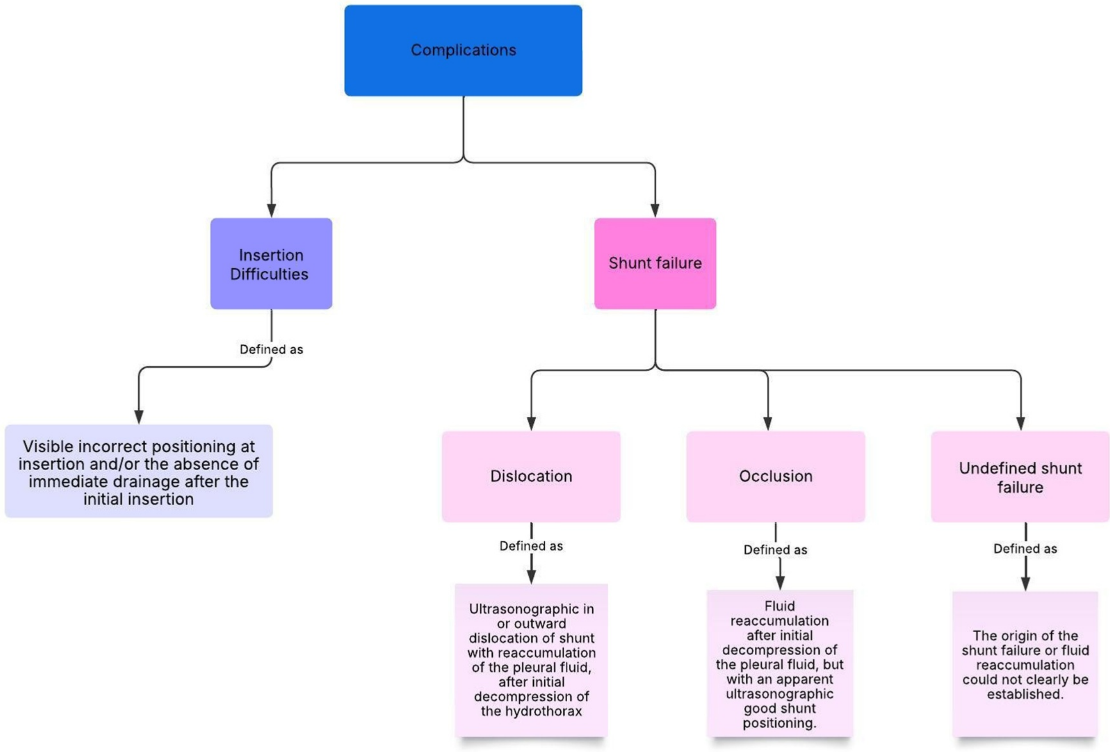


FIGURE 1 | Outcome definitions.

Rodeck shunts were chosen as the reference group, because we anticipated the highest number of patients in this group. Cases with missing data on shunt type or the primary outcome measure were excluded from the analysis. Gestational age (GA) at birth, live birth, and survival at discharge from the neonatal ward were compared separately between shunt types for unilateral and bilateral cases. A p value of < 0.05 was considered statistically significant.

3 | Results

3.1 | Patient Characteristics

Between January 2012 and December 2022, 349 fetuses underwent TAS at one of the participating centers (Supporting Information S1: Supplement 1). One case (0.3%) was excluded from the analysis because of missing information on the shunt type. In three cases (0.9%), a Double Basket shunt was used and were excluded from the comparative analysis due to the small sample size. Thus, 345 (98.9%) cases were eventually included in the analysis of the outcome measures.

The baseline characteristics per shunt type are shown in Table 2. Among the 348 cases, 190 (54.6%) were treated with a unilateral shunt, while 158 (45.4%) received bilateral shunts. This differed significantly between the different shunt types ($p < 0.001$), and was adjusted for in the analysis of the primary outcome measure. Of the first-placed shunts, 174 (50.0%) were Rodeck, 81 (23.3%) Somatex, 90 (25.9%) Harrison and three (0.9%) Double Basket. The indication for shunt placement was documented in 99.1% of the cases. Fetal hydrops were observed in 153 cases (44.3%) prior to shunt placement and did not significantly differ between shunt types ($p = 0.910$). Genetic testing was performed in 328 cases (94.3%), ranging from chromosome analysis (4%) to exome sequencing (12.4%) (Supporting Information S2: Appendix 2). Of these fetuses, an underlying genetic abnormality was identified in 66 (19%); the majority of these (39/66 62.9%) were diagnosed prenatally. The median GA at shunt placement of all first-placed shunts was 29.4 weeks [24.0–32.3] and did not differ significantly between shunt types (Table 2, $p = 0.584$). Figure 2 illustrates the number of shunts placed per year, showing an increase in the usage of Somatex and Harrison shunts and a decrease in Rodeck shunts over the years.

3.2 | Insertion Difficulties and Shunt Performance

The occurrence of insertion difficulties and shunt failure by shunt type is summarized in Table 3. Among the patients with a Rodeck shunt, 34 patients (19.5%) experienced complications related to insertion difficulties or shunt failure. In contrast, the rates were significantly higher for the Somatex and Harrison shunts, with occurrences of 38.3% ($p = 0.016$ OR 2.53, 95% CI 1.19–5.39) and 50% ($p < 0.001$; OR, 3.82 (95% CI 1.92–7.59) respectively (Tables 3 and 4). Table 4 shows that shunt type is the most important determinant of insertion difficulties or shunt failure. Other potential prognostic factors, including maternal BMI, fetal hydrops prior to shunt placement, underlying genetic abnormality, shunt laterality, and year of shunt placement, did not significantly influence the occurrence of insertion difficulties or shunt failure (Table 4).

TABLE 2 | Baseline clinical characteristics of cases with thoraco-amniotic shunts for fetal hydrothorax.

	All cases $N = 348$	Rodeck $N = 174$	Somatex $N = 81$	Harrison cook $N = 90$	p-value
Maternal body mass index[a]	25.6 (5.6)	25.5 (5.5)	24.8 (4.4)	26.6 (6.7)	0.176
Indication for shunt placement					
Fetal hydrops	153/345 (44.3)	74/172 (43)	37 (45.7)	40/89 (44.9)	0.910
Genetic testing performed	328 (94.3)	166 (95.4)	75 (92.6)	85 (94.4)	0.306
Underlying genetic anomaly	66 (19)	27 (16.3)	17 (22.7)	21 (24.7)	0.227
Shunt placement					< 0.001*
Unilateral	190 (54.6)	76 (43.7)	57 (70.4)	54 (60)	
Bilateral	158 (45.4)	98 (56.3)	24 (29.6)	36 (40)	
Gestation at first insertion in weeks	29.4 [24.0–32.3]	28.7 [23.3–32.2]	30.3 [25.4–32.4]	29.3 [24.6–32.3]	0.584

Note: Data are presented as means (standard deviation), n/N (%) or as median [interquartile range]. Double basket cases are included in all cases, but excluded from comparative analysis.
[a]Available in 267 cases.
*Statistically significant

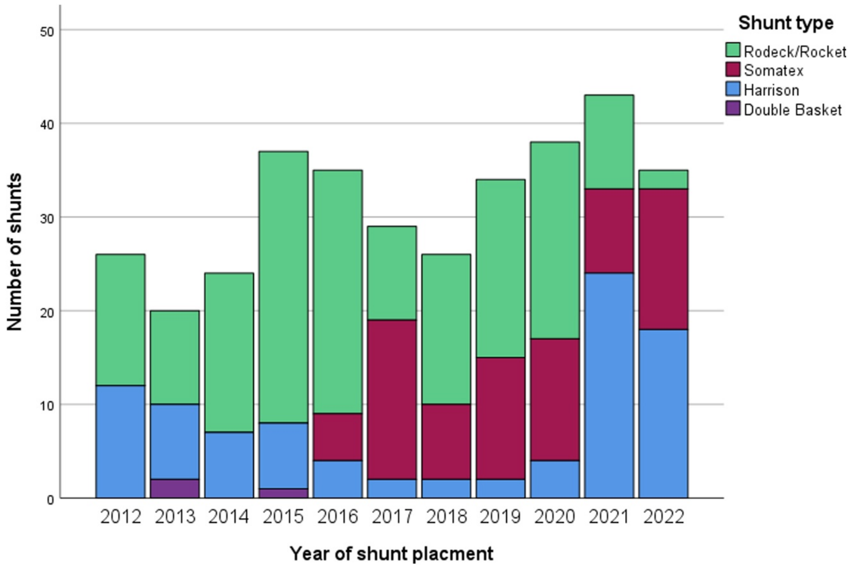


FIGURE 2 | Number of shunts placed per year.

Table 3 indicates that the incidence of incorrect shunt position at the time of initial insertion is notably higher in patients with a Somatex shunt, occurring in 16% of the cases, compared to 1.1% for Rodeck and 7.8% for Harrison shunts ($p < 0.001$). Dislocation after initial correct position was most prevalent in patients with a Harrison shunt, 31.1% compared to 11.5% for Rodeck and 7.4% for Somatex ($p < 0.001$). The occlusion rate was similar between Somatex (11/81, 13.6%) and Harrison shunts (10/90, 11.1%) and tended to occur less commonly in Rodeck shunts (12/174, 6.9%), although this was not statistically significant ($p = 0.203$).

The median duration from the first insertion to the onset of a complication in cases with uneventful shunt placement was 7 days [2–15] (Table 3). Reintervention was required in 28.4% (23/81) of Somatex cases, 32.2% (29/90) of Harrison cases and 12.1% (21/174) of Rodeck cases ($p < 0.001$).

In 280 cases, only one shunt was utilized. Among the 74 cases that required reintervention, 68 cases (91.9%) received a new shunt. 59 cases (17.0%) needed a total of two shunts, six cases (1.7%) required a total of three shunts and three cases (0.9%) involved a total of four shunts.

3.3 | Neonatal Outcomes

3.3.1 | Unilateral Shunts

In patients with unilateral shunts, the median GA at birth was similar for those with Somatex and Harrison shunts (34.9 and 34.8 weeks, respectively), and had a tendency to be later for those with Rodeck shunts (36.4 weeks), although this was not statistically significant ($p = 0.394$). Livebirth and survival at discharge were similar among the three different shunt types (Table 5).

TABLE 3 | Technical difficulties and shunt failure by shunt type.

	All cases $N = 348$	Rodeck $n = 174$	Somatex $n = 81$	Harrison cook $N = 90$	p -value
Uneventful course[a]	237 (68.1)	140 (80.5)	50 (61.7)	45 (50)	< 0.001*
Incorrect position at initial insertion	23 (6.6)	2 (1.1)	13 (16)	7 (7.8)	< 0.001*
Dislocation after initial correct position	54 (15.5)	20 (11.5)	6 (7.4)	28 (31.1)	< 0.001*
Inward dislocation	22 (40.7)	11	4	7	
Outward dislocation	30 (55.6)	9	1	20	
Unknown	2 (3.7)		1	1	
Occlusion after initial decompression of fetal hydrothorax	32 (9.2)	12 (6.9)	11 (13.6)	10 (11.1)	0.203
Unexplained shunt failure	1 (0.3)[b]	0	1 (1.2)[b]	0	0.195
Reintervention	74 (21.3)	21 (12.1)	23 (28.4)	29 (32.2)	< 0.001*
Shunt	68 (91.9)	19 (90.5)	23 (100)[c]	25 (86.2)[g]	
Other reintervention	*6 (8.1)*	*2 (9.5)*[d]	*n.a.*	*4 (13.8)*[e]	
Median duration from first insertion to complication in days[f]	7 [2–15]	6 [2–13]	7 [1.75–23.25]	7.5 [3–16.25]	0.056

Note: Data are presented as n/N (%). Double basket shunts are included in all cases, but excluded from comparative analysis.
[a]*All cases in which none of the four complications occurred.*
[b]*In one case, a new congenital pulmonary airway malformation cyst developed, resulting in no drainage.*
[c]Of the 23 patients who required a second shunt after initially receiving a Somatex shunt, 22 received a second Somatex shunt and 1 received a double-basket shunt.
[d]In one case, placement of a second shunt was not possible because of PPROM during the procedure; in one case the existing shunt probably moved and opened after an attempt to position the fetus to place a second shunt and therefore shunt placement was not necessary.
[e]In four cases, thoracocentesis was performed.
[f]All cases with insertion difficulty (defined as: cases with visible incorrect positioning during the initial insertion or cases with the absence of immediate drainage after the first insertion) were excluded as the complication occurred on the same day as the intervention took place.
[g]Of the 25 patients who required a second shunt after initially receiving a Harrison shunt, 24 received a second Harrison shunt and 1 received a Rodeck shunt.
*Statistically significant

TABLE 4 | The influence of shunt type and potential confounders on an eventful course with the occurrence of insertion difficulties or shunt failure[a].

	OR (95% CI)
Shunt type used	
Rodeck	Reference
Somatex	OR 2.534 (1.191–5.391)*
Harrison	OR 3.820 (1.924–7.585)*
Maternal body mass index	OR 1.009 (0.960–1.060)
Hydrops observed prior to shunting	OR 0.579 (0.361–1.060)
Underlying genetic abnormality	OR 1.499 (0.747–3.009)
Laterality	OR 0.868 (0.475–1.585)
Year of shunt placement	OR 0.961 (0.873–1.058)

Note: Double basket shunts are excluded in this analysis. Definition of shunt failure: cases with "dislocation" (inward or outward) with reaccumulation of the pleural fluid after initial correct position with decompression of the hydrothorax, "occlusion" cases with reaccumulation after initial decompression of the pleural fluid, but with a ultrasonographic good shunt positioning or 'undefined shunt failure' cases in which the origin of the shunt failure could not clearly be established.
[a]Definition insertion difficulty: cases with visible incorrect positioning during the initial insertion or cases with the absence of immediate drainage after the first insertion.
*Statistically significant

3.3.2 | Bilateral Shunts

In patients with bilateral shunts, the median GA at birth was similar for those with Rodeck and Somatex shunts and tended to be lower for those with Harrison shunts, although this was not statistically significant ($p = 0.240$) (Table 5). Livebirth rates were similar among the various shunt types ($p = 0.929$). Survival at discharge was similar in Rodeck (64%) and Somatex shunts (62.5%), with a trend toward lower survival in Harrison cases (45.7%), though this difference was not statistically significant ($p = 0.164$).

3.4 | Maternal Adverse Events

Table 6 provides a summary of the incidence of maternal adverse events by shunt type. Maternal adverse events were infrequent and the majority (87%) were not clinically significant (grade 1) [17, 18].

4 | Discussion

4.1 | Principal Findings

The data presented indicate that the Somatex and the Harrison shunts (with odds ratios of 2.53 and 3.82, respectively) are associated with significantly higher complication rates in comparison to the Rodeck shunt, but without difference in neonatal survival. Potential confounders, including maternal BMI, the presence of hydrops, underlying genetic abnormalities, laterality and the year of shunt placement, did not significantly affect the complication rates. In addition, the most common type of complication varies depending on the shunt type.

This study shows the complexity of factors influencing fetal outcomes after fetal surgery and the difficulty in unraveling

TABLE 5 | Birth outcomes per shunt type in unilateral versus bilateral groups.

Unilateral cases	All cases $N = 190$	Rodeck $N = 76$	Somatex $N = 57$	Harrison $N = 54$	*p*-value
Gestation at birth in weeks	35.7 [33–38.1][a]	36.4 [33.7–38.1]	34.9 [32.2–37.8]	34.8 [31.9–38.1]	0.394
Livebirth	162/189 (85.7)	65 (85.5)	49 (86)	46/53 (86.8)	0.979
Alive at discharge	136/188 (72.3)	54/75 (72.0)	43 (75.4)	37/53 (69.8)	0.791
Bilateral cases	**All cases $N = 158$**	**Rodeck $N = 98$**	**Somatex $N = 24$**	**Harrison $N = 36$**	***p*-value**
Gestation age at birth in weeks	34.1 [31.6–36.1][b]	34.6 [31.4–36.7]	34.1 [31.4–34.9]	32.9 [31.7–34.9]	0.240
Livebirth	133/149 (89.3)	81/90 (90)	21 (87.5)	31/35 (88.6)	0.929
Alive at discharge	88/157 (56.1)	57/89 (64.0)	15 (62.5)	16/35 (45.7)	0.164

Note: Data are presented as median [IQR] or as n/N (%). Double basket shunts are included in all cases, but excluded in comparative analysis.
[a]Available in 187 cases. Three cases with missing values on GA at birth. Values missing in 1 Rodeck case and in 2 Harrison cases.
[b]Available in 148 cases. Ten cases with missing values on GA at birth. Values missing in 9 Rodeck cases and 1 Harrison case.

TABLE 6 | Maternal adverse events per shunt type.

	All patients $N = 348$	Rodeck/Rocket $n = 174$	Somatex $n = 81$	Cook harrison $N = 90$
Shoulder pain[a]	3/346 (0.9)	1/173 (0.6)	0	2/89 (2.2)
Need for additional diagnostic examinations[a]	11/347 (3.2)	6 (3.4)	1 (1.2)	4/89 (4.5)
Vaginal bleeding[a]	6/347 (1.7)	3 (1.7)	1 (1.2)	2/89 (2.2)
Need for abdominal surgery[b]	4/347 (1.2)	1 (0.6)	0	3/89 (3.4)
Fever[a]	7/347 (2.0)	4 (2.3)	0	3/89 (3.4)

Note: Data are presented as n/N (%). Double basket shunts are included in all cases.
[a]Grade 1 according to Spencer et al. [13] and Gijtenbeek et al. [14].
[b]Grade 3/4 according to Gijtenbeek et al. [14].

causal relationships. The relatively thin introduction needle of the Somatex shunt could lead to the assumption that premature birth will occur less frequently with its use; however, this was not observed in our study. A potential explanation for the lack of this effect may be the higher rates of reintervention observed with both the Somatex (28.4%) and Harrison (32.2%) shunts, compared to the Rodeck (12.1%) shunt. Alternatively, intrinsic factors related to the underlying disease, including fetal hydrops and polyhydramnios, could also explain the absence of reduced prematurity.

The underlying reasons for the better performance of the Rodeck shunt remain unclear; however, we hypothesize that this may be attributed to differences in material composition, structural design, and mechanical properties among the shunt types (see Table 1). In comparison to the Somatex shunt, the Rodeck shunt incorporates multiple perforations in its pigtail ends, potentially reducing the risk of occlusion. Furthermore, relative to the Harrison shunt, the Rodeck shunt exhibits greater rigidity, which may facilitate a more straightforward placement and lower the likelihood of dislocation.

4.2 | Results in the Context of What Is Already Known

Our findings align with previously published research, but this is the first comprehensive comparison of various shunt types involving a large study population across multiple international centers. Yinon et al. (2010) showed a dislocation rate of 5.7% and an occlusion rate of 10.3% in patients with a Rodeck shunt, which required reintervention with placement of a second shunt in all cases [12]. Abbasi et al. (2021) showed a similar dislocation rate in Rodeck shunts (8.5%) [13]. Grandt et al. (2022) compared the Somatex and the Harrison shunts, finding significantly higher complication rates with Harrison (73%) compared to Somatex (46.2%). However, no significant differences were observed in survival rates between the two shunt types [14]. Takahashi et al. (2024) reported on complications after shunting using a double-basket shunt, showing dislocation in 25% of the cases and occlusion in 24% [19].

4.3 | Clinical Implications

During the study period, we noted a change in practice, that is, an increase in the usage of Somatex and Harrison shunts, alongside a decline in Rodeck shunts. This decline is primarily attributed to the withdrawal of the Rodeck shunt from the market. The challenges faced by manufacturers to meet the stringent requirements set forth by the European Medical Device Regulation (EU-MDR) have made it increasingly difficult to develop new, or improve existing medical devices [20].

This highlights a critical issue: the need to balance patient safety with regulatory compliance. While regulatory oversight is essential, it has become increasingly clear that current frameworks may be ill-suited to meet the needs of rare disease treatments. There is a growing debate on whether devices used to treat low-prevalence diseases, including the TAS shunts, should be subject to the same stringent regulations as high-demand products [21, 22]. Drawing inspiration from the success of the U.S. Orphan Drug Act in the pharmaceutical industry, which has greatly expanded access to treatments for rare diseases, there is rising support for a similar approach for medical devices [23]. The goal of EU-MDR is to protect European citizens by enhancing the safety of medical products–a goal likely achievable for high volume devices. However, in specialized fields involving low-volume medical devices, the MDR may result in market withdrawals or inflated prices [24]. By adapting regulations to the unique needs of rare disease patients, we can safeguard both patients' welfare and sustain trust in the industry while accelerating the availability of life-saving medical devices.

4.4 | Research Implications

Future studies should aim to evaluate long-term neonatal outcomes, including survival rates, developmental milestones, and quality of life. Although this study found no significant influence of genetic abnormalities on the occurrence of complications, future research should focus on this subgroup to investigate potential interactions between specific underlying genetic abnormalities and the disease course of fetal hydrothorax.

4.5 | Strengths and Limitations

Our study stands out as the first comprehensive global comparison of shunt performance, with data from various experienced centers worldwide, which enhances the generalizability of the results. Our results add to the already published literature with the largest cohort ever reported, providing valuable insights into the performance of different shunts. Our findings raise important points about regulatory frameworks for medical devices used in rare diseases, contributing to the ongoing discussion on the accessibility of medical devices for low-prevalence diseases.

Although our study is notable for its strengths, it is important to acknowledge its limitations, which are primarily attributed to the retrospective design and the relatively small number of procedures resulting from the low prevalence of fetal hydrothorax. Due to the retrospective nature of the study, the availability of certain information, such as shunt availability and fetal anesthesia prior to shunt placement, was not systematically recorded and therefore not included in the study. While key confounders were controlled for in the statistical analysis, there may be other relevant variables that were not included in the analysis, potentially affecting the outcome. The surgeon's learning curve and experience is a potential confounder we could not adjust for; however, it is worth noting that all fetal surgeons who contributed data to this dataset were highly experienced. Additionally, the introduction of a new shunt type, that is, the Somatex shunt in 2014, might have influenced our findings regarding correct positioning of the shunt during initial insertion. Furthermore, due to the amount of neonatal deaths and missing data, this study may have been underpowered to detect differences in GA at delivery, live birth and survival to discharge.

Moreover, this study primarily examines complications, reinterventions and short-term outcomes; it does not focus on long-term maternal and neonatal outcomes, which are also important in parental counseling.

5 | Conclusions

This study, as the first international multicenter study on this subject, provides essential data on the outcomes of thoracoamniotic shunts across various types, revealing significant differences in insertion difficulties and shunt failures. Our results indicate that the Rodeck shunt is associated with less insertion difficulties and better shunt performance, as well as lower reintervention rates, but we did not observe differences in live birth rates or neonatal survival between shunt types. At the moment, the choice of shunt is often dictated by regulation and availability or personal preference rather than on scientific evidence. Recent retraction of the Rodeck shunt from the market underscores the need for a more flexible regulatory framework for medical devices intended for low prevalence diseases to secure the treatment of fetal patients in the future.

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The authors have nothing to report.

Ethics Statement

The study protocol was approved by the LUMC ethical committee (study number nWMO-22–019).

Consent

As approved by the LUMC ethical committee, informed consent was waived due to the condition's rarity, the dataset's timespan, and the use of untraceable data.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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