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Chapter 3

25 years of fetoscopic laser coagulation in twin-twin transfusion syndrome: a systematic review

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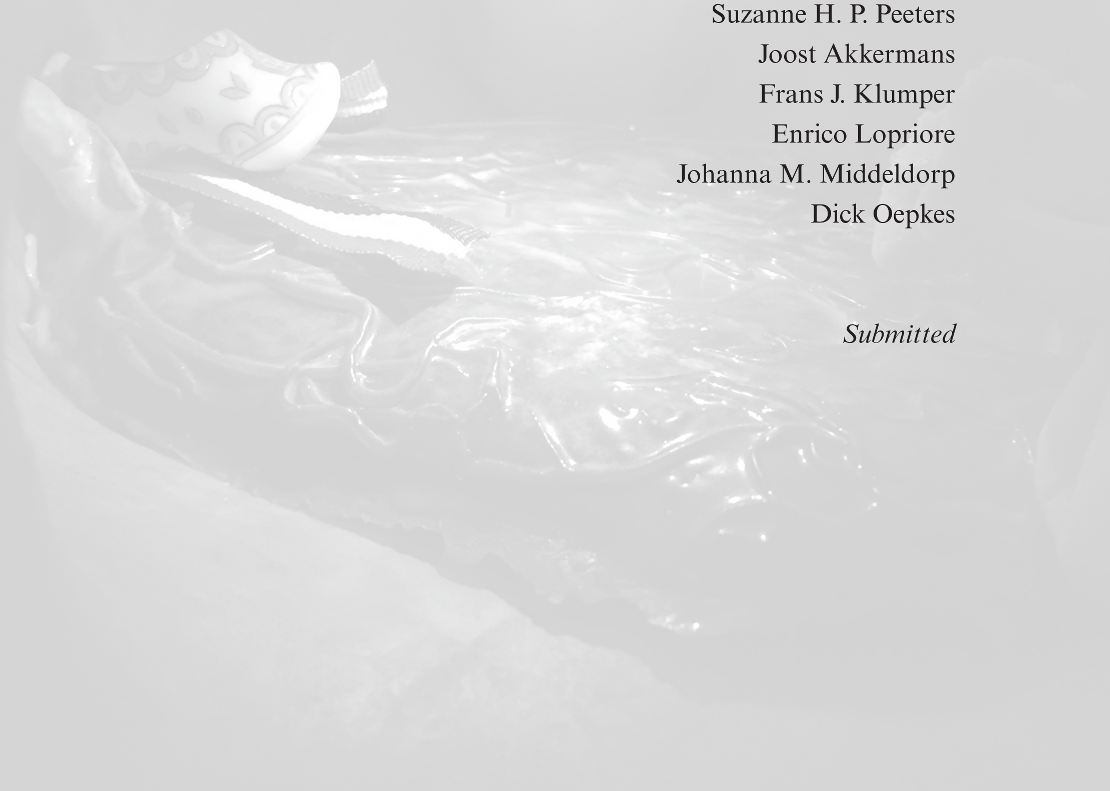
Submitted



ABSTRACT

Background. The aim of this study was to assess the perinatal outcome of pregnancies with TTTS treated with laser therapy over the past 25 years and in relation to different techniques used in this time period.

Data Sources. A systematic review of studies reporting on perinatal outcome according to the MOOSE guidelines was conducted. MEDLINE, Embase and Cochrane databases were systematically searched. Comparisons were made in respect to time period, laser technique and Quintero stages.

Results. In total 34 studies reporting on 3.868 monochorionic twin pregnancies were included. Mean survival of both twins increased from 35% to 65% (p=0.012) and for at least one twin from 70% to 88% (p=0.009) over the past 25 years. Mean gestational age at birth remained stable over the years at 32 weeks' gestation. Also we showed a significantly improved perinatal survival with the evolution of the laser technique from non-selective to selective, selective sequential and the Solomon technique (p=0.010).

Discussion. Since the inception of laser therapy for TTTS more than two decades ago, perinatal survival improved significantly. Improved outcome is associated with several factors including evolution of the laser technique, learning curve effect, better referral and improved early neonatal care.

INTRODUCTION

Monochorionic (MC) twin pregnancies are at a 10% risk of developing twin-twin transfusion syndrome (TTTS),[1,2] due to vascular anastomoses on a shared placenta. Before De Lia et al. proposed fetoscopic laser coagulation of the placental vessels in 1990,[3] serial amnioreduction was considered the only treatment option of polyhydramnios, the most prominent feature of TTTS. Serial amnioreduction was associated with mortality rates up to 60%, a median gestational age at delivery around 28 weeks, and up to 50% severe neurodevelopment impairment in survivors.[4]

Survival significantly improved after the introduction of laser coagulation, by addressing the cause of the problem, making it the accepted treatment of choice for TTTS.[5] However, results are still far from satisfactory, with mortality rates varying from 20% to 48%, and significant complications including iatrogenic preterm premature rupture of membranes (PPROM)[6] resulting in preterm delivery before 32 weeks gestation, twin anemia-polycythemia sequence (TAPS),[7] recurrence or reversal of TTTS[8] and adverse long-term neurodevelopmental outcome in 6-18% of survivors.[9]

Since the first publications on fetoscopic laser surgery, several technical modifications have been described. Coagulation of all vessels crossing the intertwin membrane was abandoned because it led to unnecessary placental loss.[10] In 1998, Quintero et al. introduced the selective laser coagulation technique.[11] This technique, which was rapidly adopted by most fetal therapy centers, aims to save as much functioning placenta tissue as possible by coagulating only true inter-twin vascular anastomoses, instead of every vessel crossing the membranous equator. In 2007 the same group proposed the sequential selective laser coagulation technique.[12]

Sequential selective laser is an adaptation whereby anastomoses are coagulated in a specific order. The aim is to obliterate the anastomoses in a sequence that allows, at least partly, an intraoperative correction of the hypoperfusion of the donor and hyperperfusion of the recipient. This is achieved by first closing the arteriovenous anastomoses from donor to recipient, starting with the largest ones, followed by the closure of the vein-to-artery anastomoses, (e.g. the vessels with a blood flow towards the donor) as the last part of the procedure. In 2008 the Solomon trial[13] was started, introducing a new adaptation to the selective technique. The rationale of the Solomon technique is coagulation of the whole vascular equator from one placenta margin to the other. With the Solomon technique, all laser spots are connected by drawing a laser line, minimizing the chance of residual anastomoses. The study showed that this technique was associated with significantly less residual anastomoses, thereby reducing the risk for TAPS and recurrence of TTTS.

This study focuses on perinatal outcome after laser therapy over the past 25 years, and the impact of the above-mentioned changes in laser treatment strategies on these outcome results. We systematically reviewed all published series since the inception of laser treatment of TTTS with respect to survival, gestational age at birth and procedural or post-operative complications in relation to the time and the laser technique used.

Data Sources

Before conduct of the systematic review a detailed protocol that included the search strategies, inclusion and exclusion criteria, outcome parameters, and methods of statistical analysis was created. This systematic review of literature was performed according to the Meta-Analysis of Observational Studies in Epidemiology (MOOSE)[14], and Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[15] where applicable.

Literature Search

An initial literature search on survival after laser coagulation for TTTS was conducted in MEDLINE, Embase and the Cochrane Library using PubMed and OVID search engines without restriction on the language or type of publication. Keywords and free text searches were performed with combinations of the following keywords: survival, perinatal survival, twin-to-twin transfusion syndrome, TTTS, twin-twin transfusion syndrome, fetofetal transfusion, placental anastomoses, laser, laser therapy, laser ablation, SLPCV, SQLPCV, sequential laser, selective laser, fetoscopy, FLOC and photocoagulation. Additionally, reference sections of eligible studies were hand-reviewed for potential eligible studies. Our search included articles published up to May 2014 that reported on pregnancy outcomes after fetoscopic laser coagulation of placental vascular anastomoses.

Inclusion and Exclusion Criteria

Randomized trials and comparative studies, as well as prospective and retrospective case-series were considered eligible for inclusion. Reasons for exclusion were studies with insufficient or overlapping data, letters, conference abstracts, review articles and case reports.

Selection and Data Extraction

All references were independently screened by two reviewers (J.A. and S.H.P.) Disagreement on eligibility of a study was resolved by discussion until consensus was reached. Studies presenting data on twin pregnancies with confirmed monochorionicity by first trimester ultrasound, affected by TTTS according to the Eurofoetus criteria[16], or the Quintero criteria[17] treated with fetoscopic laser coagulation of vascular anastomoses were included.

Studies were selected when presenting at least the number of patients treated and either survival rate of both twins, survival rate of one twin, survival rate of at least one twin or gestational age at birth. Other important parameters were complications, such as PPROM, gestational age at laser and laser technique used. In the sporadic event that study results contained also outcomes of triplets (e.g. monochorionic twins affected by TTTS and a singleton) we used the perinatal outcome results of the twins for analysis.

To prevent double counting of cases, we excluded studies reporting outcomes from pregnancies that were treated in overlapping years with other published series from the same centers.

Differences in dual survival, single survival and at least one survival, as well as gestational age at birth were analyzed on a timeline. Five-year intervals were chosen to analyze studies over time. For categorization we used the year the study was concluded as a cut-off value. Survival was analyzed per laser technique used in the series to show the impact of the proposed technical adaptations of the laser treatment. Furthermore, we combined results of all series reporting on survival results per Quintero stage to evaluate stage-based outcome.

Statistical Analysis

Continuous variables were reported as the median (range) or mean (SD), for synthesis of data medians (range) were recalculated as means (SD) using the method described by Hozo et al.[18]

Results of multiple groups were compared using analysis of variance (ANOVA) statistics. Results of categorical variables were compared using Fisher exact test or $\chi 2$ test, as appropriate. Student *t* test was used to compare normally distributed values between 2 groups. The Mann-Whitney U test was used to compare nonparametric variables. A p value <0.05 was considered to indicate statistical significance.

Statistical analysis was performed using SPSS (IBM SPSS Statistics 20 for Windows, New York: IBM, 2011.) and MS Excel (Microsoft Excel 2010. Redmond, Washington: Microsoft, 2010). Being a literature review, no approval from our Ethics Committee was needed before performing this study.

RESULTS

Flow of study inclusion

Figure 1 shows a flow diagram according to the Quality of Reporting of Meta-analyses-statement[15] with the total number of citations retrieved by the search strategy and the number included in the review. After full-text analysis a total of 34 studies were included in the time-based analysis.[10,12,13,19-49] Twelve studies[5,50-60] presented data overlapping other series of which three presented data relevant for either the technique, or stage based analysis.[56,59,60] These three studies did not overlap other series in stage-based or technique-based analyses and were included in our analysis.

Study Characteristics

The characteristics of all included studies are shown in table 1. One of the studies enrolled was a randomized controlled trial;[13] there were 13 prospective single center cohort studies,[10,12,19-21,23-27,29,31,33] 18 retrospective single center cohort studies,[28,30,32,34-45,47,48,60] two prospective multicenter cohort studies[22,59] and three retrospective multicenter cohort studies.[46,49,56]

The studies were from United States, Belgium, Australia, Canada, Spain, Poland, Italy, Taiwan, Germany, The Netherlands, Denmark, United Kingdom, France, Japan, Mexico, Brazil, China and Chile. The primary outcomes; perinatal survival of at least one or both twins and gestational age at birth, were well defined in all included studies.

There were three non-English language articles.[35,36,41] Language skills of the authors and co-workers (Chinese) were sufficient to analyze the articles.

Three authors described their series in two separate cohorts in order to display their learning curve.[21,40,43] Eight studies compared different (adaptations of) laser techniques.[12,13,21,22,31,47,49,59] Baud et al. compared outcomes of early, late and conventional selective laser surgery defined as performed before 17 weeks gestation, after 26 weeks gestation and between 17 and 26 weeks.[48]

For the stage-based analyses we replaced the Quintero stage I cases from the study by Middeldorp et al.[26], with the series of Wagner et al.[60] from our center to have the most current non-overlapping results. Furthermore the series of Quintero et al. was replaced by the study of Chmait et al. for this analysis because of overlap and the latter presenting more data.

For the overlapping series of Nakata et al.[59] and Murakoshi et al.[42], we used the latter for the time-based analysis and the selective series from Nakata for the technique-based analysis. For the study of Liu et al. it was unclear what technique was used and therefore it was excluded in the technique-based analysis.[41]

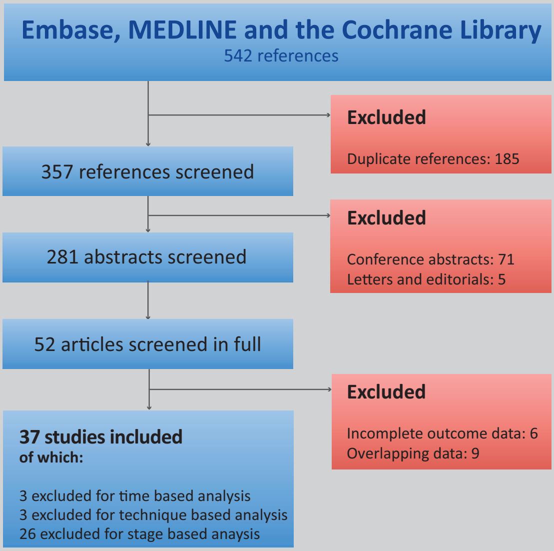


Figure 1 Flow chart of study selection according to the MOOSE guideline.

Author and year	N	Inclusion period	Type of study	Dual survival (%)	GA at birth (weeks mean/SD)	Comments
De Lia 1995	26	1988-1994	Prospective single center cohort	35	32.2 (2.8)	
Ville 1995	45	1992-1994	Prospective single center cohort	36	35.0 (3.8)	
De Lia 1999	67	1995-1998	Prospective single center cohort	57	30.0 (5.0)	
Hecher 2000 ¥*	200	1995-1999	Prospective single center cohort	48	34.0 (2.7)	Early versus late series to show learning curve effect
Quintero 2000 ¥*	89	1994-1999	Prospective multicenter cohort	39	32.0 (2.5)	Non-selective laser versus selective laser
Gray 2006 ≠	31	2002-2003	Prospective single center cohort	39	34.0 (4.5)	
Huber 2006 ≠	200	1999-2003	Prospective single center cohort	60	34.3 (2.9)	
Ierullo 2007	77	2002-2006	Prospective single center cohort	40	NA	
Middeldorp 2007 ≠	100	2000-2004	Prospective single center cohort	58	33.0 (3.7)	
Quintero 2007 ¥	193	2003-2005	Prospective single center cohort	65	33.7 (4.0)	Sequential laser versus standard selective laser
Sepulveda 2007 ≠	33	2003-2006	Prospective single center cohort	27	32.0 (3.8)	
Stirneman 2008	287	1999-2005	Retrospective single center cohort	42	32.0 (3.6)	
Cincotta 2009 ≠	100	2002-2007	Prospective single center cohort	66	31.0 (3.2)	
Nakata 2009 ¥	52	2002-2006	Prospective multicenter cohort	50	32.0 (4.2)	Excluded for time based analysis but included for technique based analysis due to overlap.
Ruano 2009 ≠	19	2006-2008	Retrospective single center cohort	26	32.1 (3.0)	
Wagner 2009 ≠	20	2000-2007	Retrospective single center cohort	65	33.0 (5.0)	Excluded for time and technique based analysis but included for stage based analysis due to overlap.
Chmait 2010 ¥	99	2006-2008	Prospective single center cohort	68	32.2 (4.5	Sequential laser versus standard selective laser
Meriki 2010 ≠	75	2003-2008	Retrospective single center cohort	60	32.0 (2.7)	
Morris 2010	164	2004-2009	Prospective single center cohort	38	33.2 (1.3)	
Yang 2010	30	2002-2008	Retrospective single center cohort	60	32.0 (4.0)	
Chmait 2011 ≠	680	2002-2010	Retrospective multicenter cohort	67	32.3 (4.4)	Excluded for time and technique based analysis but included for stage based analysis due to overlap.

Delabaere 2011	49	2006-2008	Retrospective single center cohort	59	32.0 (2.6)	Article in French
Hernandez-Andrade 2011	35	2008-2009	Retrospective single center cohort	49	32.0 (3.7)	Article in Spanish
Lombardo 2011	70	2000-2010	Retrospective single center cohort	59	32.1 (NA)	
Tchirikov 2011	80	2006-2011	Retrospective single center cohort	78	33.8 (3.2)	Use of 1mm optic versus 2mm optic
Weingertner 2011	100	2004-2010	Retrospective single center cohort	52	32.6 (3.8)	
Chang 2012 *	44	2005-2010	Retrospective single center cohort	50	30.6 (5.9)	
Liu 2012	33	2003-2010	Retrospective single center cohort	52	31.0 (6.0)	Excluded in technique based analysis due to unclear technique. Article in Chinese
Murakoshi 2012 ≠	152	2002-2010	Retrospective single center cohort	63	33.0 (NA)	
Rustico 2012 *	150	2004-2009	Retrospective single center cohort	41	32.1 (2.2)	
Sundberg 2012 ≠	55	2004-2010	Retrospective single center cohort	35	34.8 (4.0)	
Swiatkowska-Freund 2012	85	2005-2010	Retrospective single center cohort	45	32.0 (2.5)	
Valsky 2012	334	2006-2009	Retrospective multicenter cohort	68	33.2 (3.0)	GA at laser 16-26 weeks versus >26 weeks
Baschat 2013 ¥	147	2005-2011	Retrospective single center cohort	60	32.6 (3.5)	Selective laser versus Solomon laser
Baud 2013	325	1999-2012	Retrospective single center cohort	63	31.3 (4.0)	GA at laser <16 weeks versus 16-26 weeks versus >26 weeks.
Ruano 2013 ¥	102	2010-2012	Retrospective multicenter cohort	65	31.6 (4.4)	Selective laser versus Solomon laser
Slaghekke 2014 ¥	272	2008-2012	Multicenter RCT	62	32.3 (3.3)	Selective laser versus Solomon laser

Table 1 Included studies in the review. *These studies described more series over different time periods and were split up in the time-based analyses. ¥These studies described comparisons between different techniques. ≠These studies described their outcome results per Quintero stage.GA= gestational age.

Primary Outcome

A total of 3.868 women with a MC twin pregnancy complicated by TTTS treated with fetoscopic laser coagulation were included in the time-based analysis, the sample size per study ranged from 19 to 334 women. The median time span of study inclusion for all studies was 4 years (interquartile range (IQR): 2-6).

Mean gestational age at time of surgery was 20.9 weeks (±1.9).

Combining all series, the mean perinatal survival of both twins, one twin and at least one twin were respectively 53.7% (SD 14.8), 29.5% (SD 10.5) and 83.2% (SD 8.3). Overall survival of fetuses was 5.348/7.736 (69.1%). Figure 2 displays a timeline of the average perinatal survival of all studies based on their study period.

For both twins, survival rates significantly increased from 35% (1990-1995) to 65% (2010-2014) (p=0.012) and survival rates for at least one twin significantly increased from 70% (1990-1995) to 88% (2010-2014)(p=0.009). No significant change in survival of one twin was seen between 1990-1995 (35%) and 2010-2014 (23%)(p=0.248).

The overall mean gestational age at birth of all series was 32.4 weeks (SD 1.3). Figure 2 shows a timeline of the mean gestational age at birth of all studies. Gestational age at birth did not change in time for the included series (p=0.226).

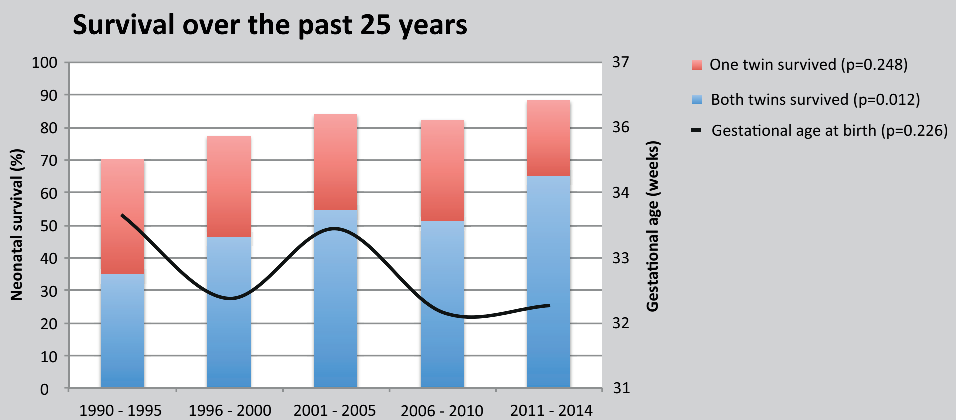


Figure 2 Survival results over a 25-year period of laser therapy for TTTS and mean gestational age at birth development.

Laser Technique

Thirty-four studies clearly specified their laser technique and eight of these studies compared two groups for which different laser techniques were used.[12,13,21,22,31,47,49,59] These groups were analyzed separately resulting in 42 subgroups describing survival results for

different laser techniques. The non-selective laser technique was used in five series,[10,19-22] 28 series used the selective laser technique,[12,21-40,43,44,46-49,59] selective sequential technique was used in six series[12,13,31,42,45,59] and three series used the Solomon technique.[13,47,49]
Figure 3 shows the results on perinatal survival for each technique. Survival of both twins improved significantly (p=0.010) over the course of introduction of new or modified techniques to the detriment of survival of only one twin (p=0.028). Overall a gradual improvement of survival at least one twin is seen for newer techniques (p=0.004).

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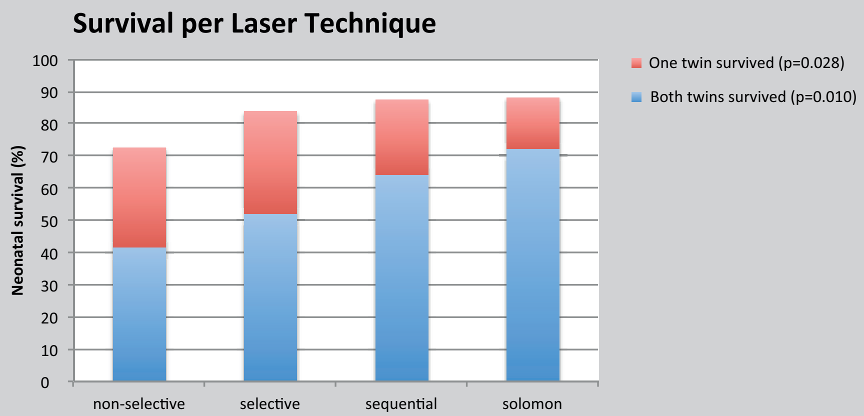

Figure 3 Laser technique based perinatal survival results

Quintero Stage

Eleven series reported perinatal survival by Quintero stage with a combined number of 1.451 pregnancies.[23,24,26,27,29-32,42,44,56,60] Most series presented data for Quintero stage I to IV (n=6).[24,26,32,42,44,56] Three studies presented data for stages II to IV.[23,27,29] Ruano et al.[30] only reported on stages III and IV, and Wagner et al.[60] only reported on stage I TTTS. The results for combined stage based outcomes after laser treatment are shown in figure 4. Although a trend was seen in decrease of survival with higher stages, no significant differences exist between Quintero stages in respect to survival of both twins (p=0.072), only one twin (p=0.081) or at least one twin (p=0.277).

Complications

Reports on post-treatment complications after laser therapy were not readily available in all studies. Only 12 (33%) of the included studies reported data on PPROM. Definitions ranged from '<37 weeks gestation' to 'within 7 days after fetoscopy' making comparison of these results impossible.[13,28,30,32,33,36,37,39,40,43,47,48]

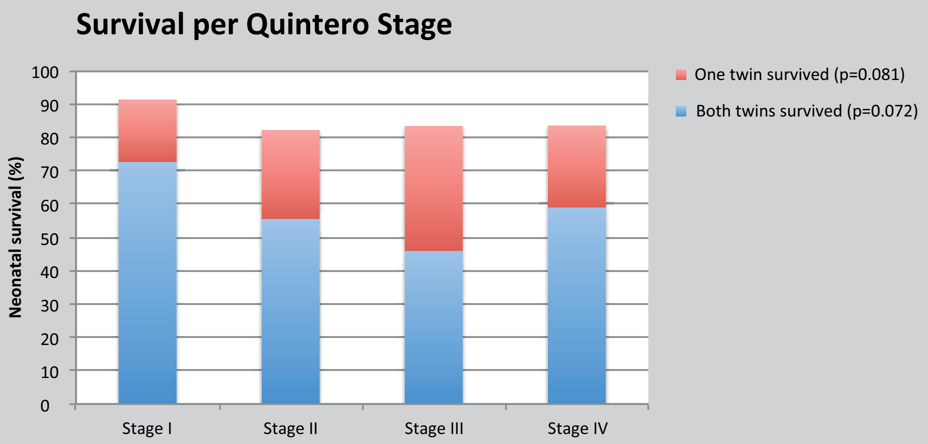

Figure 4 Quintero stage based perinatal survival results of 1.451 laser treated MC pregnancies.

DISCUSSION

In this review of all published series reporting on outcomes after fetoscopic laser treatment for TTTS, we found a significant improvement of survival of both twins and at least one twin over the past 25 years. This study also shows a significant improvement in survival of both twins with the more recently developed laser techniques. In 1990, De Lia et al. published the first results of fetoscopic laser therapy as an alternative for serial amnioreduction for the treatment of TTTS.[3] Since then the technique has undergone a variety of modifications.

There are several hypotheses to explain the improvement in perinatal survival after laser treatment in time. First of all, adaptations in laser technique such as indicated above are likely to affect survival, however the only way to demonstrate this true effect is to perform a randomized controlled trial adequately powered for perinatal survival.

Secondly, an important factor affecting treatment results is the learning curve effect. In principle, novice surgeons are assumed to perform surgery less safely and efficiently than more experienced colleagues. A learning curve represents the improvement of both the operators, from experience and practice, and, equally as important, the performance of the entire team at managing pregnancies with TTTS. Better teamwork, multidisciplinary discussion with colleagues from the neonatology department (including international audits), stimulation, controllability, and continuity may have been beneficial factors.[58]

Furthermore, since laser therapy has been accepted as the preferred treatment option knowledge and awareness in remote centers not offering this highly specialized treatment, has grown. Increased awareness may have resulted in improved timely referral and decreasing number of cases with advanced disease and poor outcomes.

With the acceptance of laser surgery as the best treatment thus far, over the years increasing number of centers started to offer this procedure. Since TTTS is rare, and both the surgical procedure as well as careful selection of cases and optimal timing of treatment is complex, concentration of care in specialized MFM centers has been advocated. With the most recent survival rates as a benchmark, (real time) monitoring and quality control are essential to prevent that a more widespread use of this technique, at least temporarily, leads to less favourable outcome due to learning curve effects and small numbers.

The finding that newer techniques have better perinatal survival results could be attributable to a true improvement in the technique. However this effect could be positively affected by the fact that new techniques are, in general, introduced and adopted sooner by the more experienced therapists after completion of their learning curve and thus likely perform better. Another important factor influencing this improved survival is based on case selection in series comparing two techniques which was evident in some studies on the sequential laser technique.[61]

With this study we hope to set a benchmark level, which established and starting centers can use to compare their individual results with. Regular structural reflection on ones' own practice is essential to prevent late detection of suboptimal performance. If less favorable outcomes are noticed, a quality cycle including further education, supervision of practice and improvement of learning environment should be initiated. We encourage starting up centers, as well as established centers, to share their performance for peer review and publish their series in order to keep updating the benchmark for other centers.[62]

Reviewing the Quintero stage-based outcome after laser treatment showed a non-significant trend in decreased survival of both twins with progression of stage, except for stage IV disease. We hypothesize that this could be explained by the low number of stage IV cases per series and possible case selection of high-risk cases by more experienced therapists.

Unfortunately, data on post treatment complications such as TAPS, recurrent TTTS or PPROM, were often not available in the reported studies or lacked uniform definitions. Iatrogenic PPROM is generally assumed to be one of the most important causes of premature delivery after laser therapy.[6] To gain better insight in the important complications of laser treatment it is imminent that we use systematic methods of reporting. Incidences are low and knowledge is largely based on small series. In order to conduct systematic reviews in these areas definitions need to be uniform when it comes to perinatal survival (e.g. alive at 28 days after birth), PPROM (e.g. before 32 weeks gestation), TAPS and recurrent TTTS.

This study has some limitations. Our findings could be influenced by publication bias. Centers that are still in their learning curve, or otherwise have less favorable results might be hesitant to publish their series when they underperform compared to the published series of established centers.

The past decades have also shown significant improvements regarding (early) neonatal care resulting in overall better outcomes after preterm birth.[63-65] The effect of the above mentioned factors are very difficult to quantify and should be taken into account when interpreting the results of this study.

Another limitation is the inclusion of series that have a large time span of data collection. This might have decreased the differences in survival over time when later series include the learning curve phase of the center. Evaluation of technical or other adaptations of surgical techniques using historic controls is hampered by bias caused by increasing experience over time, the learning curve effect and improved neonatal care.

Treatment of TTTS yielded a fair improvement in perinatal survival with the introduction of laser surgery over two decades ago. This review shows a significant increase in perinatal survival since then. Combining all published series, as a benchmark, perinatal survival of at least one twin after laser therapy can be achieved in 83% of pregnancies, and survival of both twins in 54% of pregnancies. The median gestational age at delivery in these series was 32.4 weeks. Nevertheless, we believe significant improvement opportunities prevail and we see challenges in improving instrumentation and technology for the treatment of TTTS to increase survival of both twins and, almost equally important, in prolonging pregnancies beyond 34 weeks' gestation. Survival and short-term neonatal morbidity should not be the only goals. The ultimate goal should be "disease-free survival" and focus on reducing the rate of neurodevelopmental impairment. We suggest institutions to focus on long-term pediatric neurodevelopmental outcomes. Follow-up into childhood is indispensable to determine outcome in terms of motor, cognitive and behavioral development.[66]

Fetoscopic laser treatment is often hindered by technical difficulties such as reduced visibility due to stained amniotic fluid or poor accessibility of some anastomoses due to placenta location or the position of fetal parts on the vascular equator.[67] Possibly, such limitations may affect the outcome results of the treatment. Technological innovations may aid us to overcome these limitations and help us improve our outcomes. Remarkably, technological innovations in instrumentation and equipment, common in in the field of laparoscopic surgery, appeared to be virtually absent in the fetoscopic treatment of TTTS. The equipment used 25 years ago is almost identical to what we use today. A lack of interest from commercial companies paired with complicated licensing issues for use in pregnancy may play a role.

ACKNOWLEDGEMENT

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