COMPARISON OF CERVICAL CERCLAGE AND VAGINAL PROGESTERONE IN CERVICAL INSUFFICIENCY: OUR EXPERIENCE AT CMH LAHORE

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ABSTRACT

Objective: To compare the efficacy of cervical cerclage with vaginal progesterone in patients with cervical insufficiency.

Study Design: Quasi experimental study.

Place and Duration of Study: Department of Gynecology and Obstetrics, Combined Military Hospital Lahore, from Jan 2018 to Jun 2018.

Methodology: The study involved 188 pregnant women with cervical insufficiency reporting in outpatient Department. After taking informed consent, the outcome variables age, number of mid-trimester pregnancy losses, body mass index and gestational age were recorded on specially designed proforma. Efficacy as if pregnancy was carried to 37 weeks of gestation was recorded. 93 patients were inducted in cerclage arm and 95 patients were treated with vaginal progesterone 400 mg once daily.

Results: The mean age of the patients with cervical cerclage and vaginal progesterone was 31.622 ± 1.90 years and 31.42 ± 1.86 years respectively, while mean gestational age of cervical cerclage group was 21.840 ± 1.46 weeks and vaginal progesterone was 21.46 ± 1.52 weeks. The mean number of mid-trimester pregnancy losses with cervical cerclage was 2.39 ± 0.63 and vaginal progesterone was 2.44 ± 0.84. The mean body mass index of cervical cerclage group was 27.84 ± 1.86 kg/m^2 and vaginal progesterone group was 28.01 ± 1.7 kg/m^2. Efficacy in cervical cerclage group was seen in 79 (84.9%) patients and in 82 (86.3%) patients in vaginal progesterone group.

Conclusion: Prophylactic cervical cerclage and vaginal progesterone were equally effective in preventing preterm birth in patients with high risk of cervical insufficiency.

Keywords: Cervical cerclage, Cervical insufficiency, Efficacy.

INTRODUCTION

Cervical insufficiency is a medical condition in which a pregnant woman's cervix begins to dilate and efface before her pregnancy has reached term. Definitions of cervical incompetence vary, but one that is frequently used is the inability of the uterine cervix to retain a pregnancy in the absence of the signs and symptoms of clinical contractions, or labor, or both in the second trimester[1].

It occurs in approximately 1% of all pregnant women, but rises to 8% in those who suffered a second or third trimester pregnancy loss[2,3]. Cervical insufficiency is an important cause of preterm deliveries, however, the exact etiology of pre-term birth in most cases is unknown. Preterm birth accounts for over 70% of all perinatal mortality and is an important determinant of neonatal and infant morbidity, including neurodevelopment handicaps, chronic respiratory problems, infections, neonatal intensive care unit admissions and ophthalmic problems[4]. It has been recognized that the prevention of preterm birth is crucial for improving pregnancy outcome.

Historically, several nonsurgical and surgical modalities have been proposed to treat cervical insufficiency. Although controversial, the traditional mainstay in the management of cervical incompetence is the application of transvaginal cervical cerclage. Otherwise, progesterone therapy and cervical pessary, which are noninvasive,

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may also be effective management. The availability of vaginal progesterone and cerclage for the prevention of preterm birth in women with a short cervix, singleton gestation and previous spontaneous preterm birth could create a dilemma for physicians and patients alike about the optimal choice of treatment[6].

Several studies showed that cerclage plus vaginal progesterone in women with extremely shortened cervix significantly decreased overall spontaneous preterm birth rates, prolonged pregnancy latency by 2-fold, and decreased the overall neonatal morbidity and mortality[10,11]. Cervical cerclage has been used widely in the management of pregnancies considered to be at high risk of pre-term delivery from cervical insufficiency. Its (cervical cerclage) role is to provide mechanical strength and act as a barrier to prevent infection. However; its potential benefits have been queried as it is an invasive procedure with associated complications[7,8].

One study showed cervical cerclage and progesterone pessary are equally effective methods of prolongation of pregnancy in gravid patients with incompetent cervix and threatened preterm labor. The choice of the method does not affect the mode of delivery as well as neonatal outcome[9].

One study conclusion is that the cervical pessary seems an affordable, safe, and reliable alternative for prevention of PTB in a population of appropriately selected at-risk pregnant women who have been screened for cervical length assessment at the midtrimester[6,9].

One study indicated that cervical cerclage showed more benefits in the maternal and neonatal outcome for women with an asymptomatic short cervix and prior PTB history, while cervical cerclage and vaginal progesterone therapies showed similar effectiveness for women without a history of PTB[10]. The efficacy of cervical cerclage, as well as vaginal progesterone as its need has been contentious, some authors terming one more effective on other. So there is a great need to compare the efficacy of cervical cerclage and vaginal progesterone in women with high risk of cervical insufficiency in general population of our area. This study will also pave the way for our doctor's community to select the right method in women with high risk of cervical insufficiency in our local population.

METHODOLOGY

One hundred and eighty eight subjects were selected by consecutive (non-probability) sampling technique. Sample size was calculated by using following parameters: prevalence of condition = 95%. Where q=1-p and d=3% with 95% Confidence level n=188. All pregnant women with age 25 to 35 years, gestational age 14-24 weeks on ultrasound, gravida 3 to 6, cervical insufficiency with duration 18-24 weeks gestational age as per operational definition, patients with previous history of mid trimester pregnancy losses ≥2 times and women with demonstrable prolapse of fetal membranes into endocervical canal >25% of the total cervical length or distal cervical length of <2.5cm on transvaginal ultrasound presenting at Combined Military Hospital, Lahore from January 2018 to June 2018 were included in this study. Patients with ruptured membranes, signs of chorioam-nionitis, active bleeding, and active labour were excluded from study.

Patients fulfilling the inclusion criteria from outdoor department were included in the study after permission from ethical committee and research department. Patients were evaluated by detailed history and clinical examination. Patients were divided in two groups. The effects, procedure and side effects of cervical cerclage were explained to the patient selected for this procedure. Informed consent was taken. All the procedure took place under general anesthesia. The patients were placed in lithotomy position. After scrubbing and drabbing the operation field, an encircling suture was placed around the cervix at the level of the internal os with silk no. 1 suture using round bodied needle. All the procedure was done by a consultant gynecologist with 5 years' post fellowship experience. Women were

discharged after 24 hours. Cerclage was removed electively at 37 weeks of gestation or in emergency if patient came in labour or with premature preterm rupture of membranes or abruption. Efficacy as if pregnancy was carried to 37 weeks of gestation was recorded on especially designed proforma. Other group was selected for vaginal progesterone and educated how to use vaginal progesterone 400mg once daily at night.

Data was analyzed with statistical analysis program (SPSS version 20).

Frequency and percentage was computed for qualitative variables. Mean ± SD was presented for quantitative variables like age, number of midtrimester pregnancy losses, BMI and gestational age.

Post stratification chi-square test was used with $p \leq 0.05$ considered statistically significant.

RESULTS

Demographic variables age, mean gestational age, mean number of mid trimester losses and mean BMI (table-I).

Among 93 patients in cervical cerclage group, 19 were in age group 25-30 years (20.4%) and 74 were in age group 31 to 35 years (79.5%). In 95 patients with vaginal progesterone group, 22 (23.1%) were in age group 25-30 years and 73 (76.8%) were in age group 31-35 years.

Stratification of efficacy with respect to age group was analyzed. Among cervical cerclage group, 25-30 years efficacy was found in 17 patients (18%) with no efficacy in 2 patients (2%), 31-35 years age group, efficacy was found in 62 patients (67%) with no efficacy in 12 patients (13%). On comparison with vaginal progesterone group, 25-30 years efficacy was found in 19 patients (20%) with no efficacy in 3 patients (3%), 31-35 years age group, efficacy was found in 63 patients (66%) with no efficacy in 10 patients (11%) with *p*-value 0.8.

Stratification of efficacy with respect to gestational age.

Among cervical cerclage group, efficacy was found in 11 patients (12%) with BMI <25 and no efficacy was found in 2 patients (2%). Patients group with BMI >25, efficacy was found in 68 patients (73%) with no efficacy in 12 patients (13%). Among vaginal progesterone group, efficacy was found in 12 patients (13%) with BMI <25 and no efficacy was found in 2 patients (2%). Patients group with BMI>25, efficacy was found

Table-I: Mean age, gestational age, no of mid-trimester pregnancy losses, duration of complain and BMI (n=188).

Demographic variables	Cerclage group Mean ± SD	Progesterone group Mean ± SD
Age (years)	31.62 ± 1.90	31.42 ± 1.86
Gestational Age (weeks)	21.840 ± 1.46	21.46 ± 1.52
No of mid-trimester pregnancy losses	2.393 ± 0.63	2.44 ± 0.84
BMI (kg/m^2)	27.835 ± 1.86	28.01 ± 1.75

Table-II: Stratification of efficacy with respect to gestational age.

Gestational Age (weeks)	Cerclage Group		*p*-value	Progesterone Group		*p*-value
	Efficacy			Efficacy		
	Yes	No		Yes	No	
18-20	20 (22%)	1 (1%)	0.8	18 (19%)	1 (1%)	0.8
>20	59 (63%)	13 (14%)		64 (67%)	12 (13%)	

Table-III: Stratification of Efficacy with respect to number of mid-trimester pregnancy losses.

No. of midtrimester pregnancy losses	Cerclage group		*p*-value	Progesterone Group		*p*-value
	Efficacy			Efficacy		
	Yes	No		Yes	No	
2-3	79 (85%)	6 (6%)	0.9	82 (86%)	5 (6%)	0.9
>3	-	8 (9%)		-	8 (8%)	

in 70 patients (74%) with no efficacy in 11 patients (12%) with *p*-value 0.9.

Stratification of efficacy with respect to number of previous mid-trimester pregnancy losses was shown in table-III.

DISCUSSION

Cervical insufficiency may be present in up to 1% of obstetric populations, and it therefore represents a concern frequently enough that a guideline to address the dilemmas in its management is overdue. Despite having been part of obstetric practice for over a century, both the role of cervical cerclage and vaginal progesterone remain ill defined and controversial, with wide practice variations in different clinical settings. In part the lack of clarity lacks data about effectiveness of cervical cerclage and vaginal progesterone in patients with cervical insufficiency[11-17].

Majority of the patients were from 31-35 years (78.7%) in our study. This is not unexpected as most cases of the cervical incompetence in developing countries result from traumatic insults on the cervix which increases with maternal age as termination of pregnancies and deliveries are undertaken.

Efficacy in cervical cerclage group was seen in 79 (84.9%) patients and 82 (86.3%) in patients in vaginal progesterone group, these results are consistent with Agustin indirect meta analysis which showed no statistically significant difference between vaginal progesterone and cerclage in the reduction of preterm births or adverse perinatal outcomes[16-18]. Vaginal progesterone, significantly reduced the risk of preterm birth <35 and <32 weeks of gestation, composite perinatal morbidity/mortality, neonatal sepsis, composite neonatal morbidity, and admission to the neonatal intensive care unit (RRs from 0.29 to 0.68). Cerclage, significantly decreased the risk of preterm birth <37, <35, <32, and <28 weeks of gestation, composite perinatal morbidity/mortality, and birthweight <1500 g (RRs from 0.64 to 0.70). Z Alfirevic study also showed no satistically significant differences in perinatal losses, neonatal morbidity and preterm births among three groups of vaginal progesterone, cerclage and cervical pessary (32% vs 12%; relative risk (RR) = 2.70; 95% CI, 1.10-6.67)[19] which is comparable with our study. Conde-Agudelo study showed that vaginal progesterone and cerclage were equally effective for preventing preterm birth and improving perinatal outcomes in women with with singleton gestation, previous preterm birth and a midtrimester sonographic short cervix[20] as in our study both are equally effective for preventing preterm birth in patients with previous history of preterm losses. Shao Wei Wang concluded in his study that Cervical cerclage showed more benefits in the maternal and neonatal outcomes than vaginal progesterone therapy for women with an asymptomatic short cervix and prior PTB history, while cervical cerclage and vaginal progesterone therapies showed similar effectiveness for women with an asymptomatic short cervix but without a history of PTB[21] that is consistent with our study. Several studies had proved that the use of either cervical cerclage or vaginal progesterone was effective in the prevention of PTB in patients with a cervical length ≤2.5 mm[22,23]. Recently, two professional organizations have recommended that cerclage may be considered for the management of women with a singleton gestation, prior spontaneous preterm birth and a cervical length <25 mm before 24 weeks of gestation[24]. In addition, a subgroup analysis showed that vaginal progesterone was associated with a significant reduction in the risk of preterm birth at <33 weeks of gestation and composite neonatal morbidity and mortality in women with a short cervix (<25mm), singleton gestation, and pre-vious spontaneous preterm birth[25]. The availability of vaginal progesterone and cerclage for the prevention of preterm birth in women with a short cervix, singleton gestation and previous spontaneous preterm birth could create a dilemma for physicians and patients alike about the optimal choice of treatment[9]. Thus far, there are randomized controlled trials that have directly compared vaginal progesterone and cerclage has not been performed. In the absence of this evidence, indirect meta-analysis has emerged as

an accepted and valid methodology for comparing competing interventions with each other using a common comparator. Vaginal progesterone and cervical cerclage both decreases the risk of pre-term birth and improves perinatal outcomes in singleton gestations with a midtrimester sonographic short cervix, without any demonstrable deleterious effects on childhood neurodevelopment.

CONCLUSION

Prophylactic cervical cerclage and vaginal progesterone were equally efficacious in prevention of preterm birth in women with high risk of cervical insufficiency for considerable prolongation of pregnancy. Selection of the optimal treatment needs to consider adverse events, cost and patient/ clinician preferences.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any authors.

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