Original Article

Comparison of Efficacy of Cervical Cerclage and Vaginal Progesterone in the Prevention of Preterm Labour

Sara Fayyaz, Joveria Sadaf, Sana Hafeez, Sana Aara, Aisha Ajmal and Aslam Mehmood Malik

ABSTRACT

Objective: To compare the efficacy of prophylactic vaginal progesterone with cervical cerclage in women with previous history of preterm birth.

Study Design: Randomized controlled trial study

Place and Duration of Study: This study was conducted at the Department of Obstetrics & Gynecology, Shahida Islam Medical and Dental College (SIMDC), Lodhran from April, 2020 to April, 2021 for a period of one year.

Materials and Methods: 120 women at 14-20 weeks of gestation, who had previous history of preterm birth were included in the study. Women who had rupture of membranes, multiple pregnancy, antepartum hemorrhage and severe intra-uterine growth retardation were excluded. Progesterone pessary 200mg was given vaginally once daily at night till delivery in the Group A and McDonald's stitch using prolene 1-0 was applied by the researchers themselves in the Group B. Effectiveness (yes/no) of both methods were noted by the researchers.

Results: The mean age of women in group A was 29.97 ± 5.43 and in group B was 28.63 ± 5.12 years. Majority 68 (56.67%) were between 18 to 30 years of age. Gestational age was from 14 to 20 weeks with mean gestational age of 17.19 ± 1.97 weeks. The mean gestational age in group A was 17.13 ± 1.98 weeks and in group B was 17.23 ± 1.97 weeks. Mean parity was 2.43 ± 0.79. Mean BMI was 29.81 ± 3.11 kg/m^2. Efficacy [no preterm birth (<37 weeks)] was 38 (63.33%) in group A (vaginal progesterone) and 56 (93.33%) in group B (cervical cerclage) with p-value of 0.0001.

Conclusion: Conclusion was that prophylactic cervical cerclage is more efficacious than prophylactic vaginal progesterone in women with previous history of preterm birth.

Key Words: preterm birth, progesterone, cervical cerclage

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INTRODUCTION

One of global obstetrical problem is the preterm delivery of the foetus, around 15 million annually leading to approximately 1 million neonatal deaths[1]. Preterm birth leads to high neonatal mortality as well as short and long term adverse effects[2] like respiratory illnesses, cerebral palsy, sensory deficits and learning disabilities[3].

As far as it's long term effects are concerned these individuals are at increased risk of hypertension, diabetes mellitus, metabolic syndrome and other chronic illnesses[4] . United States reported a rise in preterm birth of 9.63 % in 2015 to 9.8 5% in 2016[5].

Treatment of preterm birth is based mainly on detection of increased uterine contractions, cervical ripening and membrane decidual activation to identify patients at increased risk of preterm birth[4,5].

Women who are at increased risk of preterm labour have been subjected to progestrone, cervical pessaries and cervical cerclage[5]. Mode of administration of progestrone can be intramuscular per oral or per vaginal[7] leading to decrease in neonatal morbidity and mortality[6,7]. Patients with history of preterm birth and having shortened cervical length have been benefited by cervical cerclage application[8]. Abd Elaal NK et al[9] found 40.50% decrease in preterm birth in Progestrone group and 11.60% in cercalage group. A systemic review and meta-analysis found 72.0% reduction in the preterm birth in vaginal progestrone group and 46% in cervical cerclage group[10]. A recent study resulted that preterm birth is seen in 33.9% cases in progestrone group and 45.2%in cerclage group[11]. Previous studies showing controversial results made us to study and compare the efficacy of prophylactic vaginal

Department of Obstetrics and Gynaecology, Shahida Islam Medical & Dental College, Lodhran.

Correspondence: Dr. Sana Hafeez, Senior Registrar, Department of Obstetrics and Gynaecology, Shahida Islam Medical & Dental College, Lodhran
Contact No: 03336311448
Email: drsanahafeez@hotmail.com

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progesterone with cervical cerclage in women with previous history of preterm birth in local population. It will help us to know the local statistics and to make the practical guidelines in our practice to prevent the preterm birth, perinatal mortality and morbidity.

MATERIALS AND METHODS

Study Design: Randomized controlled trial.
Setting: Department of Obstetrics & Gynecology, Shahida Islam Medical and Dental College, Lodhran.
Duration of Study: 27th April 2020 to 26th April 2021.
Sample Size: The calculated sample size was 120 i.e. 60 in each group with 5% level of significance, 90% power of study, taking percentage of preterm delivery as 72.0% in the vaginal progesterone and 46.0% in the elective cerclage group[10].
Sample Technique: Non-probability, consecutive sampling.
Sample Selection: All 18-40 years of age women presenting with gestational age 14-20 weeks (assessed on LMP) having previous history of preterm birth having were included in the study. Patients having twin and multiple pregnancy, antepartum haemorrhage and preterm premature rupture of membrane (PPROM) were excluded. The patients having severe intra-uterine growth retardation as assessed on ultrasonography were also excluded.
Data Collection Procedure: After taking approval from ethical review committee of SIMDC Lodhran, 120 patients presenting to out-patient department who fulfilled the inclusion criteria and gave informed consent were included in the study and divided in to two groups A & B by lottery method. 200mg vaginal progestrone daily at night till delivery was given to group A. In group B cervical cerclage (McDonald stich) with prolene 1-0 applied by researchers themselves after admission in SIMDC. Both groups were monitored till delivery and results were noted as per operational definitions mentioned previously.
Statistical Analysis: Data was analyzed by SPSS 25.0 version. Age of patient, parity, gestational age, BMI were presented as mean and standard deviation. Status of gestational diabetes, pregnancy induced hypertension, education, place of living, and efficacy were presented as percentage and frequency. Both groups were analyzed in terms of efficacy by Chi-square test. P value ≤ 0.05 showed statistically significant result. Chi-square was applied post stratification to see effect of these on efficacy. P value ≤ 0.05 was considered significant.

RESULTS

Distribution of patients according to age, gestational age, parity, BMI, place of living, education status, PIH and GDM in both groups is shown in Table 1 & 2 respectively. Efficacy (no preterm birth (<37 weeks)) was 38 (63.33%) in group A (vaginal progesterone) and 56 (93.33%) in group B (cervical cerclage) with p-value of 0.0001 as shown in Table 3.

Table No.1: Demographic Segmentation

		Group A	Group B	Total
Age(years)	18-30	32(53.3%)	36(60%)	68(56.67%)
	31-40	28(46.67%)	24(40%)	52(43.33%)
	Mean±SD	29.97±5.43	28.63±5.12	29.30±5.27
Gestational age(weeks)	14-17	35(58.33%)	33(55.0%)	68(56.67%)
	18-20	25(42.67%)	27(45.0%)	52(43.33%)
	Mean±SD	17.13±1.98	17.23±1.97	17.19±1.97
Parity	0-2	28(46.67%)	35(58.33%)	63(52.50%)
	3-4	32(53.33%)	25(41.67%)	57(47.50%)
	Mean ± SD	2.57 ± 0.77	2.30±0.79	2.43 ± 0.79
BMI(kg/m $^{2)}$	≤ 30	28(46.67%)	28(46.67%)	56(46.67%)
	>30	32(53.33%)	32(53.33%)	64(53.33%)
	Mean ± SD	29.75 ± 2.92	29.83 ± 3.30	29.81 ±3.11
Place of living	Rural	18(42.86%)	22(36.67%)	40(33.33%)
	Urban	42(57.14%)	38(63.33%)	80(66.67%)
Education	Uneducated	22(36.67%)	24(40.0%)	46(38.33%)
	Educated	38(63.33%)	36(60.0%)	74(61.67%)

Table No.2: Association of Medical Disorders in Both Groups

PIH	Yes	15(25%)	18(30%)	33(27.50%)
	No	45(75%)	42(70%)	87(72.50%)
GDM	Yes	10(16.67%)	14(23.33%)	24(20%)
	No	50(83.33%)	46(76.67%)	96(80%)

Table No.3: Comparison of Efficacy between both Groups

		Group A (n=60)	Group B (n=60)
Efficacy	Yes	38(63.33%)	56(93.33%)
	No	22(36.67%)	04(6.67%)

P value is 0.0001 which is statistically significant

DISCUSSION

Factors which are responsible for the initiation of labour are targeted to prevent preterm birth. These include increased uterine contractility, preterm cervical ripening and/or activation of the membrane decidua. When compared with placebo or standard care, progesterone, cervical cerclage and cervical pessary were found to be effective in reducing preterm birth[12,13]. Aim of this study was the comparison between the efficacy of prophylactic vaginal progesterone and cervical cerclage in women with previous history of preterm birth. Efficacy was defined as no preterm birth at <37 weeks. Efficacy was 38(63.3%) in group A i.e. those women who were given vaginal progesterone and 56 (93.3%) in the group B i.e. those women in whom cervical cerclage was applied with p value of 0.0001. According to one study done by Abd Elaal NK et al[9], in the women who were given only vaginal progesterone, preterm birth was noted to be 40.5% but in those women in whom cervical cerclage was applied the rate of preterm birth was only 11.60%. One systematic review and network meta-analysis showed preterm birth rates in both groups to be 72.0% and 46.0%[10] respectively. Preterm delivery rate was 33.9% in the first group and 45.2% in the 2nd group (adjusted odds ratio: 1.72, 95% confidence interval: 0.52,5.66).[11]

Patients with or without history of preterm birth but short cervix as seen on ultrasound have reduced rate of preterm delivery and neonatal morbidity and mortality after receiving vaginal progesterone as shown by two independent randomized clinical trials[14-16] and an individual patient data meta-analysis. Patients with acute insufficiency of cervix[17] or with a previous history of preterm birth and short cervix of <25mm[18] on ultrasound were candidates of cervical cerclage. So vaginal progesterone and a cervical cerclage have a beneficial role in decreasing preterm birth in patients with previous history of preterm birth and short cervix<25mm.

Cerclage may be considered for women with singleton pregnancy, previous history of spontaneous preterm birth and cervical length of <25 mm before 24 weeks of gestation[19,20] as recommended recently by two professional organizations. The basis for this recommendation was that the individual patient data meta-analysis (IPD) of randomized control trials showed that the risk of preterm birth at <37,<35,<32,<28 and <24 weeks of gestation, total perinatal morbidity and mortality is reduced significantly in those women in whom cerclage was applied compared with no cerclage[21]. According to another IPD meta-analysis women who had a short cervix of <25 mm in the mid trimester were given vaginal progesterone which significantly decreased the risk of preterm birth at <35, <34, <33, <30 and <28 weeks of gestation, total neonatal morbidity and mortality as compared to placebo[16]. Risk of preterm birth at <33 weeks of gestation and total neonatal morbidity and mortality in women with a short cervix (<25mm), singleton pregnancy and previous spontaneous preterm birth was reduced significantly in a subgroup analysis[16].

Women who had a cervical length of less than 25 mm in the mid trimester singleton pregnancy and previous spontaneous preterm birth were given either vaginal progesterone or cerclage was applied and it was associated with decreased risk of preterm birth at less than 32 weeks of gestation [RR 0.47, 95% confidence interval (CI) 0.24-0.91, for vaginal progesterone, and RR 0.66, 895% CI 0.48-0.91, for cerclage] and total perinatal morbidity and mortality (response rate (RR) 0.43, 95% CI 0.20-0.94, for vaginal progesterone, and RR 0.64, 95% CI 0.45-0.91, for cerclage) when compared with placebo and no cerclage, respectively[22].

For prevention of preterm birth in singleton pregnancy, a cochrane review comparing cerclage with no treatment showed that there was less marked but statistically significant decrease in the preterm birth[16]. After application of cervical cerclage, the preterm births reduced consistently at all commonly reported gestational periods (<37, <34 and < 28 weeks), other clinically specified subgroups and in those women in whom cervical cerclage was applied. In a meta-analysis by Berghella et al[23], cerclage was found to be beneficial in women with singleton pregnancy, short cervix and preterm births.

CONCLUSION

According to this study prophylactic cervical cerclage was found to be more efficacious than prophylactic vaginal progesterone in women with previous history of preterm birth . In order to reduce perinatal mortality and morbidity in these women cervical cerclage should be applied according to our recommendations.

Author's Contribution:

Concept & Design of Study:	Sara Fayyaz
Drafting:	Joveria Sadaf, Sana Hafeez
Data Analysis:	Sana Aara, Aisha Ajmal, Aslam Mehmood Malik
Revisiting Critically:	Sara Fayyaz, Joveria Sadaf
Final Approval of version:	Sara Fayyaz

Conflict of Interest: The study has no conflict of interest to declare by any author.

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