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Research Article

Prophylactic Cerclage in ICSI Twins: To Do or Not to Do? A Randomized Controlled Study

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Abstract

Objective: To study the effect of prophylactic cerclage in ICSI twin pregnancies with normal cervical measurements on pregnancy outcome.

Design: a randomized controlled prospective study.

Setting: at Tanta university hospitals and outpatient clinics**.**

Patients: 120 selected cases of ICSI twin pregnancy were recruited and classified into 2 groups randomly, cerclage group (n=80cases) and control group without cerclage (n=40).

Interventions: Transvaginal ultrasound was done for number of fetuses, viability, cervical length and diameter and applying Mc Donald cerclage at 14-16weeks for cerclage group.

Main Outcome Measures: Occurrence of abortion, Preterm labour, premature rupture of membranes, the time of stitch removal, gestational age at delivery, mode of delivery, neonatal complications.

Results: The mean age (29.09 ± 3.26 years) and (28.36 ± 3.24 years) in cerclage group and control group respectively. Most patients were suffering primary infertility 68.75%. The mean gestational age for preterm labour was (32.50 ± 2.04 weeks) in cerclage group versus (30.53 ± 2.44 weeks) in control group. The mean gestational age for PROM was (32.70 ± 2.41 weeks) in cerclage group versus (29.00 ± 2.52 weeks) in control group. The mean gestational age at delivery was (34.84 ± 1.71 weeks) and (32.65 ± 2.56 weeks) in cerclage and control groups respectively .Neonatal assessment revealed that birth weight was higher in cerclage group than in control groups with mean of birth weight was (2313.13 ± 419.81 gm) in cerclage group versus (1828.25 ± 603.23 gm) in control group**.** Respiratory distress syndrome occurred (48.8%) in cerclage group versus (82.5%) in control group, with the need of NICU and mechanical ventilation for (10%) incerclage group versus (52.5%) in control group.

Conclusion: Prophylactic cerclage was effective in reducing preterm delivery in ICSI twins and minimized neonatal morbidity and mortality.

Keywords: Prophylactic cerclage, Twins, ICSI, Pregnancy outcome

Introduction

Rapid advances in ART procedures and gonadotropin stimulation protocols were linked with significant increase in the incidence of multiple pregnancies with incidence of (30 to 35%) for twins and (5-10%) for triplets [1,2]. 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 [3,4]. 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 [5].

The outcome of twin pregnancies, using meta-analyses, was contradictory where some studies support that twins conceived by ART have a higher risk of adverse pregnancy complications and neonatal morbidity and mortality [3,4,6,7], other studies denied evidence of a higher incidence of adverse outcomes [8]. Preterm labour is the most frequently met complication of multiple pregnancies due to its bad health sequalae and economic burden. The incidence of preterm births in twins is about 25% leading to adverse neonatal complications and even neonatal death. Preterm labour and low birth weight were found to be higher in ICSI twins compared to spontaneously-conceived twins after matching or controlling for at least maternal age [6,9]. Research studies

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on minimizing or preventing preterm labour in twins are less clear, due to fewer numbers being investigated and contradictory results. The studied prophylactic interventions were cerclage, progesterone and vaginal pessaries which had increasingly benefit in singleton pregnancies with short cervix [10].

In twins, cervical cerclage is an intervention aiming to prevent cervical shortening and opening, thereby reducing the risk of preterm birth. The effectiveness and safety of this procedure in multiple gestations remains controversial [10], where some studies advocate its use [11], and other studies stated that it has some benefit [12], other studies stated that it seems to be ineffective in reducing preterm birth [13], and others showed some complications owing to its use [14]. This study was conducted to assess the effect of cerclage in ICSI twins with normal cervical measurements to evaluate its efficacy in improving pregnancy outcome and prolonging gestation.

Patient and Methods

The study involved patients with twin pregnancies attending outpatient and inpatient units of Department of Obstetrics and Gynaecology, Tanta University, in the period from July 1, 2015 to May 31, 2016. All women were thoroughly informed about the study aims and through discussion about the procedure, associated benefits and risks and assigned written consent. Patients were selected carefully according to inclusion and exclusion criteria and were divided randomly into two groups: Cerclage group who were treated by prophylactic cerclage (80 cases) and Control group who were not treated by cerclage (40 cases) and served as control cases. Randomization was done simply by closed envelopes. Randomization was unequal in a 2:1 ratio to gain greater experience about cerclage in ICSI group and most patients were motivated for cerclage more than to be without cerclage and the risk & complications of prematurity were explained to all patients.

Inclusion criteria: ICSI twin pregnancy with normal cervical length ≥4cms and diameter ≤6mm, history of abortion or preterm labour with normal cervical measurements. Twins after vanishing third baby or twins after embryo reduction were also included.

Exclusion criteria: Singleton pregnancy, spontaneous twin pregnancy, triplets or more, malformed babies, uterine anomalies, uterine myoma, incompetent cervix, short cervix, cervical lesions as myoma, polyp or laceration, pervious cervical surgery, patients with active cervicitis, threatened abortion with vaginal bleeding and any patient with medical disorders.

All patients were assessed by history taking; examinations were investigated by routine investigation to check for general condition. Transvaginal Ultrasound was done at first trimester to detect number of fetuses, viability, cervical length and diameter, to exclude fetal congenital anomalies (by the nuchal translucency (NT) and nasal bone measurement scan), and uterine anomalies or fibroid.

In cerclage group the 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 mobilisation avoiding 3and 9 o'clock to prevent suspected bleeding due injury of cervical branches of uterine artery. The used suture was (ASTRALEN TAPE ASSUT, Switzerland) which is a sterile non-absorbable polyester tape, 50 cm in length, 5mm width with double needles to minimize infection.

In control group observation and follow up was applied for patients in this group with documentation of any use of antibiotics or to colytic drugs.

Follow up was conducted for all patients every 2 weeks till 28 weeks 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. Trans-abdominal ultrasound for foetal biometry, growth problem, amniotic fluid volume and fetal demise. Umbilical Doppler was done to detect any abnormalities in blood flow or twin to twin transfusion and assess fetal wellbeing beside biophysical profile. Monitoring for infections every 2 weeks by (C - reactive protein and total leucocytic count) was performed to detect signs of infection.

Antenatal corticosteroids, (Dexamethasone 6mg every 12 hours for 4 doses) were administered intramuscularly at 28 weeks and 48 hours prior to plan caesarean section (CS) to promote fetal lung maturation. Cerclage stitch was removed if PROM occurred, established preterm labour or when pregnancy reached 37 weeks.

Age, type of infertility, duration of infertility, previous obstetric history (if present), need for hospitalisation 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.

Neonatal assessment included birth weight, Apgar score (mean of Apgar score at 1 and 5 minutes), neonatal mortality and morbidity which include (Respiratory Distress Syndrome (RDS),Intra-Ventricular Hemorraghe (IVH), Necrotizing EnteroColitis (NEC), Retinopathy Of Prematurity (ROP) and Neonatal Sepsis(NS) and the need for Neonatal ICU and therapies as ventilation, blood transfusion and phototherapy were recorded for each twin. Statistical analysis was done using descriptive and analytical statistics (percentages, $\chi 2$ test, t-test and P-value) using the SPSS program, version 20.

Results

A total of 120patients with twin pregnancy were included in the study with 80 cases in cerclage group and 40 patients in the control group. Demographic data were nearly similar in both groups with no significant difference as regard age, type of infertility; duration of infertility and previous obstetric history between both studied groups.

The mean age was (29.09 ± 3.26 years) and (28.36 ± 3.24 years) in cerclage group and control group respectively (P=0.24). Most patients were suffering primary infertility 68.75% and 31.25% were suffering secondary infertility with mean duration of infertility (5.32 ± 1.35 years) and (5.24 ± 1.64 years) in cerclage group and control group respectively (P=0.49). Patients with previous history of abortion were 8.8% (n=7) and 10% (n=4) in cerclage group and control group respectively. Those

	Cerclage group (n=80)			Control group (n=40)			T-test	
							t	P-value
Age	29.09	±	3.26	28.36	±	3.24	1.158	0.249
Type of infertility								
Primary		55	(68.75%)	25	(62.5%)		0.469	0.494
Secondary		25	(31.25%)	15	(37.5%)			
Duration of infertility	5.32	±	1.35	5.24	±	1.64	0.258	0.797
Previous obstetric history								
Abortion	7	(8.8%)		4	(10.0%)		0.051	0.975
Preterm labour	8	(10.0%)		4	(10.0%)			

Table 1: Demographic data of included patients .

	Cerclage group(n=80)		Control group(n=40)		Chi-square	
	N	%	N	%	X^2	P-value
Hospitalization						
No hospitalisation	53	66.25	12	30.0	16.088	<0.001*
Abortion	0	0.0	1	2.50		
Preterm labour	17	30.0	20	50.0		
PROM	10	12.5	7	17.5		
Duration of hospitalisation	14.8 ± 0.76		15.6 ± 1.58		1.516	0.132
Need for adjuvant drugs	27	42.5	28	70	12.740	<0.001*
Maternal morbidity	5	6.25	3	7.50	0.067	0.796
Gestational age at delivery						
28 to less than 32	5	6.3	10	25.0	19.856	<0.001*
32 to less than 34	7	8.8	11	27.5		
34 or more	68	85.0	18	45.0		
Mode of delivery					0.234	0.628
Caesarean section	65	81.3	31	77.5		
Vaginal delivery	15	18.8	9	22.5		

Table 2: Antenatal follows up of cases and mode of delivery in studied groups.

with previous history of preterm labour were 10% in both groups (P=0.97), as shown in Table 1.

Antenatal follow up of patients revealed that 53 cases (66.25%) in cerclage group didn't require hospitalization corresponding to 12 cases in control group (30%). The cases who required admission in cerclage group were 27cases: 17 cases (21.25%) for preterm labour and 10 cases (12.5%) for PROM corresponding to 28 cases in control group: 20 cases (50%) for preterm labour, 10 cases (7%) for PROM and one case of abortion (2.5%). (P =0.034), as shown in Table 2.

Duration of hospitalization was (14.8 ± 0.76 days) in cerclage group versus (15.6 ± 1.58 days) in control group with no significant difference between both groups (P=0.132). Adjuvant drugs such as to colytic drugs or antibiotics were required for (42.5%) of cases in cerclage group versus (70%) in control groups with significant difference between both groups. (P <0.001)

Maternal morbidities (bleeding, cervical lacerations, infections, chorioamnionitis, puerperal sepsis, etc...) were (6.25%) versus (7.5%) in cerclage group versus control group respectively with no significant difference between both groups (P =0.796)

The gestational ageat delivery between 28 to less than 32 weeks was 5 cases (6.3%), 10 cases (25%) incerclage group and in control groups respectively. Gestational ageat delivery between 32 to less than 36 weeks was 7 cases (8.8%), 11 cases (27.5%) incerclage group and in control group's respectively. Gestational age at delivery34or more weeks was 68 cases (85.0%), 18 cases (45.0%) incerclage group versus in control group's respectively. with significant difference between both groups. (P <0.001) as shown in Table 2.

The mode of delivery was not significant (P= 0.628) in cerclage and control groups with nearly equal rates of Caesarean delivery (81.3%) versus (77.5%) and vaginal delivery (18.8%) versus (22.5%) respectively for both studied groups as showed in Table 2.

The mean gestational age for occurrence of preterm labour was (32.50 ± 2.04 weeks) in cerclage group versus (30.5 ± 2.44 weeks) in control group. The mean gestational age for occurrence of PROM was (32.70 ± 2.41 weeks) in cerclage group versus (29.00 ± 2.52 weeks) in control group, with significant difference between both groups (P<0.001)as shown in Table 3. The mean gestational age was (34.84 ± 1.71) and (32.65 ± 2.56) in cerclage and control groups respectively with significant difference between both groups (P <0.001) as shown in Table 3.

The mean of birth weight was (2313.13 ± 419.81 gm.) in cerclage group versus (1828.25 ± 603.23 gm.) in control group respectively with significant difference between both groups(P <0.001) as shown in Table 3.

	Range			Mean	±	SD	T-test	
							t	P-value
Preterm labour								
Cerclage	28	-	35	32.50	±	2.04	4.666	<0.001*
Control	24	-	34	30.53	±	2.44		
PROM								
Cerclage	28	-	35	32.70	±	2.41	7.809	<0.001*
Control	25	-	32	29.00	±	2.52		
Gestational Age								
Cerclage	29	-	38	34.84	±	1.71	5.577	<0.001*
Control	25	-	36	32.65	±	2.56		
Birth weight								
Cerclage	1025	-	2785	2313.13	±	419.81	5.130	<0.001*
Control	550	-	2700	1828.25	±	603.23		

Table 3: Mean gestational age at which PTL, PROM and delivery occurred and birth weight in studied cases.

	Cerclage		Control		Chi-square	
	N	%	N	%	X^2	P-value
Birth weight						
Less than 1500	6	7.5	13	32.5	28.124	<0.001*
1500 to less than <2500	34	42.5	25	62.5		
2500 or more	40	50.0	2	5.0		
Apgar score						
<7	8	10.0	12	30.0	7.680	0.006*
>7	72	90.0	28	70.0		
Neonatal Mortality	8	10.0	13	32.5	9.351	0.002*
Neonatal Morbidity						
RDS	39	48.8	33	82.5	12.656	<0.001*
NICU(mechanical ventilator)	8	10.0	21	52.5	26.283	<0.001*
IVH	3	3.8	2	5.0	0.104	0.747
Neonatal Sepsis	10	12.5	7	17.5	0.548	0.459
Neonatal Jaundice	21	26.3	16	40.0	2.364	0.124

Table 4: Neonatal assessment of babies born in both groups.

Neonatal assessment revealed that birth weight was higher in cerclage group than in control groups with incidence of LBW <1500gm (7.5%) versus (32.5%) in cerclage and control groups respectively. The babies weighing >1500 and <2500 gm were (42.5%) versus (62.5%) in cerclage and control groups respectively. The babies weighing more than 2500gm were (50%) versus (5%) in cerclage and control groups respectively, with significant difference between both groups (P <0.001) as shown in Table 4 and Figure 1.

Apgar score 7 or more was higher in cerclage group than in control group (90%) versus (70%) respectively with significant difference between both groups (P value =0.006) Neonatal mortality was lower in cerclage group (10%) than in control group(32.5%) with significant difference between both groups(P <0.002), Table 4.

Respiratory distress syndrome (RDS) occurred in (48.8%) cerclage group versus (82.5%) control group) with the need of NICU and mechanical ventilation for (10%)cerclage group versus (52.5%) control group. with significant difference between both groups(P value <0.001)This means significant increase in respiratory distress in control cases than in cerclage group (P =0.001) as shown in Table 4.

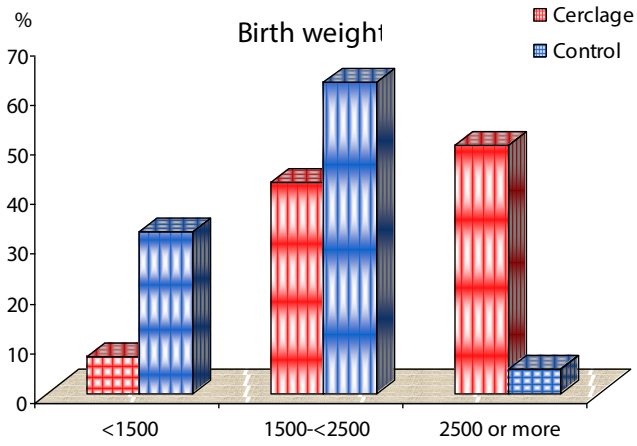

Figure 1: Birth weight in studied groups.

Intra-ventricular haemorrhage (IVH) occurred in (3.8%) cerclage group versus (5%) control group, neonatal sepsis occurred in (12.5%) cerclage group versus (17.5%) control group and neonatal jaundice occurred in (26.3%) cerclage

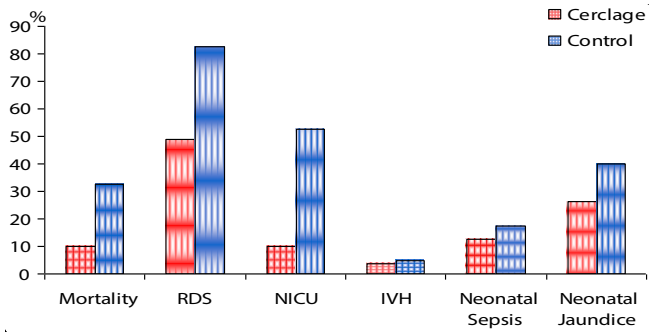

Figure 2: Neonatal morbidity and mortality in both groups.

group versus (40%) control group were nearly equal with no significant difference between both groups (P = 0.747,0.459 and 0.124 respectively)as shown in Table 4. Neonatal morbidities recorded were Respiratory distress syndrome (RDS), intra-ventricular haemorrhage (IVH), neonatal sepsis and neonatal jaundice) with the need for Neonatal ICU and mechanical ventilation. All neonatal complications are shown in Figure 2.

Discussion

Twin pregnancy and higher order pregnancies are noticeably increasing nowadays owing to the great progress and advanced in ART technologies and these pregnancies are considered high risk pregnancies due to the many complications that occur during or after the course of pregnancy either to the mother, foetus or new-born. These complications are more and more if these pregnancies are the result of ART procedures rather than spontaneous pregnancies [7,15].

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 sequalae on new-borns. Several measures were tried to prevent PTL in multiple pregnancies such as bed rest, progesterone, prophylactic tocolysis and prophylactic cerclage and pessary but none were 100% effective [16-18].

In this study cerclage was done in 80 cases and 40 cases were treated conservatively without cerclage. Demographic data (Age, type of infertility, duration of infertility and previous obstetric history) were nearly similar with no significant difference in both groups.

Hospitalization was required more in patients without cerclage (70%) while only (42.5%) of patients in cerclage group required hospitalization. The main indications for admission were abortion, preterm labour, and PROM (0%), (30%), and (12.5%) in cerclage group versus (2.5%), (50%), and (17.5%) in control group respectively.

Maternal morbidities were not significantly increased in cerclage than in control group even less (6.25%) in cerclage versus (7.5%) in control group indicating safety of the procedure.

These results are in agreement with that of Hiroyuki, et al. [19] who conducted a similar study on 65spontaneous twin pregnant women classified into 2 groups; Group A with cerclage applied and Group B treated without cerclage and they found that the patients in Group B were significantly ($p < 0.05$) more likely to require hospitalization at an earlier stage of gestation than were those in Group A and they concluded that elective cervical cerclage was an appropriate intervention to avoid delivery before 32 weeks' gestation in nulliparous women with twin pregnancies and reduced the costs of managing twin pregnancies [13].

The mean gestational age in this study was (34.84 ± 1.71 weeks) and (32.65 ± 2.56 weeks) in cerclage and control groups respectively indicating the significant effect of cerclage in prolonging gestation. Neonatal birth weight mean was (2313.13 ± 419.81 gm) in cerclage group versus (1828.25 ± 603.23 gm) in control group. These results were lower than that of Mamas, et al. [20] who conducted a study on 31 twin pregnant women using the modified shirodkar procedure and reported a mean gestational age of 35 ± 4 weeks in twin pregnancy at the time of delivery. The same authors documented mean birth weight of 2,352 gm in twins which is nearly similar to our results.

Another study conducted by Roman, et al. [14] reporting that the mean gestational age at delivery was (34.7 ± 3.3 weeks) in cerclage group while the mean in control group was (35.2 ± 2.9 weeks) with neonatal birth weight in cerclage group was (2,140 ± 616 gm) versus (2,310 ± 635 gm) in control group. The authors denied the efficacy of prophylactic cerclage in improving pregnancy outcome in twins.

Another study done by Galindo, et al. [11] conducted a study on 129 patients carrying twin pregnancy resulted from ART where prophylactic cerclage (McDonald technique) was performed in 46 while the remaining 83served as controls. There was a significant difference in gestational age in weeks (35.65 ± 1.96 vs. 33.79 ± 5.28, $P<0.05$), average weight in gm (2358.8 ± 462.73 vs. 2103.90 ± 711.78, $P<0.05$).They concluded that patients with prophylactic cerclage had better gestational age and better birth weight compared to those without cerclage and should be considered as routine in twin pregnancies from ART.

Respiratory distress syndrome (RDS) occurred in (48.8%) cerclage group versus (82.5%) control group with the need of NICU and mechanical ventilation for (10%) cerclage group versus (52.5%) control group respectively. This means significant increase in respiratory distress in control cases than in cerclage group with very high numbers in NICU admission with ventilator therapy due to prematurity.

Mamas, et al. [20] reported that half the neonates (51.6%) delivered from twin pregnancies were admitted in the NICU. Hansen, et al. reported that 60% required NICU admission [21]. Roman, et al. [14] reported (42.8%) NICU admission in cerclage versus (38.1%) in control group. These high NICU was decreased by prophylactic cerclage to only (10%) in our study.

Neonatal mortality was lower in cerclage group (10%) than in control group (32.5%) and these results were opposite to the study done by Rafael, et al. [22] who reported perinatal deaths (19.2%)in cerclage versus (9.5%) in non cerclage group.

A recent study was conducted by Collins, et al. [10] to evaluate the role of cerclage, progesterone and cervical peccary in prevention of preterm labour in twins and stated that the role of cerclage in twins has not been adequately researched in women with previous preterm birth, and should not be used on the basis of a short cervix only allowing flexibility of its prophylactic use. That study concluded

that cerclage, vaginal pessaries and progesterone should not be routinely used in twin pregnancies without an additional high-risk factor such as prior history of preterm birth or short cervix, until further evidence is obtained [19].

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 [20], the second aspect is that it allowed obstetricians to avoid the emergency need for cerclage which proved to be of no value [23,24]. The third aspect is that cerclage allowed free activity of patients and minimized bed rest with its psychological and economical aspects [20].

Conclusions

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 neonatal morbidity and mortality. Prophylactic cerclage was not associated with increased maternal morbidities so we advocate its use in ICSI twins to reduce medical and economic burdens.

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Conflicts of interest

All authors have no conflicts of interest**.**

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