

# An Integrative Review on Arabin Pessary: The New Kid on the Block in Womb Wellness

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## ABSTRACT

Preterm birth as a result of cervical insufficiency is one of the most common causes for perinatal mortality and morbidity. Alongside the traditional approach of interventions like cervical cerclages and pharmacotherapy like progesterone, newer methods like Arabin pessary are burgeoning, thanks to their safer and more effective outcomes. Articles of Arabin pessary elucidating its mechanism of action, its outcomes and its comparison with other methods were collected, and an integrative review has been penned to shine a better understanding on its utilization.

**Keywords:** Cervical length, Preterm birth, SPTB.

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## INTRODUCTION

When delivery of the fetus occurs before 37 weeks of pregnancy, then it is termed as preterm labor (PTL) which contributes to one of the prevailing causes of death among children less than the age of 5.<sup>1,2</sup> The WHO defines preterm birth (PTB) as extreme preterm, which is delivery of fetus <28 weeks, delivery before 28–32 weeks as very preterm, and delivery before 32–37 weeks as late preterm.<sup>3</sup> There are various causes of PTB, like stress, infections, chronic conditions, and cervical insufficiency.

In cervical insufficiency, the cervix dilates painlessly, generally during the second trimester, culminating in pregnancy loss that otherwise would have been an uneventful pregnancy.<sup>4</sup> Traditionally, management options for cervical insufficiency include cervical cerclage which is a surgical procedure, progesterone therapy, and or both. The introduction of the Arabin pessary since the last decade for the management of cervical insufficiency has given hope as it is a simple out-patient procedure. Prediction of PTL is possible by knowing risk factors such as previous preterm birth, current pregnancy whether, artificial reproductive technique (ART) pregnancy, multiple pregnancies, and more reliably by measuring cervical length by ultrasound. This review provides information on Arabin pessary use and evaluates the literature evidence available regarding its efficacy in various high-risk populations, like pregnant women with short cervix, funneling in pregnancy diagnosed by ultrasound, twin pregnancy, and previous cervical conization surgery.

### Cervical Length and Its Significance

When ultrasound shows a short cervix, it is a strong risk factor for PTB. The length of the cervix is most precisely determined using a transvaginal ultrasound (TVS), with the length varying with gestation and progressively shortening as gestational age advances.<sup>3</sup> At mid-trimester, the length of the cervix is generally expected to be around 35 mm. The length of the cervix is inversely related to the greater incidence of PTB, with a shorter cervix posing a greater in the risk for PTB. This risk is further accentuated when there are other risk factors.<sup>5</sup>

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### Available Treatment Options for PTB

The treatment of a short cervix normally includes surveillance, progesterone, cervical cerclage, bed rest.<sup>2,6</sup> In our country, cervical cerclage comprising McDonalds stitches and pharmacological options like progesterone is used to prevent preterm birth.

A recent systematic review in 2017 has shown that progesterone appears to be ineffective in preventing PTB though it exists some controversy surrounding this.<sup>7</sup> In women with a very short cervix (with a cervical length of <15 mm) cervical cerclage can be beneficial but is ineffective overall.<sup>8</sup>

Hence, there has been intensive research to find an alternative along the lines of a vaginal pessaries. Use of Arabin pessary in women with an increased risk of PTB has been shown to have promising outcomes. Studies have also shown that the use of the Arabin cervical pessary can help in decreasing the occurrence of spontaneous delivery in pregnancies less than 34 weeks.<sup>9,10</sup>

But each method comes with own its sets of challenges and downfalls. **Table 1** compares the popular treatment options available for preventing PTB.

**Table 1:** Comparison of treatment options for prevention of preterm labor

<i>Cervical cerclage</i>	<i>Progesterone</i>	<i>Arabin pessary</i>
Traditional, more commonly used	Commonly used	Upcoming
Longer hospital stays	Not required	Not required
Invasive	Non-invasive	Non-invasive
Cannot be monitored once stitch placed	Cannot be monitored	Can be monitored using MRI
Cannot be done in women with h/o cone biopsy, increased vascularity of cervix	No evidence in women with previous PTB	No relative contraindications
Can be combined with oral progesterone	Mechanical reinforcement often required	Can be combined with oral progesterone
Associated with risk of PPRM, scarring, tears, and inflammation of fetal membranes	Can affect fetal progesterone target tissues, pituitary and testes and causes chronic conditions	Increased vaginal discharge due to accumulation

### Arabin Pessary and Its Functional Considerations

Traditionally, pessaries were used in the management of genital prolapse. Up until recently, there was very little evaluation regarding the utilization of pessaries to prevent PTB, and they were used more in a sporadic manner. In the year 2022, Abdel-Aleem published a Cochrane review on cervical pessaries for preventing preterm birth.<sup>11</sup> The review concluded that there is moderate-to-low quality evidence that cervical pessary reduces the chances of PTB before 37 weeks compared to progesterone and cerclage. However, data on improvements in perinatal outcomes is inconsistent. Clear conclusions could not be drawn from heterogenous data and detection bias. Data on cervical pessary vs cerclage included only 13 women in this Cochrane review.

After this, in the later part of the 70's, Mr Hans Arabin of West Germany was one of the first to design a silicone round shaped conical pessary with the objective to encompassing the cervix as close to the internal os as possible, in order to support, compress and therefore cause an inclination of the cervix and hopefully rotate it more facing the sacrum. This action of the cervical pessary was to shift the cervix as posteriorly as possible in order to diverge the uterine load more towards the anterior lower segment and maintain constant pressure, additionally for the cervical os to remain closed.<sup>12,13</sup>

The pessary might also help to prevent progressive dilatation of the internal os, leading to the dissociation of the amnion and chorion, especially if the pregnant woman is in an upright position.<sup>14</sup> Another hypothesis also suggests that the pessary helps in keeping the cervical mucus plug intact by supporting the attachment of the remaining cervical tissue, which ultimately provides protection against any ascending infection and thus helps to maintain the pregnancy.<sup>15,16</sup>

Clinical examinations have shown that, more the longer the pessary *in-situ* in the same place during pregnancy, the greater is the chance for the cervix to likely become edematous and thick, which can then can be confirmed through MRI.<sup>17</sup> It has also been put forth that the pessary might decrease the Ferguson reflex, which is a positive feedback loop where the oxytocin is released upon any pressure on the cervix or vaginal walls via transmission to the hypothalamus and pituitary, thereby preventing any development of contractions.<sup>18</sup>

### Arabin Pessary and Its Technical Considerations

#### What Sizes Can Be Utilized?

Pessaries are available in various sizes in order to help with better adjustment to each of the patient's individual parameters.

The proximal inner diameter that is currently used differs between 32 and 35 mm along with the distal diameter of the outer part, which differs between 65 and 70 mm. The height range of the pessary also varies (17, 21, 25, 30 mm) thereby accommodating the variation in uterine size. There are also perforations within the device, which thereby help to allow for any release of the accumulated vaginal discharge.<sup>19</sup>

Normally, a 32 mm diameter is sufficiently enough to completely encompass the cervix in most women without any risk of lacerations. In conditions, with the presence of an edematous wide cervix or in cases of a U shaped or with any wider V-shaped funneling, a 35 mm diameter is often suggested to help in decreasing the pressure applied to the membranes, therefore ultimately preventing any release of prostaglandins.

In primigravida and women of shorter stature, an outer diameter of 65 mm is essential for the pessary to be in place inside the vagina, while diameters of 70 mm are selected in multiparous and tall women.

In singleton pregnancies, Pessaries of lesser heights (17–21 mm) are generally chosen, whereas pessaries with a height of 25 mm or more are used in patients with uterine extension. In cases of uterine prolapse, it is prudent to choose pessaries of 30 mm in height.<sup>19</sup>

#### How Should the Pessary be Inserted?

An initial TVS is performed to measure the cervical length of the women and to also rule out funneling. Specific tests on Fibronectin or Interleukins can be done. It is prudent to also take a vaginal and cervical swab and manage the positive cases with the available local protocols in place. It is usually not necessary for any use of anesthesia or analgesia, nor is there any need to wait for the results of the swab tests. The patient should be then counselled regarding the procedure and the necessity for the same, and finally should be then cleared of any doubts regarding the same.<sup>19</sup>

The pessary needs to be lathered with an antibacterial cream for lubrication and an easier fitting. Following this, it should then be squeezed in-between the thumb and the fingers and should be then proceeded to introduce the pessary longitudinally or upright into introitus.

The pessary inside the vagina unfolds in such a manner that the smaller or the inner ring is pointed towards the cervix. The nearest part of the dome of the pessary is then, with much care pressed along the upper fornix until the cervix is wholly encompassed and then, the anterior aspect of the pessary is pushed marginally posteriorly towards the sacrum.<sup>19</sup>

Then, the patient is instructed to stand and ambulate a few steps and is then enquired regarding any sensations. If the patient opines

any discomfort or unrest, either the position or the choice of the size of the pessary should be reevaluated. The position of the pessary is then confirmed by either a clinical examination or ultrasonography.

### Change or Removal of the Pessary

At term, around 37 weeks routinely, the pessary should be removed. The proper position of the pessary can be monitored under serial ultrasonography, or MRI. Under aseptic conditions, the pessary is taken out without the requirement for any anesthesia by repositioning the cervix back along the inner ring of the pessary. In cases of cervical edema, the patient should be counseled regarding the possibility of some pain during removal.<sup>19</sup>

In conditions of any discomfort or some minor bleeding, a cervical smear and a clinical examination can be performed by using a speculum, in order to rule out the possibility of any erosions and lacerations. It has to be followed by the removal of the pessary, and cleaning it under running water, and then reinserting, as long as there are no suspicious or imminent dangers.

In cases where there are signs of any imminent delivery or the presence of any severe contractions, the pessary should always be discarded. Non removal can lead to an increasing pressure on the cervix, therefore causing a higher risk of venous congestion or any other lesions.<sup>19</sup> In the case of any confirmed PPROM, the pessary can only be retained if chorioamnionitis can be ruled out confidently and uterine contractions are absent, especially when PPROM happens at an early gestational age.

### Evidence of Arabin Pessary Efficacy and Clinical Application

#### *In Asymptomatic Women with Short Cervix on TVS*

There is still a debate regarding the implementation of universal TVS screening for all singleton pregnancies, with debates questioning whether universal screening is the right choice or quality mid-trimester scan by trained personnel in high-risk patients is the better option.

In *Pesario Cervical para Evitar Prematuridad (PECEP)*, a multicenter random case control study Goya et al., 385 women were assigned to two groups: The pessary group and the conservative management group. Based on the utilization of pessary in screened by TVS, suggested that in participants between the gestational ages of 18–22 weeks with a short cervical length of <25 mm, the pessary decreased the poor outcome instances and helped in sustaining a prolonged pregnancy as compared to the controls. Delivery before 34 weeks was less in the pessary group (6 vs 27%). Hence, it helped in having a better neonatal outcome.<sup>20</sup>

In a RCT by Hui et al., 108 women having a cervical length of <25 mm detected at a routine second-trimester TVS, of singleton pregnancies, were recruited. Two randomized groups were created, with only one group receiving the pessary. In the rates of delivery between the two groups, delivery before 34 weeks occurred in 9.4% among the pessary group compared to 5.5% in the control group ( $p=0.46$ ), and the results showed no significant differences.<sup>21</sup> A similar outcome was reported by Nicolaidis et al.<sup>22</sup> This finding correlated with an apparent low need for pessary repositioning in the second study, thereby correlating statistically but non-significantly to the almost doubling rate of preterm birth among the pessary group.

#### *In Women with Singleton Pregnancies with High Risk for PTB*

Funneling on TVS is a very important predictor, with a significant correlation between funneling and delivery before 33 weeks of

gestation. Funneling has a three times greater risk compared to only abnormal cervical length.<sup>23</sup> In the study by Tsikouras P et al., 50% of the cases having a cervical suture inserted delivered before 33 weeks of gestation, in contrast to 19.6% of them who were not treated with a cerclage procedure but had a pessary inserted.<sup>23</sup>

When we come to comparing the treatment by cerclage vs pessary, Alfrevic et al. made a retrospective comparison in women with a previous history of SPTB <34 weeks and made 3 groups. In the first group, comprising of 142 cases managed with cerclage, the second of 59 cases with vaginal progesterone, and the third group of 42 cases by pessary, it was revealed that, there were no other significant variations in the rates of SPTB, perinatal loss or morbidity, apart from a higher rate of SPTB before 34 weeks of gestation in the vaginal progesterone as compared to the pessary groups.<sup>24</sup>

In a study done by Rahman RA et al., 81% of the cases had a pessary insertion along with the addition of progestogen therapy either through the parenteral or vaginal route, more than 50% delivered >37 weeks, with the majority of the preterm being late preterm.<sup>25</sup> Study concluded that pessary are beneficial in reducing preterm births in Malay population.

In the work done by Barinov et al., women with high risk of spontaneous preterm birth were randomly assigned into two groups, comprising of one group comprising of circular cervical cerclage with progestogen and another of an Arabin pessary with progestogen or both.<sup>26</sup> The two groups showed no significant differences in the rate of preterm birth.

#### *Women with Twin Pregnancy*

In a pilot case–control study by Arabin et al. pessaries were applied for cases with short cervix and showed that the pessary significantly decreased SPTB in twin pregnancies. The average gestational period during delivery was 33 + 2 weeks in the control group, whilst it was 35 + 6 weeks in the pessary group proving the superiority of pessary over conservative management.<sup>13</sup>

Another pilot study showed similar results and was found to have a significant decrease in SPTB with an average gestational age for delivery being 4 weeks later than in that of the controls with no pessary applied among mono chorionic twin pregnancies with short cervical length where pessary was applied after laser treatment for twin-twin transfusion syndrome.<sup>27</sup>

In a Dutch trial, 403 women with multifetal pregnancies were recruited. These women had prophylactic pessary insertion due to the presence of cervical length being <25th percentile before 20 weeks. The incidence of poorer neonatal outcomes was 12% when compared to 29% in the no-pessary group.<sup>28,29</sup>

Due to a lack of evidence suggesting that either vaginal progesterone, 17-hydroxyprogesterone caproate or cerclage has any beneficial effect on the prolongation of twin gestation, the positive outcome from the use of Arabin pessary is reassuring.

#### *In Women with a Previous Cone Biopsy*

A normal cervix consists of about 30% of smooth muscle tissue at the internal os, but has only 6% at the external os. A large cone biopsy can result in the loss of the collagen-rich area, leading to the loss of the structural integrity of the cervix.

Usually, either emergency or prophylactic cerclage application has been found to help reduce the rate of SPTB in such patients.<sup>30–32</sup>

An observational study by Kyvernitakis has shown that vaginal progesterone combined with cervical pessary may be beneficial in this group and the mean gestational age at delivery was found to be 37 + 6 weeks.<sup>33,34</sup>

### Follow-up of Pessary In-Situ What Next?

The pessary should be retained up-until around 37 weeks unless in cases of certain contraindications.

Arabin pessary has minimal side effects and is a relatively safe device. Women should be educated regarding the possible side effects of pessary insertion, primarily vaginal discharge. It can often be mistaken for either PPROM or cervical infection, and this does not form grounds for discontinuation. Sexual Activity is not generally contraindicated, with reported rates being similar in both the study and control groups, as shown by Goya et al.<sup>20</sup>

In cases of asymptomatic women with only cervical shortening, hospitalization is not routinely advocated. Adequate bed rest in a conducive home environment suffices. But in cases of having early cervical shortening with the presence of any other additional risk factors, it is wise to admit the patient in the initial period and to then follow up the patient by TVS as described by Goya et al.<sup>20</sup>

Adjuvant medications like progesterone or indomethacin have no contraindications. As mentioned above, studies have shown beneficial outcomes with the combination of vaginal progesterone. Either in cases where progressive TVS shows any further shortening, vaginal progesterone can be considered, or pessary can be added prophylactically in cases where vaginal progesterone has been started.

In cases where there is extreme funneling with absent inner cervical length, indomethacin, vaginal progesterone, etc., can be started much before pessary insertion, and then after the pessary insertion, is made to be put in the Trendelenburg position. This decreases the pressure on the internal os thereby decreasing the release of prostaglandins and thus providing an interval for the application of corticosteroids.<sup>19</sup>

### CONCLUSION

Arabin pessary is a safe instrument that is affordable, simple to use, and has minimal side effects. Pessary has shown evidence of benefit in prolongation of pregnancy in women with twin pregnancy, previous surgery such as conization and in a few selective populations with short cervix and funneling of cervix. Literature is in favor of Arabin pessary as a non-inferior option comparable to cerclage and progesterone therapy. Though cerclage is a simple procedure, it carries the risk of surgical and anesthesia risk, as well as the inherent risk of rupture of membranes and PTB. Women at high risk of PTB should be offered Arabin as a treatment option with or without progesterone therapy. Early elective insertion in women with a risk of PTB has shown promising results. Especially in low-income countries with a higher burden of PTB, there is a strong need for low-cost, low-technology preventative interventions like the Arabin pessary, which can be applied easily even at the grass roots level. Introduction of this device into the market, more research regarding its use, and providing training on its insertion and usage will help combat the disease burden.

### FUTURE PERSPECTIVE

As preterm birth is multifactorial and most often idiopathic, data on various therapies should be generated from all types of populations, including low-income countries, with multi-centric Data supporting various treatment options. Data is lacking if preterm birth can be prevented by combination of techniques like pessary with progesterone therapy vs individual therapies in different high-risk groups such as women with short cervix and funneling. Types of

pessaries that can be customized based on cervical length and funneling require further innovations. Selection bias from health care providers and pregnant women regarding specific modality of treatment affects robust data generation.

### RECOMMENDATION

With available evidence, Arabin Pessary can be used in pregnant women with twin gestation and with previous surgeries like conization. However, isolated risk factors such as short cervix and funneling of the cervix have conflicting data on the use of pessary except in certain population like the Malay and Dutch groups. Easy availability, and cost-effective pessary can be used in low and middle-income countries across different geographic groups so that robust data can be generated regarding its efficacy in preventing PTL and improving neonatal outcomes.

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