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Chapter 7

Identification of essential steps in laser procedure for twin-twin transfusion syndrome using the Delphi methodology: SILICONE study

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ABSTRACT

Objective. To determine, by expert consensus, the essential substeps of fetoscopic laser surgery (FLS) for twin-twin transfusion syndrome (TTTS) that could be used to create an authority-based curriculum for training in this procedure among fetal medicine specialists.

Methods. A Delphi survey was conducted among an international panel of experts (n=98) in FLS. Experts rated the substeps of FLS on a five-point Likert-type scale to indicate whether they considered them to be essential, and were able to comment on each substep, using a dedicated online platform accessed by the invited tertiary care facilities that specialize in fetal therapy. Responses were returned to the panel until consensus was reached (Cronbach's $\alpha \ge 0.80$). All substeps that were rated ≥ 4 by 80% of the experts were included in the evaluation instrument.

Results. After the first iteration of the Delphi procedure, a response rate of 74% (73/98) was reached, and in the second and third iterations response rates of 90% (66/73) and 81% (59/73) were reached, respectively. Among a total of 81 substeps rated in the first round, 21 substeps had to be re-rated in the second round. Finally, from the initial list of substeps, 55 were agreed by experts to be essential. In the third round, the 18 categorized substeps were ranked in order of importance, with 'coagulation of all anastomoses that cross the equator' and 'determination of fetoscope insertion site' as the most important.

Conclusions. A total of 55 substeps of FLS for TTTS were defined by a panel of experts to be essential in the procedure. This list is the first authority-based evidence to be used in the development of a final training model for future fetal surgeons.

INTRODUCTION

A randomized trial, published in 2004, established fetoscopic laser surgery (FLS) as the best treatment modality for twin-twin transfusion syndrome (TTTS).¹ With an incidence of 10% in monochorionic twin pregnancies, TTTS is rare and treatment is offered in a limited number of specialized maternal-fetal medicine (MFM) expert centers around the world.² With the economic growth of developing countries and the identification of new potential indications for FLS, such as twin anemia-polycythemia sequence and selective fetal growth restriction, the expectation is that, in the future, a greater number of FLS procedures will be performed. Objective assessment of technical performance is essential for such complex procedures. In order to maintain optimal performance and quality of care, increasing attention is being given to the teaching, training, retention of skills and quality control of FLS. Even large fetal treatment centers have limited numbers of TTTS cases,³ therefore the teaching and training of this procedure are challenging. Currently, standardized surgical training programs for FLS are unavailable. As surgical errors and suboptimal technique are also yet to be defined, teachers often base their training on personal experience and individual preference. Learning technical skills from an experienced mentor will probably continue to play a significant role in future training. However, there is an increasing need for a standardized tool to train and evaluate trainees. Similar issues have been raised in other invasive obstetric procedures and surgical areas, such as endoscopy.4,5

An essential first step towards the creation of a training curriculum is to determine the items that need to be assessed, preferably by using quality indicators.⁶ These indicators can be derived from the outcomes of studies, historical data and expert opinions. The elements need to be measurable, so they can be used in the assessment of trainees during their learning process, to monitor performance and maintain quality control. Authority-based indicators for FLS can be obtained using the Delphi method for international expert consensus. The Delphi methodology is an internationally-accepted tool that allows a group of individuals to achieve consensus on a complex problem effectively, by structuring the group communication process.^{7,8}

The aim of this study was to achieve expert consensus regarding the substeps that are considered to be essential in performing FLS for TTTS, which can be used as a framework for standardized training. Furthermore, we aimed to create an instrument that could be used to evaluate a surgeon's technical performance during FLS, both in a high-fidelity simulator training model and in real-life situations, and serve as a means for quality control.

METHODS

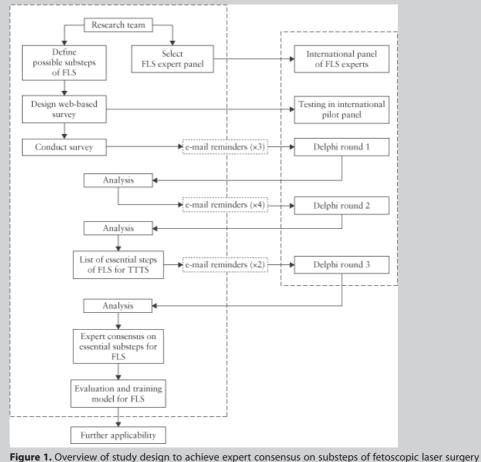
Study design

This study is part of the SILICONE project (SImulator for Laser therapy and Identification of Critical steps of Operation: New Education program), conducted with the aim of developing a standardized training program for FLS in cases of TTTS. In the first part of the project, we intended to develop an evaluation instrument based on the essential steps of treatment. In the second part of the project, not included in this study, the instrument will be validated and used to evaluate a training session that uses a SILICONE simulator.

The Delphi methodology was used to achieve expert consensus on which substeps of FLS performed for TTTS are essential. The Delphi methodology is, in essence, a series of sequential questionnaires or 'rounds', followed by controlled feedback, that seeks to gain the most reproducible consensus among a panel of experts.⁹ Consensus occurs because the views of the participants converge through a process of informed decision-making.⁸ The Delphi method was first developed by the Research ANd Development (RAND) Corporation, a non-profit global policy think-tank, formed in 1950 to offer research and analysis to the USA armed forces.¹⁰⁻¹² It is an anonymous process in which ideas are expressed to the participants in the form of a questionnaire. In repeated rounds, respondents are questioned individually, with self-administered surveys. In each subsequent round, the results of the previous round are provided, thus enabling the range of answers to converge towards a consensus. An overview of the study design is presented in Figure 1.

A panel of experts in FLS was presented with a list of substeps of the procedure and asked to rate each substep, using a Likert scale from 1 (strongly disagree) to 5 (strongly agree), with the level at which they believed the step should be included in an evaluation tool. In addition, all participants were encouraged to clarify their ratings in a comments box. Each round started with a new questionnaire consisting of a list of these substeps. The participation of the FLS experts was not disclosed to the other experts (quasi-anonymity). The total response rate was based on the number of fully completed surveys. We identified an initial list of possible substeps of FLS during the first iteration of the survey from three sources: expert opinion, textbooks on fetal therapy and published peer-reviewed literature. Each substep of FLS that was identified from any of these three sources was included in the survey. Before the first iteration of the study, an international pilot panel meeting took place that consisted of senior FLS experts from several large

international centers, with extensive experience in fetoscopic surgery. They assessed the survey for comprehensiveness and integrity. After taking into account their comments, invitations to participate in the survey were sent out.



(FLS) for twin-twin transfusion syndrome (TTTS) that are essential to the procedure.

Selection of experts

All FLS experts included in the study were selected through membership lists of MFM organizations (Society for Maternal-Fetal Medicine (SMFM), Eurofoetus, USFetus, North American Fetal Therapy Network (NAFTnet), International Fetal Medicine and Surgery Society (IFMSS), International Society of Ultrasound in Obstetrics and Gynecology (ISUOG), World Association of Perinatal Medicine (WAPM), The American Congress of Obstetricians and Gynecologists (ACOG), North American

Society of Obstetrics Medicine (NASOM) and Society of Obstetric Medicine of Australia and New Zealand (SOMANZ)). We defined an expert as someone who currently performs FLS for TTTS. Furthermore, all experts were identified as leaders in the field of fetal therapy as evidenced by their role as opinion leaders within their MFM organizations and supported by their track record of publications in peer-reviewed literature. The expert panel was selected specifically to represent a wide geographic area including Australia, Asia, Canada, Europe, South America and the USA. We invited 98 individuals from 23 different countries to participate. The size of Delphi panels can vary widely and there is disagreement about what constitutes an appropriate panel size. Panel size in Delphi studies is considered to be researcher- and situation-specific. For this study, we aimed to contact the entire international community of MFM specialists who had extensive experience with FLS.

Surveys

Delphi round 1

At the start of the first round, an e-mail was sent to all FLS experts that included: the invitation, background, short instructions and the link to the first survey. Later, for each round, multiple reminders were sent out to non-responders. The first survey consisted of two parts: in Part I (Appendix S1), the participants were asked to rate each possible substep of FLS for TTTS; in Part II, the experience and surgical practices of the survey respondent and of their center were obtained. The estimated time to complete Round 1 was 15 min.

The first round of data was analyzed and results were pooled. Two of the authors (M.W. and S.P.) independently categorized the comments on the basis of the presence of essential elements. For each substep we ascertained if the essential element of the comment consisted of an addition or a substitution to the substep. A third author (J.A.) assessed the categorized comments and the revised substeps independently for clarification and to make sure all further areas were explored. Figure 2 shows how the comments were incorporated into the second round of the survey.

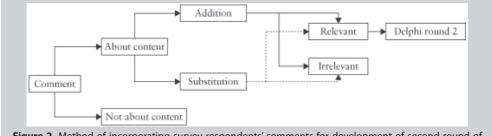


Figure 2. Method of incorporating survey respondents' comments for development of second round of Delphi survey.

Delphi round 2

In the second round, the results of the first round were made available to the FLS experts (Appendix S2).

The second Delphi round was sent out 1 month after the first, to optimize the response rate and ensure that participants remained interested in the process. In accordance with the Delphi method, participants were asked to re-rate substeps for which no consensus had been achieved. In this round, some of the substeps were altered on the basis of the feedback of the FLS experts from the first round. The substeps for which consensus had been achieved in the first round could not be re-rated in the second questionnaire, but were available for review.

Delphi round 3

Based on the results from the first two rounds, a list of all essential substeps of FLS for TTTS was defined. In order to use this final list for evaluation and training with the SILICONE simulator, a third round of the Delphi procedure was carried out to determine the appropriate distribution of importance of the steps. For the purpose of Part 2 of the SILICONE project, only the substeps that could be simulated were included in this round. The included substeps were categorized into 18 items, and those categorized within the domains 'diagnostic procedure', 'presurgical management' and 'follow-up ultrasound examination' were excluded. All respondents rated the level of importance of the 18 categorized substeps on a Likert scale of 0–10, with respect to each other. With this order of importance, we were able to give a certain value to each separate substep, and we incorporated this into the evaluation tool.

Statistical analysis

For this study, the concept of consensus was predefined as a condition of homogeneity or consistency within the opinions of the FLS experts. There are no established criteria for determining consensus using a Delphi methodology.^{6,12}

Cronbach's α was chosen as the statistical index for quantifying the reliability of a summation of entities, in this case the view of the experts in FLS. In this study, an α -value of 0.80 defined an acceptable and high level of consensus.^{6,13}

Rate of agreement

To ascertain whether consensus was reached for each substep separately, the rate of agreement (RoA) was used. The RoA is defined as:

$$RoA (\%) = \frac{(strongly) agree (n) - (strongly) disagree (n)}{(strongly) agree (n) + (strongly) disagree (n) + indifferent (n)} \times 100\%$$

Scaled responses to the categorical items (strongly disagree to strongly agree) were analyzed as percentages (Appendix S2). Feedback to the panel of experts included providing the Cronbach's α score of the previous round, percentages and means of the answers to all items and the RoA for each item separately. After reaching a consensus (Cronbach's $\alpha \ge 0.80$), only the substeps with an RoA of 80% or higher were included in the final evaluation tool. Substeps with an RoA of less than 20% were not reassessed and were removed from the evaluation tool.

In the second round of the Delphi procedure, the substeps with 20% < RoA < 80% were re-rated. After the final round, only items with an RoA $\geq 80\%$ were included in the final evaluation tool. The other substeps were excluded from the list.

Data were collected using our online survey tool, www.deltafetus.nl, and analyzed using SPSS version 21.0 (IBM SPSS Statistics for Windows, Version 21.0, IBM Corp., Armonk, NY, USA).

The study was performed by the Departments of Obstetrics and Pediatrics at the Leiden University Medical Center, Leiden, The Netherlands, in association with Hospital Italiano de Buenos Aires, Buenos Aires, Argentina; Jackson Fetal Therapy Institute, Miami, FL, USA; University of Southern California, Keck School of Medicine, Los Angeles, CA, USA; Liverpool Hospital, Liverpool, Australia; and the University Hospitals KU, Leuven, Belgium. The data were collected between February 2014 and July 2014.

RESULTS

In the first round, a response rate of 74% (73/98) was reached. Table 1 presents a summary of characteristics of the FLS experts. The majority of the participants (77%; 56/73) worked at university hospitals. Most of the responding experts were MFM specialists, a minority (7%; 5/73) were pediatric surgeons. All the experts also performed other antenatal procedures besides FLS for TTTS. Almost all had more than 5 years' experience performing FLS, except for two who had been performing the procedure for only 2 and 4 years, respectively. The mean length of experience with FLS of the participating experts was 10.2 years. The most frequently mentioned teaching centers for FLS were King's College Hospital, London, UK (n=15); University Hospitals KU Leuven, Belgium (n=15); University Hospital Center Paris - Hôpital Necker-Enfants Malades, Paris, France (n=10); and Jackson Fetal Therapy Institute, Miami, FL, USA (n=7).

In the subsequent rounds of the survey, the response rate was 90% (66/73) for round 2 and 81% (59/73) for round 3.

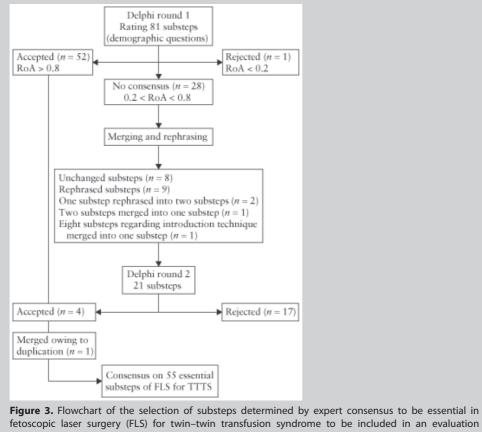
Substeps

After the first round of the Delphi procedure, a Cronbach's α score of 0.911 was reached, and consensus was attained, on 52 of the 81 substeps (Figure 3). In the second round (Appendix S2), the 28 substeps for which no consensus was reached were merged and rephrased into 21 substeps, because, according to most FLS experts, these substeps were not well formulated. One clearly inappropriate substep, 'mark recipient with laser spot on left upper leg', was purposely incorporated into the first survey round as a check for validity. This item was excluded after the first round. After the second round, consensus was reached on another four substeps (RoA \ge 80%). One substep was removed from the final list owing to duplication. Table 2 shows the list of substeps that were included in the evaluation end tool.

Experts	n/N (%)
Type of hospital	
university hospital	56/73 (77%)
private hospital/tertiary care facility	11/73 (15%)
public hospital	5/73 (7%)
other	1/73 (1%)
Medical specialty	
obstetrics and gynecology	6/73 (8%)
pediatric surgery	5/73 (7%)
Maternal Fetal Medicine (MFM)	62/73 (85%)
Antenatal invasive procedures	
amniocentesis	69/73 (95%)
chorionic villus sampling	59/73 (81%)
intrauterine transfusion	64/73 (88%)
fetal shunt placement	62/73 (85%)
bipolar cord occlusion	50/73 (68%)
open fetal surgery	16/73 (22%)
Experience	
years currently working as MFM specialist (mean; range)	17.3 (5.0 - 36.0)
years performing FLS for TTTS (mean; range)	10.2 (2.0 - 25.0)
Number of lasers performed annually	
<10	12/73 (16%)
10-25	27/73 (37%)
25-50	18/73 (25%)
50-100	12/73 (16%)
>100	4/73 (5%)
Centers	n/N (%)
Number of lasers performed annually	
<10	11/73 (15%)
10-25	23/73 (32%)
25-50	18/73 (25%)
50-100	18/73 (25%)
>100	3/73 (4%)
Experience	
years laser performed at center (mean; range)	10.5 (1.0 - 25.0)
no. of surgeons performing laser (median; range)	2 (1 - 5)
no. of trainees (median; range)	1 (0 - 9)

Table 1. Experience and surgical practice and center characteristics of the 73 experts in fetoscopic laser surgery (FLS) who responded to the survey.

MFM: maternal fetal medicine FLS: fetoscopic laser surgery TTTS: twin-to-twin transfusion syndrome



instrument. RoA, rate of agreement.

Some substeps were considered more important than others. 'Coagulation of all vascular anastomoses that cross the vascular equator' and 'determine site of insertion of fetoscope' were items that were considered as most important during FLS. Table 3 shows a list of the 18 most important substeps that can be used for training and evaluation in order of importance.

No.	Domain and substeps
1.	Diagnostic procedure
1.1	Make sure advanced ultrasound scan is performed to exclude fetal anomalies
1.2	Confirmation of monochorionicity, diagnosis, Quintero stage of TTTS
1.3	Consider cervical length measurement
1.4	Consider risk of complications (cervix shortening, fetal deterioration etc)
1.5	Determine whether laser is best treatment option (and consider alternatives)
1.6 1.7	Determine whether laser procedure should be performed as soon as possible or expectant management can be an option Obtain full informed consent
1.7	
2.	Pre-surgical management
2.1	Blood group and Rhesus typing should be known, respect local protocols concerning Rh-D prophylactics
2.2	Prescribe all procedure-related medications (tocolytics, antibiotics etc)
2.3	Determine and arrange type of anesthesia
3.	Preparation in operating room
3.1	Knowledge of technical equipment (ultrasound, scopy tower, laser, instruments)
3.2	Positioning of screens, assistants and lights
3.3	Determine laser modus and power settings
3.4	Positioning of patient
4.	Ultrasound examination (together with sonographer)
4.1	Identification of both fetuses, presentation and position
4.2	Visualize placenta localization, umbilical cord insertions
4.3	Assess deepest pockets of amniotic fluid
4.4	Determine expected position of vascular equator
4.5	Determine site of insertion of fetoscope
4.6	Choose type of introduction (set) and type of fetoscope
5.	Sterile procedure and anesthesia
5.1	Surgical briefing (time out) about (complete) procedure to fetal therapy team
5.2	Aseptic procedure for surgeon, scrub nurse and sonographer
5.3	Monitoring maternal condition (during complete procedure)
5.4	Placement of sterile covers over patient and instruments
6.	Positioning and connection of instruments (pre-insertion)
6.1	Connection of fetoscope (orientation, focus and white balance)
6.2	Connection of laser fiber to laser machine, insertion of fiber in fetoscope
7.	Insertion
7.1	Performance of all manipulations under ultrasound visualization
7.2	In case of local anesthesia: administer anesthetic to skin and peritoneum
7.3	Make adequate-size skin incision with surgical knife
7.4	Correct use of (Seldinger or trocar) technique for insertion

- 7.5 Awareness of location of maternal uterine vessels and intestines, and placental edge during insertion
- 7.6 Insertion of shaft/scope

8. Orientation

- 8.1 Assess visibility (optional: score visibility)
- 8.2 Determine need for amniotic exchange
- 8.3 Confirm position of placenta, fetuses and cord insertions
- 8.4 Identification of intertwin dividing membrane (and use for reference)
- 8.5 Mapping of placental surface and vascular equator

9. Laser coagulation

- 9.1 Coagulation of all vascular anastomoses that cross the vascular equator
- 9.2 Prevent the unnecessary sacrifice of placental tissue

10. Assessment during procedure

- 10.1 Prevent unnecessary delay during procedure
- 10.2 Check for complications(e.g. bleeding, rupture intertwin membranes
- 10.3 Identify and record number and type of anastomoses coagulated

11. Amniodrainage

- 11.1 Controlled drainage of polyhydramnios
- 11.2 Assess adequate drainage (ultrasound guided) until pre-defined level to decrease uterine distention and promote patient comfort

12. Closure

12.1 Closing skin incision (suture or suture free adhesive product)

13. Direct post-operative management

- 13.1 Inform patient, partner/family and referring specialist
- 13.2 Administration (surgical report, fetal therapy database)
- 13.3 Instructions for monitoring of maternal and fetal condition

14. Follow up ultrasound examination

- 14.1 Knowledge of follow-up until delivery of (un)complicated monochorionic pregnancies
- 14.2 Assessment of fetal condition including bladder filling, deepest vertical pockets and Doppler flows
- 14.3 Knowledge of MCA-PSV measurement to detect post-laser TAPS
- 14.4 Signs of iatrogenic perforation of the intertwin membrane
- 14.5 Signs of amnion-chorionic separation
- 14.6 Record which fetus is former donor and recipient, respectively
- 14.7 Knowledge of signs and options with regards to iatrogenic PPROM

Table 2. The 55 essential substeps of fetoscopic laser surgery (FLS), performed in cases of twin-twin transfusion syndrome (TTTS), to be included in an evaluation and training instrument.

FLS: fetoscopic laser surgery TTTS: twin-to-twin transfusion syndrome PPROM: preterm premature rupture of membranes, MCA-PSV: middle cerebral artery peak systolic velocity, TAPS: twin anemia polycythemia sequence.

- 1 Coagulation of all vascular anastomoses that cross the vascular equator
- 2 Determine site of insertion of fetoscope
- 3 Ultrasound identification of placenta, fetuses, umbilical cord insertions and expected vascular equator
- 4 Mapping of placental surface and vascular equator
- 5 Identification of intertwin dividing membrane (and use for reference)
- 6 Prevent the unnecessary sacrifice of placental tissue
- 7 Confirm position of placenta, fetuses and cord insertions
- 8 Choose and prepare type of introduction (set) and type of fetoscope
- 9 Connection of fetoscope and laser equipment (including white balance and orientation of the scope)
- 10 Prevent unnecessary delay during procedure
- 11 Controlled amniodrainage until pre-defined level (to decrease uterine distention and promote patient comfort)
- 12 Placement of sterile covers over patient and instruments
- 13 In case of local anesthesia: administer anesthetic to skin and/or peritoneum
- 14 Identify and record number and type of anastomoses coagulated
- 15 Performance of all manipulations under ultrasound visualization
- 16 Make adequate-size skin incision with surgical knife
- 17 Assess visibility (optional: score visibility)
- 18 Closing skin incision (suture, or suture free adhesive product)

Table 3. The 18 substeps of fetoscopic laser surgery (FLS) for twin-twin transfusion syndrome, determined to be essential by expert consensus, in order of importance.

DISCUSSION

We achieved an international expert consensus on the technical approach and identification of the essential steps of FLS for TTTS. We produced a list of 55 substeps that are deemed to be essential during FLS. All items were ranked in order of importance, with 'coagulation of all vascular anastomoses that cross the vascular equator', 'determination of site of insertion of fetoscope' and 'ultrasound identification of placenta, fetuses, umbilical cord insertions and expected vascular equator' as the most important substeps. This list can be used as a reference guide to improve the standardization of training in fetoscopic techniques.

A large number of FLS experts participated in our Delphi procedure; 74% of all FLS experts worldwide took part in the first round. We were pleasantly surprised by how involved and interested the international group of FLS experts was. The high Cronbach's α score – 0.911 – after the first round of the Delphi procedure confirms homogeneity within the panel of experts.

In 1988, Julian De Lia first performed laser therapy as treatment for severe TTTS.¹⁴ Over the last two decades, the procedure has undergone many changes. The era in which a handful of pioneers performed and personally adjusted fetoscopic laser surgery in their own centers has now moved into a time in which there is a need for a more standardized

approach, enabling the training of many next-generation fetal surgeons worldwide with comparable quality of work. The curriculum suggested here, based on expert consensus, provides the best available basis for such a training program.

Specific operative situations may require deviation from the recommended standard technique. Therefore, strict adherence to the teaching instrument developed may not always be desirable. We suggest that these guidelines should be used primarily as an instrument for training.

Similar research has not been performed previously in fetal therapy. However, in other surgical fields the Delphi methodology has been used to create an authority-based curriculum for evaluation and training.^{5,6} As such, the Delphi methodology has been an effective method of achieving expert consensus in the first phase of developing a training model for laparoscopic surgery.^{6,15}

In this study, FLS items were ranked to determine their order of importance. In the eyes of an expert, some substeps are a natural part of the procedure and are performed automatically, however, for a novice, attention to these substeps is vitally important. By assigning value to the specific elements, we were able to emphasize certain substeps in the list of objectives to attain during training.

The Delphi methodology can be used to develop a curriculum that reflects international consensus as opposed to simply local expertise. Studies employing Delphi make use of individuals who are presumed to have the best knowledge of the topic being investigated. Usually, consensus is only achieved among experts after protracted discussions. The Delphi method does not require the panel to meet, and thus largely avoids these discussions. Also, experts from different geographic locations can be recruited,¹¹ as in this study, which recruited a large panel from 23 different countries. In the Delphi methodology, participants have access to the group's responses, and may change their views in line with what others are saying.¹⁶ Providing a summary of opinions ensures that consensus is reached quickly, by two, or at most three, rounds.⁸ The web-based design speeds up the process, improves feasibility and lowers associated costs. In addition, the anonymous nature ensures that outcomes are not influenced inappropriately by a single dominant group member and allows the opportunity to re-evaluate one's own 'answers'.¹¹

It is important to note that the existence of a consensus does not mean that the correct answer, opinion or judgment has been found,¹⁶ however, by using an expert panel, an acceptable accuracy is created. A potential limitation of the methodology is that the significance of each step, in terms of outcome, is not addressed. Although consensus was reached for a specific substep, this study does not provide information on whether this substep is associated with better or worse outcomes when performed. One of the substeps that did not meet our consensus criteria concerned the laser technique used. In a recent multicenter randomized controlled trial, the Solomon laser technique (complete dichorionization of the vascular equator) was shown to reduce postoperative fetal morbidity in severe TTTS.¹⁷ Although this study provides the highest level of evidence, which might imply that all centers should adopt this new technique, not all experts considered this step to be essential in an evaluation instrument for future fetal surgeons. Moreover, steps such as 'check for limb abnormalities of recipient' and 'determine placental sharing' were considered to be time-consuming rather than contributory, and therefore were not included.

Another limitation is that it is lengthy and quite time-consuming for the facilitator and the participant to take part in a Delphi procedure, compared to a single-round survey. Even though each round took only 5–15 min to complete, not all panel members maintained interest and responded in the second and third rounds of our survey, which is probably related to the relatively time-consuming process and the fact that it was a web-based questionnaire that participants can ignore or avoid more easily.

In summary, attention must be paid to the evaluation and training of fetal surgeons, to maintain a high standard of clinical performance. This study provides a first step towards an authority-based training curriculum and an evaluation tool for FLS performed in cases of TTTS. Further research should focus on the applicability of the instrument in simulator training as well as in real-life situations.

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