

Local injection of diluted vasopressin at the time of the modified Shirodkar cerclage

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Abstract

Objective: To report surgical outcomes of the modified Shirodkar method performed using diluted vasopressin.

Case presentations: The age range of patients who underwent hydrodissection was 24-39 years (Mean age 30.9 years). Out of the 10 cases, four (40%) of them had failed McDonald cerclage in previous pregnancies, four (40%) of them had emergency cerclage, one (10%) of them had previous second trimester (T2) miscarriage/miscarriages and short cervix on USS and one (10%) had short cervix on ultrasound alone as indications. Four (40%) of them had the stitch performed after 20 weeks of gestation and six (60%) had it done before 20 weeks.

During the procedure no single case of adverse cardiac events or raised blood pressure was noted. Estimated blood loss (EBL) ranged from 5 to 10 ml (mean EBL - 6.5 ml). Four (40%) procedures were recorded as difficult procedures by the operator. Not a single case of tonic uterine contractions was recorded following the procedure. One (10%) of them had a vaginal delivery at term, one (10%) had a vaginal delivery at 26 weeks, four had CS (40%) at term, and four (40%) of them delivered vaginally between 34-37 weeks. Only one (10%) case had a retained piece of stitch in the cervix and in one (10%) the stitch was left in-situ as requested by the patient. Only one (10%) patient had delivered at 26 weeks, eight of them (80%) had continued their pregnancies beyond 34 weeks.

Conclusion: Our experience shows that judicious use of local injection of diluted vasopressin to perform hydrodissection during the modified Shirodkar cerclage is a safe and efficacious method and would increase the overall quality of the technique by reducing the blood loss and enhancing the plane of dissection.

Key words: modified Shirodkar cerclage, McDonald method, preterm birth, vasopressin, hydrodissection, cervical cerclage

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Introduction

Cervical cerclage is a key intervention that prevents spontaneous preterm birth in high-risk women¹. Many methods of cervical cerclage are in practice amongst obstetricians, whilst controversies exist regarding the effectiveness and safety of these methods². The McDonald method involves the application of thread around the mid cervical level as a purse string. This is a relatively easy method³. Although the McDonald method of cervical cerclage is widely in practice, a previous failed McDonald method may necessitate a Shirodkar method⁴. Although there are no randomized controlled trials (RCT) to compare the efficacy of various cervical cerclage techniques, one comparative study showed that the modified Shirodkar method was superior to the McDonald method⁵. Figuera et al, reported that Shirodkar prolonged the duration of the pregnancy in obese women as opposed to the McDonald method⁶. Cervical cerclage is associated with some risks. Surgical manipulation of the cervix can cause uterine contractions, bleeding or infection which may lead to miscarriage or preterm labour². These risks must be carefully balanced against the benefits before considering the procedure.

During the modified Shirodkar method, dissection of the bladder away may lead to bleeding, making the surgical field less clear. Furthermore, the surgeon has to operate within a narrow space. This could lead to accidental puncture of cervical vasculature or even fetal membranes in some cases. However, it appears that placement of a stitch at the level of the internal os of the cervix could give more beneficial effects than placing it at a lower level.

In our unit, we have started to use hydrodissection techniques using diluted vasopressin to improve the surgical outcomes in selected patients. Randomized clinical trials have shown that infiltration of vasopressin to minimize blood loss in various gynecological surgical procedures is a safe and effective option⁷. Food and drug administration authority (FDA) advice to use only if the benefit outweighs the risk in pregnancy⁸.

In our setting, we started to use diluted vasopressin to perform dissection of the bladder base (hydrodissection) at the time of the modified Shirodkar cerclage in carefully selected patients. As this method of modification has not been described in the literature before, we aimed to analyse the outcomes of this method.

Case presentations

Data of 10 patients who underwent the modified Shirodkar cerclage were analysed retrospectively. Patient's operative notes, and diagnosis cards were traced for the purpose of analysis. All of these patients had undergone hydrodissection using diluted vasopressin during the modified Shirodkar cerclage procedure.

These procedures were performed by an experienced single operator in two different tertiary care centers in Colombo, Sri Lanka from January 2018 to November 2020.

Indications for this method were a history of at least one failed McDonald cerclage, cervix shorter than 2 cm, anatomically distorted cervix and open cervix at the time of presentation (less than 4 cm).

The patients were carefully evaluated by a consultant anesthetist for potential contraindications for the use of vasopressin. All relevant information regarding the procedure and outcomes was collected from clinical records after obtaining permission from the medical directors of the respective centers.

Technique

The procedure was performed under spinal anesthesia. The patient was placed in the dorsal lithotomy position. The bladder was emptied. One vial of vasopressin (20 units) was diluted in 200 ml of normal saline (0.1 units/ml). 40 ml of diluted vasopressin solution was infiltrated into the vaginal mucosa at the level of vesico-cervical reflection (Figure 1). Before infiltrating, negative aspiration was applied to the syringe to test accidental puncture of blood vessels and then slow injection of vasopressin was carried out. This produced blanching at the surgical site.

A 2-3 cm transverse incision was made at the level of vesico-cervical reflection using a pair of curved scissors. A scalpel could be of use for this purpose. The bladder was then dissected upwards using fingers and scissors. A fairly bloodless field was created between the bladder base and cervix and the surgeon could see as far as the level of the internal os (Figure 2).

All the key steps of the modified Shirodkar method were performed following the same techniques that have been described above^{3,4} (Figure 3).



Figure 1. **Diluted Vasopressin being infiltrated to vaginal mucosa at the vesico-vaginal junction.**

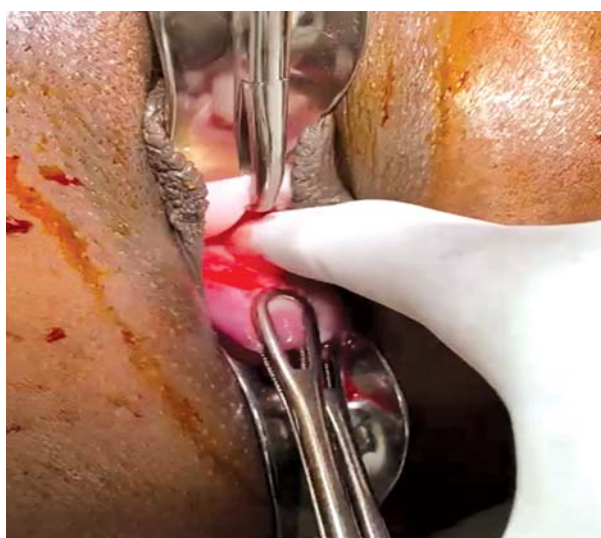


Figure 2. **Bladder is dissected upwards using fingers and scissors.**

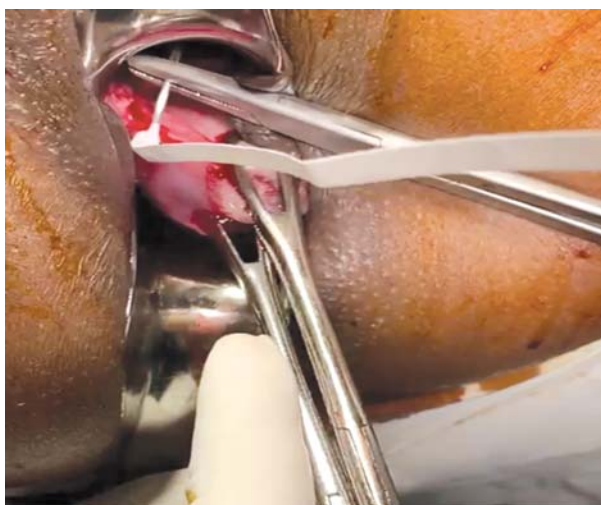


Figure 3. **Stitch is placed around the level of internal os.**

Post-procedure scan was performed to make sure of correct placement of the stitch and fetal viability. Removal of the stitches were done at 36 weeks as an outpatient procedure.

Results

Demographic details, patients' characteristics, indications, details of the procedure such as blood loss during the procedure, hemodynamic changes, post-operative complications and outcomes were extracted from clinical records. Surgeons' perceptions regarding the technical difficulty the procedure were obtained from recording the experience of the operator and assistant and the relative time taken for the procedure.

The age range of patients who underwent hydro-dissection was 24-39 years (Mean age 30.9 years). Out of the 10 cases, four (40%) of them had failed McDonald cerclage in previous pregnancies, four (40%) of them had emergency cerclage, one (10%) of them had previous second trimester (T2) miscarriage/miscarriages and short cervix on USS and one (10%) had short cervix on ultrasound alone as indications. four (40%) of them had the stitch performed after 20 weeks of gestation and six (60%) had before 20 weeks. During the procedure no adverse cardiac events or raised blood pressure was noted. Estimated blood loss (EBL) ranged from 5 to 10 ml (mean EBL - 6.5 ml). Four (40%) procedures were recorded as difficult procedures by the operator. Not a single case of tonic uterine contractions was recorded following the procedure. One (10%) of them had a vaginal delivery at term, one (10%) had a vaginal delivery at 26 weeks, four had CS (40%) at term, and 4 (40%) of them delivered vaginally between 34-37 weeks. Only one (10%) case had a retained piece of stitch in the cervix and in one (10%) the stitch was left in-situ as requested by the patient. Only one (10%) patient had delivered at 26 weeks, eight of them (80%) had continued their pregnancies beyond 34 weeks.

Brief descriptions of the individual cases, procedures, post-procedure and outcomes are shown in Table 1.

Table 1. Brief description of the procedures

| Case summaries | Procedure | Postoperative period | Outcomes |
|--|---|---|--|
| 39 years, G1P0 known PCOS, chronic HT and history of subfertility for 10 years. Cervical length was 2cm at 16 weeks. Asymptomatic. BMI 32kg/m ² . | 30 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Procedure mildly difficult due to high maternal BMI. EBL 5 ml. | No post procedure uterine contractions. Patient was discharged on the same day. | Elective CS at 37 weeks. Stitch removed post-delivery. BW 2.4kg. Postpartum period unremarkable. |
| 24 years, G1P0, presented with vague abdominal pain and vaginal discharge. Noted short cervix (2cm) at 22 weeks. Cervical os was partially opened. BMI 26kg/m ² . Emergency cerclage performed. | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Procedure was straightforward. EBL 5 ml. | No post procedure uterine contractions. Patient was discharged on the same day. | VD at 35 weeks. Stitch removed at 35 weeks in the ward. BW 2.8 kg. Postpartum period unremarkable. |
| 37 years, G2 P0, history of T2 miscarriage, PCOS, APLS and a 12 years history of secondary subfertility. Cervical length 2.2cm at 15 weeks on USS. BMI 30kg/m ² . | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Procedure was fairly difficult due to high maternal BMI. EBL 10 ml. | No post procedure uterine contractions. Mild PV bleeding noted. Patient discharged the following day. | Elective CS at 37 weeks. Stitch removed postdelivery. An Unicornuate uterus noted. BW 2.09 kg. Neonatal jaundice secondary to poor feeding. |
| 29 years, G3P0, history of two T2 miscarriages. One failed McDonald cerclage (Inserted at 14 weeks). PIH treated with Methyldopa. Cervical length 2.5cm at 14 weeks. BMI 30kg/m ² . | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Procedure fairly difficult due to a previously traumatized cervix. EBL 10 ml. | No post procedure uterine contractions. BP was mildly elevated on the next day. Patient was discharged the following day. | Elective CS at 37 weeks. Stitch left in site as per patient's request. BW 3.2kg. Postpartum period unremarkable. |
| 28 years, G3P2, two previous preterm deliveries at 30 and 32 weeks. Presented with vaginal discharge. Short cervix of 2cm at 20 weeks. BMI 24kg/m ² . Emergency cerclage performed at 20 weeks. | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Fairly difficult procedure due to vulval varicosities and short cervix. EBL 5 ml. | No post procedure uterine contractions. Patient discharged on the same day. | Frequently presents with intermittent contractions. Stitch removed at 36 weeks at the OPD. VD at 36 + 2 days. Post-partum period unremarkable. |
| 33 years, G2P1, previous CS, presented with contractions and cervical length of 2 cm with funneling at 26 weeks. BMI 28kg/m ² . Emergency cerclage performed at 26 weeks. | 40 ml diluted vasopressin infiltration done. Had a HR of 90-100 bpm throughout the procedure, presumed secondary to anxiety. BP normal. Fairly easy procedure. EBL 5 ml. | No post procedure uterine contractions. Patient was kept under observation for 24 hours prior to discharge. | Elective CS at 38 weeks as requested by the patient. Stitch removed post-delivery. BW 3.03kg. Postpartum period unremarkable. |

(Continued)

| Case summaries | Procedure | Postoperative period | Outcomes |
|---|--|--|--|
| 28 years, G4 P0, history of APLS managed LMWH and aspirin. G1: T1 miscarriage G2: T2 miscarriage G3: T2 miscarriage at 22 weeks with a failed McDonald's stitch. G4: Twin pregnancy with Dichorionic Diamniotic twins, had a cervical length of 2cm at 16 weeks. A mixed picture of cervical insufficiency and thrombophilia. Cerclage was performed at 14 weeks. BMI 24kg/m ² . | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Difficult procedure. Distorted anatomy due to previous cervical tear. EBL 10 ml. | Bleeding from the cervical incision site noted. LMWH was withheld for 48 hours. | Presented with contractions and bulging membranes at 26 weeks. Stitch was removed in the labour room. Cervical lacerations were sutured in the theater. BW of both premature neonates were below 0.5kg. Both died on day 1. |
| 31 years old, G4P2, One T2 miscarriage, two preterm deliveries at 32 and 34 weeks (with insertion of McDonald cerclage in G3 at 14 weeks). Cervical length of 2.5cm at 14 weeks. No medical complications. BMI 32kg/m ² . | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Procedure was fairly difficult due to maternal body habitus. Two assistants held up the vaginal wall to provide adequate visualization of the surgical site. EBL 5 ml. | No post procedure uterine contractions. Subsequently presented a few times with intermittent contractions. | Stitch removed at OPD. Small piece of Mersilene tape was left in situ in the posterior part of the cervix accidentally. VD at 39 weeks. Retained Mersilene tape removed from cervix post-delivery. postpartum period unremarkable. |
| 29 years old, G1 P0, presented with vaginal discharge at 20 weeks. Cervical os was opened (3 cm) with bulging membranes. Emergency cerclage performed. | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Fairly difficult procedure due to bulging membrane. EBL 5 ml. | No post procedure uterine contractions. Admitted for further observations for 2 weeks. | Delivered vaginally at 34 weeks. BW 1.9 kg No neonatal complications. |
| 31 years, G3P0, history of two T2 miscarriages. One failed McDonald cerclage at (Inserted 15 weeks). Cervical length 2.5cm at 14 weeks. BMI 25kg/m ² . | 40 ml of diluted vasopressin infiltration done. No maternal cardiac or BP issues noted. Procedure fairly easy. EBL 5 ml. | No post procedure uterine contractions. Patient discharged on the same day. | Delivered vaginally at 34 weeks. BW 1.9 kg Baby was admitted to NICU. |

Discussion

Many studies have shown the beneficial effect of vasoconstriction in gynecological surgery in terms of blood loss, easy dissection and shorter surgical time. But therapeutic use of vasopressin during pregnancy is limited due to its potential adverse effects such as the ability to induce uterine tonic contractions and cardiovascular side effects. However, we propose that judicious use of this vasoconstrictor can be used to improve the surgical outcomes in selected pregnant women.

This modification is practiced in our unit based on the evidence that myometrial and endometrial VPR and OTR are down regulated in early pregnancy and the number of OTR levels is lowest in the cervical region⁹. In addition, there is evidence to show that procedures performed using vasopressin locally showed a significant reduction in blood loss without any cardiac adverse events in pregnant women¹⁰.

We also witnessed that injecting diluted vasopressin into the mucosa at the vesico-cervical junction would cause a negligible impact on the cardio vascular system and uterine tone. In our series, we did not encounter a single case that had increased uterine contractions or miscarriage immediately after the local injection. This could be partly due to safety measures taken such as careful selection of patients, preparation of injection and double checking prior to infiltration. Moreover, we found that dissection using diluted vasopressin helps the surgeon create a good surgical field and hence less trauma to the cervix.

Literature describing vasopressin use during the modified Shirodkar method is limited. We share our experience to fill this void and suggest that further studies should be undertaken to find the optimal dose and volume of vasopressin needed to be injected. In our experience, out of 10 women, only one patient miscarried after 4 weeks of the procedure. We believe that other factors could have contributed towards this outcome. None of our patients showed any cardiac adverse events during the procedure. Furthermore, not a single woman in our group developed uterine contractions following the procedure. The surgeon felt much more comfortable with this method and a significant improvement in the technique was noted within a short period of time. Hydrodissection using vasopressin

seems to be promising in terms of safety and efficiency. Our experience shows that hydrodissection using diluted vasopressin can not only help surgeons to perform the surgery easily but also produce substantial clinical benefits. This could be mainly due to vasoconstriction causing a relative avascular field to operate and by creating a clear plane of dissection at the site of injection. This method helps to reduce the operational time and may reduce harm to the fetus. Further, it reduces the trauma to the cervix as the surgeon's confidence increases due to enhanced visibility of the surgical field during the procedure. We suggest that surgeons performing this modified method should obtain informed consent from the patients and inform the anesthesiologists before using vasopressin.

Conclusions

Our experience shows that hydrodissection using diluted vasopressin during the modified Shirodkar method appears to be safe and efficacious. This method appears to increase the overall quality of the technique by reducing the blood loss and enhancing the plane of dissection. Apart from careful selection of patients, use of optimal dose and ensuring that it is not being injected into a blood vessel by careful testing can minimize the potential risks. This method could be considered as an alternative procedure to abdominal cerclage methods. Further comparative studies should be conducted before recommending this method.

Conflict of interest

Authors state no conflict of interest.

Informed consent

Informed consent has been obtained from all individuals included in this study.

Ethical approval

The research related to human subject use has complied with all the relevant national regulations, and institutional policies, and is in accordance with the tenets of the Helsinki Declaration, and has been approved by the Authors' Institutional Review Board or equivalent committee.

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