Ultrasound Obstet Gynecol 2019; **54**: 10–15
Published online in Wiley Online Library (wileyonlinelibrary.com). **DOI:** 10.1002/uog.19192

Opinion

Variation in outcome reporting across studies evaluating interventions for selective fetal growth restriction

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The recent investigation of variation in outcome reporting across studies evaluating treatments for twin-to-twin transfusion syndrome (TTTS) highlighted the high variability in the outcomes reported and their definition[1]. Similar heterogeneity in outcome reporting has been identified in studies of other conditions related to women's and newborns' health, including pre-eclampsia, childbirth trauma and endometriosis[2–8]. There is a need for a focused effort to improve the quality of research studies on multiple pregnancy complications and their treatment. As these pregnancies are uncommon, multicenter observational studies and large international trials hold the key to providing future insights into the efficacy and safety of potential interventions. Meta-analyses of studies are hindered by variable outcome reporting and definitions, precluding rapid resolution of important clinical questions. In research areas in which patient population is scarce, studies are pragmatically challenging to perform and yet their clinical significance is high and standardized outcome reporting is even more important. Although the problem of research waste is increasingly recognized[9], it is ethically imperative that this is addressed imminently in research involving the willing participation of dedicated mothers keen to contribute to better care for their babies and others yet to come. There is an urgent need for sound evidence on which to base the antenatal management of women with high-risk multiple pregnancy, and every investigation reported should contribute effectively to the advancement of medical research and patient care[10].

TTTS is the most widely studied complication of monochorionic twin pregnancy. The introduction of fetoscopic laser treatment for TTTS has benefited women and their babies worldwide. Despite over 20 years of research on TTTS, the recent systematic review on outcome reporting across studies evaluating treatments for TTTS identified only six randomized controlled trials on this subject[1]. Evidence remains scarce relating to the optimal surgical approach, prognostic factors of outcome before and after laser treatment, and use of laser in Stage-I TTTS, triplet pregnancy or TTTS co-existent with selective fetal growth restriction (sFGR). Other similarly important clinical questions, including the use of rescue cerclage in twin pregnancy and the use of fetoscopic interventions in sFGR or twin anemia–polycythemia sequence (TAPS), have yet to be addressed.

We welcome the development of a core outcome set for studies of interventions for TTTS[11]. However, we question whether these core outcomes can be generalized to other interventions in multiple pregnancy or if different outcomes may be of greater importance to clinicians and families facing different multiple pregnancy complications. A key condition to consider is sFGR, which complicates between 10% and 15% of monochorionic twin pregnancies[12,13]. A consensus definition of sFGR was recently reached[14]. Moreover, Gratacós *et al.* proposed a classification system for stratifying monochorionic twin pregnancies affected by sFGR according to umbilical artery Doppler patterns into three types that correlate well with perinatal outcome[15]. Interventions for sFGR include expectant management with delivery in the event of fetal compromise, cord occlusion of the compromised twin and fetoscopic laser ablation of the communicating placental vessels; however, the optimal management has not yet been determined[16]. Now that a clear definition of and classification system for sFGR are available, the next step is to design and carry out studies to determine the optimal management for this condition. Consistency in the collection of data and reporting of outcomes and outcome measures across future studies on sFGR is important in order to develop an efficient research infrastructure. Moreover it should be kept in mind that the outcomes of interest in these studies might differ from those identified as relevant for TTTS[17].

We investigated systematically the variation in outcome reporting across studies evaluating interventions for sFGR in monochorionic diamniotic twin pregnancies, according to the methodology reported in the linked systematic review of outcome reporting in TTTS[1] and the Cochrane Collaboration handbook, COMET initiative handbook and other core outcome sets in development[18–25]. MEDLINE, EMBASE, CINAHL, Clinicaltrials.gov and The Cochrane Library databases were searched electronically using a comprehensive search strategy (Appendix S1). Thirty-nine studies were included in the analysis, comprising 21 retrospective and 13 prospective cohort studies, three non-comparative studies, one case–control and one cross-sectional study (Table 1)[13,15,26–62]. Fetal, neonatal

Table 1 Characteristics of 39 studies evaluating interventions for selective fetal growth restriction (sFGR) in monochorionic diamniotic twin pregnancy

Study	*Study design*	*Mothers* (n)	*Offspring* (n)	*Intervention 1*	*Intervention 2*	*sFGR definition*
Koch (2017)[48]	Retro cohort	25	44	Expectant	Laser	EFW < 10th percentile in one twin
Panciatici (2017)[58]	Prosp cohort	2	2	Cord occlusion		Not specified
Rustico (2017)[37]	Retro cohort	140	217	Expectant	Cord occlusion	EFW < 10th centile in one twin OR EFW discrepancy > 25%
Wang (2017)[57]	Non-comparative	4	3	Cord occlusion		Not specified
Halling (2016)[61]	Cross-sectional	24	48	Expectant		Birth-weight discordance ≥ 20%
Parra-Cordero (2016)[59]	Non-comparative	90	87	Cord occlusion		EFW < 10th centile OR AC < 10th centile with intertwin discordance ≥ 25%
Peng (2016)[60]	Retro cohort	16	NS	Cord occlusion		EFW < 2nd centile in one twin
Ishii (2015)[62]	Non-comparative	10	13	Laser		EFW of smaller twin < −1.5 SD
Pasquini (2015)[27]	Retro cohort	42	77	Expectant		AC of smaller twin ≤ 10th centile for gestational age
Peeva (2015)[28]	Retro cohort	142	NS	Laser		< 22 weeks: AC < 5th centile; ≥ 22 weeks: EFW < 5th centile AND EFW difference ≥ 25%
Yinon (2015)[29]	Retro cohort	23	20	Cord occlusion		EFW < 10th centile in one twin AND EFW discordance ≥ 25%
Zuckerwise (2015)[30]	Retro cohort	16	NS	Expectant		EFW discordance > 20%
Has (2014)[32]	Retro cohort	12	11	Cord occlusion		EFW < 10th centile in one twin AND intertwin EFW discordance ≥ 25%
Machado (2014)[31]	Retro cohort	18	33	Expectant		EFW < 10th centile in one twin
Chalouhi (2013)[33]	Retro cohort	45	44	Laser	Cord occlusion	EFW < 5th centile AND EFW discordance >25% AND absent/reverse end-diastolic flow in UA Doppler
Visentin (2013)[34]	Prosp cohort	14	28	Expectant		EFW < 10th centile in one twin
Bebbington (2012)[36]	Retro cohort	24	NS	Cord occlusion		EFW < 10th centile in one twin AND intertwin weight difference > 25%
Gao (2012)[35]	Case–control	38	NS	Expectant		Birth weight < 10th centile AND intertwin EFW discordance > 20%
Lanna (2012)[38]	Retro cohort	30	28	Cord occlusion		Not specified
Ishii (2011)[39]	Retro cohort	101	152	Expectant		EFW < 10th centile in one twin
Weisz (2011)[40]	Prosp cohort	37	74	Expectant		EFW < 10th centile in one twin
Chang (2010)[42]	Prosp cohort	27	54	Expectant		EFW < 10th centile in one twin
Smith (2010)[41]	Retro cohort	Unclear	Unclear	Expectant		Birth-weight discordance > 25%
Chang (2009)[44]	Prosp cohort	24	48	Expectant		EFW < 10th centile in one twin
Ishii (2009)[45]	Retro cohort	63	104	Expectant		EFW < 10th centile in one twin
Machado (2009)[43]	Retro cohort	12	24	Expectant		Birth-weight discordance ≥ 20%
Gratacós (2008)[46]	Retro cohort	49	76	Expectant	Laser	EFW < 10th centile in one twin
Lewi (2008)[13]	Prosp cohort	28	50	Expectant	Cord occlusion	16 weeks: difference in AC ≥ 90th centile 20–26 weeks: EFW discordance > 20%
Lewi (2008)[47]	Prosp cohort	29	53	Expectant	Cord occlusion	Birth-weight discordance > 25%
Lopriore (2008)[49]	Retro cohort	50	94	Expectant		EFW < 10th centile in one twin
Acosta-Rojas (2007)[52]	Prosp cohort	9	16	Expectant		EFW < 10th centile AND intertwin growth discordance > 25%
Gratacós (2007)[15]	Prosp cohort	134	105	Expectant	Cord occlusion	EFW < 10th centile in one twin
Kennelly (2007)[50]	Retro cohort	22	40	Expectant		AC < 5th percentile AND absent/reversed end-diastolic flow in UA Doppler
Muñoz-Abellana (2007)[51]	Prosp cohort	80	135	Expectant	Cord occlusion	EFW < 10th centile in one twin

Contd. over.

Table 1 *Continued*

Study	*Study design*	*Mothers* (n)	*Offspring* (n)	*Intervention 1*	*Intervention 2*	*sFGR definition*
Halvorsen (2006)[53]	Retro cohort	13	26	Expectant		Birth weight < −2 SD in one twin
Adegbite (2005)[54]	Retro cohort	15	30	Expectant		Birth-weight discordance > 20% with normal amniotic fluid in larger twin OR AC < 5th centile with abnormal UA Doppler waveform in smaller twin
Gratacós (2004)[55]	Prosp cohort	40	73	Expectant		EFW < 5th centile AND intertwin growth discordance > 25%
Gratacós (2004)[56]	Prosp cohort	42	75	Expectant		EFW < 5th centile AND intertwin growth discordance > 25%
Quintero (2001)[26]*	Prosp cohort	30	41	Expectant	Laser	EFW < 10th percentile; AND absent/reversed end-diastolic flow in UA after January 2000

Only first author of each study is given. *Third comparison: cord occlusion. AC, fetal abdominal circumference; EFW, estimated fetal weight; Retro, retrospective; Prosp, prospective; UA, umbilical artery.

and perinatal mortality were reported commonly across the included studies. Over half of the included studies reported live birth, intrauterine demise and neonatal mortality, although most did not report mortality by smaller or larger twin status. A quarter of the studies reported fetal parameters as study outcomes, including eight (21%) studies that evaluated umbilical artery Doppler, four (10%) fetal neurological morbidity in the surviving twin and one (3%) hypertrophic cardiomyopathy. Pregnancy outcomes, including preterm delivery, mode of delivery and preterm prelabor rupture of membranes, were reported in around one-third of the included studies, but maternal, procedure-related and childhood outcomes were reported infrequently. Although neonatal morbidity was reported relatively frequently, there was inconsistency in the choice of morbidity outcomes. The most commonly reported were intraventricular hemorrhage, respiratory distress syndrome and necrotizing enterocolitis, but a wide range of others were included. Figure 1 illustrates fetal, neonatal and childhood outcomes reported across the largest 20 studies. Table 2 lists the frequency of outcomes reported across the included studies.

Outcomes identified through a systematic review of published studies reflect largely the outcomes healthcare professionals and researchers have considered important to collect, measure and report. The balance of outcomes reported in the included papers focused primarily on perinatal survival and neonatal morbidity outcomes, while maternal, procedural and childhood outcomes were reported relatively infrequently.

We observed important differences in the pattern of outcome reporting, particularly with regard to fetal outcomes, between the studies evaluated in this systematic review and those included in the review of TTTS studies[1]. The review of TTTS studies identified fetal outcomes that were frequently reported, including recurrence of TTTS or development of TAPS. These outcomes are not relevant to sFGR and were not identified in any of the included sFGR studies. In sFGR, fetal Doppler findings are typically used to identify disease progression and plan the timing of delivery. Doppler findings in the umbilical and middle cerebral arteries and ductus venosus were reported relatively frequently as outcomes after intervention for sFGR, whereas these parameters were not reported as outcomes in any of the studies investigating TTTS. Furthermore, 69% (27 studies) of papers investigating sFGR reported intrauterine death (IUD) as an outcome, in contrast to only 31% (31 studies) of TTTS studies included in the earlier review. The most frequently reported neonatal morbidity outcomes in both TTTS and sFGR studies were intraventricular hemorrhage (IVH) and periventricular leukomalacia (PVL). IVH was reported in 51% (20 studies) of sFGR and 16% (16 studies) of TTTS studies, while PVL was reported in 46% (18 studies) of sFGR and 17% (17 studies) of TTTS papers. Therefore, we conclude that, in TTTS or sFGR studies in which neonatal morbidity is reported, the conditions of greatest interest to the investigators are neurological; however, it is noteworthy that substantially more sFGR studies report neurological outcomes. In view of the fact that the management of sFGR aims at preventing IUD of the smaller twin and subsequent mortality or neurological morbidity in the surviving cotwin, the relative importance of these outcomes may differ between sFGR and TTTS studies. Fetoscopic intervention for sFGR is of particular interest because, even though it is associated with a high risk of IUD, it may protect the larger twin from the consequences of cotwin demise without requiring cord occlusion and still afford the smaller twin a chance of survival. Consistent reporting of IUD and neurological morbidity is clearly essential to determining the clinical utility of interventions for sFGR.

Fetoscopic intervention in sFGR is known to be more technically challenging than in TTTS, principally due to the absence of polyhydramnios, which limits the

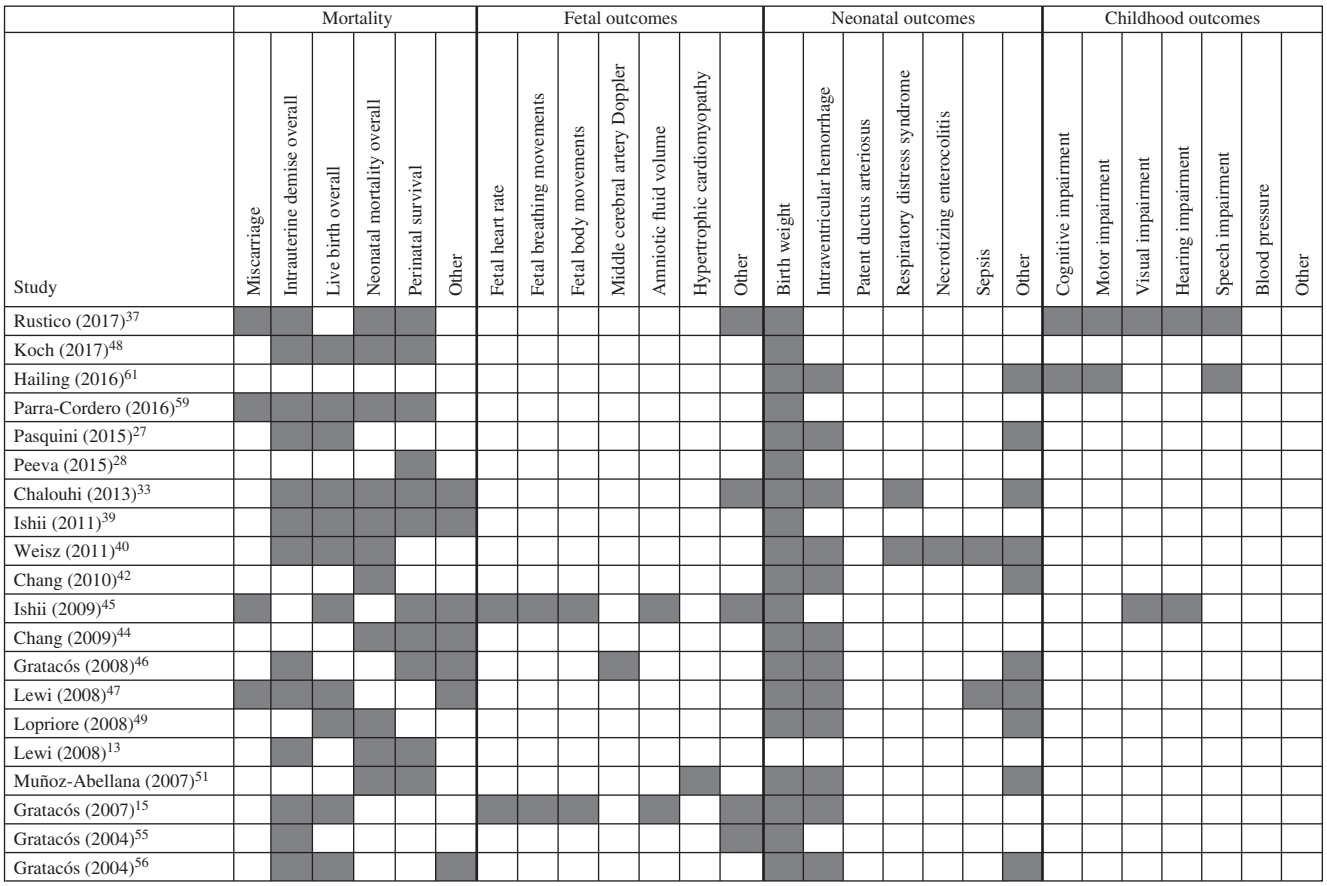

Figure 1 Reporting of fetal, neonatal and childhood outcomes in 20 largest studies investigating interventions for selective fetal growth restriction in monochorionic diamniotic twin pregnancy. Only first author of each study is given. Shaded cell indicates that outcome was reported.

Table 2 Variation in outcomes reported across 39 studies evaluating interventions for selective fetal growth restriction in monochorionic diamniotic twin pregnancy

Outcome	*Studies (*n*)*
Fetal, neonatal and perinatal mortality	
Miscarriage	6
Termination of pregnancy	10
Intrauterine demise overall	27
Intrauterine demise per twin	21
Double intrauterine demise	13
Live birth overall	22
Live birth per twin	10
Neonatal mortality overall	26
Neonatal mortality per twin	9
Perinatal mortality overall	8
Perinatal mortality per twin	8
Perinatal survival	19
Fetal outcome	
Middle cerebral artery Doppler	4
Ductus venosus Doppler	5
Umbilical artery Doppler	8
Neurological morbidity in surviving twin following cord occlusion	4
Other	7
Pregnancy and birth outcome	
Preterm prelabor rupture of membranes	11
Mode of delivery	12
Gestational age at delivery	39
Preterm delivery	14
Procedure-to-delivery time interval	3
Other	8

Table 2 *Continued*

Outcome	*Studies (*n*)*
Procedure-related outcome	
Membrane septostomy	3
Intrauterine infection	5
Other	7
Neonatal outcome	
Birth weight	35
Apgar score	7
Intertwin birth-weight discordance	14
Intraventricular hemorrhage	20
Periventricular leukomalacia	18
Retinopathy of prematurity	2
Hypertrophic cardiomyopathy	2
Respiratory distress syndrome	8
Intubation and mechanical ventilation	3
Necrotizing enterocolitis	8
Sepsis	6
Neonatal intensive care unit admission	6
Other	12
Childhood outcome	
Cognitive impairment	6
Motor impairment	6
Visual impairment	3
Hearing impairment	3
Behavioral disorder	4
Blood pressure	1
Other	1

visibility and access to the placental anastomoses. It is particularly disappointing, therefore, to find that there is poor reporting of procedural complications and maternal outcomes in both TTTS and sFGR studies reporting the use of fetoscopy. Since this intervention is increasingly being offered to mothers, it is important to be able to assess the risk of maternal and procedural complications and it is possible that these complications might differ in frequency following fetoscopy for sFGR compared to fetoscopy for TTTS. Inadequate safety reporting is a common pattern in studies of outcome reporting, but in order to fully evaluate the balance of risks and benefits it is vital that potential harms, as well as benefits, of each intervention are reported[5].

The outcomes identified through these reviews of TTTS and sFGR studies have been shown to be important to researchers but may not hold the same relevance to other stakeholders, including women with a twin pregnancy complicated by sFGR. In particular, morbidity outcomes other than neurological complications may be important to parents. Moreover, long-term outcomes are likely to be more important to them than short-term morbidity. A small minority of published studies in both TTTS and sFGR have collected and reported childhood outcomes, including long-term neurodevelopmental outcomes. The duration of follow-up should be a key consideration when planning future studies, balancing feasibility with identifying important outcomes. With high variation in the reported length of follow-up and definition of outcomes in TTTS and sFGR studies, expert consensus and stakeholder consultation are needed to agree on the optimal follow-up duration and outcomes that should be assessed. It is likely that outcomes important to parents and other stakeholders will be comparable between TTTS and sFGR, but their perspective deserves to be as thoroughly investigated as that of clinical researchers.

sFGR in monochorionic diamniotic twin pregnancy is an uncommon condition with key differences from TTTS and other pathologies of monochorionic pregnancy that influence the outcomes investigated between these studies. A research agenda will need to be developed to prioritize unanswered research questions that can be addressed within internationally collaborative observational studies and large international trials. A core outcome set for sFGR studies should be developed to assist in planning future research, either in addition to a core outcome set for TTTS or as a separate component within a larger core outcome set for studies in complicated monochorionic pregnancies.

In planning future studies on TTTS and sFGR, we have the opportunity to consider outcomes beyond infant survival that are clinically relevant and important to parents. We also have the duty to ensure that robust, clearly defined outcomes covering both the benefits and the risks of interventions are reported across all studies, minimizing research waste and setting standards for high-quality evidence generation and synthesis across the field of high-risk obstetrics.

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Appendix S1 Search strategy

