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Optimizing Cervical Cerclage with Dydrogesterone: Evidence from a Case Series

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Abstract: ***Preterm birth remains a leading cause of neonatal morbidity and mortality worldwide, with cervical insufficiency a major contributor to spontaneous pre-term birth. While cervical cerclage is an established intervention for restoring cervical competence, its effectiveness may be enhanced by adjunctive progesterone therapy, which possesses immunomodulatory properties and promotes uterine quiescence, reduces inflammatory pathways associated with preterm labor. This retrospective case series describes four pregnant women diagnosed with cervical insufficiency in the second trimester who were managed with either elective or emergency McDonald cerclage along with sustained-release oral dydrogesterone. All patients also received individualized supportive therapy, including tocolytics, calcium supplementation, aspirin, L-arginine, micronutrients and a few cephalosporin antibiotics and metronidazole to avoid postpartum infections. Across all cases, timely cerclage placement combined with continued dydrogesterone therapy was associated with suppression of uterine irritability and extension of gestation to term or near-term. No patient demonstrated cerclage failure, membrane rupture, or persistent uterine contractions. Early signs of infection noted in two patients were effectively managed with antibiotics, preventing progression to chorioamnionitis. All neonates were delivered healthy without the need for NICU admission. This case series highlights the synergistic benefit of combining mechanical reinforcement with hormonal support in women with cervical insufficiency. Oral dydrogesterone 30 mg SR supplementation appeared to maintain uterine quiescence and may have contributed to prolongation of pregnancy and favorable neonatal outcomes. These findings support further evaluation of oral dydrogesterone 30 mg SR as an adjunct to cerclage in high-risk cervical insufficiency.***

Keywords: Cervical cerclage, Dyhydrogestrone, cervical insufficiency, cervical competence, preterm birth

1. Introduction

Preterm birth continues to be a major global health challenge, accounting for the highest rates of perinatal morbidity and mortality and emphasizing the need for effective preventive strategies. It is estimated that about 70% of neonatal deaths and complications are due to preterm birth(1). According to the WHO, it is defined as birth before 37 completed weeks of gestation or fewer than 259 days from the first date of a woman's last menstrual period. Globally, the prevalence of preterm birth is reported as approximately 10–11%, with more than 15 million babies born prematurely each year, resulting in nearly 1 million neonatal deaths (2). Survivors are at risk of long-term complications, including neurodevelopment impairment, chronic lung disease, and metabolic disorders, which impose significant individual and societal burdens (3).

Among the multiple etiological factors, cervical insufficiency or funneling has emerged as a major contributor to spontaneous preterm birth. The onset of cervical insufficiency is usually earlier than 24 weeks of gestation. It is characterized by painless cervical dilatation leading to cervical shortening and funneling, which predisposes to pregnancy loss and preterm labor (4). It is estimated to occur in approximately 1–2% of all pregnancies, yet it may account for as many as 15% of pregnancy losses occurring between 16 and 28 weeks of gestation (5).

The etiologies of cervical insufficiency may be congenital, acquired, or related to underlying pathological processes. Congenital causes include collagen and elastic deficiencies, Müllerian duct malformations, or in-utero exposure to diethylstilbestrol. Acquired factors encompass rapid or repeated cervical dilatation, cervical lacerations during delivery, uterine curettage, or procedures such as cervical conization. In addition, underlying conditions such as subclinical infection or local inflammation can contribute to cervical dysfunction, resulting in incomplete closure or flaccidity of the internal os and, ultimately, an inability of the cervix to support the growing fetus and amniotic fluid (6).

Management of cervical shortening to prevent preterm birth includes both pharmacological and non-pharmacological options. Progestogens serve as the principal pharmacological intervention by suppressing uterine contractility and preserving cervical integrity, whereas non-pharmacological measures such as cervical cerclage and pessary placement offer mechanical reinforcement. Accurate assessment of cervical length cervical length is crucial in guiding these interventions, with transvaginal ultrasound regarded as the gold standard.

cervical length measurements obtained between 16 and 24 weeks of gestation serve as reliable predictors of preterm

birth, with most studies defining a "short cervix" as 15–30 mm and a cervical length below 25 mm considered the most clinically significant threshold for elevated risk (6,7).

Cervical cerclage is the most widely used and effective treatment for cervical insufficiency. By surgically reinforcing the internal os, it restores cervical competence, prevents premature dilatation from gravitational forces, reduces the load on the lower uterine segment, and ultimately helps prolong gestation and improve term birth rates. It is recommended for women with a history of recurrent mid-trimester loss, those with significantly shortened cervix, or in cases of progressive funneling with membrane prolapse,(8) though it does not completely remove the risk of preterm birth in patients with cervical insufficiency (9). Although both cervical cerclage and progesterone therapy are effective in reducing preterm birth, each intervention has important limitations. Cerclage carries a success rate of 80% to preventing preterm birth and progesterone alone fails to prolong pregnancy beyond 34 weeks in nearly two-thirds of high-risk cases (10,11).

Emergency cerclage, in particular, may be unsuccessful when underlying factors such as anatomical cervical weakness or subclinical infection activate the preterm birth cascade. In situations where the internal os is ≥2.4 cm dilated, surgical intervention is typically recommended; however, combining cerclage with adjunctive progesterone may offer additional uterine stabilization and help reduce the risk of subsequent cervical opening (12). Evidence suggests that progesterone reduces uterine contractions, improves cervical integrity, and lowers the risk of preterm birth when used alongside cerclage (11). Many failures of rescue cerclage occur when progesterone is not supplemented (13). Preliminary data from recent observational series suggest that combined cervical cerclage plus vaginal progesterone may further reduce preterm birth rates compared with either intervention alone, although randomized controlled trials are lacking(14). In the PREGNANT trial, treatment with vaginal progesterone gel at a dose of 90 mg among pregnant women identified at mid-gestation with a cervical length of 10–20 mm was associated with a statistically significant reduction in preterm birth rates before 33 weeks of gestation (8.9% vs. 16.1%; RR 0.55, 95% CI 0.33–0.92). (15). Therefore, continuous progesterone after emergency cerclage may help maintain uterine quiescence and reduce recurrence of cervical dilatation.

Dydrogesterone, a stereoisomer of natural progesterone, binds selectively to progesterone receptors and is characterized by excellent oral bioavailability, safety, and tolerability. It closely mimics the physiological actions of endogenous progesterone while lacking estrogenic, androgenic, glucocorticoid, or mineralocorticoid activity, and exerts beneficial anti-estrogenic effects at the endometrial level. Its elimination half-life is approximately 5–7 hours. In addition, dydrogesterone possesses immunomodulatory properties that favor a pregnancy-protective Th2 immune environment while suppressing pro-inflammatory cytokine activity at the maternal–fetal interface. In parallel, it exerts inhibitory effects on uterine contractility through suppression of prostaglandin synthesis and oxytocin receptor expression, collectively contributing to uterine quiescence and prolongation of pregnancy latency in women at risk of preterm labor (16,17). Compared with natural progesterone, it offers higher bioavailability, fewer side effects, and greater receptor selectivity, allowing for much lower therapeutic doses, estimated to be 10–20 times less than those required for progesterone. Clinical evidence further supports its role in reducing the risk of miscarriage and preterm birth (18,19). A dual approach, combining the mechanical support of cerclage with the hormonal benefits of dydrogesterone, is therefore considered a rational strategy in high-risk women.

This case series from Jeeva Women's Hospital, Satara, India, reports the management of cervical insufficiency using McDonald cerclage with adjunct sustained-release dydrogesterone. The objective is to assess the role of dydrogesterone supplementation in maintaining uterine quiescence following cervical cerclage.

2. Case Series

2.1 Case 1

A 27-year-old female, gravida 2 para 1, was diagnosed as pregnant for the second time. She had a history of preterm labor in her first pregnancy at 32 and 35 weeks. In her previous pregnancy, cervical dilation of 1 cm was observed in the third trimester, but with careful management, she was able to continue until 37 weeks and delivered successfully.

In her current pregnancy, at 18 weeks, she presented with complain of pain and pressure symptoms. Transvaginal ultrasonography revealed a cervical length of 3.02 cm. A prophylactic cervical cerclage was performed. She was prescribed oral progesterone in the form of dydrogesterone 30 mg SR until delivery, along with iron and folic acid supplements and L- arginine. The patient was advised to continue progesterone support. The suture was removed at 37 weeks of gestation, and she delivered a healthy 2 kg baby.

2.2 Case 2

A 20-year-old female primigravida presented at 24 weeks of gestation. Transvaginal ultrasonography revealed funneling of the internal os with bulging of the fetal membranes into the cervical canal, indicating progressive cervical dilatation. An emergency cervical cerclage was performed to prevent preterm delivery.

Post-procedure ultrasonography (26^{th} week) demonstrated a closed cervix with a residual cervical length of 2.65 cm, confirming successful placement of the cerclage. Despite the intervention, uterine irritability persisted, necessitating pharmacological management to achieve uterine quiescence. The patient was initiated on oral 10 mg dydrogesterone, two tablets stat, followed by a maintenance dose of 30 mg sustained-release dydrogesterone once daily. Isoxsuprine was also added for 15 days. This regimen coincided with stabilized uterine activity and cessation of further contractions.

In addition, the patient was prescribed isoxsuprine, a calcium supplement, low-dose aspirin and a multivitamin preparation. Following stabilization, the patient was maintained solely on 30 mg SR daily until 36 weeks of gestation, without the need for additional tocolytic agents. The medication was

discontinued at 36 weeks, and cerclage removal was performed and she delivered a healthy 3 kg baby at 38 weeks. There were no complications.

2.3 Case 3

A 27-year-old primigravida (G1P0), female, presented at 22 weeks of gestation for routine antenatal evaluation. Transvaginal ultrasonography revealed a short cervical length of 2.2 cm. A prophylactic cervical cerclage was performed. Post-cerclage, the patient was commenced on oral 30 mg sustained-release (SR) once daily until 36 weeks of gestation. She also received isoxsuprine, a calcium supplement, low-dose aspirin, L- arginine, and weekly HCG 5000 IU injections. No uterine contractions or other complications were observed throughout the course of pregnancy. At 38 weeks of gestation, an elective cesarean section was performed due to cephalopelvic disproportion (CPD), resulting in the delivery of a 3.2 kg healthy, full-term neonate.

2.4 Case 4

A 27-year-old primigravida (G1P0), presented at 17 weeks of gestation with pressure symptoms. Transvaginal ultrasonography revealed a short cervix measuring 2.2 cm. An elective cervical cerclage was performed. Follow-up evaluation at 24 weeks demonstrated a well-maintained cervical length of 3.1 cm. The ongoing management included oral dydrogesterone 30 mg SR once daily, supplementation with iron, folic acid, calcium and vitamin D3, along with levothyroxine. At 38 weeks of gestation, the patient continued to have a stable clinical course with no complications. Cerclage removal was performed and she delivered a healthy 3 kg baby.
All four neonates were healthy. None required admission into the neonatal intensive care unit.

3. Discussion

Cervical insufficiency is a mid-trimester phenomenon characterized by painless cervical dilatation leading to pregnancy loss or early preterm birth without uterine activity. The ideal cervical length that predicts higher risk is generally accepted as <25 mm in the mid trimester (before ~24 weeks gestation), though shorter lengths (for example ≤15 mm) are associated with especially high risk and may influence stronger or more urgent interventions (7,14).

In the current series of four patients, all were diagnosed with cervical shortening or funneling (cervical length <25 mm) in second trimester. They were managed with combined cervical cerclage and dydrogesterone therapy plus supportive measures, all pregnancies progressed without significant complications, and gestations were extended to term. These outcomes suggest that a dual combination of cerclage and hormonal strategy may enhance cervical competence, suppress uterine irritability, and prolong latency in high-risk pregnancies.

Our findings align with existing literature. A systematic review and meta-analysis reported that combining vaginal progesterone with cerclage significantly reduced the risk of preterm bleeding before 37 weeks compared with progesterone alone (RR 0.75; 95% CI 0.58–0.96). Compared with either cerclage or progesterone alone, the combination further decreased preterm birth before 28 weeks, lowered neonatal mortality, prolonged gestational age, and reduced neonatal intensive care admissions, supporting the synergistic effect of mechanical and hormonal interventions (21). Evidence indicates that the risk of recurrent cervical dilatation after rescue cerclage typically reported at 7–8% can be further reduced when adjunct progesterone therapy is used. Progesterone enhances uterine quiescence, reduces inflammatory mediators, and improves cervical stability, thereby supporting the mechanical effect of the cerclage and lowering the likelihood of failure or recurrent shortening (13, 22, 23).

Reviews on cervical cerclage reaffirm its efficacy in preventing preterm birth, highlighting the importance of appropriate patient selection, optimal timing, and close surveillance. According to a study by He et al. (6) the success of cervical cerclage and the resulting pregnancy outcomes largely depend on when the procedure is performed. Elective cerclage conducted between 14 and 18 weeks of gestation yields the most favorable outcomes and is widely recommended in clinical practice. However, when cervical insufficiency is diagnosed later (between 19 and 27 weeks), an emergency cerclage should be performed without delay, followed by vigilant postoperative monitoring and infection control to ensure the best possible results. In the present series, considering the gestational age and timing of intervention, Cases 1, 2 and 3 underwent Emergency cerclage at respective weeks 19th, 22nd and 24th while Case 4 (at 17 weeks) underwent Elective cerclage placement. These cases highlight the importance of timely identification and management of cervical shortening with cerclage and appropriate pharmacological support to ensure pregnancy continuation and optimal perinatal outcome.

All four patients underwent cervical cerclage using the McDonald technique, the preferred first-line approach due to its simplicity, minimal invasiveness, and favorable outcomes compared with more complex options such as the Modified Shirodkar, Guard Suture method, or transabdominal cerclage. In these cases, timely intervention prevented progression to cerclage failure, eliminating the need for a Modified Shirodkar stitch, which is generally reserved for situations where the McDonald technique is inadequate or has previously failed. Our findings align with existing evidence showing that transvaginal McDonald cerclage effectively prolongs pregnancy and supports optimal neonatal outcomes in women with cervical insufficiency (24).

Several guideline reviews, such as FIGO's Good Practice Recommendations and the clinical practice guidelines by the Society of Obstetricians and Gynecologists of Canada (SOGC)'s Maternal Fetal Medicine committee, also highlight that many international protocols recommend cerclage in conjunction with progesterone for singleton pregnancies with prior spontaneous preterm birth and a shortened cervix. In particular, endorse ultrasound-indicated cerclage for women with cervical length <25 mm in the context of a prior mid-trimester loss or spontaneous preterm birth (25,26).

Evidence from one of the meta-analyses demonstrates that vaginal progesterone in singleton pregnancies with a mid-trimester cervical length ≤25 mm significantly reduces preterm birth at <36, <35, <34, <32, <30, and <28 weeks of gestation; spontaneous preterm birth at <33 and <34 weeks of gestation , as well as neonatal morbidity, including NICU admission and low birth weight (11). Network meta-analyses further support the preventive roles of vaginal progesterone and cerclage, particularly in high-risk women with short cervix (27).

Dydrogesterone, a potent oral progestogen structurally and pharmacologically similar to natural progesterone, has a strong affinity for progesterone receptors. Although recent studies on its combined use with cerclage for cervical funneling are limited, oral dydrogesterone has shown promising results in reducing preterm birth risk compared to other progestogens such as 17-α hydroxyprogesterone caproate (28).

In these current cases, cerclage restored or maintained cervical length, and adjunctive oral dydrogesterone 30 mg SR likely contributed to uterine quiescence and reduced stress on the suture. None of the neonates required NICU care, and all pregnancies progressed without the need for additional tocolytics beyond the initial 15 days course. Although a few patients showed early signs suggestive of chorioamnionitis or amnionitis, high vaginal swabs were obtained and infection was closely monitored. These cases were successfully managed with appropriate antibiotics, and metronidazole. Importantly, no patient developed uterine irritability or membrane rupture, underscoring the value of timely detection, vigilant surveillance, and prompt intervention in preventing complications following emergency cerclage.

This case series has a few limitations, including a small sample size, lack of a cerclage only comparison group, and variability in supportive treatments. Its observational design limits conclusions about dydrogesterone's independent effect, and results may not apply to severe cervical shortening (<10mm), multiple gestations, or infections. Future randomized studies comparing cerclage with and without dydrogesterone, stratified by cervical length and risk factors, are warranted. Despite these limitations, our findings suggest that combining mechanical and hormonal therapy may yield favorable outcomes in high-risk cervical insufficiency.

4. Conclusions

This case series underscores the role of cervical cerclage with adjunctive dydrogesterone in stabilizing the cervix and maintaining uterine quiescence, thereby supporting successful pregnancy continuation in women with cervical shortening. Cervical cerclage is an established intervention for pregnancies at high risk of preterm birth, and in women with a cervical length ≤25 mm or additional risk factors, combined mechanical and progestogen therapy may offer advantages over monotherapy. The selection of progestogens should prioritize agents with favorable pharmacokinetics, receptor specificity, and safety, such as oral dydrogesterone**.** However, high-quality evidence evaluating oral progesterone formulations in specific high-risk subgroups remains limited. These findings highlight both the potential value of combination therapy and the need for further prospective research.

Conflicts of interest

The authors declare no conflicts of interest.

Ethics approval

All patients provided informed consent for the use of anonymized images from their diagnosis and treatment for research purposes, ensuring that all identifying information would be removed. Written informed consent was obtained from the patients described in this case series.

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