

Comparison of two emergency cervical cerclage techniques in twin pregnancies: a retrospective cohort study matched with cervical dilation

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Abstract

Background: Emergency cervical cerclage (ECC) is of potential value in twin pregnancy, when the cervix is dilated to >1 cm. McDonald and Shirodkar were two main techniques of transvaginal cerclage at present. As ECC at extremely high risk of spontaneous preterm birth (sPTB) especially for twins with cervical dilated $[?] \geq 3$ cm and prolapsed membranes, so which technique has more advantages is still uncertain. **Objectives:** The aim of our study was to evaluate the effectiveness of ECC performed with combined McDonald-Shirodkar technique in twin pregnancies between 18–26 weeks with painless cervical dilation 1–6cm. **Methods:** A retrospective, cohort study matched with the degree of cervical dilation was conducted. The study group (case group) included twin pregnancies who underwent combined McDonald-Shirodkar approach with cervical dilation $[?] \geq 1$ cm between 18–26 weeks of gestation at four institutions, from December 2015 to December 2022. To minimize confounding factors, we elucidated the causality structure using a DAG (Figure 1) and performed 1:1 case-control Matching. A control group performed McDonald approach. The primary outcome was gestational age (GA) at delivery. The secondary outcomes were pregnancy latency, the rates of sPTB at <28 , <30 , <32 , <34 weeks, and neonatal outcomes. Additional sub-analysis was performed by dividing the patients into two subgroups of cervical dilation $[?] \geq 3$ cm and < 3 cm. **Results:** 84 twin pregnancies were managed with either combined McDonald-Shirodkar approach (case group: $n=42$) or McDonald approach (control group: $n=42$). Demographic characteristics were not significantly different in two groups ($p>0.05$). After adjusting for confounders which were represented by a directed acyclic graph (DAG, Figure 1), median GA at delivery was significantly higher (30.5 vs 27 weeks, Bate: 3.40, 95% confidence interval (CI): 2.13–4.67, $p<0.001$) and median pregnancy latency was significantly longer (56 vs 28 days, Bate: 24.04, 95% CI: 13.31–34.78, $p<0.001$) in the case group compared with the control group. Rates of sPTB at <28 , <30 , <32 , and <34 weeks were significantly lower in the case group than in the control group. For neonatal outcomes, there were higher birth weight (BW) (1543.75 vs 980g, Bate: 420.08, 95%CI: 192.18–647.98, $p<0.001$) and significantly lower overall perinatal mortality (7.1% vs 31%, aOR: 0.16, 95% CI: 0.04–0.70, $p=0.014$) in the case group compared with the control group. And when cervical dilation $[?] \geq 3$ cm, combined McDonald-Shirodkar procedure can significantly reduce perinatal mortality (8.3% vs 46.7%, aOR:0.09, 95%CI: 0.01–0.77, $p=0.028$), significantly decrease the risk of delivery at <28 , <30 weeks, prolong GA at delivery and pregnancy latency compared with McDonald procedure. **Conclusions:** ECC performed with the combined McDonald-Shirodkar procedure in twin pregnancies with cervical dilation 1–6 cm in mid-trimester pregnancy may reduce the rate of sPTB and improve perinatal and neonatal outcomes compared with McDonald procedure, especially for twins with cervical dilation of 3–6 cm and prolapsed membranes.

Introduction

Twins account for 0.5–4.0% of all births, in the last decade, the rate of twin pregnancies has increased substantially in China^{1,2,3}. During 2012 to 2020, the twinning rate increased by 13.3% from 2.84 to 3.22 per 100 total births⁴. Since fertility policy had changed in China from two-child policy in 2014 and three-child policy in 2021, the rate of multiple births has shown an upwards trend⁵. Twin pregnancies are associated with 50% incidence of preterm birth (PTB) and at increased risk for low birth-weight (LBW), they are five times more likely to have early neonatal and infant death and complications related to prematurity and LBW⁶. The most important risk factor for PTB in twins is short cervical length prior to 24 weeks⁷⁻⁹. Twin pregnancies with cervical dilation ≥ 1 cm in the second trimester are associated with a poor prognosis, and more than 90% will result in sPTB¹⁰⁻¹³. The data on the efficacy of cervical cerclage based on dilated cervix is limited in twin pregnancies, whereas it is widely accepted in singleton pregnancies. In 2019, the Society of Obstetricians and Gynaecologists of Canada (SOGC)¹⁰ and in 2022, the Royal College of Obstetricians Gynaecologists (RCOG)¹⁴ suggested that emergency cervical cerclage (ECC) as a salvage measure in both singleton and multiple gestations, when the cervix is dilated to >1 cm without contractions. So ECC represents one of the best-commonly surgical interventions to prevent sPTB in obstetrics. While the technique has been widely studied and evaluated, controversy remains regarding certain aspects of the therapeutic indication and complementary management tests to be performed¹⁵⁻²⁰. Currently, two most commonly performed cerclage procedures are modifications of Shirodkar and McDonald^{21,22}. ECC may have higher chance of failure and other complications such as preterm premature rupture of membranes (PPROM), chorioamnionitis are more common^{23,24}. It has been suggested that cerclage placement closer to the internal os may be associated with improved perinatal outcome^{25,26}. Unlike the known methods, our novel technique is characterized by a combination of the Shirodkar and McDonald's techniques, application of a cervical balloon dilator (Aiyuan) to replace the membranes into the uterus before placement of Shirodkar suture. The aim of our research is to compared the effectiveness of this novel technique to McDonald method, and to observe whether this ECC technology has the best maternal and neonatal outcomes in twins with cervical dilation of 1-6cm and/or prolapsed membranes without contraction between 18-26 weeks of gestation.

Materials and Methods

Study design and participants

In this retrospective cohort study, twin pregnancies were matched with the degree of cervical dilation at diagnosis. The patients in our study had comprised all twins with asymptomatic cervical dilation 1-6cm and/or with prolapsed membranes up to the external os at 18–26 weeks of gestation from December 2015 to December 2022 at four Medical Institutions: Women's Hospital, Zhejiang University School of Medicine; Huzhou Maternity and Child Health Care Hospital; Shaoxing Maternity and Child Health Care Hospital; and The First People's Hospital of Fuyang. The study was approved by the institutional Review Boards at each participating institution.

In case group, cerclage procedures were performed under a combination of the McDonald and Shirodkar's techniques. Specific operations are as follows:

Firstly, using the McDonald's technique with 1-0 non-absorbable sutures, under spinal anesthesia, the suture was not tightened. A cervical balloon dilator (Aiyuan) was introduced to the cervical canal with gentle pressure to replace the membranes into the uterus before suturing, and the balloon at the top of the catheter was filled with 10-20 ml saline. Secondly, with the Shirodkar technique, a Mersilene tape was inserted above the junction of the cervix with dissection of the bladder and rectum and tried to place the tape as close to the internal cervical os as possible. Thirdly, remove the balloon slowly after draining the saline, tightened the Mersilene tape first, then tightened the 1-0 non-absorbable suture.

A control group were matched one-to-one with the case group, according to the cervical dilation at diagnosis of ± 2 cm, GA of ± 3 weeks at presentation of diagnosis and maternal age of ± 5 years. We used case-control matching in Statistical Packages of Social Sciences (SPSS) for Windows, version 25.0 (SPSS, Chicago, IL, USA). Cerclage procedures were performed under McDonald's techniques.

The decision to perform which cerclage technique was based on individual physician and patient prefe-

rences, and antenatal steroids were offered to all women [?] 24 weeks of gestation. The exclusion criteria were included as follows: history of multi-fetal pregnancy reduction to twins at >14 weeks, fetuses with structural or chromosomal abnormalities, medically indicated PTB (twin-twin transfusion syndrome, severe preeclampsia, placental abruption, PPROM, or placenta previa), and cerclages placed for other indications (history-indicated cerclage or ultrasound-indicated cerclage). Patients who did not deliver in the four hospitals or were lost to follow-up by telephone were also excluded.

Interventions

All the patients were informed of the potential benefits and risks of ECC, signed informed consent. The attending physicians were senior obstetricians and their fixed team. The preoperative evaluation included assessment of vaginal bleeding or discharge, serum white blood cell (WBC) count and C-reactive protein level, intra-amniotic infection, and uterine contractions. The degree of cervical dilation was determined by pelvic exam and/or speculum exam and specimens for mycoplasma, chlamydia, bacterial vaginosis, candidiasis and trichomonas's were collected at the time of exam. An isolated finding of vaginal discharge was evaluated for a definitive diagnosis and antibiotics were used for at least 48 hours empirically according to a drug sensitivity test. Patients tested positive for chlamydia and their sexual partners were treated. Clinical chorioamnionitis was defined as maternal fever of [?]38deg C with one of the following conditions: maternal tachycardia (>100 beats/minute), fetal tachycardia, (>160 beats/minute), WBC >15 x 10³/L, or uterine tenderness. Evidence of intra-amniotic infection was a contraindication for ECC. Preoperative prophylactic antibiotics was offered to all patients, and perioperative indomethacin and nifedipine were administered and continued 48 hours postoperatively.

Medical data

The following variables were collected from patient medical records: maternal age, parity, pregestational body mass index (BMI), use of in vitro fertilization, chronicity, maternal major comorbidities including pregnancy-associated hypertensive disorders and gestational diabetes mellitus, membrane prolapse beyond external os, manipulation of membranes during the cerclage, cervical dilation in cm at diagnosis, GA at the time of cervical dilation, GA at the time of cerclage, GA at delivery, interval from diagnosis of cervical dilation to delivery, rates of sPTB, rates of PPROM, surgical technique, selection of sutures and additional tocolysis.

GA was determined by evaluating the last menstrual period and crown-rump length measurement on early ultrasound. Chronicity was determined by early ultrasound.

Neonatal outcomes included birth weight, Apgar score at 5 minutes, admission to the neonatal intensive care unit (NICU), severe neonatal complications and neonatal or perinatal mortality.

Primary and secondary outcomes

The primary outcome was GA at delivery. The main secondary outcomes were as follows: maternal outcomes of pregnancy latency, rate of sPTB at <28, <30, <32 and <34 weeks; and neonatal outcomes. The primary and secondary outcomes were also evaluated in the subgroups of women with cervical dilation of <3cm and [?] 3cm to evaluate the efficacy of combined McDonald-Shirodkar technique in less or more severe cases.

Sample size calculation

Post-hoc sample size estimation: Using the primary outcome measure of GA at delivery, a sample size of 42 achieves 99.30% power to detect a mean of paired difference of 3.5 with a significance level (alpha) of 0.05, using a two-sided paired Wilcoxon signed-rank test. Using the secondary outcome measure of sPTB at <32 weeks of gestation, in a paired experimental design, this sample size allowed the detection of a significant difference of 33.3% in the rate of PTB at <32 weeks. At the error level of α -value of 0.05, a total sample size of 84 women achieved a power of 93%.

Statistical analysis

Statistical analysis was performed using SPSS for Windows, version 25.0. A two-sided p-value of <0.05 indicated statistical significance. Continuous variables are presented as median (interquartile range) and categorical variables as number and percentage. Significance between groups was assessed by the McNemar test for categorical variables and the paired-samples t-test for continuous variables with a normal distribution. Wilcoxon rank sum test, a non-parametric test, was performed for continuous variables with non-normal distribution. Multivariable logistic regression, after adjust for confounders (presented in DAG), was performed to identify risk factors associated with sPTB. Kaplan–Meier curves were generated for GA at delivery according to the different subgroups (cervical dilation $< 3\text{cm}$ and $[\geq] 3\text{cm}$) and compared using the log-rank test to assess the prolongation of pregnancy observed in each subgroup.

Results

We identified 108 twin pregnancies screening with cervical dilation 1-6cm at 18–26 weeks of gestation who met inclusion criteria. Some twins were identified when cervical length was suspected shorten by transvaginal ultrasound, which prompted a physical exam. At last, 48 women underwent a combination of McDonald-Shirodkar technique(cases) and 60 were followed up McDonald techniques(controls). To minimize confounding factors, we elucidated the causality structure using a DAG (Figure 1) and performed 1:1 case-control Matching. After re-matching, 42 cases and 42 controls were obtained. Participant demographic characteristics were similar for each group (Table 1).

Maternal outcomes

Maternal outcomes are described in Table 2 and Table 3. Analyses were adjusted for maternal age, gestational BMI, ART pregnancy, operative hysteroscopy, prior cervical surgery, prior sPTB, GA at diagnosis, amniotic membrane prolapse, WBC, CRP at diagnosis. Compared with the control group, median GA at delivery was significantly higher (30.5 vs 27 weeks, Bate: 3.40, 95% CI:2.13-4.67, $p<0.001$) and median pregnancy latency was significantly longer (56 vs 28 days, Bate:24.04, 95% CI:13.31-34.78, $p<0.001$) in the case group. McDonald-Shirodkar combined technique was associated with significantly lower incidence of sPTB at <28 weeks (16.7% vs 57.1%, aOR: 0.15, 95% CI: 0.05-0.44, $p= 0.001$), <30 weeks (38.1% vs 76.8%, aOR: 0.17, 95% CI: 0.06-0.48, $p= 0.001$), <32 weeks (54.8% vs 88.1%, aOR: 0.16, 95% CI: 0.05-0.50, $p= 0.002$), and <34 weeks (73.8% vs 92.9%, aOR: 0.22, 95% CI: 0.05-0.90, $p= 0.036$). The mode of delivery and the rates of PPROM <34 weeks did not differ between the two groups. The Kaplan–Meier curves in Figure 2 showed that the cumulative percentage of patients with delayed birth was significantly higher in case group than in the control group. The log-rank test showed a significant increase in pregnancy prolongation ($p < 0.001$).

Neonatal outcomes

Neonatal birth weight was significantly heavier in the case group than in control group (1543.75 vs 980g, Bate:420.08, 95%CI: 192.18-647.98, $p<0.001$). There was significantly lower overall perinatal mortality (7.1% vs 31%, aOR: 0.16, 95% CI: 0.04-0.70, $p=0.014$) in the case group than in the control group. There was no difference in composite adverse neonatal outcomes (12.5% vs 27.3%, aOR: 0.48, 95% CI: 0.13-1.68, $p=0.249$) and NICU admissions (77.5% vs 90.9%, aOR: 0.26, 95% CI: 0.06-1.16, $p=0.078$) (Table 2 and Table 3.)

Pregnancy outcomes according to the degree of cervical dilation

We separately analyzed the subgroups with cervical dilation $[\geq]3\text{cm}$ and $<3\text{cm}$. In the subgroup of twin pregnancies with cervical dilation $[\geq]3\text{cm}$, 24 women were in the case group and 15 were in the controls. There were no significant differences between the groups in sPTB at <32 , and <34 weeks; however, there were significant differences in median GA at delivery (30.5 vs 26 weeks, Bate:4.96, 95%CI: 2.69-7.23, $p< 0.001$), median pregnancy latency (44 vs 22 days, Bate:35.14, 95%CI: 13.97-56.31, $p = 0.002$), sPTB at <28 weeks (16.7% vs 73.3%, aOR: 0.08, 95% CI: 0.01–0.41, $p = 0.003$), <30 weeks (33.3% vs 93.3%, aOR: 0.03, 95% CI: 0.01–0.38, $p = 0.006$) and birth weight (1542.35 vs 802.5 g, Bate:735.41, 95%CI: 355.68-1115.14 $p< 0.001$)(Table 4 and Table 5). The Kaplan–Meier curves generated for GA at delivery by cervical dilation $[\geq]3\text{cm}$ and log-rank test for pregnancy prolongation showed significant differences between the

groups ($p < 0.001$) (Figure 3).

In the subgroup with cervical dilation < 3 cm, 18 women were in the case group and 27 in the controls. There were significant differences in median GA at delivery (32.5 vs 28 weeks, Bate: 3.24, 95%CI: 1.48-5.01, $p = 0.001$), median pregnancy latency (59 vs 29 days, Bate: 20.54, 95%CI: 6.13-34.95, $p = 0.007$), sPTB at < 28 weeks (0% vs 34.0%, aOR: 0.21, 95% CI: 0.05–0.98, $p = 0.047$), sPTB at < 32 weeks (50.0% vs 81.5%, aOR: 0.17, 95% CI: 0.04–0.75, $p = 0.019$), and the rates of birth weight > 1000 g (88.9% vs 55.6%, aOR: 0.12, 95% CI: 0.02–0.74, $p = 0.022$). (Table 4 and Table 5). The Kaplan–Meier curves generated for GA at delivery by cervical dilation < 3 cm and log-rank test showed a significant difference in prolongation of pregnancy between the groups ($p = 0.038$) (Figure 4).

COMMENT

Several findings are notable from this retrospective, cohort study. First, when cervical dilation 1-6 cm in twins, ECC performed with the combined McDonald-Shirodkar procedure is of more benefit, with reduction in the rates of sPTB at < 28 , < 30 , < 32 and < 34 weeks, significantly prolongation of latency (8 weeks), higher GA at delivery, higher birth weight and lower perinatal mortality than with McDonald procedure. Second, when cervical dilation > 3 cm, combined McDonald-Shirodkar procedure has more obvious advantages with significantly reduction sPTB at < 28 , < 30 weeks, and overall perinatal mortality, also with prolongation pregnancy (by more than 6 weeks), greatly improved GA at birth, and higher birth weight compared with McDonald technology.

Some previous studies suggested no difference in outcomes when women receiving Shirodkar were compared with those receiving McDonald cerclages^{27, 15, 16, 22}. Also some researches indicated that Shirodkar superior to McDonald because of that the advantage of Shirodkar cerclage placed higher on the cervix.^{16, 28, 29} However, all studies are committed to singleton pregnancy with cervical incompetence, no well-designed studies comparing the efficacy of these methods for ECC in twin pregnancy have been published. Since the occurrence mechanism of sPTB is different between twin and singleton pregnancies^{24, 30, 31}, preventive measures should be treated differently. In addition to the patient population, cerclage position may effect the variability of cerclage efficacy, and higher cerclage is associated with a lower incidence of sPTB. Recently, Alper Basbug et al²⁷ conducted a retrospective study compared the efficacy of modified Shirodkar and McDonald cerclage techniques in singleton pregnancy with cervical dilation > 1 cm, although they found there had no differences in rates of sPTB and GA at birth, but the interval from cerclage to delivery was significantly longer in Shirodkar group than in McDonald group (83.8 ± 37.6 vs 63.7 ± 38.9 days, $p = 0.08$). Therefore, we can assume that ECC performed Shirodkar technique had longer pregnancy latency than McDonald technique, and in our study, we underwent combined McDonald-Shirodkar technique which involves the dissection of the bladder with suture placement as high as feasible around the supravaginal. Our research had indicated that this technology may reduce rates of sPTB and improve maternal and fetal outcomes when compared with McDonald technology.

In our cohort research, we used a 1-0 non-absorbable sutures when undergone McDonald's technique and use a Mersilene tape when conducted Shirodkar technique, and in a RCT research on cervix cerclage materials suggested that monofilament suture did not reduce rate of pregnancy loss when compared with a braided suture³². Zhi- Min Xu et al³³ conducted a retrospective case-control study compare the efficacy of two stitches versus one stitch in women with ECC in singleton pregnancies and indicated that the procedure with two stitches can prolong the pregnancy and improve the neonatal prognosis more effectively, and it was similar to our research that we also use two stitches in case group. Resul Karakus et al³⁴ reported a new a technique, using a combination of the Shirodkar and McDonald's techniques to trying to place the Mersilene tape as high as possible on the uterine cervix for ECC and proposed this method is safe, effective, and had better fetal and neonatal outcomes in singleton pregnancies compared with McDonald method. But their study had a small sample size and all the cases in the study were singleton pregnancies.

The efficacy of cerclage was reduced in cases which cervical dilatation has begun and the fetal membranes have prolapsed into the vagina, because the larger the cervical dilatation, the higher the difficulty of operation

and the higher the risk of failure^{23,35,36}. The currently available literature lack of evidence for cervical dilation of 4 cm or more, in 2019, SOGC¹⁰ suggested ECC may be considered in women in whom the cervix has dilated to < 4 cm without contractions. The only published study comparing ECC in twin pregnancies with cervical dilation 4-6cm showed an overall positive effect on pregnancy and neonatal outcomes³⁷, which indirectly supported a potential benefit of ECC in twin pregnancies with cervical dilation [?] 4cm.

In our study, the cervical dilation was 1-6cm and more than 50% of cases with amniotic membranes prolapsed beyond the external os. And our conclusions were consistent with Chanjuan Zeng's³⁸ and we believed that in the urgent situation of cervical dilation of 4-6cm and bulging membranes, ECC may be the only salvage measure for prolonging gestation and improving neonatal outcome. In addition, our study assume that ECC performed with the combined McDonald- Shirodkar procedure is the best option of surgical therapy in twin pregnancies with cervical dilation of 3-6 cm and prolapsed membranes.

At present, most prior publications and guidelines on cervical cerclage suggest GA at cervical cerclage placement is up to 24 weeks of gestation. However, in clinical practice, prolongation of gestation can significantly improve neonatal prognosis and reduce perinatal mortality for women with asymptomatic cervical dilation [?] 1 cm or prolapsed membranes up to the external os at 24-26 weeks of gestation. And ,in 2022 ,RCOG¹⁴ suggested that ECC as a salvage measure in the case of premature cervical dilatation with exposed fetal membranes in the vagina can be considered up to 27⁺⁶ weeks of gestation. Recently, some retrospective cohort studies^{39,40} indicated that Ultrasound-indicated cervical cerclage (UIC) placement in twins may dilated to 26-28 week's of gestation. And in our study, the GA of ECC placement extended to 26 weeks. Due to the small sample size, more large sample studies are needed to confirm this conclusion.

Strengths and limitations

The strengths of our study are that it is a retrospective, cohort study matched with the degree of cervical dilation in ECC technology in twin pregnancy, which undertook a subgroup analysis for cervical dilation [?] 3cm and < 3cm. There are no prior dedicated retrospective, cohort matched studies in this population. Our study adds to the current limited literature on ECC technique in twin pregnancies. Despite the small sample size, we were able to show a significant benefit of this novel technique in twin pregnancies with cervical dilation 1-6cm. Furthermore, our study proposed the potential benefit of this novel technique even in women with cervical dilation [?]3cm and prolapsed membranes, in whom had a high chance of sPTB before 28 weeks and we first to suggest that ECC placement may be extended to 26 weeks of gestation in twins. Also, our study does have some limitations. Firstly, because of the retrospective nature of this study, selection bias was inevitable despite our attempts to reduce this by matching one-on-one with controls. Secondly, there could be a potential concern that the patients considered subjectively to have a higher risk of PTB tend to receive combined McDonald-Shirodkar procedure, resulting in possible selection bias. However, the clinical characteristics between the two groups were similar, suggesting that selection bias was minimal. Due to these limitations, future randomized control studies with large samples are warranted to evaluate the efficacy of each treatment and confirm our findings.

Conclusions: In addition, we suggested that ECC placement may be extended to 26 weeks of gestation in twin pregnancy. ECC performed with the combined McDonald-Shirodkar method in twins with cervical dilation 1-6 cm may reduce the rate of sPTB and improve perinatal and neonatal outcomes compared with McDonald procedure, especially for twins with cervical dilation of 3-6 cm and prolapsed membranes.

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Details of Ethics Approval

The study protocol was approved by the Ethical Committee of Women Hospital, Zhejiang University, School of Medicine in Hangzhou (IRB-20230054-R) and has been carried out according to the declaration of Helsinki.

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