

Indication for cerclage and complete occlusion of cervical canal and external os: technique and retrospective study

Ludwig Spätling, Alfons Kraus, Christina Pistofidou

Dept. of Obstetrics and Gynecology, Klinikum Fulda gAG, Germany

Summary

In case of cervical insufficiency, a cerclage prolong pregnancy. It should be answered if an additional complete occlusion of cervical canal and external os (COCCEO) improves the results. The technique is described in detail. In consecutive 10 years periods 69 patients were treated by a cerclage, 138 patients by an additional COCCEO. One abortion occurred in the cerclage group. No fetal mortality and only a minor morbidity of mother and newborn were observed in the COCCEO group. In the prophylactic and uncomplicated therapeutic groups no differences in outcome could be seen indicating no additional benefit of COCCEO. In case of exposed membranes both groups showed a prolongation of pregnancy by 11 weeks, although the patients of the COCCEO group had more risks. So, the latter group could profit by COCCEO. In case of late and complicated abortion in history COCCEO women could benefit from COCCEO.

Keywords:

Cervical insufficiency, exposed membranes, cerclage, complete occlusion of the cervix

Introduction

The subjective experience of the benefit of a cerclage is opposed by the difficulty of proving it. The assumed simplicity of the procedure has probably led to significant over therapy in earlier years. In the meantime, however, sufficient data are available showing a significant reduction in preterm birth through the use of cerclage (1). In the fifties of the last century Shirodkar first described a relatively invasive method in which a silk band was placed under the vaginal epithelium around the cervical tissue after preparation of the bladder and rectum (2). Two years later McDonald published a much less invasive method which can be regarded as standard today. In this method a non-resorbable band is placed through the epithelium and cervical stroma in the sense of a tobacco pouch suture (3). Szendi described in 1961 for the first time the complete cervical closure as an emergency measure in case of amniotic sac prolapse (4). Knowing that a large proportion of miscarriages and premature births are caused by ascending infection, Saling took up this method and further developed total cervical closure as a preventive measure to avoid habitual abortions and premature births (5).

In the following years we optimized this method, which is described below. In order to gain experience with this method, all surgical procedures for the prophylaxis of abortions or premature births and for the therapy of cervical insufficiency including amniotic sac prolapse were performed at the Klinikum Fulda from 1997 onwards as a combination of cerclage according to McDonald and the further development of complete occlusion of cervical canal and external os (COCCEO). The question should be answered whether the additional performance of a COCCEO represents an improvement. Knowing that a comparison with a collective treated exclusively with cerclage can be methodically criticized, we compared a 10-year period during which only cerclage was performed with the following 10-year period during which the combination of cerclage and total cervical occlusion was performed.

Indications

loaded medical history: habitual abortion, condition after late abortion (with infection), cervix length < 25 mm measured by sonography, progressive shortening of the cervix
Emergency: amniotic sac prolapse (not before 24 h antibiotics was applied)

Contraindications

Malformation of the fetus incompatible with life; amniotic death; pre-existing rupture of the membranes; amniotic infection; bleeding; labor Gestational age > 28 weeks +/-; Gestational age < 12 weeks +/-

+/-: in individual cases the procedure was performed before 12 weeks of pregnancy and after 28 weeks of pregnancy

Cerclage according to McDonald (Fig 1-3)

In spite of the well-known McDonald cerclage method, it seemed to us to make sense to mention the optimizing measures that have been developed over decades of application.

A disinfectant vaginal suppository is inserted the day before. In the case of prolapse and partial prolapse, we consider perioperative antibiotics to be useful. The operation is performed under spinal anesthesia. We use Octenidine for vaginal disinfection. The operation should be performed in threes if possible. Insertion of a hanging and Breisky Speculum to unfold the vagina, grasping the front and rear lip of the external os with a slight pulling movement caudally with tissue forceps. In case of amniotic sac prolapse, push up the amniotic sac with a small swab. We always use a Mersileneband with needles at the ends (Ethicon BT3-5 mm, 40 cm). The larger needles, which are also available, are almost hindering. Half of the tape is marked with a Pean clamp. Tape ends of the same length make knotting easier, especially when the tape is in the desired high position. In order to place the tape as high as possible, we place the blunt needle on the vaginal skin at the fold and push it cranially under slight pressure without piercing the skin. Only when we have reached the desired height we do increase the pressure until the needle penetrates the skin with the tip of the needle. With a slight noise and sudden decrease in counterpressure the needle lies in front of the cervical stroma. We try to avoid puncturing the stroma, as this is often very soft and we want to avoid damaging the amniotic membranes, especially in the case of prolapse or funnel of the inner cervix. We start always puncturing at 6 o'clock, then at 3 o'clock out and again in, using less

than the 10 mm between both punctures. We prick out at 12 o'clock. The index finger of the free hand can make it easier to find the needle tip. The tape is then pulled through to the exact half. The Pean clamp is then at 6 o'clock and can be removed. In contrast to Shirodkar's cerclage, the convexity of the needle always points towards the center of the cervix.

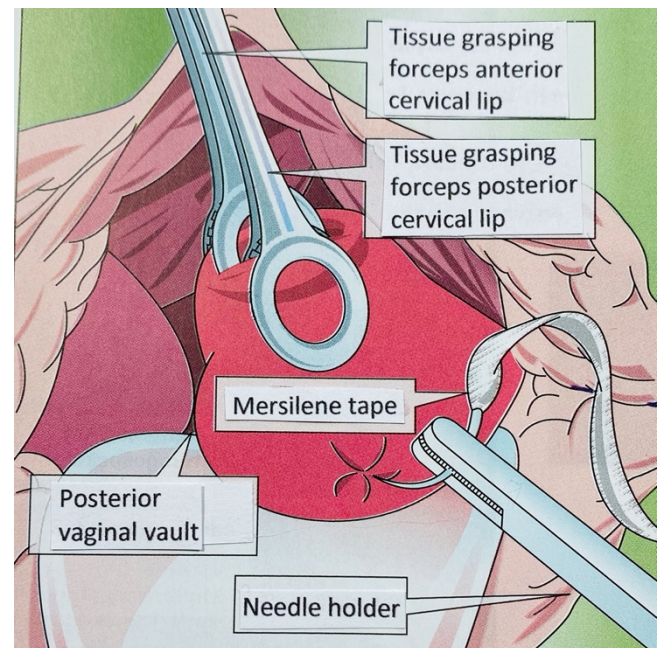


Figure 1: Placing the cerclage tape, 1st step
Instructions for placing the cerclage tape high: The blunt needle of the cerclage set is firmly clamped with a strong straight needle holder at the transition of the outer to the middle third. To gain additional height, the tip of the needle is placed as high as possible at 6 o'clock on the vaginal skin and pushed cranially on the cervical stroma. Then the tip of the needle is pushed with slight pressure through the vaginal skin (which is usually accompanied by a slight crack-like noise) and not into the cervical stroma. This prevents injury to the amniotic sac in the case of amniotic sac prolapse. The needle is advanced between the vaginal skin and the stroma and poked out at 3 o'clock. The index finger of the free hand can be used as a support. If the amnion prolapses, a total cervical closure should be connected

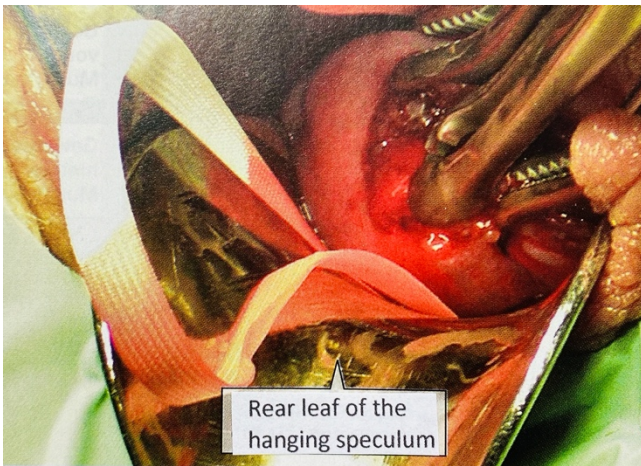


Figure 2: Placing the cerclage tape in the case of amnion prolapse

If the amniotic membranes protrudes, they are pushed cranially with a tightly-fitting swab. While tightening the band, the swab is slowly withdrawn so that the membranes remain distal.

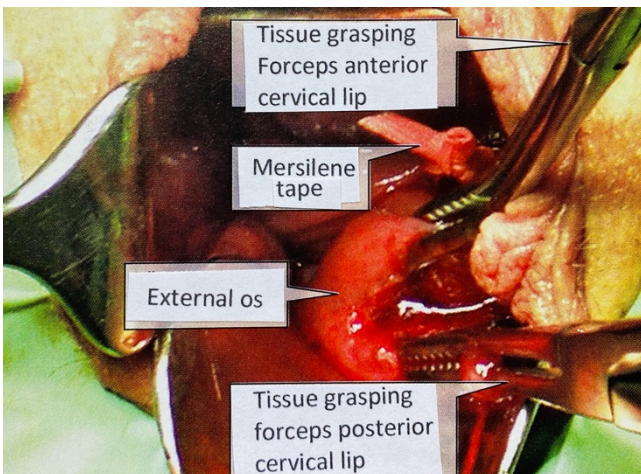


Figure 3: The bar of the tape is knotted

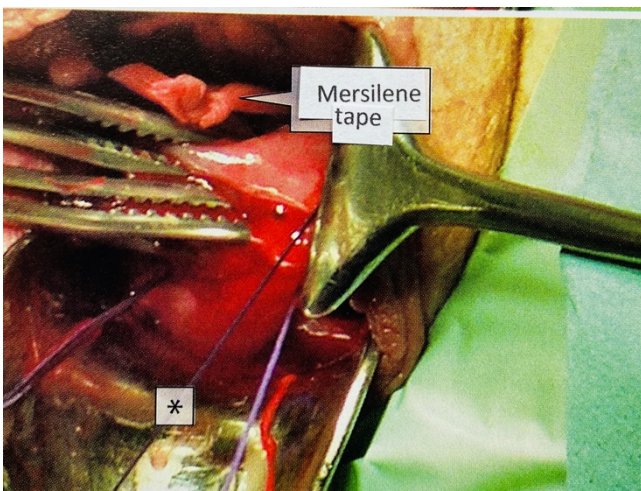


Figure 4: Attaching the lateral retaining threads
Usually the presentation is done with Breisky Specula. An angled speculum was chosen for photographic presentation.

(*) The lateral holding thread is placed well outside the external cervix. This holds the cervix in place when the grasping forceps have to be removed during the further surgical steps.

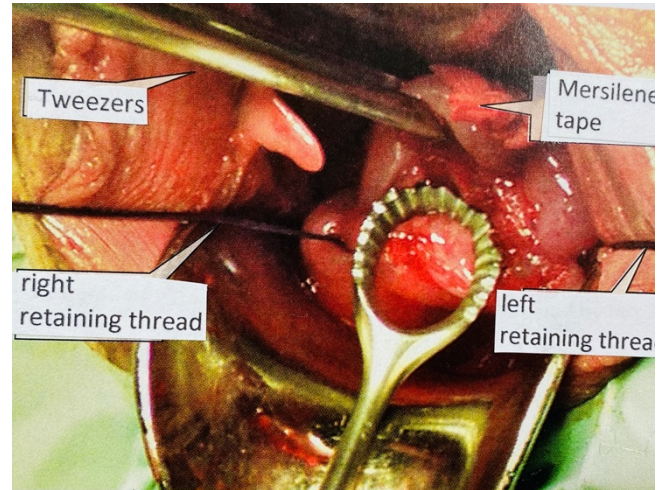


Figure 5: Curettage of the cervical canal with the brush curette
(brush curette, Aesculap ER 580 R)

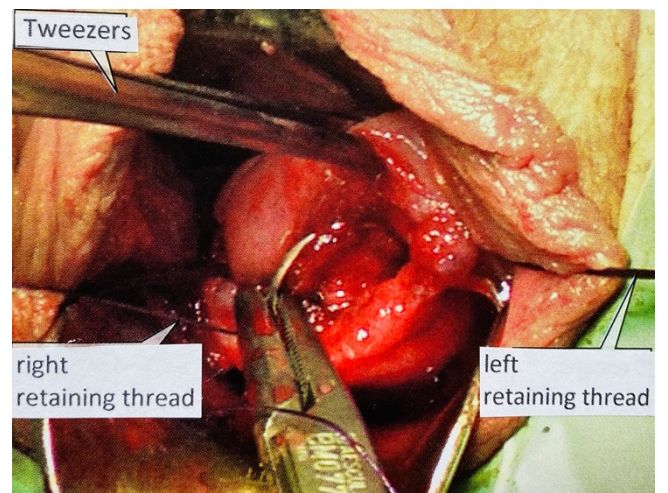


Figure 6: Inner suture of the cervical canal

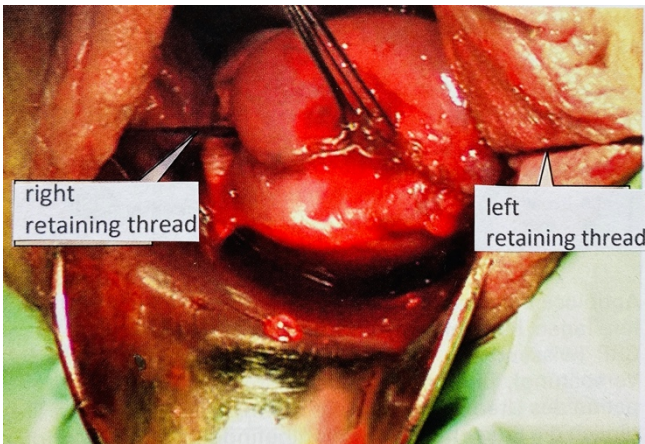


Figure 7: The cervical canal is closed. Four closing threads are laid and cut off very short.

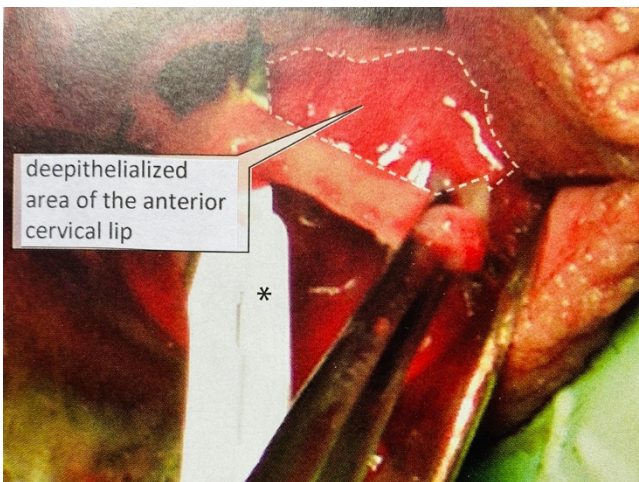


Figure 8: Deepithelialization of the cervix with Swan-Morton scalpel
(*) Angled double-sided sharpened conisation knife (Swan-Morton)

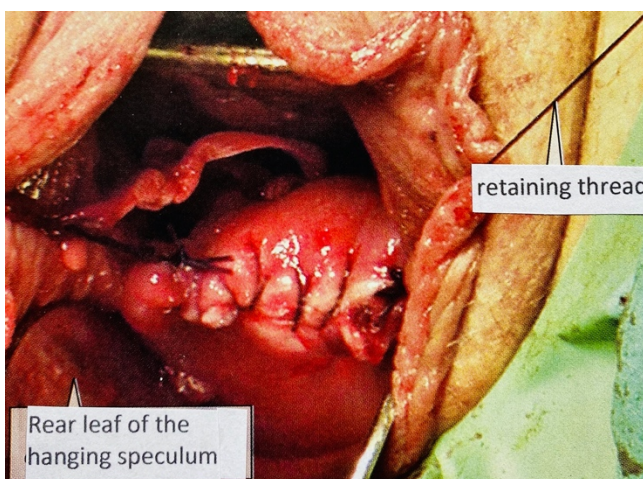


Figure 9: Final continuous closure of the cervix
The deepithelialized areas of the outer cervix are sutured together with a continuous thread. Care should be taken to ensure that the stitch spacing is not too wide, so that wound can quickly cover with skin. The holding threads are knotted with the continuous suture.

Now we go in the same way from 6 over 9 to 12 o'clock. Accepting the needle with the help of a second needle holder can be helpful. After the needles have been cut off, we knot the tape. The best way to knot is to choose a simple knot and pull the tape laterally with both index fingers directly at the knot. Meanwhile, the assistant carefully removes the swab holding back the amniotic sac.

We do not knot with maximum force, but we would like to palpate the inner cervical os about 5 mm (fingertip) wide. This is followed by three knots with alternating directions and the knot of a small bar of approx. 2 cm, which makes it easier to find it later for removal.

If a rupture of the membranes occurs during the cerclage procedure, a COCCEO should be performed.

TIP: For later removal with approx. 36 weeks of pregnancy we take a long pair of dissecting scissors without further preparation after a gynecological examination, grasp the bar with a long straight clamp, pull it to the right until the tape distal to the knot becomes visible, push the closed pair of scissors under the tape, tilt and open them a little so that the band slides between the branches. Then we cut and remove the tape.

We place an indwelling catheter in the bladder until the patient can stand up again independently. A tamponade, the tip of which we moisten with Povidon-Jodine, is rarely necessary. Because of a possible triggering of uterine contractions we prescribe a bolustocolysis with fenoterol (4 µg/12 min) for at least 24 hours.

Perioperative measures for COCCEO

Diagnostic confirmation through speculum examination, palpation, vaginal ultrasound, native preparation for microscopy, microbiology. 48 hours pre-treatment with antibiotic mostly cephalosporin (despite the enterococcal gap), sometimes also in combination with metronidazole. After reading the antibiogram adaptation of the antibiotics

In a so-called emergency procedure for amniotic sac prolapse, COCCEO is only performed after at least 24 hours of prior antibiotic treatment.

The operation is performed under spinal anesthesia. In case of amniotic sac prolapse Trendelenburg position, low-dose bolustocolysis weight-adapted, usually 4 µg/12 min, every 6 min after the operation. Leave bolustocolysis for 2-3 days. The dose is no longer increased in order not to conceal contractions caused by a beginning amniotic infection.

Leave antibiotics for 5 days. In the first days, determination of leukocytes, CRP (knowing about the 16 hour delay), temperature and external palpation of the uterus. In addition, several times a day, the question of well-being as a very sensitive indicator of an incipient infection is asked. If there are signs of an amniotic infection, the COCCEO is opened and birth is initiated. Discharge is possible from the 5th postoperative day if the course is unremarkable.

Performance of Complete Occlusion of Cervical Canal and External Os (Fig 4-9)

A cerclage according to McDonald (see above) is always performed before a COCCEC. Application of two holding threads at 3 and 9 o'clock with a clear distance to the cervix canal (Vicryl 0, CT-2 plus). These threads hold the cervix during the curettage of the cervical canal. In addition, the tissue can be tightened with a window clamp or tweezers that grasps the cervix. For cervical curettage we use a brush curette (Aesculap ER 580R). Since the cervical canal is closed cranially by the cerclage, there is no need to fear that the amniotic sac will be injured, even if a prolapsed amniotic sac was previously repositioned by the cerclage. Curettage is performed vigorously with the aim of removing the lining of the cervical canal so that a complete adhesion of the walls can be achieved.

This is supported by the subsequent joining of the anterior wall with the posterior wall of the cervical canal, which is achieved by 2-4 single button sutures with a fine curved needle with a diameter of 14 mm (Vicryl 2-0, CT -3 plus). The sutures must be cut short to avoid wicking later. While the cervix is now only fixed to the holding threads, an approx. 3-5 mm wide epithelial strip is removed from the entire circumference of the portio uteri with an angled conisation knife with a double-sided cut

(Swan-Morton). To ensure that vision is impaired as little as possible by the bleeding, one starts with the posterior cervical lip. Overall, a stronger bleeding only disturbs for a short period of time, as the deepithelialized area of the cervix is now continuously closed under knotting of the retaining threads in such a way that the deepithelialized areas lie on top of each other and the suture compresses the wound. A Vicryl suture of strength 0, CT-2 plus is used for this purpose. A not too superficial suture with stitch distances of about 4 mm improves healing. An indwelling bladder catheter and always a light tamponade soaked with Povidon-Jodine at the tip are placed for 24 hours.

Results

The age of the patients at 30 years was not different in both collectives (Tab.1). Gravidity and parity were each 0.3 lower in the COCCEC collective operated on 10 years later. The indication for cerclage was prophylactic in 20% and therapeutic in 80%. For COCCEC the figures were 22% and 78%. The percentage of multiples in the COCCEC group was twice as high as in the cerclage group. The preoperative cervical length was 24 mm in the COCCEC collective and 19 mm in the cervical collective. It should be mentioned that vaginal sonography was not yet available for the entire period in the cerclage collective and the indicated figure also includes estimates. This also applies to the information on the width of the cervix.

In the median, the patients in the COCCEC collective were inpatient for 6 days longer (16.5 days) than those in the cerclage collective. These figures are strongly influenced by some long-distance patients. The time of surgery was almost identical with 20w+0d and 20w+1d, respectively. The delivery was performed in the cerclage collective with a median of 36w+0d in the complete COCCEO collective with 37w+0d. This is also remarkable because three times as many patients with amniotic sac prolapse were treated in the COCCEO collective (Table 3). In the cerclage collective, one pregnancy ended with a late abortion (Table 5). The "baby take home" rate was 100% in the COCCEO collective. With both

procedures, the pregnancy could be prolonged by about 16 weeks in median.

In the COCCEO collective, the percentage of amniotic infection syndromes was more than three times higher than in the cerclage collective. However, since these were detected very early through intensive monitoring, neither the mothers nor the newborns became seriously ill (Table 5). The fetal outcome was not significantly different in the two collectives (Table 4).

The separate evaluation with the diagnosis of amniotic sac prolapse included five times as many patients in the COCCEO collective with 17. It should be emphasized that despite the advanced findings, a pregnancy prolongation of on average 10w+5d was achieved in only two amniotic infection syndromes (Table 3).

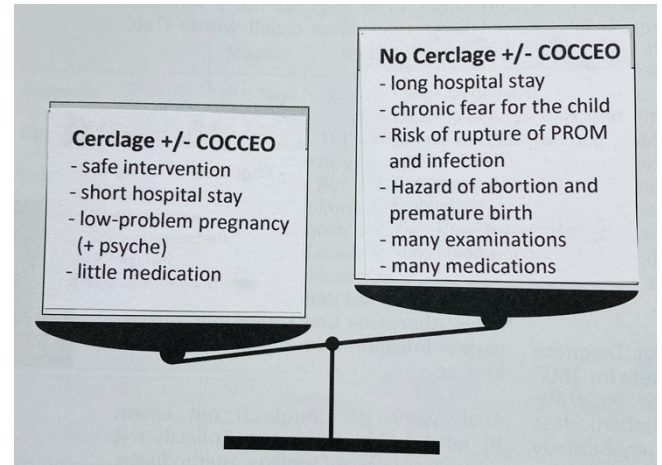
Discussion

The evaluation of 138 consecutive cases of a COCCEO combined with a cerclage according to McDonalds with therapeutic and prophylactic indication shows that this method is very efficient and low-risk despite the creation of a closed space in the cervical canal with the potential risk of an abscess and consecutive ascending infection.

Even though the comparison with a McDonalds cerclage group operated on 10 years earlier has methodological deficits and was obviously carried out in a significantly lower-risk group, it shows, especially after the proof of the positive effect of vaginally applied progesterone in cervical insufficiency (6), that there is no indication for COCCEO for prophylaxis and treatment of simple cervical insufficiency. In this group, a McDonalds cerclage is sufficient, especially if it is placed very high. It is conceivable that the longer cervical canal after the operation can also lead to the formation of a mucus protecting the fetus.

In recent years, we have been performing COCCEO combined with cerclage only prophylactically in the case of a condition following late abortion, a history of which may be additionally burdened by interventions on the uterus.

The great success of pregnancy prolongation combined with a remarkably low complication rate of COCCEO combined with cerclage in the collective of women with amniotic sac prolapse allows us to perform this operation when no colpitis is present. In case of colpitis we perform only a cerclage after therapy.



In one case, the amniotic sac opened during performing a cerclage. Here we did not stop surgical operation, but completed the operation with COCCEO. After the usual course of treatment at the clinic, the patient had an unremarkable pregnancy and was delivered by a healthy child after 37 weeks.

A wait-and-see conservative procedure for amniotic sac prolapse is not advisable. A retrospective examination showed significant advantages for the patients who received cerclage (7). The low complication rate of a cerclage but also of a COCCEO almost always results in an undisturbed course of pregnancy which hardly differs from that of a woman who is not affected. On the other hand, a wait-and-see approach is often accompanied by weeks of stay in hospital with a large number of examinations, strict bed rest, labor-inhibiting measures and the psychological strain caused by the mother's constant fear for her child. (Fig. 10)

Last year, Brix and colleagues (8) published a prospective randomized study comparing cerclage (McDonald or Shirodkar) alone or in combination with an "occlusion". In this study, no additional

benefit was seen, neither in the prophylactic nor the therapeutic group, from an additional "occlusion". The method of "occlusion" differs greatly from the methods we described, since neither a scraping and suturing of the cervical canal is performed, nor is the deepthelialized surface of the portio uteri sutured to each other. Our comparison also shows no differences between the corresponding groups. However, the "baby take home" rate is about 10% higher. It also appears that the high-risk group with amniotic sac prolapse has not been treated. The 17 mothers who were treated for amniotic sac prolapse with COCCO in our comparison were able to take all their children home. The study conducted by Brix and colleagues also shows once again how differentiated even prospective randomized studies must be viewed and evaluated.

A cerclage alone does not only seem to support the cervix mechanically, but also may restore the protective function of the cervical mucus, if the cervical canal is reconstructed with sufficient length. If this is successful, the total closure of the cervix, as Saling (1981) primarily intended to protect against infection, is not necessary. However, if a finding has progressed so far that a sufficiently long and protective cervix can no longer be built up with a cerclage, as is the case in the group with amniotic sac prolapse, we always consider COCCO to be indicated after sufficient antibiotic pre-treatment. Of course, it is also useful in cases of rupture of membranes during the operation.

The low-risk performance of cerclage according to McDonalds and the considerable gain in the patient's quality of life by avoiding a long inpatient stay associated with high costs leads us to consider whether cerclage should not also be performed in a collective up to 32 weeks of pregnancy with progressive cervical insufficiency.

The top position determined for the Perinatal Centre at the Klinikum Fulda by the AQUA Institute (9) is based not only on the good management of neonatology, but also on the condition in which the neonates are handed over to the pediatricians. The

described procedure for cervical insufficiency, the magnesium supplementation during pregnancy (10), but also the therapy in case of imminent premature birth, mainly with bolustocolysis (11), plays a significant role in this context. In addition to the fact that it is thus possible to bring many children into the viability zone, it is generally better to avoid premature births than to treat them. Success in avoiding preterm birth is not shown by the effect of a single measure, the success of which may not be scientifically verifiable, but by the sum of various individual measures in an overall concept of obstetric and neonatal work.

Recommendation

- Prophylactic therapy of cervical insufficiency is rarely indicated, especially with regard to the positive effect of progesterone.
- In the case of a heavily loaded medical history (multiple operations/curettages, condition after septic abortion, condition after late abortion) prophylactic application of a cerclage combined complete cervical occlusion is recommended.
- Always place the cerclage as high as possible to restore the protective mucus in the cervical canal
- in case of progressive shortening under progesterone a Cerclage is recommended.
- If the cerclage alone cannot build up a sufficiently long cervix and in case of prolapsed amniotic sac, a complete closure of the cervix should be applied.

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Prof. Dr. Ludwig Spätling
Frauenklinik
Klinikum Fulda gAG
Pacelliallee 4
D 36043 Fulda (Germany)
ludwig@spaeling.net

	Cerclage n = 69 Median	min	max	Cerclage +COCCEO n = 138 Median	min	max
Age (years)	30	18	42	30	18	43
Gravidity	3,1	1	9	2,8	1	10
Parity	1,1	0	5	0,8	0	6
Multiples	5=7% gem	1=1,4% tri		17=12% gem	4=3% tri	
Cervix (mm)	19			24		
Os-width (mm)	2	0	20	5	0	35

Table 1: Anamnestic readings of cerclage- and COCCEO group (gem= Gemini; tri= triplets)

	Cerclage n = 69 Median	min	max	Cerclage +COCCEO n = 138 - Median	min	max
Days in hospital (n)	10,5	3	67	16,5	4	84
Surg at (wop+days)	20+0	11+4	30+0	20+1	10+6	29+0
Birth at (wop+days)	36+0	20+4	41+3	37+0	24+2	41+4
difference: surg - birth (weeks + days)	16+5	0+5	28+2	16+0	0	27+5
Mode of birth	sp 65%	cc 13%	scc 12%	sp 40%	sc 21%	scc 28%

Table 2. Clinical data of cerclage and COCCEO Group (surg=surgery; sp= spontaneous; cc=caesarian; scc=secondary caesarean section; wop=weeks of pregnancy)

	Cerclage median	min	max	COCCEO median	min	max
Prolaps of amniotic membranes	3=4%			17=12,3%		
surg at (wop+days)	21+6	20+4	24+6	21+5	18+2	25+1
Os-width (mm)	17	10	25	20	10	35
Birth at (wop+days)	33+4	30+5	39+0	32+3	24+2	41+1
difference: surg - birth (weeks + days)	11+0	5+6	18+3	10+5	0	24+0
AI (n) / (wop+days)	0			2	27+1	29+0

Table 3. Sub-evaluation of patients with prolapse of amniotic membranes of the Cerclage- and the COCCEO group (surg=surgery; wop=weeks of pregnancy; PROM= premature rupture of membranes; AI= Amnioninfection)

Fetal outcome	Cerclage			Cerclage + COCCEO		
	N=69	mean	min - max	N=138	mean	min - max
Perinatal Mortality	N = 0			N = 0		
Birth weight (g)		2665	640 - 4130		2468	460 - 4340
Apgar1 Apgar 5 Apgar 10		7,8 8,8 9,2	1 -10 1 -10 6 -10		7,6 8,5 8,8	1-10 1-10 5-10
pH art		7,19	7,18- 7,4		7,22	7,07- 7,43

Table 4. fetal outcome of cerclage- and COCCEO group

	Cerclage	median	min - max	Cerclage+COCCEO	median	min - max
Complication (n)	23 of 69 (33%)			45 of 138 (33%)		
PROM n / wop+days	n= 9 (13%)	32+2	26+1 - 35+2	n=15 (11%)	30+1	25+1- 39+4
preterm Labor n / wop/days	n=14 (20%)	30+4	24+0 – 36+3	n=30 (22%)	30+0	18+6- 36+5
AI / wop+days	n=2 (3%)	28+2	26+5 – 30+0	n=15 (11%)	28+0	18+6- 33+4

Table 5. Complications of cerclage - and COCCEO group. (wop=weeks of pregnancy; PROM= premature rupture of membranes; AI= Amnioninfection)