Patient's experience with Arabin cervical pessary during pregnancy: a questionnaire survey

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Abstract

Objective To investigate women's experience with the cervical pessary for prevention of preterm birth. Design: Retrospecitve questionnaire study. Setting: Tertiary care hospital in Italy. Population: 166 pregnant women treated with Arabin cervical pessary within one center. Methods: A questionnaire was administered to all women after delivery. Main outcome measures: Data about patient's experience before the insertion (adequacy of the information received), during treatment (follow-up, impact on daily life, perceived discomfort, side effects) and at the time of removal (pain, patient's expectation met regarding the treatment) were analysed. Results: Information received before the insertion of Arabin pessary was considered adequate in 163/166 (98.2%). An increase of vaginal discharge was experienced by 70/166 (42.2%) women. Discomfort or other side effects were reported in 13.8% and 16.3% of cases, respectively. Overall, 77% of women reported an improved quality of life and 94% considered the follow-up during pregnancy adequate. Removal was moderately painful for 58/166 (35%) of women. Patient's expectations regarding the treatment were exceeded in the majority of cases (75.3%). In a final step, we compared our results to previous studies suggesting that clinical experience of the health care specialists in charge may explain why the discrepancy of results. Conclusion: Although some trials report high rates of non-compliant patients, this could not be confirmed by our study. In contrast, most women reported a positive experience and were motivated to continue the treatment when they were continuously followed by experienced clinicians.

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Running title: Patient's experience with cervical pessary

Abstract

Objective To investigate women's experience with the cervical pessary for prevention of preterm birth.

Design: Retrospective questionnaire study.

Setting: Tertiary care hospital in Italy.

Population: 166 pregnant women treated with Arabin cervical pessary within one center.

Methods : A questionnaire was administered to all women after delivery.

Main outcome measures: Data about patient's experience before the insertion (adequacy of the information received), during treatment (follow-up, impact on daily life, perceived discomfort, side effects) and at the time of removal (pain, patient's expectation met regarding the treatment) were analysed.

Results : Information received before the insertion of Arabin pessary was considered adequate in 163/166 (98.2%). An increase of vaginal discharge was experienced by 70/166 (42.2%) women. Discomfort or other side effects were reported in 13.8% and 16.3% of cases, respectively. Overall, 77% of women reported an improved quality of life and 94% considered the follow-up during pregnancy adequate. Removal was moderately painful for 58/166 (35%) of women. Patient's expectations regarding the treatment were exceeded in the majority of cases (75.3%). In a final step, we compared our results to previous studies suggesting that clinical experience of the health care specialists in charge may explain why the discrepancy of results.

Conclusion : Although some trials report high rates of non-compliant patients, this could not be confirmed by our study. In contrast, most women reported a positive experience and were motivated to continue the treatment when they were continuously followed by experienced clinicians.

Keywords : Arabin pessary, preterm birth, patient's experience, obstetrics, vaginal discharge.

Introduction

Globally, preterm birth was reported with an incidence of 10.6% in 2014,[1] with wide variations among continents and countries in absolute numbers and rates of preterm births, and in absolute and relative numbers of perinatal and neonatal death.[2] Even within Europe, preterm birth rates ranged between 4.9% in Lithuania and 11.4% in Hungary in 2015.[3]

Primary prevention of preterm birth would be most desirable, but it demands the involvement of publicly funded and supported health concepts without immediate benefit to individual health care specialists, by the implementation of policies to reduce physical stress for pregnant women,[4] by smoke-free legislation,[5]by the prevention of teenage pregnancies,[6] by promoting healthy diets,[7] or possibly by the use of medications such as aspirin[8] or omega-3-fatty acids.[9-11]

In contrast, secondary prevention of preterm birth describes treatment concepts when first signs are already recognizable but expected to be reversable. Thereby, a short cervical length (CL) measured by transvaginal sonography is one of the earliest signs and sonographic assessment of CL is therefore recommended to be applied in high-risk patients or even for screening in whole populations. Cervical cerclage, vaginal progesterone and a cervical pessary specially designed to prevent preterm birth are present options that are discussed for secondary prevention in singleton and twin pregnancies. The question which method should be chosen does not solely depend on the methods themselves but also whether these pregnant women are followed within dedicated preterm birth clinics by experienced clinicians. Therefore, Di Renzo et al. already demanded in 2017 clinical training for the application of cerclage and cerclage pessaries within the European guideline for Preterm Birth.[12] However, adequate practical training is neither described nor audited in many observational or randomized controlled trials.

During the past decade, Arabin cervical pessary has been investigated in different settings in both singleton[13-15] and twin pregnancies.[16-22] It promotes an inclination of the uterocervical angle as visualized by MRI or clinically.[23,24] This mechanism is supposed to reduce the pressure on the lower uterine segment at the level of the internal cervical os and the cervix as studied in vivo by a change in maternal position[25,26] or in vitro by biomechanical engineering.[27]

However, what has been completely neglected up to now is that a clinical success also requires experience following a learning curve.[28] Up to now, there are incidental reports on side effects of the cervical pessary, but women's views and satisfaction rates have not yet been systematically investigated apart from the rates of early removal or discharge within randomized controlled trials (RCTs).[13,17]

The discrepant rates of complaints, early removal, and success in preventing preterm birth within both singleton and twin pregnancies finally motivated us to investigate women's experience with the cervical pessary within our own cohort of 10 years and to compare the results with publications where the consideration of a learning curve was no issue.

Material and Methods

At Careggi University Hospital in Florence (Italy) a total of 205 women were treated with Arabin cervical pessary for prevention of preterm birth from June 2010 to June 2020. The treatment was performed by three clinicians who had received extensive training before. The average treatment per physician was 68.3 in this series with individual differences. After the insertion of a cervical pessary there was a second control after 48 hours to verify whether the pessary was still surrounding the cervix and not displaced. Only in case of patients with an extremely short cervical length, an additional transvaginal ultrasound examination was performed to exclude rapid progress of cervical shortening.

Retrospectively the electronic database was used to contact the total cohort. 34/205 women (16.6%) had changed address and 5/205 (2%) refused to participate. The remaining 166 women were contacted and were administered a questionnaire inquiring about their experience before the insertion (adequacy of the information received), during treatment (follow-up, impact on daily life, perceived discomfort and other side effects) and at the time of removal (presence of pain, degree to which patient's expectation about the treatment were met). The questionnaire is available as Supporting Information (Supporting file 1). For vaginal discharge and pain, numerical rating scales (NRS) from 0 to 10 were used. The pain-intensity level was assigned as follows: NRS: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, and 7-10 = severe pain.[29] This study was approved by the Institutional Ethics Committee (*Comitato Etico Regionale per la Sperimentazione Clinica della Regione Toscana;* approval number: 18058).

The total cohort and specific subgroups were analysed. We chose to compare women who delivered either before or after 34 weeks because this more or less defines the success of treatment, and earlier delivery might have an impact on patient's reported experience or expectations.

Statistical analysis was performed with Graph Pad INSTAT3 software package (San Diego, CA, USA). Continuous variables were expressed as mean and standard deviation; categorical variables were indicated by percentage. We used the one sample z-test for proportions or the multinomial test to compare questionnaire's answers in the study population, and the chi-square test to compare the answers between the subgroups. A p-value of < 0.05 was considered significant.

Results

The characteristics of the study cohort of 166 patients that answered the questionnaire are demonstrated in in Table 1. Table 2 summarizes the answers given by the patients. Information received before the insertion of Arabin pessary was considered adequate in 163/166 cases (98.2%). An increase of moderate vaginal discharge (mean NRS score 5.3), a side effect that is also indicated in the instructions, was experienced by 70/166 (42.2%) women. Discomfort or any other side effect were reported in a minority of cases (13.8% and 16.3%, respectively) (Table 2). Most women (128/166) reported an improved quality of life (77.1%) and even more (94.0%) considered the follow-up, received by always the same physician, adequate (Table 2). Removal was moderately painful for 58/166 women (35%), with a mean NRS score of 6.7 ± 2.1. Patient's expectations of treatment outcome were exceeded in the majority of cases (75.3%) and almost all patients (91.6%) reported that they would choose the pessary treatment again or recommend it to a friend in a similar situation (Table 2).

Our study population included 118 Italian and 48 foreign women. There were no significant differences in

the answers given between the two subgroups, including side effects (p = 0.49), perceived adequacy of the information (p = 0.56) and of the follow-up received (p = 0.33). Among singleton pregnancies, 26/118 (22%) had a spontaneous preterm birth before 34 weeks, while 92/118 (78%) delivered after 34 weeks. 16/43 twin pregnancies (37%) and 4/5 triplet pregnancies (80%) delivered before 34 weeks secondary to spontaneous preterm labor. 3/166 patients (2%) had iatrogenic preterm birth (two for vaginal bleeding in placenta previa, one for HELLP syndrome). One patient (0.6%) required early removal of the pessary due to discomfort. In general, women who delivered later ([?] 34 weeks) reported more frequently improvements of daily life, experience better than expected and the wish to re-use the device (Table 3).

Finally, we compared our results with respect to side effects and clinical experience with details reported in RCTs investigating the outcome after cervical pessary treatment. The results are demonstrated in Table 4. There seems to be a negative association of increased early removal with the experience of the clinicians involved in the treatment and the practical training received.

Discussion

One of the main findings of this study was that apart from vaginal discharge no significant side effects or discomfort were experienced by the vast majority of patients. Moreover, the level of patient's satisfaction was high and only one patient required early removal due to discomfort.

In contrast to the PECEP trial,[13,17] in which all women treated with a cervical pessary had vaginal discharge, this symptom was only present in about 50% of our patients. Other clinical trials report a higher rate of vaginal discharge in women with pessary treatment compared to women without pessary in pregnancy, with a highly variable rate reported in the pessary group, depending on the study: 10.5% in Nicolaides et al.,[15] 86.7% in Saccone et al.,[14] and 73.3% in Dugoff et al.[30]On the other hand, pelvic discomfort is less frequently reported (Table 4). Since in most studies increased vaginal discharge is the most common side effect of pessary treatment, the patient should be advised of this even before positioning it. To prevent accumulation of vaginal fluids, Arabin cerclage pessaries that we used are characterized by perforations of the silicone ring that favour release of vaginal discharge.[20] However, it should be remembered that vaginal discharge due to Arabin pessary is not the same as that observed in "triple I" or pPROM. Therefore, there is no indication to treat it with antibiotics. As our study showed, 77.1% of women reported that they had received adequate and comprehensive information about the possibility of vaginal discharge. Communication is an essential part of treatment, as accurate counselling can be helpful in increasing patient's compliance and satisfaction with the treatment.

Encouraging data in relation to the impact of the treatment on patient's daily life emerged from our study. The fact that the majority of patients reported positive changes in their lives during treatment may be in part related to the decreased concern about the risk of preterm birth. In addition, the presence of the pessary supporting the cervix may give relief of pressure sensations while walking or standing in some patients.[24]

Patients of foreign nationality did not report a different experience with the treatment, or a different perception of the assistance and information received compared to Italian patients, while women who delivered before 34 weeks reported adequacy of the information received, positive changes in daily life, sense of satisfaction and consideration of a possible reuse of the device with a lower frequency compared to women who delivered after 34 weeks. This could be explained by the fact that childbirth occurred at low gestational ages and, consequently, in some women a negative experience related to the prematurity of their child may also have had an impact on the reported experience with the pessary.

This is the first study of maternal experience about pessary treatment. A strength of this study is that all women included were assisted by operators that were trained in proper pessary placement. This study also has limitations, which include the retrospective design and the absence of a control group.

Conclusions

Although some randomized trials report high rates of non-compliant patients, this could not be confirmed by our data. In contrast, most women treated with Arabin pessary for prevention of preterm birth reported

a positive experience, and the main side effect was vaginal discharge. Women were motivated to continue with the treatment when they were continuously followed by experienced clinicians.

Disclosure of Interest

The authors report no conflict of interest

Author contributions

VS: project development, data collection, data analysis, interpretation of data, manuscript writing. NS: project development, data collection, data analysis, manuscript editing. AD: data collection, manuscript editing. FM: data collection, data analysis, manuscript editing. LB: data analysis, manuscript editing. AM: project development, data analysis, manuscript editing. MDT: project development, interpretation of data, manuscript editing.

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Table 1) Mean characteristics of the study group of 166 women treated with a cervical pessary for preterm birth by experienced clinicians during an observation period of 10 years.

Characteristics
Age (years)
Body mass index (kg/m2)
Ethnicity White Asian Black
Nulliparous
Parous
History of preterm birth
Singleton pregnancy Multiple pregnancy: Twin pregnancies
Triplet pregnancies
Spontaneous preterm birth <34 weeks in the index pregnancy: Singleton pregnancy Twin pregnancies Triplet pregnancies

Table 2) Results of the questionnaire investigating maternal views and experiences before, during and after treatment with cervical pessary (n=166)

Related issues	Possible answers n (%)	Possible answers n (%)	Possible answers n (%)	p-value*
Adequate information before insertion	Yes 163 (98.2%)	No 3 (1.8%)		< 0.001
Information received before insertion regarding possible vaginal discharge	Yes 128 (77.1%)	No 38 (22.9%)		< 0.001
Vaginal discharge during the treatment NRS (Mean ± SD)	Yes 70 (42.2%) 5.3 ± 2.7	No 96 (57.8%)		0.05
Any other side effect during the treatment	Yes 27 (16.3%)	No 139 (83.7%)		< 0.001
Change in daily life during the treatment	Yes, positive 128 (77.1%)	Yes, negative 11 (6.6%)	No 27 (16.3%)	< 0.001
Discomfort during treatment	Yes 23 (13.9%)	No 143 (86.1%)		< 0.001
Adequate follow-up	Yes 156 (94.0%)	No 4 (2.4%)	No response 6 (3.6%)	< 0.001
Expectations regarding the treatment	Better than I expected 125 (75.3%)	Worse than I expected 17 (10.2%)	As I expected 24 (14.5%)	< 0.001
Pain at removal NRS (Mean ± SD)	Yes 58 (34.9%) 6.7 ± 2.1	No 108 (65.1%)		< 0.001

Related issues	Possible answers n (%)	Possible answers n (%)	Possible answers n (%)	p-value*
In a similar situation would you chose the pessary treatment again or recommend it to a friend?	Yes 152 (91.6%)	No 14 (8.4%)		< 0.001

* One proportion z-test or multinomial test employed. Null hypothesis value set at 0.50 for dichotomous questions, and 0.33 for three-choice questions.

NRS, numerical rating scale.

Table 3) Results of the subjective experience stratified for gestational age at deliver of either before or after 34 weeks of gestation.

	< 34 weeks 50 n (%)	[?] 34 weeks 116 n (%)	p-value*
Adequate information before insertion	47 (94.0%)	116 (100.0%)	0.03
Information received before insertion regarding possible vaginal discharge	37 (74.0%)	91 (78.4%)	0.56
Vaginal discharge during the treatment	16 (32.0%)	54 (46.6%)	0.09
Any other side effect during the treatment	10 (20.0%)	17 (14.7%)	0.49
Positive changes in daily life during the treatment	29 (58.0%)	99 (85.3%)	0.007
Discomfort during treatment	6 (12.0%)	17 (14.7%)	0.81
Adequate follow up	43 (86.0%)	113 (97.4%)	0.07
Experience was better than expected	25 (50.0%)	100 (86.2%)	< 0.001
Pain at removal	13 (26.0%)	45 (38.8%)	0.16
Would re-use Arabin pessary	38 (76.0%)	114 (98.3%)	<0.001

* chi square test

	Our study	**Goya et al. 2012[13]**	**Saccone et al. 2017[14]**	**Goya et al. 2016[17]**	**Dang et al. 2019[19]**	**Liem et al. 2013[16]**	**Nicolaides et al. 2016[15]**	**Nicolaides et al. 2016[18]**	**Dugoff et al. 2018[30]**
Investigated device	Arabin pessary	Arabin pessary	Arabin pessary	Arabin pessary	Arabin pessary	Arabin pessary	Arabin pessary	Arabin pessary	Bioteque cup pessaries

	Our study	Goya et al. 2012[13]	Saccone et al. 2017[14]	Goya et al. 2016[17]	Dang et al. 2019[19]	Liem et al. 2013[16]	Nicolaides et al. 2016[15]	Nicolaides et al. 2016[18]	Dugoff et al. 2018[30]
Number of subjects with pessary placed (n)	166	190	150	68	148	401	460	588	60
Singleton/Twin pregnancies	Twin Singletons and twins	Singletons	Singletons	Twins	Twins	Twins	Singletons	Twins	Singletons
Teaching/ Audit Details	Yes *The treatment was performed by three clinicians who had received extensive training before*	Not specified	Yes *The physicians had received practical training in the placement of the device. Pessary insertion training consisted of a didactic session and a hands-on session.*	Yes *The central team in turn instructed the other centers in the use of the* pessary	Yes *Well-trained staff involved in pessary treatment*	No *No specific training was provided*	Yes *The research-team members who inserted the pessaries had received practical training in the placement of the device.*	No *Many research team doctors were involved in the insertion of the pessary and they did not receive supervised training in doing so*	Yes *In addition to didactic and hands-on training, all staff was required to demonstrate competence in pessary placement on a live model*
Vaginal discharge	42.2%	100%	86.7%	100%	70%	26%	10.5%	42.1%	73.3%

	Our study	Goya et al. 2012[13]	Saccone et al. 2017[14]	Goya et al. 2016[17]	Dang et al. 2019[19]	Liem et al. 2013[16]	Nicolaides et al. 2016[15]	Nicolaides et al. 2016[18]	Dugoff et al. 2018[30]
Early removal due to discomfort/pain	0.6%	<1% (one patient who needed removal and replacement of the pessary)	0	Not specified	Not specified	<28 weeks: 30% 28-32 weeks: 9% 32 - 36 weeks: 0 32-36 weeks: 4%	10.2% of participants requested early removal for: - discomfort (5.4%) - vaginal discharge (4.1%) - vaginal bleeding (0.7%)	5%	1.7% expelled it during sexual intercourse 1.7% requested pessary removal due to apprehension regarding potential discomfort with sexual intercourse
Discomfort during treatment	13.9%	Mean pain score: 4 (scale 0–10) during pessary insertion	3.3%	Mean pain score: 4 (scale 0–10) during pessary insertion	Discomfort (17%) Pain 4%	4%	11.4%	5.8%	1.7% removal for discomfort during sexual intercourse
Pain during removal (mean score on a 0-10 scale)	6.7	7	Not specified	7	Not specified	Not specified	Not specified	Not specified	Not specified

	Our study	Goya et al. 2012[13]	Saccone et al. 2017[14]	Goya et al. 2016[17]	Dang et al. 2019[19]	Liem et al. 2013[16]	Nicolaides et al. 2016[15]	Nicolaides et al. 2016[18]	Dugoff et al. 2018[30]
Clinical results	22% of singleton and 37% of twin pregnancies delivered before 34 weeks.	Among women with CL[?]25 mm, spontaneous delivery < 34 weeks of gestation and neonatal composite adverse outcomes were significantly less frequent in the pessary group than in the expectant management group	Among women with asymptomatic short CL [?]25 mm, use of a cervical pessary, compared with no pessary resulted in a lower rate of spontaneous preterm birth at less than 34 weeks of gestation	Cervical pessary associated with significant reduction of PTB < 34w in twin pregnancies with short CL [?]25 mm	In women with twin pregnancies and cervical length <38 mm cervical pessary and 400 mg vaginal progesterone resulted in similar rates of PTB at < 34 weeks. The pessary reduced poor perinatal outcomes. In women with CL <28 mm, pessary reduced PTB <34 weeks and improved composite poor perinatal	No significant difference in total group but a 6-fold reduction of composite poor perinatal outcome y in the pessary group in patients with a CL< 38 mm between 16 and 20 weeks	No significant differences in preterm birth <34 weeks between singleton pregnancies with pessary placed for short CL<25 mm and the expectant management group.	No significant differences in preterm birth <34 weeks between unselected twin pregnancies with pessary and the expectant management group.	Cervical pessary use was not associated with prevention of PTB in women with a singleton pregnancy, short CL and no prior sPTB

	Our study	Goya et al. 2012[13]	Saccone et al. 2017[14]	Goya et al. 2016[17]	Dang et al. 2019[19]	Liem et al. 2013[16]	Nicolaides et al. 2016[15]	Nicolaides et al. 2016[18]	Dugoff et al. 2018[30]

Table 4) Comparison of our results with those of other studies in terms of side effects, experience and training of clinicians, and clinical results.

PTB, preterm birth. CL, cervical length