Case Control Study

Prophylactic Trans-vaginal Cervical Cerclage versus Conservative Management in Triplet Pregnancies

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ABSTRACT

Background: To compare the effect of prophylactic trans- vaginal cervical Cerclage versus the conservative treatment in management of triplet pregnancies and also the effect of parity on gestational age and birth weight in triplet pregnancies. **Patients and Methods**: 40 women with triplet pregnancies were divided into 2 groups. Group 1 (20) received prophylactic cerclage. Group 2 (20) with no Cerclage [conservative management]. Each group subdivided into two half; half of the women were primi-para and the other half were multi-para (including unipara &multi-para), women with possibility of cervical insufficiency were excluded and pregnancy was followed in all women until delivery.

Results: There was no significant difference between the both groups regarding the gestational age at time of delivery (31.45±4.68 in Cerclage group versus 32.65±4.01 in non Cerclage), the miscarriage rate (20% in Cerclage versus 15% in conservative management group) and time of delivery (35% delivered before 34 w, 35% between 34w and 36w, and 10% after 36w in cerclage group versus 35%, 40%, 10% in conservative management group respectively).

There was no significant difference between both groups regarding the neonatal birth weight (1390±467.24 in cerclage group versus 1405±475.7 in conservation group) & NICU admission (90% in both groups). parity has effect on gestational age of delivery (75% of prime para delivered before 34 wks. 20 % between 34-36 weeks and 5% after 36weeks while in multi para (35%,40%, and 10%) respectively.

Conclusion: Prophylactic trans- vaginal cervical cerclage in triplet pregnancies regarding pregnancy prolongation and neonatal outcomes is similar to conservation. Parity has effect on pregnancy prolongation & consequently the neo-natal outcomes.

Key Words: Cervical cerclage, preterm birth, triplets

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INTRODUCTION

The rate of multiple gestations, particularly triplet has increased considerably over the past three decades, due to wide spread of assisted reproductive technology (ART) and delayed childbearing [1-3]

Multiple pregnancies are considered high risk due to high incidence of maternal& neonatal complications. [4-6]

The risk of adverse neonatal outcome increases with the increased number of fetuses, due to preterm birth and / or low birth weight [2].

75 to 100 percent of triplets are born prematurely. The average gestational age for singletons, twins, and triplets is 39, 35 and 32 weeks, respectively [7].

The rates of low birth weight (LBW<2500 grams) and very low birth weight (VLBW <1500 grams) in triplets are 95 percent and 35% respectively. while the rates

of LBW (<2500 grams) and LVBW(<1500 grams) in singletons are 6.5 and 1.1 percent respectively [8].

In addition to clinical risks of triplet pregnancies the medical costs and expenses are four times higher for triplet pregnancies compared with singleton pregnancy^[3].

Several methods have been proposed to decrease prematurity, there is conflict regarding bed rest, recent studies concluded that no improvement in the number of very low birth weight infants or neonatal outcomes following bed rest [9, 10].

Vaginal progesterone is beneficial in high risk singleton pregnancies in decreasing preterm delivery rate, but not in multiple pregnancies [11, 12].

Vaginal cervical cerclage was first described by Shirodkar and then MC Donald in the 1950 [13, 14].

There is controversy regarding the efficacy of

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prophylactic cerclage placement in preventing preterm delivery and the adverse neonatal outcomes in triplet pregnancies [15-18].

The aim of this study was to compare the effect of prophylactic trans- vaginal cerclage versus the expectant management in triplet pregnancies and also the effect of parity on gestational age & birth weight in triplet pregnancies.

PATIENTS AND METHODS

Forty women with triplet pregnancy were recruited from the attendees of Minia university hospital for obstetrics, gynecology and paediatrics during the period from 2010 to 2015.

They were counseled about cerclage versus non cerclage by the end of the first trimester and written informed consent was taken from all women.

Women were divided into 2 groups: Group 1, 20 women and were subjected to elective cerclage. Group 2, 20 women received conservative management.

Inclusion criteria

Women with triplet pregnancy, which occurred spontaneously, after induction or after ART were inleuded.

Exclusion criteria

- •Possible cervical incompetence; history, clinical or uls evaluation.
- •PROM or chorio ammonites.
- •Uterine bleeding.
- •Fetal demise or fetal anomalies.

All patients were subjected to history taking with exclusion of women with past history of cervical incompetence.

General, abdominal and local examination with exclusion of women with local examination suggestive of cervical incompetence (physically indicated cerclage).

Investigations (RH type, ABO group, CBC, liver and renal function tests, C-reactive protein and urine analysis).

U/s evaluation (at 11 -13 wks.), abdominal for viability and major anomalies and vaginal for cervical evaluation. Accurate evaluation need certain precautions by emptying the bladder, patient in dorsal lithotomy position, the cervix measured along its longitudinal axis, should occupy 50-75% of the image and avoid excessive pressure on the cervix by the probe, as the cervix appears longer and obscure funneling, also the full bladder has the same

effects. The cervical canal and the surrounding cervical mucosa need to be identified and avoid inclusion of the isthmus into the measurement. The external so is the point where the anterior and posterior lips of the cervix come together, the cervical mucosa appears as homogenous and hypo echoic structure compared to the surrounding stroma and the internal os is located at the end of cervical mucosa The cervical length will be the distance between the internal and external os (2.5cm), the examination should last for 35- minutes and three measurements should be obtained and we use the shortest one. Funneling which is protrusion of the amniotic membranes into the cervical canal should be noticed.

Group 1 women were admitted between 12- 14 wks. to hospital, 24h before the procedure with avoidance of vaginal douches.

The procedure:

Spinal anaesthesia.

Dorsal lithotomy position.

High vaginal swab for culture.

Disinfection of the vulva and vagina with providine iodine (10%)

Grasping of the anterior and posterior cervical lips using ring forceps.

MC Donald cerclage is placed using 5 mm mersilene suture circumferentially around the cervix, the knot is tied at 6 o'clock to avoid bladder irritation.

Indomethacin rect. Supp. 100mg, twice daily for 3 days.

Prophylactic intravenous antibiotics for 24h after cerclage, then oral for 6 days.

Patients discharged 72h after the procedure and instructed to avoid intercourse, vigorous physical activity, but bed rest was not recommended and follows up visit after 2 weeks of discharge.

All women in both groups were followed as out patients, they were seen every 2 weeks, where general, abdominal and ULS examination was done (serial growth & cervical length ultrasound) women who developed hypertension, diabetes or fetal demise were excluded.

Both groups received prophylactic IM progesterone injection weekly and prophylactic treatment of vaginal infection monthly in the form of clindamycin vaginal cream + cynoconazole 80 vaginal ovule until delivery.

Biophysical profile was done starting at 32 wks. Weekly until delivery.

Corticosteroids (dexamethasone) 6 mg/12for 4 doses were given to both groups at 28 wks.

Cerclage was removed after 36wks of pregnancy.

All women with successful cerclages were delivered by caesarian section.

The cerclage was considered successful if the patient reached 34 weeks.

Statistical method:

The collected data were coded, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 20.

Descriptive statistics were done for numerical data by mean, standard deviation and minimum& maximum of the range, while they were done for categorical data by number and percentage.

Analyses were done for quantitative variables using independent sample t test for parametric data between the two groups.

Chi square test was used for qualitative data between groups

The level of significance was taken at $(P \ value < 0.05)$

RESULTS

The 40 women divided into 2 groups; group 1 (cerclage), half of women were primi-para and the other half were multi-para (including uni-para & multi-para) and group 2 (no cerclage) half of women were primipara and the other half were multi-para.

There was no significant difference between the both groups regarding the demo-graphic data (table-1).

Women in both groups were nonsmoker and none of them had past history, local examination or vaginal uls findings suggestive of cervical incompetence.

In group 1 the gestational age at time of cerclage was similar between 12 -14 wks.

Table 1: Showing the demographic data of both groups. There was no significant difference between both groups regarding the demographic data. Women with past history of preterm labour were excluded from the study. As regard the type and the method of occurrence of the pregnancy the majority occurred after lcsi, followed by induction of ovulation then spontaneous pregnancy.

Table 1: Demographic Data of both groups

	With cerclage (n=20)	Without cerclage (n=20)	P value
Age	31.3 ± 1.06	31.48 ± 1.02	0.599
Advanced maternal age	1 (5%)	1 (5%)	1
Parity Nullipara Multipara	9 (45%) 11 (55%)	11 (55%) 9 (45%)	0.527
History of preterm labor	0 (0%)	0 (0%)	
Pregnancy type Spontaneous ICSI Induction	4 (20%) 10 (50%) 6 (30%)	4 (20%) 9 (45%) 7 (35%)	0.937

Table 2: Showing the pregnancy outcome in both groups. There was no significant difference between the both groups regarding gestational age, the abortion rate and the delivery time (<34,>34 and>36 wk.). Spontaneous preterm

labor was the most common cause of delivery, followed by premature rupture of membranes. Corticosteroids were given to all women exceeding 28wks. All women exceeding 32wks were delivered by caesarean section.

Table 2: Pregnancy out comes

	With cerclage (n=20)	Without cerclage (n=20)	P value
Gestational age at delivery	4 (20%)	3 (15%)	
Abortion (< 28w)	7 (35%)	7 (35%)	
Delivery < 34 w	7 (35%)	8 (40%)	0.976
Delivery > 34 w	2 (10%)	2 (10%)	
Delivery >36 w			
Gestational age at delivery	31.45 ± 4.68	32.65 ± 4.01	0.390
PROM	6 (30%)	5 (25%)	0.723
Gestational age at delivery	weight	NICU admission	Survival
< 28 w (n=7)	(700-850)	7 (100%)	0 (0%)
	771.42 ± 63.62	,	· /
28-34 w (n=14)	(950-1500)	14 (100%)	9 (64.3%)
,	1221.42 ± 194.85		, ,
34-36 w (n=15)	1500-1900)	15 (100%)	12 (80%)
,	1633.33 ± 145.97	` '	, ,
>36 w (n=4)	(2100-2500)	0 (0%)	4 (100%)
(= .)	2325 ± 184.84	,	,
Spontaneous preterm labor	14 (70%)	15 (75%)	0.723

Table 3(A and B): Showing the neonatal outcome in both groups. There was no significant difference in the neonatal birth weight between the both groups. 90% of neonates in both groups were admitted to NICU and there was no

significant difference between the both groups regarding the survival rate. Neonatal admission to NICU and weight was dependent on the gestational age at delivery. All neonates delivered before 36 wks. were admitted to NICU.

	With cerclage (n=20)	Without cerclage (n=20)	P value	
Neonatal weight	1390 ± 467.24	1405 ± 475.7	0.815	
NICU admission	54 (90%)	54 (90%)	1	
Outcome Survived Died	12 (60%) 8 (40%)	13 (65%) 7 (35%)	0.744	

Table 4: Showing the difference between the nulliparous and the mult i-para regarding the pregnancy type and gestational age at delivery. Triplet pregnancy occurred after induction in most cases

of multipara (50%) and after lcsi (75%) in most cases of primipara . 75% of primipara delivered before 34wks, 20% delivered between 34-36 wks. and 5% after 36w while in multi-para (35%,40% and 10%), respectively.

Table 4: Effect of parity regarding pregnancy type & gestational age

	Nullipara (n=20)	Multipara (n=20)	P value
Pregnancy type	(1. 1.0)	(4 10)	0.002*
regnancy type			0.002
Spontaneous	2 (10%)	6 (30%)	
ICSI	15 (75%)	4 (20%)	
Induction	3 (15%)	10 (50%)	
Gestational age at delivery	15 (75%)	6 (35%)	
Delivery < 34 w	4 (20%)	11 (40%)	0.017*
Delivery > 34 w	1 (5%)	3 (10%)	
Delivery >36 w			

DISCUSSION

With the widespread practice of assisted reproductive technology (ART) and delayed age of child bearing, the incidence of multiple gestations, has increased^{[19].}

Multiple gestations are associated with a high incidence of maternal and neonatal complication and the risk of adverse neonatal outcome increases with increasing number of fetuses, as a result of preterm birth and /or low birth weight^[20].

Management of triplet pregnancies is controversial and several ways to increase the gestational age have been proposed &used including bed rest ,progesterone administration and cerelage ,but their effectiveness remains un proven^[21].

This study revealed that prophylactic vaginal cervical cerclage in triplet gestations which is a routine in our community is not beneficial regarding the prolongation of pregnancy or the neonatal outcomes when compared with conservative management.

The time of prophylactic cerclage was between 12 - 14 wks., because after that time the maneuver will be difficult with increased risk of chorio –amnionities and premature rupture of membrane and this in agreement with many studies^[22-24].

The results of this study in agreement with many studies:

Rebarber *et al* $^{[16]}$ found no benefit from cerclage placement regarding pregnancy prolongation & neonatal outcomes when compared to the women without cerclage, the study was done on 3000 triplet but cerclage was done on 248 patients.

Bernasko *et al* ^[15] found no significant difference in the mean gestational age between cerclage and non cerclage groups, the study was done on 95 triplet pregnancies.

Moragianni *et al* ^[25] compared the outcomes of triplet pregnancies in women with a symptomatic cervical shortening with and without a cervical cerclage and found no benefit with cerclage placement.

Moragianni *et al* ^[26] concluded that triplet pregnancies complicated by cervical shortening diagnosed on biweekly transvaginal u/s surveillance do not benefit from cerclage placement.

This study revealed that the parity has role in prolongation of pregnancy in triplet pregnancies, 75% of nulliparous delivered before 34w compared to 35% in multipara and 5% of nulliparous delivered after 36w compared to 10% in multi-para and this in agreement with Luke *et al* [8] and this can be explained by increased elasticity of muscle muscle

fibers and consequently dispensability of uterus with increased parity.

The results of this study differ from:

Leonidas and eudoxia [27] founded that multiple pregnancies conceived with the aid of fertility treatment benefited from the prophylactic application of cervical vaginal cerclage.

Goldman *et al* [18] found a significant increase in the mean gestational age of 35w with cerclage versus 30.7 w for women without.

This study was limited by small sample size, retrorespective nature and lack of randomization. But in this study we tried to control the other risk factors for prematurity e.g. infection by prophylactic treatment and prophylactic tocolysis by using intra muscular progesterone.

This study tried to show the effect of parity on prolongation of pregnancy and consequently the neonatal outcome.

CONCLUSION

Prophylactic vaginal cervical cerclage in triplet pregnancies regarding pregnancy prolongation and neonatal outcomes is similar to conservation.

Women with past history of preterm labor and short cervix by U/S may be benefit from prophylactic cerclage.

Parity has effect on pregnancy prolongation & consequently the neo-natal outcomes.

CONFLICT OF INTEREST

There is no conflict of interest.

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