

DOI: <http://dx.doi.org/10.18203/2320-1770.ijrcog20203971>

Original Research Article

## Utility of prophylactic cervical cerclage in intra-cytoplasmic sperm injection twins: a prospective study

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**Received:** 06 July 2020

**Revised:** 28 August 2020

**Accepted:** 29 August 2020

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### ABSTRACT

**Background:** Several interventions have been used to reduce the rate of preterm birth and prolonging gestation in a twin pregnancy and routine usage of cervical cerclage in twin pregnancy conceived after intra-cytoplasmic sperm injection (ICSI) procedure has found to be beneficial.

**Methods:** Prospective case series studies, series of expectant mothers with twin pregnancy conceived by ICSI were studied under tertiary care hospital setting. A total of 108 cases with twin pregnancy were included during a period of 2016 to 2019. Obstetric profile of all the cases was taken; cervical cerclage procedure was done at 14-16 weeks of gestation (McDonald method) after a normal nuchal translucency scan and a double marker test. Pregnancy outcome parameters like abortion, preterm labour/delivery, premature rupture of membranes (PROM), and mode of delivery, gestational age at delivery, birth weight and neonatal complications were assessed.

**Results:** Mean age of the mothers was  $30.61 \pm 4.45$  years, rates of the pregnancy outcome parameters were abortion 0%, preterm labour 11.1%, premature rupture of membranes (PROM) 9.3%, mean gestational age at delivery was  $34.56 \pm 1.71$  weeks. Neonatal outcome parameters were mean birth weight was at  $2279 \pm 470$  grams, 77.8% of the neonates had normal APGAR scores. The rates of NICU admission was 28%, RDS- 24.1%, 3.7% had sepsis and 92.6% of neonates survived and 7.4% died.

**Conclusions:** In ICSI twin pregnancies with normal cervical measurements, prophylactic cervical cerclage is effective in prolonging pregnancy and preventing preterm delivery and thereby minimizing neonatal morbidity and mortality.

**Keywords:** Prophylactic cervical cerclage, Twins, Intra-cytoplasmic sperm injection, Pregnancy outcome

### INTRODUCTION

In the recent years, with the advent of various fertility treatments the rate of multiple pregnancies represents a high proportion of total deliveries.<sup>1</sup> With the use of assisted reproductive techniques (ARTs), the twinning rates has increased in many countries, and undeniably the incidence of preterm birth also increased with the high rate of twin.<sup>2</sup>

With a prevalence of less than 2% of all pregnancies, twin pregnancies account for more than 25% of spontaneous early preterm births.<sup>3,4</sup>

Preterm labour and low birth weight were found to be higher in intra-cytoplasmic sperm injection (ICSI) twins compared to spontaneously-conceived twins after matching or controlling for at least maternal age.<sup>5,6</sup>

Meticulous surveillance during pregnancy should be considered for ICSI twin pregnancies because antenatal

and neonatal complications were found to be higher in ICSI pregnancies than spontaneous pregnancies.<sup>7,8</sup> The increased rate of complications in ICSI twins is still unclear and many explanations owed these complications to either assisted reproductive techniques, characteristics of the infertile couple, or underlying infertility.<sup>9</sup>

Preterm delivery is the most important determinant of neonatal morbidity and mortality. The risk of preterm birth is 8-9 times more in twin than in singleton pregnancy.<sup>10</sup> Therefore twin pregnancy is considered as high-risk pregnancy and every effort should be made to prolong the pregnancy in order to reduce the perinatal complications.<sup>11</sup>

Several interventions have been used to reduce the rate of preterm birth in a twin pregnancy, such as bed rest, prophylactic tocolysis, nutritional advice, administration of 17 $\alpha$ -hydroxyprogesterone caproate, vaginal progesterone, cervical pessary, and cervical cerclage (CC). Unfortunately, these interventions have shown mixed results in reducing the risk of preterm birth in twin pregnancy in different settings.<sup>12</sup> In spite of the advance in modern obstetric practice, preterm labour remains a difficult problem to prevent, stop or even delay in higher-order pregnancies.<sup>13,14</sup>

Moreover, routine prophylactic CC has been approached as a policy for prolonging gestation, and some evidence exists suggesting that its routine use in twin pregnancies is beneficial.<sup>15</sup> The purpose of this study is to evaluate the utility of prophylactic cervical cerclage for preventing preterm birth in twin pregnancies conceived by ICSI.

The objective of the study was to study the utility of prophylactic cervical cerclage for prolonging gestation and preventing preterm birth in twin pregnancy conceived by ICSI technique.

## **METHODS**

### ***Study design and study setting***

A prospective case series study was done where in a series of expectant mothers with twin pregnancy conceived by intra-cytoplasmic sperm injection (ICSI) were studied under tertiary care hospital setting (Mathrutva Fertility Centre, Bengaluru, Karnataka, India).

### ***Study population and sample size***

All women with twin pregnancy following ICSI procedure in our hospital for prophylactic vaginal cervical cerclage were included in the study. A total of 108 cases with twin pregnancy were included during a period of 2016 to 2019. Cases with malformed babies, cervical lesions, polyp or laceration, previous cervical surgery, threatened abortion with vaginal bleeding,

patients with active cervicitis and patients with medical disorders were excluded from the study.

### ***Study variables***

Maternal information data variables related to clinical profile and obstetric profile of the women like age, type of infertility, duration of infertility, previous obstetric history (if present), need for hospitalization and duration of admission, occurrence of preterm labour and its time, time of membrane rupture (premature preterm rupture of membranes PROM) and the need for adjuvant drugs such as antibiotic or tocolytics were recorded. Fetal complications e.g. intrauterine growth restriction (IUGR), fetal demise and twin to twin transfusion syndrome, gestational age at delivery, and type of delivery (vaginal or caesarean) were recorded.

New born information includes neonatal study variables included birth weight, Apgar score (mean of Apgar score at 1 and 5 minutes), common conditions of neonatal mortality and morbidity and the need for neonatal ICU and therapies like ventilation, blood transfusion and phototherapy were recorded for each twin.

Follow up study variables was conducted for all patients every 2 weeks till 28weeks then weekly till delivery by reviewing symptoms of preterm labour, PROM, bleeding, fever or vaginal discharge. Examination was done to check for general condition and any signs of infection. The wellbeing of the fetus was monitored regularly through ultrasound studying the biophysical profile. Monitoring for infections every 2 weeks by (C- reactive protein and total leucocytic count) was performed to detect signs of infection and a vaginal swab taken to rule out cervicitis or vaginitis before putting the stitch.

### ***Intervention***

Cervical cerclage procedure was done at 14-16 weeks. Under general anaesthesia and empty bladder, vaginal cerclage (McDonald method) including 4 bites in the cervix all around at the level of internal os without bladder mobilization avoiding 3 and 9 o'clock to prevent suspected bleeding due injury of cervical branches of uterine artery. The used suture was (mersilene tape) which is a sterile non-absorbable polyester tape, 50 cm in length, 5 mm width with double needles to minimize infection. Antenatal corticosteroids, (betamethasone 12 mg 2 doses 24 hours apart) were administered intramuscularly at 28 weeks. Cerclage stitch was removed if PROM occurred, established preterm labour or when pregnancy reached 37 weeks.<sup>16</sup>

### ***Ethical clearance***

The ethical clearance for the conduct of the study was taken from the institutional ethical committee.

### Statistical analysis

The collected data of study variables was entered into an excel sheet and after appropriate data filtration, the data sheet was transferred and analysed using SPSS software version 20.0. Descriptive statistics like percentages, rates, mean and standard deviation were used to describe the data. The rates of different outcome variables were compared among women with history of preterm, abortion versus women without such history and the difference in rates was tested using inferential statistics like Chi-square test and Student t test and a P value of less than 0.05 was considered to be statistically significant.

### RESULTS

A total of 108 women with twin pregnancy conceived after ICSI procedure were included in the study over period of four years in our hospital (Table 1).

**Table 1: Study of the obstetric profile (n=108).**

Variable	Frequency	Percentage
<b>Age group (in years)</b>		
<20	02	1.9
20-25	10	9.3
26-30	42	38.9
>30	54	50.0
Mean±SD		30.61±4.45
<b>Type of infertility</b>		
Primary	52	48.1
Secondary	56	51.9
Mean±SD (in years)		5.29 ± 2.99
<b>Previous obstetric history</b>		
Abortion	32	29.6
Preterm labour	10	9.3
Ectopic pregnancy	06	5.6
IUD	04	3.7
Previous uterine surgery	07	6.4

The obstetric profile of the patients revealed that the mean age of the women was at 30.61 years where 50% of them were in aged more than 30 years. All the patients had history of infertility where 48.1% of them had primary and 51.9% had secondary infertility. Previous obstetric history revealed that nearly 30% (32 cases) of them had history of abortion, 9.3% (10 cases) of them had history of preterm labour, 6 cases had history of ectopic pregnancy, 4 cases of intra uterine death (IUD) and 7 cases had undergone uterine surgery (Table 1).

Cervical cerclage was done during 14-16 weeks of gestation and regular antenatal follow ups were under taken which revealed that 27.8% (30 cases) of them required hospitalization with a mean duration of 13.2±1.3 days. Some of the patients developed preterm labour (11.1%) and premature rupture of membranes (9.3%)

during the antenatal period. None of the patients had abortion during this period. (Table 2)

**Table 2: Pregnancy outcomes (n=108).**

Outcome variable	Frequency	Percentage
<b>Maternal</b>		
Abortion	00	00.0
Preterm labour	12	11.1
PROM	10	09.3
Hospitalization	30	27.8
<b>Mode of delivery</b>		
Elective LSCS	68	63.0
Emergency LSCS	38	35.2
Vaginal delivery	02	01.9
<b>Gestational age at delivery</b>		
Early preterm (<34 wks)	32	29.6
Late preterm (34-37 wks)	10	09.3
Term (>37 wks)	06	05.6
Mean±SD (weeks)		34.56±1.71
Range (weeks)		30– 38

Majority of them were delivered by caesarean section (98%) where in 63 cases underwent elective LSCS and 38 cases underwent emergency LSCS for known indications. Only in 2 cases babies were delivered vaginally. In about 75.9% (82 cases) of the cases were late preterm deliveries, 20.4% (22 cases) cases were early preterm deliveries and 3.7% (4 cases) were term deliveries. The mean gestational age at the time of delivery was at 34.56±1.71 weeks (Table 2).

**Table 3: Neonatal outcomes (n=216 neonates).**

Outcome variable	Frequency	Percentage
<b>Birth weight (gms)</b>		
<1500	18	8.3
1500 to <2500	128	59.3
≥2500	70	32.4
Mean±SD		2279±470
Range		750-2900
<b>Apgar score</b>		
<7	48	22.2
≥7	168	77.8
<b>Neonatal morbidity</b>		
NICU admission	60	27.8
RDS	52	24.1
Neonatal Sepsis	8	3.7
Neonatal jaundice	52	24.1
<b>Neonatal mortality</b>		
Died	16	7.4
Survived	200	92.6

Neonatal outcome parameters were assessed and it was noted that the mean birth weight was at 2279±470 grams, where in neonates having normal birth weight was 32.4% (70 neonates), 59.3% (128 neonates) had low birth weight and 8.3% (18 neonates) had very low birth weight. Most of the neonates had normal Apgar scores (77.8%).

Morbidity profile of the neonates revealed that 27.8% (60 neonates) were admitted in NICU, 24.1% (52 neonates) had respiratory distress syndrome (RDS) and similar proportion of neonates had jaundice and 8 neonates had neonatal sepsis. Out of 216 neonates born to 108 mothers, 200 survived (92.6%) and 16 (7.4%) of them died (Table 3).

## DISCUSSION

With availability of plethora of options in assisted reproductive technologies (ART), the incidence of twin pregnancy is steadily increasing and ICSI is one of the ART methods which is used in cases of infertility. Twin pregnancy is high risk pregnancy associated with many complications and These complications are even more if these pregnancies are the result of ART procedures rather than spontaneous pregnancies.<sup>17,18</sup>

Preterm labour (PTL) is by far the most common complication in these patients due to over distension of the uterus and leads to prematurity with its adverse sequelae on new-borns. Several interventions have been used to reduce the rate of preterm birth in a twin pregnancy, such as bed rest, prophylactic tocolysis, nutritional advice, administration of  $17\alpha$ -hydroxyprogesterone caproate, vaginal progesterone, cervical pessary, and cervical cerclage (CC). Unfortunately, these interventions have shown mixed results in reducing the risk of preterm birth in twin pregnancy in different settings.<sup>12,19-21</sup>

However, in the recent studies it has been shown that cervical cerclage is effective in prolonging the pregnancy and reducing preterm delivery in twin pregnancies conceived by ART methods and thereby preventing the associated complications both maternal and neonatal.<sup>16,22</sup>

Similarly, this study was done among 108 women with twin pregnancy conceived by ICSI procedure. However, there were no controls in our study. The outcome parameters are discussed as follows-

### ***Prolonging the duration of pregnancy and rate of preterm births at <32 weeks***

In this study the mean gestational age at the time of delivery was at  $34.56 \pm 1.71$  weeks and preterm births at less than 32 weeks were only 4 cases (3.7%). The study results were in consonance with other studies conducted elsewhere.<sup>16,22-24</sup>

In a study done by Michelle et al showed that The rates of spontaneous preterm birth <32 weeks were 10.4% with cerclage and after adjusting for various study variables, in the cerclage group there was a significant reduction of spontaneous preterm birth <32 weeks (adjusted odds ratio (aOR) 0.24, CI 0.06–0.90,  $p=0.035$ ), spontaneous preterm birth <36 weeks (a OR 0.34, CI 0.04–.81,  $p=0.013$ ). In a similar study by Houlihan, et al in the prediction of

spontaneous delivery <32 weeks, logistic regression analysis demonstrated that the risk was reduced with the insertion of cervical cerclage (odds ratio, 0.22 (95% CI, 0.058–0.835);  $p=0.026$ ).<sup>25,26</sup>

In the one of the systematic review and meta-analysis conducted by Li et al concluded that cerclage placement is beneficial for the reduction of preterm birth and the prolongation of pregnancy in twin pregnancies with a cervical length of <15 mm or dilated cervix of >10 mm. However, the benefit of history-indicated or twin alone-indicated cerclage is less certain in twin pregnancies with normal cervical length.<sup>27</sup>

Contrasting conclusions were deduced after systematic review and meta-analysis studies done by Jia et al, Rafael et al and Jarde et al wherein, in twin pregnancies no significant difference was observed between cervical cerclage group and no cerclage group in effective intervention for prolonging pregnancy and preventing preterm births. This difference in the outcome with respect to prolonging pregnancy and preventing preterm births among these studies can be attributed to the different study settings, difference in the inclusion criteria, procedure adopted, regional variations, pre-existing condition of the cervix and the obstetric profile of the study subjects.<sup>15,28,29</sup>

### ***Neonatal morbidity and mortality***

Prolonging the pregnancy and preventing the preterm birth will lead to better neonatal outcomes. In this study the mean birth weight of the newborns was  $2279 \pm 470$  grams with rates of VLBW at 8%, LBW at 59.3% and normal birth weight of 32.4%. Most of the new-borns (77.8%) had normal Apgar scores with overall NICU admission rate at 28%, RDS 24.1%, neonatal jaundice at 24.1% and neonatal sepsis at 3.7%. Majority of the neonates survived 92.6% and with neonatal mortality of 7.4%.

In a similar study done by Ayman et al in similar set of patients revealed mean birth weight of  $2313 \pm 419$  grams which is in consonance with our study.<sup>16</sup> There was significant reduction in the neonatal mortality (10%) and morbidity with respect to RDS, sepsis, NICU admission in cervical cerclage group compared with no cerclage group. Similar neonatal outcomes were observed by Abdulmalek et al in another study done by Michelle et al, also showed that there was a significant increase in birth weight (median 2278 versus 1665 g,  $p<0.001$ ) and decrease in perinatal death <30 days (1.6 versus 12.9%,  $p=0.001$ ).<sup>22</sup> These results are also consistent with those of a recent retrospective cohort study done by Houlihan et al where there was a significant increase in mean birth weight in the cerclage group (2338 grams) compared with no cerclage group (1687 grams).<sup>26</sup> However some of the systematic reviews and meta-analysis studies revealed that there is no evidence the cerclage is an effective

intervention for preventing and reducing perinatal deaths or neonatal morbidity.<sup>15,28,29</sup>

The pregnancy and neonatal outcomes depend upon multiple factors like maternal characteristics, study setup, the procedure adopted, biological variations among the individuals etc. Further research is essential, ideally randomized control trials, multi-centric studies to generate sound evidence to know the effectiveness of prophylactic cervical in multiple pregnancies resulting from ART methods.

In ICSI twin pregnancies with normal cervical measurements, prophylactic cervical cerclage is effective in prolonging pregnancy and preventing preterm delivery and thereby minimizing neonatal morbidity and mortality.

Even the studies not advocating the use of prophylactic cerclage in multiple pregnancies pointed to some benefit of cerclage in 3 aspects. The first aspect is prolonging gestation till corticosteroid therapy is given if preterm labour or PROM occurred.<sup>30</sup>

The second aspect is that it allowed obstetricians to avoid the emergency need for cerclage which proved to be of no value.<sup>31,32</sup> The third aspect is that cerclage allowed free activity of patients and minimized bed rest with its psychological and economical aspects.<sup>30</sup>

So, it is advisable to advocate its use in ICSI twin pregnancy. However further randomized control trials are required to reinforce its utility.

## CONCLUSION

Prophylactic cerclage seems to be effective in reducing preterm delivery in ICSI twin pregnancies with normal cervical measurements even in those with prior history of preterm labour and minimized associated with increased maternal morbidities so we advocate its use in ICSI twins to reduce medical and economic burdens.

## ACKNOWLEDGMENTS

We the sincerely thank the study subjects and the family members of the patients for their co-operation and support for the smooth conduct of the study. The authors thank all the residents and seniors of our Mathrutva fertility Centre for their support and guidance. The authors are also grateful to authors/editors/publishers of all those articles, journals and books from where the literature for this article has been reviewed and discussed.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Manjunah CS, Bandi J. Utility of prophylactic cervical cerclage in intra-cytoplasmic sperm injection twins: a prospective study. *Int J Reprod Contracept ObstetGynecol* 2020;9:4004-9.