

Use of a uniconcave balloon in emergency cerclage

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Pushing bulging fetal membranes back into the uterine cavity effectively without rupture of fetal membranes during emergency cerclage is a concern to obstetricians. We have developed a new uniconcave balloon device for repositioning fetal membranes into the uterus during emergency cerclage. Our technique can be accomplished easily with few complications.

Key words: cervical insufficiency, emergency cerclage, uniconcave balloon

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Problem: bulging fetal membranes

Cervical insufficiency with bulging fetal membranes during the second trimester is a serious complication of pregnancy, leading to stillbirth or preterm delivery.¹ Women who present with advanced cervical dilation on physical examination may benefit from emergency cerclage.²⁻⁸ However, membranes are easily ruptured intraoperatively, especially when the cervix is widely dilated and the fetal membranes are prolapsed beyond the external os.^{5,6} Pushing bulging fetal membranes back into the uterine cavity during cerclage with a sponge swab or Foley catheter is difficult. Overfilling the urinary bladder to reduce prolapsed fetal membranes without direct mechanical contact is often not sufficient as a single method.⁹ Other less utilized techniques include inflatable devices, such as a metreurynter or a rubber balloon.⁶⁻⁸

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Industry Academic Cooperation Foundation of Hallym University holds a patent in Korea on the balloon device, with K-Y.L as an inventor.

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Our solution

We designed a new uniconcave balloon device for repositioning fetal membranes into the uterus and report its use in 103 patients who underwent emergency cervical cerclage for bulging membranes from March 2010 through March 2013 at Hallym University Medical Center (Video Clip). Women had internal cervical os dilation at least 1 cm, with membranes visible at or beyond the external os by speculum examination. We excluded women who had multifetal gestations, fetuses with major malformations, ruptured membranes, vaginal bleeding, persistent regular uterine contractions, clinical chorioamnionitis, or prior prophylactic cerclage. The study was approved by the ethics committee of our hospital.

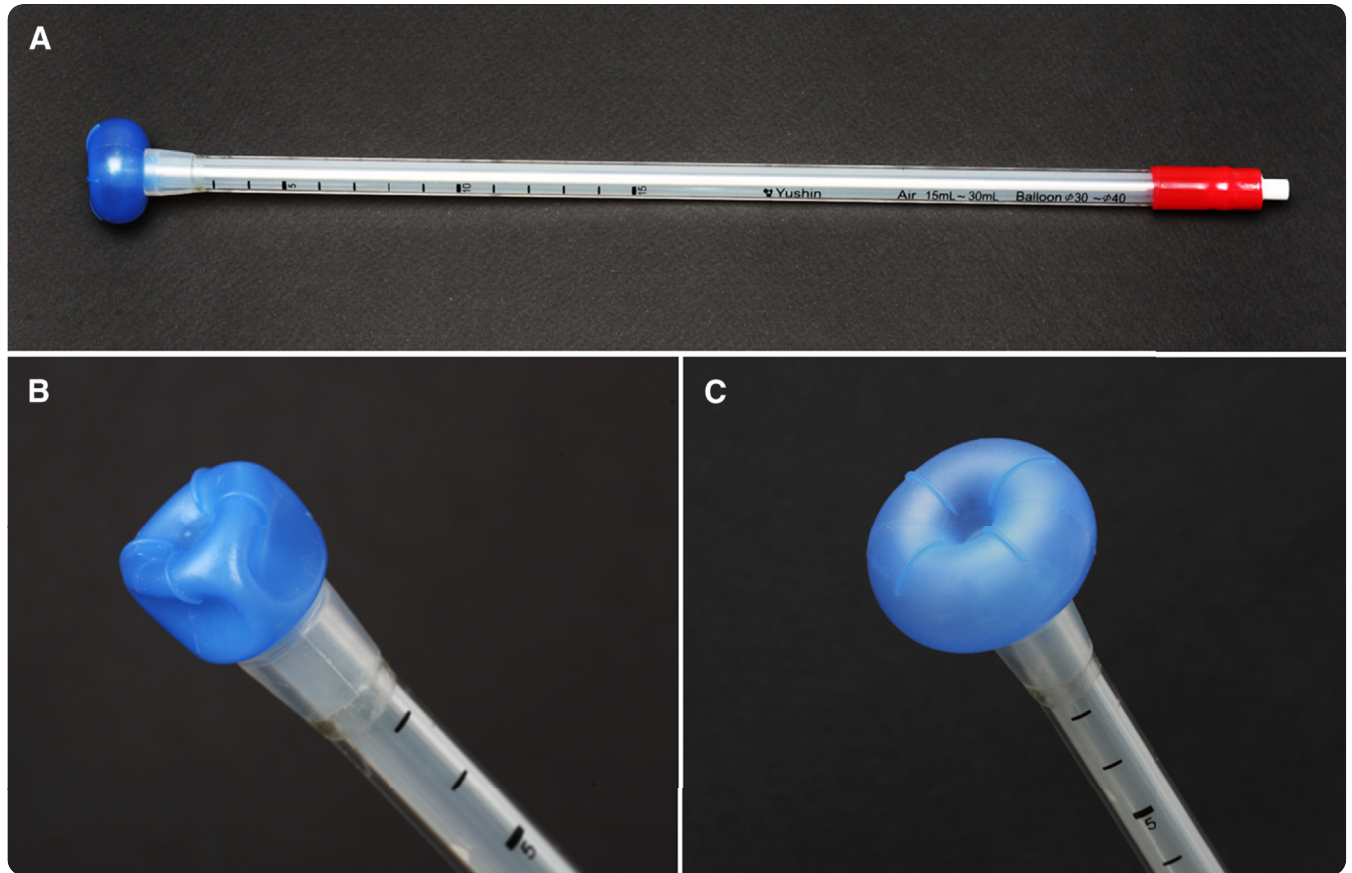
The uniconcave balloon is shown in Figure 1. In comparison with other balloon devices, the shape of our balloon is uniconcave, so that it can push the bulging amniotic sac in adjustment to its spherical shape, allowing the fetal membranes to be placed back into the uterus safely and effectively. It has a shape similar to that of a red blood cell or a donut, which provides maximum surface area to allow the force exerted on the membranes to be evenly distributed. This causes less trauma and decreases the likelihood of rupturing the membranes. The firm shaft allows physician to grip the device with one hand, leaving the other hand entirely free and convenient to suture the cervix. The shaft also has centimeter gradations marked on it to

indicate the insertion depth during the procedure. Since we have various sizes of the balloon, we can choose the appropriate size according to degree of cervical dilation.

The procedure (Figure 2) was performed under general anesthesia in the Trendelenburg position. Transabdominal amniocentesis was performed under ultrasonographic guidance to reduce the amount of amniotic fluid. The fetal membrane and the cervix were exposed using 2 Simpson retractors (Figure 2, A, and Figure 3, A), and the cervical edges were gently grasped with 2 atraumatic forceps (Figure 2, B). While the cervix was retracted using the forceps, the uniconcave inflated balloon was advanced via the cervical canal to push the bulging membranes back into the uterine cavity (Figure 2, C, and Figure 3, B). A McDonald cervical cerclage was then performed over the shaft: 1 purse-string suture with a 5-mm polyester tape was placed (Figure 2, D, and Figure 3, C). The balloon was then deflated, and the purse-string suture was tied as the instrument was withdrawn from the cervix (Figure 2, E, and Figure 3, D). All patients were given cephalosporin intravenously in the operating room. After the surgery, the patients were treated with bed rest and continued tocolysis for 3 days. The procedure was defined as successful when the internal cervical os was closed with intact membranes replaced into the uterus.

During the 3-year study period we performed 103 emergency cervical cerclages with the uniconcave balloon device. Of the 103 women, 12 were excluded. Eleven patients did not have complete medical records, and 1 fetus had a major cardiac anomaly. Table 1 shows the patients' characteristics. The mean gestational age at cerclage placement was 21.4 ± 2.5 weeks. Cervical dilation ranged from 1–10 cm. The pregnancy outcomes are described in Table 2. Of the 91 patients, 23 (25.3%) delivered <24 weeks' gestation and 34 (37.4%) delivered ≥ 32 weeks. The mean gestational age at delivery was 29.4 ± 6.7

FIGURE 1
Uniconcave balloon



A, Device is composed of balloon, shaft, and valve for air injection. Inflated balloon is not deformed or moved backwards when pushing bulging fetal membranes because of supportive part on rear side of balloon. Device has centimeter gradations on shaft, so that depth of insertion can be noted. **B**, Deflated balloon. **C**, Inflated balloon, shaped like red blood cell or donut.

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FIGURE 2
McDonald operation using uniconcave balloon

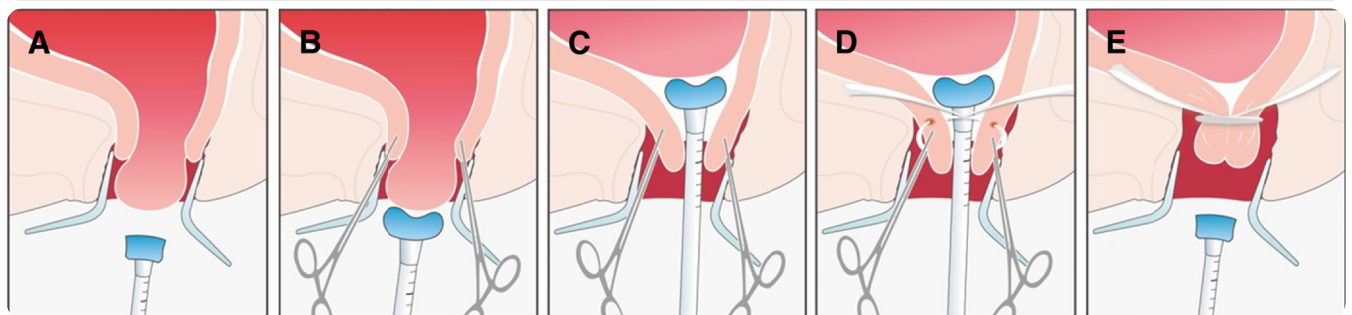
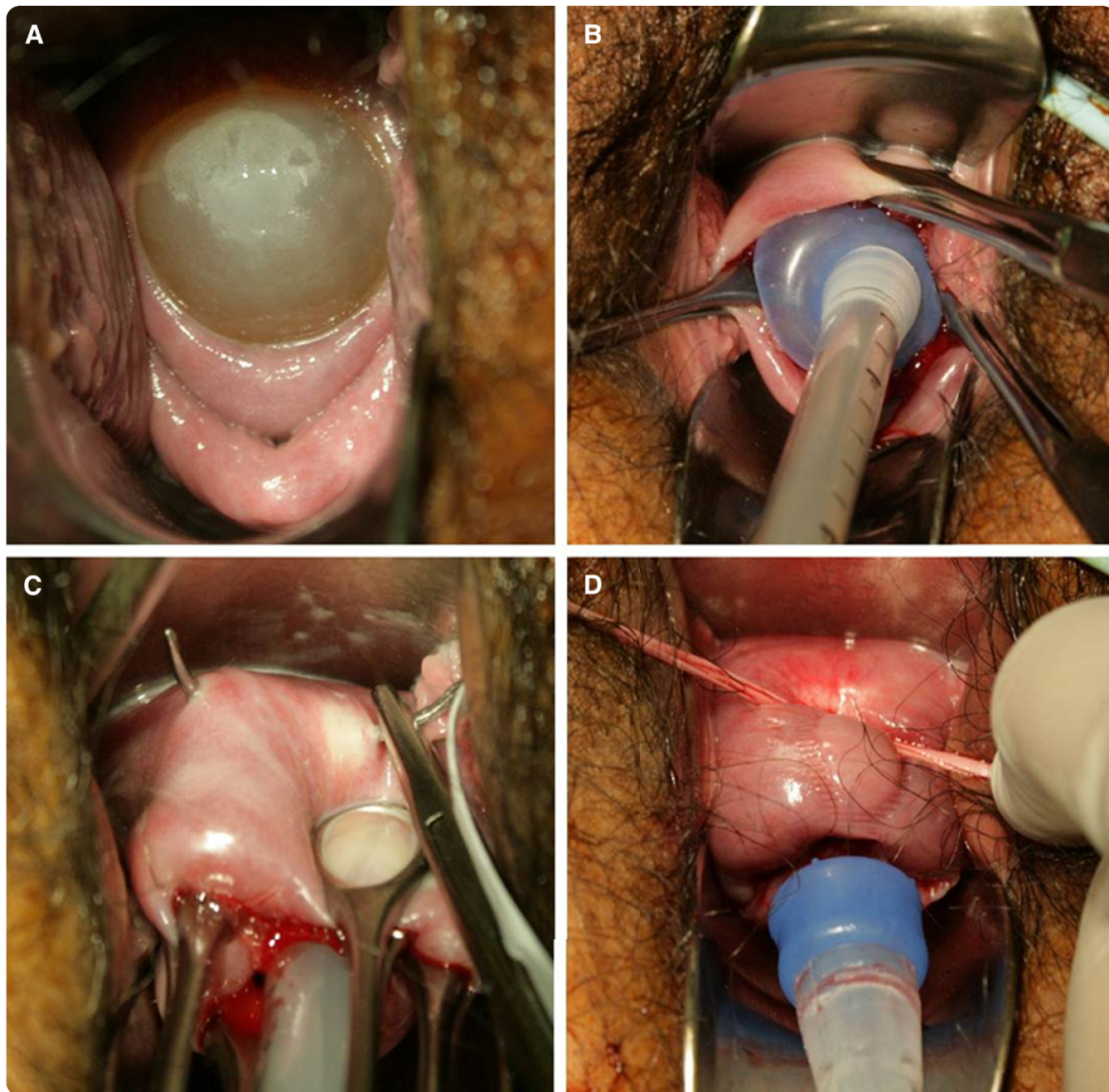


Illustration of uniconcave balloon used in cerclage procedure. **A**, Bulging fetal membranes are visualized. **B**, Cervix is grasped and retracted with 2 atraumatic forceps, and adequately inflated balloon then gently pushes fetal membranes back into uterus. **C** and **D**, After fetal membranes are replaced in uterus, sutures are placed as high as possible in accordance with McDonald technique. **E**, Balloon is deflated. Purse-string suture is tied as instrument is withdrawn from cervix.

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FIGURE 3

Photograph demonstrating McDonald operation using uniconcave balloon device



A, Bulging fetal membranes are observed. **B**, Inflated balloon gently pushes fetal membranes back into uterus. **C**, Once fetal membranes are back in uterus, sutures are placed in accordance with McDonald technique. **D**, Purse-string suture is tied as deflated balloon is withdrawn from cervix.

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weeks. The mean prolongation of pregnancy after cerclage placement was 55.2 ± 43.0 days (range, 1–140 days). Of the 91 pregnancies, 71 (78.0%) ended in live birth, and the mean birthweight was 1.89 ± 1.0 kg; 66 of the 71 live births survived.

Eleven of the 91 patients had complete cervical dilation with full bulging of membranes into the vagina. In these patients, cerclage was performed at 22.5 weeks (range, 17.0–24.5 weeks), pregnancy was prolonged for a median of 19

days (range, 1–114 days), and the median gestational age at delivery was 25.5 weeks (range, 18.5–39.0 weeks). Of the 11 patients, 8 gave birth to live infants. One newborn who was born at 23.3 weeks died of neonatal necrotizing colitis

TABLE 1
Characteristics of women undergoing emergency cervical cerclage

Characteristic	Total n = 91 (%)
Maternal age, y	33.2 ± 3.5
Obstetric history	
Parity	
Nullipara	39 (42.9)
Primipara, multipara	52 (57.1)
Previous pregnancies	
No. of women delivering at 16-32 wk	18 (19.8)
No. of women delivering at 32-36 6/7 wk	6 (6.6)
No. of women delivering >37 wk	33 (36.2)
Gestational age at cerclage placement, wk	21.4 ± 2.5
Maternal serum WBC count on admission, ×10 ³ /mL	10.6 ± 2.3
Cervical dilation at cerclage, cm	3.5 ± 2.0
<3 cm	33 (36.3)
≥3 cm	58 (63.7)
Location of fetal membranes	
Visible at external cervical os	40 (44.0)
Beyond external cervical os	51 (56.0)

Data are mean ± SD or n (%), unless otherwise specified.

WBC, white blood cell.

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22 days after delivery. The remaining 7 neonates are still alive with no remarkable disability.

Cerclage was technically successful in all cases. Rupture of membranes did not

occur at the times of cerclage in any patient, and there were no operative or anesthetic complications. Our successful experience in a relatively large number of patients leads us to conclude

that obstetricians could perform emergency cerclage with this uniconcave balloon easily and safely with few complications such as rupture of membranes. We expect that our technique will be a great help to the patients with cervical insufficiency and bulging fetal membranes. ■

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TABLE 2
Pregnancy outcomes after emergency cervical cerclage

Pregnancy outcome	Mean ± SD, n (%)
Gestational age at delivery, wk	29.4 ± 6.7
<24	23 (25.3)
24-27 6/7	23 (25.3)
28-31 6/7	11 (12.1)
32-36 6/7	15 (16.5)
≥37	19 (20.9)
Prolongation of pregnancy, d	55.2 ± 43.0
Live birth	71 (78.0)
Birthweight >1500 g	40 (44.0)

Data are mean ± SD or n (%).

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