J. Perinat. Med.
31 (2003) 122–133

Is treatment with vaginal pessaries an option in patients with a sonographically detected short cervix?*

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1 Introduction

It is recognized that a short cervix detected by transvaginal ultrasound (TVS) before 28 weeks' gestation is a strong predictor of spontaneous preterm birth (SPB) for both singleton [2, 3, 13, 15, 18, 19, 34] and twin pregnancies [11, 14, 20, 33, 37, 38]. However, the potential prediction has not yet been sufficiently translated into effective preventive measures. Performing longitudinal TVS in risk patients and diagnosing a short cervix or opening of the internal os is therefore still combined with a dilemma for the obstetrician.

Vaginal pessaries have been used for pelvic organ prolapse. Meanwhile, most models are made of flexible silicone so that they can be folded and easily inserted. Specifically designed pessaries have been proposed to support the cervix in pregnant patients with complaints of prolapse (painful pressure downwards predominantly during standing and walking) or in patients who are exposed to physical strain or increased intrauterine pressure or who present with ultrasound signs of an incompetent cervix. However, prevention of SPB has not yet been convincingly proven in prospective trials. In the few series known from the literature, the indication was based on the history or clinical findings during digital examination [7, 9, 10, 21, 26, 28, 36].

The objective of this pilot study was to determine whether the placement of a specifically designed vaginal pessary might reduce the rate of SPB in pregnant women with a short cervix, defined as a result below the 10th centile according to own normal values for singleton [5] and twin pregnancies [6].

2 Patients and methods

Between January 1997 and July 2001, ultrasonographic examinations were undertaken with a 8.5 MHz transvaginal probe of ATL 5000 HDI technologies at the high risk outpatient clinic run by one examiner from our center. Examinations were performed in all twin pregnancies as well as in singleton pregnancies with a risk of SPB, determined by a history of SPB only before 36 gestational weeks or early symptoms of preterm birth such as feelings of pressure or contractions. Patients were examined in both a supine and upright position. Measurements of the cervical length (CL) and the width of the internal os (funneling) were obtained as described previously [5].

Data from the obstetric and gynecologic history, clinical and laboratory findings, pregnancy outcome and the results obtained by longitudinal TVS were prospectively collected by a SPSS data base. All data were obtained by review of the data base.

* The first author has a direct ownership interest in the company that manufactures pessaries including those used in the study. The company is privately held and the profit used to support the Clara Angela Foundation for Research and Development.

Since patients with an ultrasonographic CL ≤ 15 mm have nearly a 50 % risk of early spontaneous preterm delivery [15] we decided to use a silicone pessary in patients with the most critical prognosis, e.g. with a CL ≤ 15 mm between 22 and 24 weeks from 1998 onwards. In these patients, the cervix appears to be straight without curvature [35]. The patients were informed about the intended therapeutic effect, the possible side effects and about the fact that there are no prospective randomized trials based on TVS. The pessary was only used when consent was achieved. Evaluation for bacterial vaginosis and other infection and the presence of fetal fibronectin was performed in each patient before pessary placement.

A flexible ring-like silicone pessary was used whereby the outer and inner diameter vary between 65 mm and 70 mm and between 32 and 35 cm respectively, the height of the curvature may vary between 21 and 30 mm. The curvature of the pessary is upwards so that the larger diameter is supported by the pelvic floor. The smaller inner diameter is supposed to encompass the cervix, after application the pessary changes the inclination of the cervical canal, directing it more posteriorly (figure 1). Thus the weight of the pregnancy is more on the anterior lower segment, as can be observed by TVS in selected cases (figure 2a and b). The insertion of the pessary can be facilitated by spreading a gliding compound, preferably antibiotic creams that do not destroy the natural flora.

Since the results of the first 11 patients appeared promising (table I), patients were already informed about the treatment possibilities of a vaginal pessary when the CL was < the 10th centile according to our own reference values [5, 6]. Iams et al. [19] had previously shown that in patients with a CL < the 10th centile, the risk for SPB is increased.

Retrospectively, a matched-pair analysis was performed in all patients who underwent TVS at 18 to 28 weeks' gestation and a CL < the 10th centile. For the matched control analysis 12 pairs with singleton pregnancies and 23 pairs with twin pregnancies were compared.

To make cases and controls comparable we matched patients with pessary treatment versus patients without pessary treatment for the gestational week at placement and the absolute CL in a supine position, separately for singleton and twin pregnancies. Thus each case was individually paired with a control subject where the cervical length did not differ by more than 2 mm at the same gestational week. Singleton pregnancies were only matched with singleton, twin pregnancies only matched with twin pregnancies. Patients with severe regular contractions, blood loss or premature rupture of membranes were not regarded as candidates for pessary treatment and thus excluded. Further variables which might influence the outcome (previous preterm birth, premature contractions, bacterial vaginosis, fibronectin) were compared in each subgroup. Patients with iatrogenic preterm birth were excluded from the study. For 3 patients with early cervical shortening no

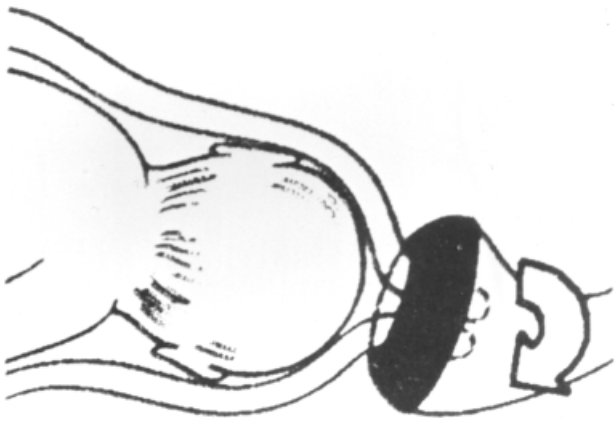
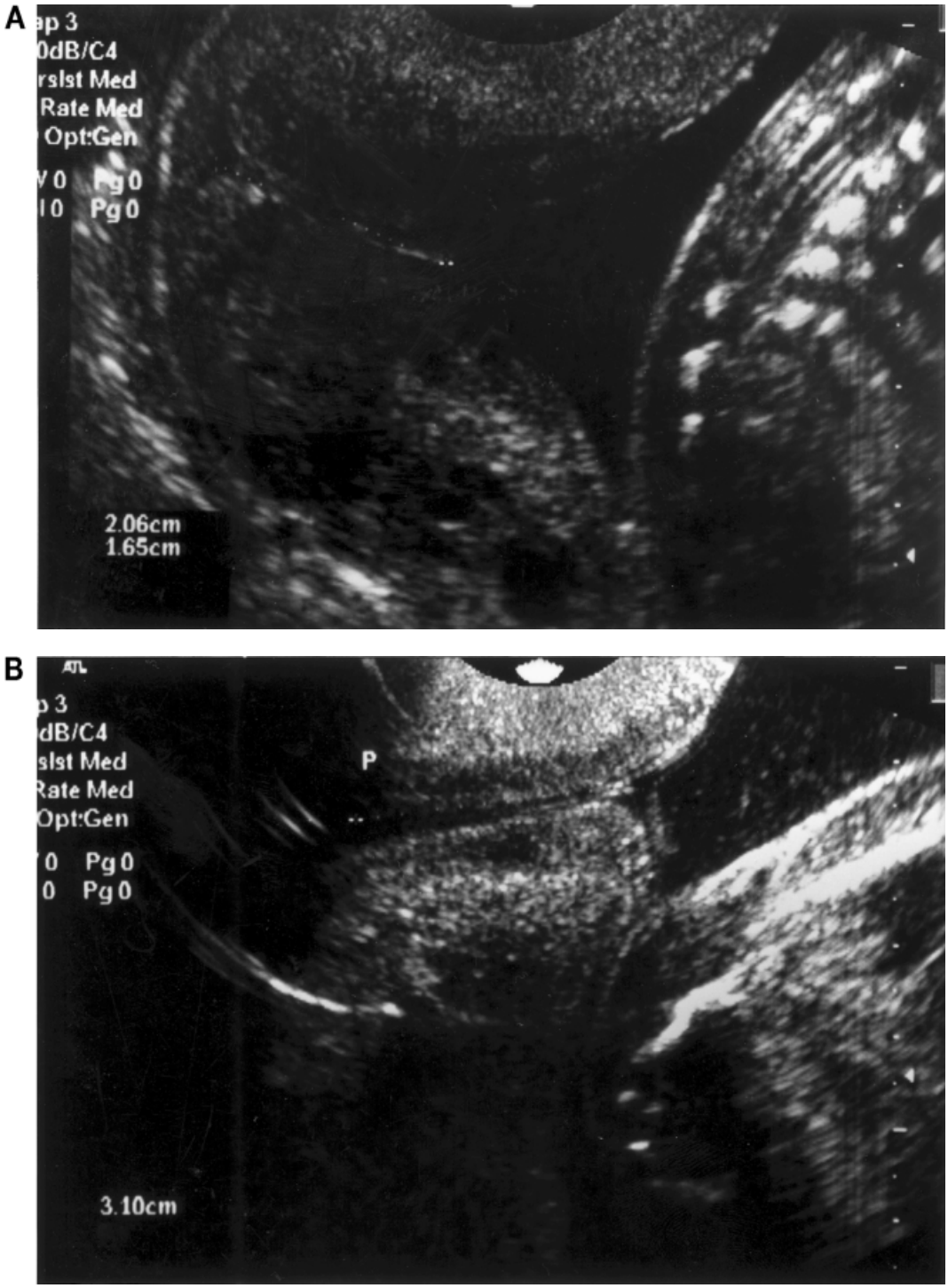


Figure 1. Sagittal view of a cervix with cerclage pessary demonstrating the movement of the pessary in situ (posterior part to the posterior fornix, anterior part towards the symphysis).


A
2.06cm
1.65cm
B
P
3.10cm

control cases could be found, in all these patients pregnancy was prolonged for more than 12 weeks so that the exclusion could not provoke bias in favor of pessary treatment.

Questionnaire evaluation within the treatment group was performed on a case by case basis, scoring complaints of descensus, discharge, pain at insertion or removal and whether patients would chose this treatment again. Patients were also encouraged to give open comments.

The clinical characteristics and outcome of patients who underwent pessary treatment were compared to the group with matched controls. Statistical evaluation was performed by SPSS version 10.0 and included the student-t test for continuous variables, the χ^2-test for categorical variables and the Mann Whitney test for continuous variables that were not normally distributed. Life table analysis was applied to permit comparison between the two subject groups and to exhibit the pattern of gestational age at delivery of individuals with or without pessary treatment.

3 Results

Among the total group of 11 patients who presented with a CL ≤ 15 mm before 24 weeks the mean interval between insertion and delivery was 13+2 (9–17) weeks + days for the 4 singleton and 12+5 (8+1–18+3) weeks for the 7 twin pregnancies (see table I). Though the average risk was high within this group (15) there was no SPB under 32 weeks (see table I).

Between 16 and 28 gestational weeks, the CL was < the 10th centile according to our own reference values in 35 singleton and 72 twin pregnancies. For the matched control analysis, 12 pairs with singleton pregnancies and 23 pairs with twin pregnancies were compared.

The characteristics of the matched pair population are displayed in table II. There was no significant difference in the maternal age, parity, number of prior abortions, prior spontaneous preterm deliveries or the gestational age of the prior preterm births (range: 21–34 gestational weeks), of positive fibronectine assays (limit: 50 ng/ml) in the cervicovaginal fluid, the CL and the mean gestational age when a value of the CL was < the 10th centile and a pessary indicated in the treatment group (see table II). Within twin pregnancies, the number of patients with bacterial vaginosis was higher than in the control group which apparently did not increase the rate of preterm birth within this group ($p < 0.001$). Funneling in an upright position was increased in the treatment groups, e.g. among twin ($p < 0.001$) and singleton ($p = 0.015$) pregnancies but only among twin pregnancies in a recumbent position ($p = 0.003$) (see table II).

In twin pregnancies, 13/18 patients with positive fibronectin assay were symptomatic in terms of premature contractions either at the time of testing or later. In singleton pregnancies, the rate was 9/13.

Within the treatment group only 1/12 singleton pregnancy and 5/23 twin pregnancies were admitted to hospital compared to 5/12 and 12/23 patients respectively in the control group (table III).

Table I. Gestational age at start of treatment, delivery and interval between pessary insertion and delivery in a preselected pilot study with a cervical length of less than 15 mm before 24 gestational weeks (n=11)

Group	Treatment	Delivery	Interval between treatment and delivery		
	mean (range) weeks + days		Δ min weeks + days	Δ max	Δ mean
Singletons (n=4)	22+2 (20–23+3)	35+3 (32+4–38+6)	9	17	13+2
Twins (n=7)	22+5 (18+6–23+6)	35 (32–37+1)	8+1	18+3	12+5

◀ **Figure 2.** Transvaginal sonogram of a triplet pregnancy with shortening of the cervix (2.06 cm) and funneling (1.65 cm fuunnel width) and the endocervical canal directed anteriorly (a). After placement of a pessary the endocervical canal appears longer (3.1 cm) and more directed towards the sacrum (b).

Table II. Patient demographics and risk factors for preterm birth in each subgroup of the case-control study with a cervical length of below the 10th centile determined at the gestational week of pessary insertion, respectively the week of matched controls

	Singleton pregnancies (n=24)			Twin pregnancies (n=46)		
	Pessary (n=12)	No pessary (n=12)	Significance*	Pessary (n=23)	No pessary (n=23)	Significance*
Maternal age (mean/ range)	32 (26–43)	32 (25–38)	ns	32 (27–40)	32 (24–40)	ns
Nulliparous (n, %)	1 (8 %)	3 (25 %)	ns	15 (65 %)	16 (70 %)	ns
Prior abortions (n, %)	7 (58 %)	6 (50 %)	ns	3 (13 %)	1 (4 %)	ns
Prior SPB (n, %)	6 (50 %)	7 (53 %)	ns	3 (13 %)	0	ns
Gestational age of prior SPB (mean/ range)	28 (23–34)	28 (21–34)	ns	29 (20–34)	–	ns
Gestational age at TVS (mean/range)	24 (20–27)	24 (20–27)	ns	23 (20–27)	24 (21–27)	ns
Fibronectin+ (n, %)*	4 (33 %)	7 (53 %)	ns	18 (78 %)	10 (43 %)	ns
Bacterial vaginosis (n, %)	3 (25 %)	1 (8 %)	ns	6 (26 %)	1 (4 %)	p<0.001
Funneling supine position (n, %)	1 (8 %)	1 (8 %)	ns	12 (52 %)	5 (22 %)	p=0.003
Funneling upright position (n, %)	10 (83 %)	5 (42 %)	p= 0.015	23 (100 %)	10 (43 %)	p<0.001
CL supine position (mm, mean/range)	29 (20–35)	28 (10–34)	ns	25 (4–33)	27 (7–33)	ns
CL upright position (mm, mean/range)	24 (11–30)	26 (10–30)	ns	17 (0–25)	24 (7–33)	ns

*Test: Mann-Whitney
*Fibronectin was determined > 24 and < 28 gestational weeks

Table III. Days of admission and intravenous therapy with ß-mimetics for prevention of preterm birth in each subgroup of the case-control study

	Singleton pregnancies (n=24)		Twin pregnancies (n=46)	
	Pessary (n=12)	No pessary (n=12)	Pessary (n=23)	No pessary (n=23)
Admission (n patients, total days)	n=1, 7 days	n=5, 95 days	n=6, 216 days	n=12, 215 days
Admission (mean/range per patient admitted)	7 (7) days	19 (7–28) days	36 (3–68) days	18 (1–63) days
Tocolytic treatment (n patients, total days)	n=1, 3 days	n=3, 30 days	n=5, 64 days	n=10, 52 days
Tocolytic treatment (mean/ range per patient with tocolysis)	3 (3) days	10 (7–16) days	13 (2–28) days	5 (1–11) days

The mean duration of hospital stay among those admitted for the treatment and the control groups respectively was 7 and 19 (7–28) days for singleton and 36 (1–63) and 18 (1–63) days for twin pregnancies (see table III).

Intravenous betamimetics (ritodrine) were administered in only 1/12 singleton pregnancy and 5/23 twin pregnancies within the treatment group compared to 5/12 and 10/23 patients respectively in the control group (see table III). The mean duration of intravenous tocolytic treatment among the patients who received tocolysis was 3 and 10 (7–16) days for singleton and 13 (2–28) and 5 (1–11) days for twin pregnancies, for the treatment and the control groups respectively (see table III).

The mean interval between TVS (< the 10th cen-

tile) and delivery was 99 (70–134) days in the treatment and 67 (2–130) days in the control group (p = 0.0184). For twin pregnancies, the mean interval was 85 (43–129) days in the treatment and 67 (21–100) days in the control group (p = 0.001) (table IV). The mean gestational age at delivery was 38 (36+6–41) weeks for singleton pregnancies in the treatment group and 33+4

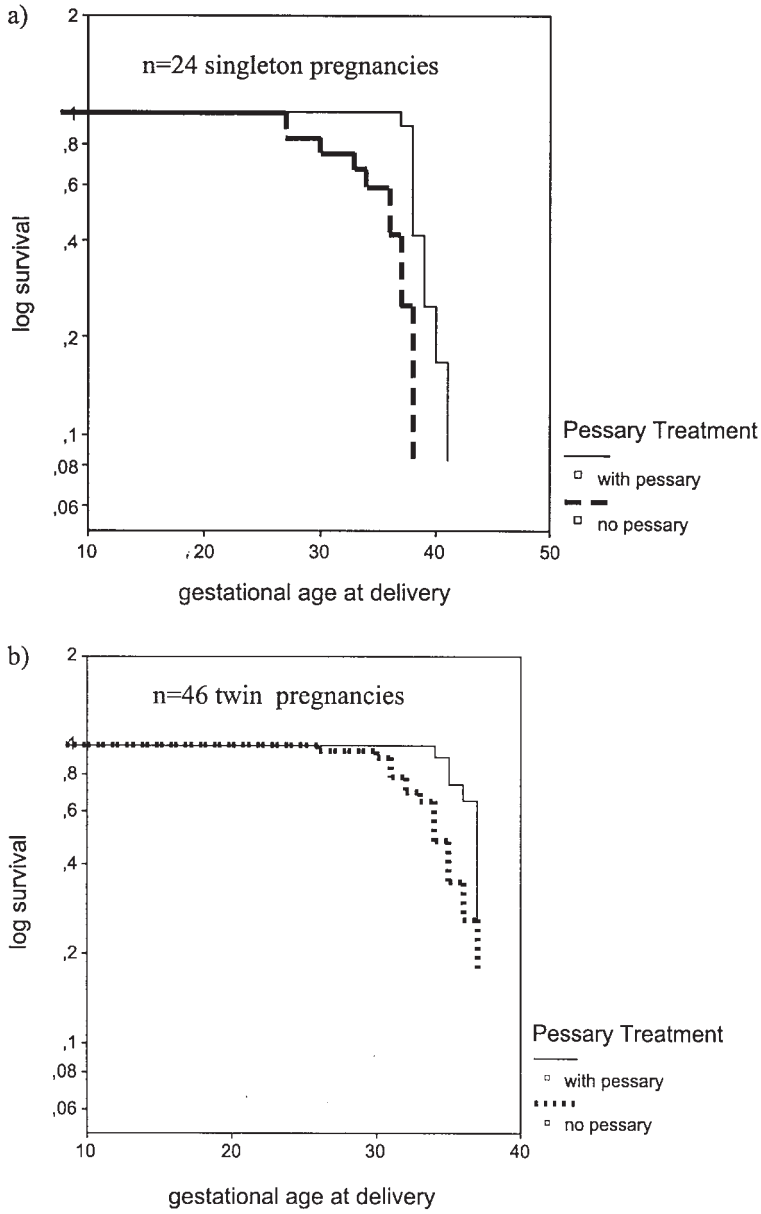


Figure 3. Gestational age at delivery expressed as logrank survival with and without pessary treatment started between 20 and 28 weeks of gestation: (a) in 24 singleton pregnancies, matched pairs; (b) in 46 twin pregnancies, matched pairs.

Table IV. Pregnancy outcome for each subgroup of the case-control study

Preterm birth	Singleton pregnancies (n=24)			Twin pregnancies (n=46)		
	Pessary (n=12)	No pessary (n=12)	Significance* (n=23)	Pessary (n=23)	No pessary	Significance*
< 28 weeks (n,%)	0	2 (17%)	ns	0	1 (4%)	ns
< 32 weeks (n,%)	0	3 (25%)	ns	0	7 (30%)	p<0.001
< 36 weeks (n,%)	0	6 (50%)	p<0.001	8 (35%)	12 (52%)	ns
Interval (days, mean/ range) between TVS before treatment or controls and delivery	99 (70–134)	67 (2–130)	p=0.0184	85 (43–129)	67 (21–100)	p=0.001
Gestational age (weeks+days) at delivery (mean/ range)	38 (36+6–41)	33+4 (26–38)	p=0.02	35+6 (33–37+4)	33+2 (24+4–37+2)	p=0.02

*Test: Mann-Whitney

(26–38) weeks in the control group (p = 0.02), for twin pregnancies it was 35+6 (33–37+4) and 33+2 (24+4–37+2) respectively (p = 0.02) (see table IV).

Among the 12 singleton pregnancies with pessary, there was no preterm delivery < 36 weeks compared to 6 cases in the control group (p < 0.001), whereby 3 cases were even < 32 weeks. Out of the 23 twin pregnancies with pessary, there were 8 cases of preterm birth < 36 weeks whereby no case was < 32 weeks, compared to 12 cases of a delivery < 36 weeks and 7 cases of preterm birth < 32 weeks in the control group (p < 0.001) (see table IV).

Life table analysis demonstrated that in patients with a short cervix treatment with a vaginal silicone pessary could prolong pregnancy up to spontaneous birth compared to a group without that treatment in both singletons and twin pregnancies (see figure IIIa and b).

Questionnaire evaluation within the treatment group on a case by cases basis indicated that the number of patients with complaints of descensus declined from 9 before therapy to 3 patients after therapy but complaints of discharge increased from 8 to 17 patients after the application of a pessary (table V). Patients experienced the removal as more painful than the application but had no painful experiences during therapy.

In general, all patients who were treated and delivered at our center had a positive opinion of the treatment; one patient was indifferent but all others would undergo the same treatment in a further pregnancy or recommend it to a friend (see table V).

Nevertheless, though it is generally believed that vaginal silicone pessaries at least do no harm, we were confronted with a patient with unexpected sequelae who had been admitted to our center due to threatening preterm birth at 27 weeks. Since the contractions had stopped and the cervix was shortened with funnelling throughout the cervix we used a vaginal pessary. At 32 gestational weeks, the patient was discharged and further controlled in a peripheral hospital. Though she had increasing complaints of pressure, blood loss and finally even premature rupture of membranes, the pessary was only removed during an advanced stage of labor. Soon after forceps delivery due to fetal distress she spontaneously lost a small ring-shaped part of her cervix. Pathologic examination revealed cervical tissue with a thrombosis of a cervical vein, which was probably due to the increased pressure, and edema of the cervix. Six weeks after delivery, the cervix had recovered a

Table V. Subjective experience of pessary treatment within the therapy group of the case-control study

Response (n)	Singleton pregnancies (n=11/12)		Twin pregnancies (n=18/23)		Total (n=29/35)	
	n (%)	Score* (x, range)	n (%)	Score* (x, range)	n (%)	Score* (x, range)
Claims of descensus before therapy	5	6,6 (4–9)	4	7,1 (7–8)	9	6,9 (4–9)
Claims of descensus after therapy	2	6,5 (4–8)	1	7	3	6,7 (5–8)
Claims of discharge before therapy	5	4,2 (2–7)	3	4 (2–6)	8	4,1 (2–7)
Claims of discharge after therapy	7	6 (2–9)	10	5 (3–7)	17	5,4 (2–9)
Pain during insertion	3	5 (3–6)	10	5,5 (1–9)	13	5,3 (1–9)
Pain during removal	4	6 (2–9)	11	6 (2–9)	15	6 (2–9)
Chose again?	11		17	(1× "don't know)	28	(1× "don't know)
Recommend to others?	11		17	(1× "don't know)	28	(1× "don't know)

*Score: the patients were able to rank their answers between 0 (no complaints) and 10 (severe complaints)

normal shape but was shortened to a length of 2.5 cm.

4 Discussion

Transvaginal ultrasonographic examination of the cervix can be regarded as the best imaging modality for the detection or exclusion of patients at risk for SPB [12]. In contrast to digital examination, TVS allows the examiner to detect that the opening of the internal os is combined with a shortening of the endocervical canal length. In a pilot study with multiple pregnancies, we demonstrated that this is even more evident when the mother is in an upright position [4]. Ultrasonographic cervical assessment has suggested that there is a wide spectrum of the disease and may detect or exclude a risk for preterm delivery irrespective of whether cervical shortening is a primary or secondary event.

Cervical incompetence is traditionally considered as a cause of recurrent mid trimester abortion. Premature cervical ripening may be the result of a congenital disorder of the connective tissue, exposure to diethylstilbestrol in utero, traumatic damage to the structural integrity, uterine overdistension, repetitive bleeding or vascular lesions in the placenta leading to membrane destabilization and local or intrauterine infection inducing an increase of cytokines and prostaglandines [29]. Therefore preterm parturition is regarded as a syndrome with multiple etiologies which may lead to a condition in which there is activation of all components of the common terminal pathway with uterine contractility, membrane activation and cervical incompetence [30].

Since the pathophysiology of premature ripening of the cervix and premature labor varies between singleton and multiple pregnancy, we have collected and interpreted our data separately for singleton and twin pregnancies. An association between a short cervix and/ or opening of the internal os (funneling) and SPB has been demonstrated in several studies both for singleton [2, 3, 13, 15, 18, 19, 34] and twin pregnancies [11, 14, 20, 33, 37, 38]. Cervical incompetence is not an all-or-nothing phenomenon, but more often a continuum. We have therefore performed longitudinal examinations in both study groups. While the detection of a short cervix may alert physicians at an early stage of pregnancy the optimal management of patients has not been determined.

Hospitalization for bed rest in multiple pregnancies was introduced into clinical practice without adequate controlled evaluation of its efficacy. The policy has been subjected to limited well-controlled evaluation to clarify the beneficial or adverse effects. Women's views of hospitalization and costs have not yet been assessed. Currently no sound evidence exists to support a policy of routine hospitalization for bed rest in multiple pregnancies. For women with uncomplicated twin pregnancy, results suggest that such a policy may even be harmful since the risk of very preterm birth seems to be increased [8].

Nevertheless, based on the studies of Papiernik [27] we believe that a reduction of physical stress for women with multiple pregnancies in an outpatient setting is advisable.

Lash introduced the term "incompetent cervix" in 1950 describing a first attempt at operative closure of the cervix [22]. Mc Donald [24] and Shirodkar [32] reported on a vaginal approach of a cervical cerclage during pregnancy to prevent second trimester abortion and preterm delivery preferably for patients with a history compatible with an incompetent cervix. With the introduction of TVS, the question arose as to whether cervical cerclage would be an option to prevent SPB in patients with a short cervix. Heath et al.[17] reported a reduction in the rate of SPB in patients who underwent cervical cerclage and had a cervical length ≤ 15 mm at around 23 gestational weeks. The rate of spontaneous onset of labor < 32 weeks was lower (1 versus 11), in the study than in the control group. All infants survived except for 1 child in the control group who died in the neonatal period. In contrast, within a randomized trial and a larger series of the same group it was found that cerclage was ineffective at reducing the rate of SPB (Nicolaides, unpublished]. Hassan et al. [16] performed a retrospective study in patients with a short cervix < 15 mm whereby 25/77 patients underwent cerclage placement. The risk for spontaneous onset of preterm delivery did not differ, but patients with a cerclage had a higher rate of premature rupture of membranes (PROM) (65 % vs. 36 %, $p < 0.05$). It was speculated that cerclage placement might predispose patients with a short cervix to a local inflammatory reaction. Accordingly, within a randomized controlled trial, Rust et al. [31] stated that cerclage did not reduce the rate of SPB in patients with a cervical length < 25 mm or funneling > 25 %. However, Althuisius et al. [1] found that cerclage was effective in preventing SPB < 34 weeks' gestation in patients with a cervix < 2.5 mm compared to a group with expectant management (1/10 versus 5/8). In conclusion, the data suggesting that cerclage might have a systematic place in treating risk patients for SPB and a short cervix as determined by TVS are not yet convincing.

Vaginal pessaries have been designed for pregnant women to direct the cervix more posteriorly and thus change the inclination of the cervical canal so that the weight is more directed to the anterior lower segment. This might prevent further opening of the internal os or even premature rupture of membranes based on pressure-related problems. Pessaries have the advantage that they are operator independent, non-invasive, easily to place or to remove and not expensive. As early as 1959, Cross reported on the use of a pessary for the treatment of cervical incompetence [7]. Several other authors followed using different models. Most of the published studies were either retrospective or case controlled (9, 21, 26, 28, 36], Forster et al. were the only ones who conducted a prospective randomized study, comparing cerclage with pessary [10]. They did not find significant differences between these groups. Nevertheless, the study included a high number of low risk patients with the only indication being a history of SPB. In a more recent review article on the use of pessaries for the treatment of cervical incompetence and prevention of preterm delivery the author concluded that pessaries may be considered in women who are not eligible for cerclage or in cases of cervical changes detected by TVS [25].

To date, only Ludmir et al. compared 15 patients with cervical shortening and some dilatation diagnosed by TVS at around 22 weeks who were either treated with bed rest (n = 8) or with a vaginal pessary (n = 7) [23]. Pessary treatment resulted in a prolongation of pregnancy of a mean of 9.2 ± 4.6 gestational weeks whereas bed rest alone only resulted in a prolongation of 5.1 ± 3.6 gestational weeks ($p = 0.03$). These results are comparable to our results of patients with pessary treatment and a cervical length at around 22 weeks of < 1.5 cm (see table I).

None of the previously published studies reported on a complication following the use of the pessaries. However, some basic guidelines should be considered. We recommend informing patients that there is not yet strong evidence that cervical pessaries prevent SPB.

Using TVS to detect a short cervix and/or funneling and the application of a pessary does not mean that other screening methods or interventions (e.g. screening for pH-values, infections and antibiotic treatment) should be neglected. On the contrary, since SPB may be a multifactorial process, bacterial vaginosis and other infections have to be excluded before application and, if necessary, treated. The pessary should be removed in cases with PROM, blood loss, increasing contractions or pain.

The obstetrician should check whether the cervix is not too firmly surrounded by the upper ring of the pessary, especially when the patient reports on specific complaints such as blood loss or pain. The pessary may stay in place until around 37 weeks. There might be some increase of abacterial discharge. However, the spectrum of the vaginal flora will usually not be substantially altered.

We experienced a complication (venous thrombosis in cervical tissue) following the use of a pessary in a patient who was followed up by a referring hospital (see above). This might have been prevented if the pessary had been removed after the first complaints or at least at an earlier stage of labor after PROM.

In conclusion, insertion of a vaginal pessary may be a cost-effective preventive treatment in patients at risk for SPB not due to poor placental invasion and/or infection, but mainly based on TVS results demonstrating a change of mechanical properties of the cervix such as shortening of cervical length or funneling. Since the allocation within retrospective matched pair studies might be biased by hidden confounders, prospective studies are needed to corroborate our preliminary results.

Abstract

Objective: The purpose was to determine the effect of vaginal pessaries in patients at risk for spontaneous preterm birth (SPB).
Study Design: Transvaginal sonography (TVS) was longitudinally performed to measure cervical length (CL) in 258 singleton at risk for SPB and 282 twin pregnancies. Pairs with or without treatment were matched for gestational age and the CL at examination.
Results: In 4 singleton and 7 twin pregnancies the CL was < 15 mm before 24 weeks, the mean interval between pessary insertion and delivery was 13+2 and 12+5 weeks respectively. For the matched control analysis, 12 pairs with singleton and 23 pairs with twin pregnancies were compared. For singleton pregnancies, the mean interval between TVS and delivery was 99 (70–134) days in the treatment and 67 (2–130) days in the control group ($p = 0.0184$), the mean gestational age at delivery was 38 (36+6–41) and 33+4 (26–38) weeks respectively ($p = 0.02$). For twin pregnancies, the interval was 85 (43–129) days in the treatment and 67 (21–100) days in the control group ($p = 0.001$), gestational age at delivery was 35+6 (33–37+4) and 33+2 (24+4–37+2) respectively ($p = 0.02$). Within singleton pregnancies with pessary, there was no SPB < 36 weeks compared to 6/12 cases in the control group ($p < 0.001$). Within twin pregnancies, the rates were 8/23 cases with SPB < 36 weeks but none < 32 weeks, compared to 12/23 cases with SPB < 36 weeks and 7/23 cases < 32 weeks in the control group ($p < 0.001$).
Conclusions: Insertion of a vaginal pessary may be a cost-effective preventive treatment in patients at risk for SPB. Prospective controlled trials are needed.

Keywords: Cervical insufficiency, spontaneous preterm birth, transvaginal ultrasound, vaginal pessaries.

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Received July 3, 2002. Revised October 13, 2002. Accepted October 23, 2002.

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