

**27th INTERNATIONAL CONGRESS ON
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**PREINDUCTION CERVICAL PRIMING IN PATIENTS WITH HYPERTENSION AND RENAL
DISEASES BY MEANS OF HYGROSCOPIC RODS - DILAPAN™**

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OBJECTIVE: To evaluate Dilapan, hygroscopic cervical dilator, as a cervical ripening agent in pregnant women with hypertensive and renal disorders.

MATERIALS and METHODS: From July 1, 1993 to July 1, 1995, 32 pregnant women with hypertensive and renal disorders were preinduced by means of Dilapan. Bishop scores were <5 prior to the intracervical insertion of Dilapan.

Dilapan remained in situ for 12 hours. Bishop scores were evaluated at removal and induction of labor was initiated.

The mean week of pregnancy was 37+6 days. Patients with previous uterine surgery were excluded.

RESULTS: The mean Bishop score prior to preinduction was 3.8 points, after the preinduction the score was 6.1. Mean gain was 2.3 points.

Successful preinduction/augmentation of Bishop score >2 was 27 patients. Uterine contractions were initiated by Dilapan only in 8 patients.

Twenty five patients were delivered vaginally (21 spontaneous; 4 forceps). Eight patients underwent Caesarean section.

No side effects were noted.

CONCLUSION: The described protocol of cervical ripening proved very efficient, well tolerated by patients and cost effective.

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The Czech Republic has undergone many political, social, and economic changes in the recent past which have made an impact on provision of healthcare.

Obstetricians were faced with the challenge of treating an increased number of patients with eclampsia as changes in life style contributed to an increase of hypertension in pregnancy. Improved health care allows patients with renal disease to have pregnancies which would have been contraindicated previously. Therefore a well organized nationwide prenatal program was established to provide early diagnosis and treatment of EPH gestosis.

As a result of our aggressive efforts, the eclampsia rate in 1994 was 1 in 3556 deliveries. This decrease in the frequency of preeclampsia necessitated fewer immediate pregnancy terminations by Cesarean section but the rise of pregnancies complicated by hypertension necessitate a higher frequency[y] of inducement of labor.

The management of patients with hypertensive and/or renal disease includes delivery on or before the calculated day of delivery. Most of these women should not pass their estimated date of delivery. The problem then may be an unripe cervix. There are four possible solutions in the treatment of an unripe cervix:

1. Postpone the pregnancy termination
2. Delivery by Cesarean Section
3. Induction of labor with an unripe cervix
4. Preinduction treatment of the cervix

There are many possible preinduction methods to ripen the cervix. These include:

1. Instrumental
 - 1.1. Laminaria
 - 1.2. Dilapan
 - 1.3. Atads double balloon device
 - 1.4. Nipple stimulation (Hippocrates method)
 - 1.5. Unprotected intercourse
2. Medical
 - 2.1. Prostaglandin preparations
 - 2.2. Estrogens
 - 2.3. Relaxin
 - 2.4. Maternal granulocytes

After a careful review of the above mentioned needs, we chose to conduct a clinical evaluation using Dilapan cervical dilator as a ripening method in patients with hypertensive and renal disease in pregnancy.

Dilapan is a solid rod manufactured from Hypan – a hygroscopic polymer of polyacrylonitrile used in intracervical application for cervical dilation and in near or post-term pregnancies for pre-induction cervical maturation.

In our study Dilapan rods 4mm in width and 65mm in length were applied.

Materials and Methods

The study was performed at the 2nd Dept. Gyn. Obst. in Brno. From July 1, 1993 to June 30, 1995, 32 pregnant patients with hypertensive and renal disorders were preinduced by means of Dilapan rods intracervical application after obtaining patient consent.

<u>Indications for the Induction</u>	<u>Number of Patients</u>
EPH Gestosis	11 (34,4%)
Chronic hypertension	13 (40,6%)
Renal disease	<u>8 (25,0%)</u>
Total	32 (100%)

The eligibility criteria were:

1. EPH gestosis, chronic hypertension, renal disease.
2. 36 – 40 weeks pregnancy.
3. Singleton pregnancy.
4. Vertex pregnancy
5. Bishop score >5
6. Reactive Non-Stress Test (NST)

The exclusion criteria were:

1. < 36 weeks of pregnancy.
2. Bishop score >5.
3. The evidence of uterine contractility.
4. The presence of contraindications of vaginal delivery (cef[ph]alopelvic disproportion, placenta praevia, etc.)
5. Uterine scar.
6. Rupture of the membranes.
7. Infection of the lower genital tract.
8. Chronic fetal hypoxia.

The morning of the day of Dilapan insertion, the assessment of fetal well-being was performed (US biometry and fetal movements, NST, amnioscopy) and Bishop score were evaluated. At 7:00 p.m. the Bishop score was re-evaluated and, if no changes occurred, a sterile Simmonds speculum was introduced. The cervix and the vagina were cleansed with Betadine solution and after stabilization of the cervix, the upper lip was captured with ring forceps. After a gentle traction in vagina axis, 4 Dilapan rods were moistened with Betadine and inserted into the cervical canal so that the internal os would be gradually dilated by Dilapan expansion. If no bleeding occurred a sterile gauze was applied to the upper vaginal posterior fornix to maintain the rods in place. After reassurance of the fetal well being by CTV 30 minutes NST, the patient was transferred either to the obstetrical ward or was allowed to go home. The next day, after 12-14 hours of Dilapan in situ, the next check up was performed and the rods were manually removed. A reassessment of Bishop score, preferably by the same obstetrician, was obtained. In cases of cervical maturation (Bishop score >5) an induction of labor was initiated by:

1. Oxytocin infusion if Bishop score >8.
2. Prostin extraamniotic[ly] (PGE2) if Bishop score >5>8.

If no cervical maturation occurred a second Dilapan administration was performed at 7:00 p.m. of the same day. If both dilations did not result in a sufficient cervical dilation, the case was considered a failure, and, generally a Cesarean section was performed.

Results

Thirty-two (32) patients were included in the study. After a detailed explanation of the method, none of them declined participation in the study.

Table I. Patient Characteristics

<u>Variable</u>	<u>Result</u>
Mean week of pregnancy	37+6 days
Mean Bishop score prior to preinduction	3.8%
Mean Bishop score after preinduction	6.3%
Mean gain in Bishop score	2.3 points

Seven (7) patients required a second Dilapan insertion (21.7%). Successful preinduction, defined as Bishop score >5, was obtained in 27 patients (84.4%). Uterine contractions were initiated by Dilapan administration only in 8 patients (25%).

Table II Represents delivery methods.

TABLE II. Delivery Methods

<u>Method</u>	<u>Number of Patients</u>	<u>Percent</u>
Vagina deliveries	25	78.15
- Spontaneous	8	25
- Induced	17	53.1
Cesarean Section	8	25

The indication[s] for Cesarean section were unsuccessful preinduction and induction of labor and acute fetal hyoxia.

No side effects other than premenstrual-like lower abdominal pain were noted. The duration of the stages of labor did not differ between patients undergoing a simple induction of labor and a spontaneous delivery. Neither the frequency of blood loss greater than 300ml, nor postpartum injury[ies] greater than episiotomy were different from the norm of our delivery ward. Perinatal mortality was zero.

Discussion

The preinduction results obtained with Dilapan are comparable with other routinely used preinduction methods, namely locally applied PGE₂ gels (Krammer et al. 1995, Fergusson et al. 1988).

More than half of the patients preinduced by PGE₂ established labor before the end of the ripening phase, and increased uterine activity is noted in almost all of them (Sanchez – Ramos et al. 1992). A lower frequency of unexpected uterine activity and hypercontractility frequency when Dilapan is used suggests an advantage of this agent for administration in high risk pregnancies where an unexpected delivery may introduce treatment problems and influence perinatal results. It is ideal for the labor and delivery of high risk patients to occur during the day time when the complete staff of obstetricians and neonatologists are available to provide highly specialized care for the mother and the neonate. Thus the initiation of the parturition during the preinduction in these patients is rather a negative outcome.

It is assumed that the local irritation of cervical tissue initiates the arachidonic acid cascade resulting in endogenous prostaglandin release and thus augmentation of cervical ripening and inducement of myometrial activity. A study testing the serum levels of PG metabolites during and after Dilapan administration are[is] necessary to support this premise and would be of interest.

In comparison with laminaria, a cervical dilation device made of seaweed, Dilapan requires shorter intervals to reach complete dilation. Dilapan seems to produce cervical changes and results more closely resembling a ripe cervix than did laminaria (Blumenthal et al. 1990). Furthermore, Dilapan appears to be superior to laminaria because its use is associated with the need to use fewer devices and the induction to delivery interval is shorter.

Dilapan is sterile and does not increase the frequency of inflammatory complications in mother and her fetus/neonate.

The smooth surface of the device and its gradual radial dilation minimizes the possibility of cervical and uterine tissue injury at insertion, during the dilation, and at the time of removal. The preliminary clinical and pathohistomorphologic results of our clinical trial do support the safety of Dilapan administration.

Except for rare pre-menstrual-like cramps following Dilapan insertion, the procedure is not connected with pain and does not necessitate analgesia.

No disruption of fetal membranes at the insertion was noted. The grade of dilation is proportional to the number of inserted Dilapan rods. In our study no more than 4 devices were inserted.

In comparison to PGE₂ gel administration where only inpatient care is recommended, no hospitalization is necessary with Dilapan patients. The lack of hyperstimulation and reduced incidence of labor during the ripening process associated with the use of the dilators suggests that they might be appropriate for preinduction cervical ripening in selected outpatients. Such a practice could further lower the cost associated with the use of osmotic dilator (sanchezm- Ramoz[s] et al., 1992).

The lack of negative side effects enables the shortening of fetal monitoring interval to only 30 minutes after the insertion of the device.

A suggestion for increasing the effectiveness of the method by coating Dilapan with PGE₂, relaxin, or estrogens needs further investigation and clinical trials.

Last, but not least, the use of Dilapan is cost effective not only for its lower cost in comparison to commonly used preinduction cervical priming methods, but by lowering Cesarean Section rate.

Conclusions

Our preliminary results proved a high efficacy of Dilapan hygroscopic cervical dilators in priming the unripe cervix prior to the induction of labor in patients with hypertensive and renal diseases. They provide a high obstetrical comfort, are well tolerated by the patient, are safe both for the mother and her fetus/neonate and are cost effective.

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