Eligibility criteria for labor induction with prostaglandins

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Summary

Particular conditions exist at the end of some pregnancies which cause an increase in maternal and fetal risk. A valid alterantive for these pregnancies is represented by the administration of prostaglandins, in order to obtain labor induction.

The goal of our study was to define the eligibility criteria and the epidemiological characteristics that correlate most with a favorable obstetrical outcome.

The study was conducted on 133 informed, consenting patients subjected to labor-induced delivery with prostaglandins E_2.

The mode of delivery in relationship to parity demonstrated that the pluriparous patients had fewer difficulties in labor and in its induction: of the 43 pluriparous cases, none had a cesarean section for failed induction and 95.3% delivered vaginally.

One hundred percent of the patients with a Bishop score of more than 4 went into labor, as opposed to 81% of the patients with a score of less than 4.

Therefore, taking into consideration the cost of the method, we retain that choosing an active position is valid, respecting the eligibility criteria for the induction of labor described above.

Key words: Labor induction; Prostaglandin E_2.

Introduction

There are particular conditions that occur at the end of some pregnancies which cause an increase in maternal and fetal risk.

The presence of an oligoamnios, a post-term pregnancy, an unaccentuated intrauterine growth retardation or any low to medium maternal pathology, in general, do not reguire immediate delivery, but these pathologies definitely involve intensive monitoring of the pregnancy. Consequently, obstetric management costs increase, often along with patient stress. In any case, regardless of the intensity of the monitoring applied, the elevated risk persists.

A valid alternative for these pregnancies is labor induction permitting vaginal delivery in a reasonably brief time.

In recent years, the administration of prostaglandins in order to induce labor has become accepted practise. The immense efficiency of these substances, discovered in 1936 by Von Euler, has been widely demonstrated, compared with the classic protocol of using oxytocin to treat unfavorable cervix ripening [1-2].

There is still heated debate regarding its formulation, the means of administration and the dosage necessary to obtain the best response with the least maternal and fetal risk possible [3-4-5-6].

Regarding the means of administration, it is either applied vaginally or intracervically and is correlated with cervical ripening [3].

Another variable concerns the quantity used (especially in the case of vaginal administration), which varies from study to study; with dosages that have continually decreased throughout the years as the quality of the gel in which the prostaglandins are suspended, has improved. Obviously, a reduction in the dosage with the same results has demonstrated a reduction in undesirable side effects and increased compliance by the patient.

One of the most consolidated methods is that proposed by Zanini and collaborators, which provides for an intracervical administration of 0.5 mg of dinoprostone (PgE_2) for a Bishop score <=4 or the vaginal application of 2 mg of the substance for a Bishop score of >=5 [3-7].

Along with the "classic" PgE_2 in various studies other prostaglandins are used: in particular misoprostol (PgE_1), which seems to obtain discreet success thanks to its high efficiency and low cost [8].

The eligibility criteria for labor induction with prostaglandins continues to be more vast: it has even been demonstrated that patients with a previous cesarean section can be given these substances safely. The dogma "once a cesarean, always a cesarean" is no longer valid, in light of the fact that a vaginal delivery or its induction does not cause significant risk of uterine rupture or other complications [9].

Another indication for labor induction with PgE_2, particularly discussed in the literature, is post-term pregnancy (>=42 weeks). It has been widely demonstrated that this condition increases the level of fetal risk. Two schools are divided on their obstetric thinking: the first proposes labor induction, while the second proposes increased intensive monitoring of maternal and fetal conditions [10-11-12]. The results of certain case-controlled studies on mortality and morbidity have not revealed significant statistical differences between the two methods regarding the newborn's mortality and morbidity risk, though the experiences of the Canadian multi-center study in 1992 revealed a lower frequency of cesarean sections for acute fetal suffe-

ring in the induced-labor group compared to the control group and a greater prevalence of perinatal mortality and morbidity in the second group [13].

The goal of our study was to define the eligibility criteria and the epidemiological characteristics that correlate most with a favorable obstetric outcome, understood as the time necessary for labor induction and the frequency of vaginal deliveries in the patients who undergo treatment with PgE_2.

Materials and Methods

The study was conducted on 133 informed, consenting patients subjected to labor induced delivery with prostaglandins E_2, over the course of four years, from March '92 to May '96.

The eligibility criteria for induction were the presence of a single fetus, a cephalic presentation and a gestational age of more than 35 weeks.

Patients with an anamnesis for glaucoma, retro-colitis, asthma, multiparity (over 5), fetal weight estimated below 2000 g, the presence of severe eclampsia, a hemorrage in the third trimester, fetal distress, in active labor or a twin pregnancy were all excluded from the study.

The drug used was the prostaglandins commercialized by Upjohn (Prepidil) in gel form; the means of administration was intracervical (0.5 mg) or vaginal (2 mg) and the choice was determined by the condition of the uterine cervix (Bishop score <=4 and >=5, respectively).

The administration of the gel was repeated every 8-12 hours for a maximum of three applications per side. The calculation for the interval of administration was flexible in order to allow the patients a good night's rest. In certain cases the number of applications was greater with a greater interval between each dosage.

Before administering the gel, each patient underwent cardiotocografic monitoring for at least 30 minutes and an obstetric visit to assign their Bishop score. Immediately following the induction, cardiotocografic monitoring was repeated for a least two hours, to discover any undesirable maternal (uterine hypertonus) or fetal (suffering) side-effects.

When induced labor was successful, at the discretion of the obstetrician, oxytocic augmentation was given, eventually followed by a rexi, in order to maintain correct uterine activity.

Several details were taken into consideration: parity, the gestational age, the Bishop score in correspondance to the induction, the number and mode of application(s) of prostaglandins, the clinical evolution, the mode of delivery and the Apgar index. To have a more complete evaluation, the time for induction and labor were also examined: in the first case, the time necessary to achieve a 3 cm dilatation starting from the first application of Prepidil was calculated; in the second case, the time elapsed from the above-mentioned dilatation until complete dilatation. The maximum time for induction was fixed at 48 hours, after which the induction was considered a failure.

Results

Of the 133 patients recruited, 90 were nulliparae (67.7%) and 43 pluriparae (32.3%). Indications for inducing labor were mostly in the pregnancies over 41 weeks (n=50, 37.6%) the gestosis (n=29, 21.8%), intrauterine growth retardation (n=19, 14.3%) and preterm rupture of membranes (n=11, 8.3%). (Table 1).

Table 2 shows the subdivision of these indications according of gestosis to parity: in the pluriparae patients there was a higher percentage cases, while in the nulliparous patients there was a higher quota of post-maturity.

Table 1. — *Indications for labor induction*

	N	%
Post-term	50	37.6
Gestosis	29	21.8
IUGR	19	14.3
PROM	11	8.3
Diabetes	4	3
Oligoamnios	4	3
Macrosomia	4	3
Colestasis	2	1.5
Isoimmunization	2	1.5
Fetal movement reduction	1	0.7
Others	7	5.3

The age group most represented was between 21 and 34 years, basically equal to that of the general population.

Gestational age ranged from 35 weeks (2 cases) to 43 weeks (2 cases). The Table 3 graphic shows the increased representation of the 42-week range.

The number of applications of prostaglandins given and the route was calculated: Table 4 shows that 60% of the patients received only one dose of prostaglandins.

Table 5 represents the existing correlation between the doses applied and parity: in more that 66% of the cases, the pluriparous patients received only one application, while 57% of the nulliparous patients required more than one application.

Table 6 shows the existing correlation between the number and site of application of PgE_2 and the frequency of cesarean sections.

The next table domonstrates the subdivision of the route of delivery in all the analyzed population: 80% of the patients delivered vaginally while 20% had cesarean section deliveries.

The mode of delivery in relationship to the parity again demonstrated that the pluriparae patients have fever difficulties in labor and in its induction: of the 43 pluriparae cases, none had a cesarean section for failed induction and 95.3% delivered vaginally (Table 8).

The length of labor, and above all, the time needed for induction were much lower in the first group (Table 9).

The clinical evolution was also more favorable in the pluriparous patients: 93% were successful in induction versus 68% of the nulliparous patients (Table 10).

Minor side effects were present in four cases, such as vomiting, diarrhea, fever and vaginal burning respectively.

An oxytocin infusion was administered in 36 cases (27.1%); of these, 27 had vaginal deliveries (75%) and 25% had cesarean sections.

An abdominal operation for missed induction of labor was necessary in five cases (13.9%). The average time of labor in the patients given oxytocin infusion was 4 hours and 55 minutes, and 2 hours and 41 minutes for those not given the oxytocin infusion.

The goal of the study was also to evaluate the Bishop score in relationship to the level of cervical ripening: in 75% of the patients the cervical score was not particularly favorable to begin labor (Bishop score <=4).

Table 2. — *Indications and parity*

	nulliparae N	%	pluriparae N	%
Post-term	37	41.2	13	30.4
Gestosis	18	20	11	25.6
IUGR	13	14.4	6	14
PROM	9	10	2	4.6
Diabetes	1	1.1	3	7
Oligoamnios	2	2.2	2	4.6
Macrosomia	2	2.2	2	4.6
Colestasis	1	1.1	1	2.3
Isoimmunization	–	–	2	4.6
Fetal movement reduction	1	1.1	–	–
Others	6	6.7	1	2.3

Table 3. — *Gestational age*

Weeks	35	36	37	38	39	40	41	>=42
n. patients	2	3	4	17	23	24	10	50
%	1.5	2.6	3	12.7	17.1	18	7.5	37.6

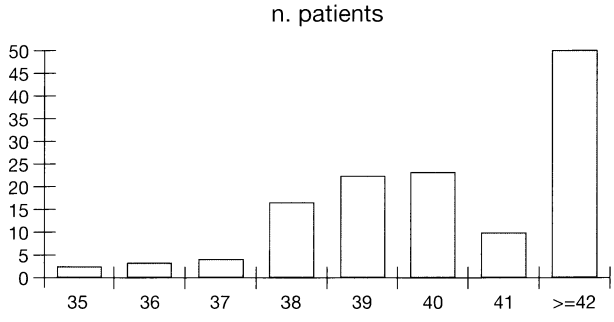

Table 4. — *Dose and application of PGE_2*

	1C	2C	3C	1V	2V	1C+1V	1C+1V	2C+1V	4C+1V
N	62	32	7	19	5	2	1	4	1
%	46.5	24.1	5.3	14.2	3.8	1.5	0.8	3.0	0.8

*C = intracervical route
*V= vaginal route

In reference to the existing relationship between the Bishop score and parity, it is obvious that a higher quota of "unripening cervixes" was present in the nulliparous patients (Bishop score 1-2), while the pluriparous patients had a more favorable initial cervical score (Table 11).

The existing relationship between the Bishop score and the clinical evolution of the induced-labor cases were then considered: 100% of the patients with a score of more than 4 went into labor, as opposed to 81% of the patients with a score of less than 4. Of the first group (Bishop score >4), 84.2% had a vaginal delivery (Table 12).

For a more complete evaluation, attention was also placed on the Apgar index given in the 1st and 5th minutes of birth. The safety of using prostaglandins is also demonstrated by the fact that no newborns had less than an index of 7 at the 5th minute of birth (Table 13).

Particular care was given to the post-term patients; as mentioned previously, there were 50 in the study. The results of the obstetric outcome are comparable to the rest of the population: 100% of the patients with a Bishop score of more than 4 achieved labor and of these 92.4% had a vaginal delivery (Table 14).

When parity was correlated with clinical evolution it resulted that 100% of the pluriparous patients went into labor and 84.6% had a vaginal delivery. (There were no cesarean sections for failed induction in this group) (Table 15).

Comments and conclusions

Our study brings to light results that deserve particular attention and should be compared with the data given in the literature.

As described above, numerous indications were considered valid for the use of protaglandins, most representative being the post-term patients (gestational age >=42 weeks). As reported in the volume of the literature in question, the fetal risk at this time of pregnancy increases significantly. In fact, there are more neonatal deaths, a higher frequency of meconium aspiration and a lower Apgar index at birth [14].

Hannah and Collaborators [13] demonstrated that in the post-term patients given PgE_2 in order to induce labor, the number of cesarean sections was lower compared to that of the patients in which only the maternal and fetal conditions were monitored (24.5% us 21.2%).

At our Department, the percentage of cesarean sections, as shown in Table 15, was 16.7% in the pluriparous

Table 5. — *PGE_2 dose and parity*

		1C	2C	3C	1V	2V	1C+1V	1C+1V	2C+1V	4C+1V	Total
Nulliparae	N	38	22	5	14	5	1	1	3	1	90
	%	42.2	24.4	5.6	15.6	5.6	1.1	1.1	3.3	1.1	
Pluriparae	N	24	10	2	5	–	1	–	1	–	43
	%	55.8	23.3	4.7	11.6	–	2.3	–	2.3	–	

Table 6. — *PGE_2 dose and mode of delivery*

	1C	n=62	2C	n=32	3C	n=7	1V	n=19	2V	n=5	1C+1V	n=2	1C+2V	n=1	2C+1V	n=4	4C+1V	n=1	Total
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Vaginal delivery*	51	82.2	26	81.2	6	85.7	17	89.5	5	60	1	50	1	100	1	25	–		106
Cesarean section	11	17.8	6	18.8	1	14.7	2	10.5	2	40	1	50	–		3	75	1	100	27

Spontaneous delivery + vacuum extractor

Table 7. — *Mode of delivery*

	N
Spontaneous delivery	100
Vacuum extractor	7
Cesarean section for failed induction	12
Cesarean section for other	15

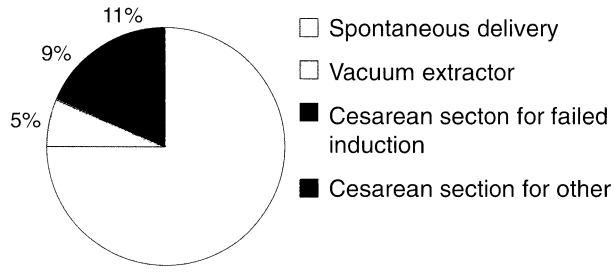

Table 8. — *Mode of delivery and parity*

	nulliparae N	%	pluriparae N	%
Spontaneous delivery	59	65.6	41	95.4
Vacuum extractor	7	7.8	–	–
Cesarean section for failed induction	11	12.2	–	–
Cesarean section for other	13	14.4	2	4.6

Table 9. — *Labor and induction time versus parity*

	nulliparae	pluriparae
Average labor time (h. min.)	3.39	2.34
Average induction time (h. min.)	9.05	6.34

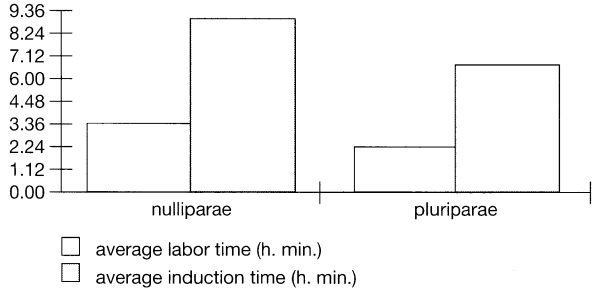

Table 10. — *Clinical evolution and parity*

	nulliparae N	%	pluriparae N	%
No modification of Bishop Score	10	11.1	–	
Modification of Bishop Score	8	8.9	1	2.3
Labor	72	80	42	97.7
Vaginal delivery (induction)	62	68.9	40	93.1
Cesarean section for failed induction	11	12.3	–	
Vaginal delivery (no induction)	4	4.4	1	2.3
Cesarean section for other	13	14.4	2	4.6

patients and 25% in the nulliparous patients. If these percentages are compared with obtained from the general population, not induced, with date the same risk factors, we can demonstrate that the number of cesarean sections is noticeably lower. Moreover, it is important to emphasize that in the reported cases with post-term pregnancies

Table 11. — *Bishop Score and parity*

B.S.	nulliparae N	%	pluriparae N	%
0	1	1.1	–	
1	13	14.4	2	4.7
2	12	13.3	6	14.0
3	18	20	8	18.6
4	24	26.7	16	37.2
5	19	21.2	5	11.5
6	3	3.3	6	14

Table 12. — *Clinical evolution and Bishop Score*

	<= 4 N	%	> 4 N	%
No modification of Bishop Score	10	10	–	
Modification of Bishop Score	9	9	–	
Labor	81	81	33	100
Vaginal delivery (induction)	74	74	28	84.8
Cesarean section for failed induction	12	12	–	
Vaginal delivery (no induction)	5	5	–	
Cesarean section for other	9	9	5	15.2

Table 13. — *Apgar score*

	1st minute	5th minute
1	–	–
2	4	–
3	1	–
4	3	–
5	6	–
6	4	–
7	4	3
8	13	9
9	65	15
10	33	106

Table 14. — *Post-term. Bishop Score and clinical evolution*

	<= 4 N	%	> 4 N	%
No modification of Bishop Score	5	13.5	–	
Modification of Bishop Score	4	10.8	–	
Labor	28	70.2	13	100
Vaginal delivery (induction)	25	64.9	12	92.4
Cesarean section for failed induction	7	18.9	–	
Vaginal delivery (no induction)	1	2.7	–	
Cesarean section for other	4	8.1	1	7.6

undergoing labor induction, there were no significant cases of neonatal morbidity and all the infants had an Apgar index of over 7, five minutes from birth; this does not agree with the studies reported in the literature which largely document an increase in neonatal morbidity in both the brief outcome and the medium to long-term outcome.

Of the 133 patients studied, approximately two-thirds were nulliparous (90 versus 43); this distribution is typical of the general population in our region. This characteristic emphasizes the importance of the results obtained in terms of success for induction, which is obviously more difficult to achieve in nulliparous as opposed to pluriparous patients.

Table 15. — *Post-term. Clinical evolution and parity*

	nulliparae		pluriparae	
	N	%	N	%
No modification of Bishop Score	5	13.5	–	
Modification of Bishop Score	4	10.8	–	
Labor	28	70.2	13	100
Vaginal delivery (induction)	26	70.3	11	84.6
Cesarean section for failed induction	7	18.9	–	
Vaginal delivery (no induction)	1	2.7	–	
Cesarean section for other	3	8.1	2	15.4

Table 16. — *Bishop Score and vaginal delivery*

	nulliparae		pluriparae	
	N	%	N	%
B.S. < = 4	48 / 68	70.6	31 / 32	96.9
B.S. > 4	18 / 22	81.8	10 / 11	90.9

As criteria to be included in the study, patients with a gestational age greater than 35 weeks were admitted, even though certain studies have shown that it is possible to induce sooner [15].

Concerning the location and dose of administration, Table 4 demonstrates the prevalence of the intracervical route. In more than half of the cases, a single cervical or vaginal dose was sufficient to initiate labor.

A parity relationship definitely exists, since in the pluriparous patients there was less need for repeated dosages. These results are comparable to those of Nuutila [5] in which in the vaginal administered group (2 mg of PgE_2) a single dose was needed in 55% of the cases and in the intracervically administered group it was 61.5%. A study in 1990 by Zanini *et al.* already showed how low the quota was for multiple administrations: only 15 cases out of 103 [3].

The results concerning the route of delivery were very encouraging: the number of cesarean sections (due to lack of induction or other causes) in the entire studied population was 20%. These figures are scarcely higher than the number of operations that are given to the general population at our Clinic (in the last three years it has ranged between 13 and 16%). It should be noted, however, that in this study only patients with high obstetric risk and therefore with an augmented probability of cesarean section were recruited.

In a 1996 analysis, Darroca demonstrated that prostaglandins are truly efficient in reducing the number of cesarean sections: by carrying out a comparison between PgE_2 and a placebo, the percentage was 13% and 31.6%, respectively [16].

Table 8 shows the relationship between the mode of delivery and parity. The pluriparous patients responded better to induced labor than the nulliparous patients (95.4% and 73.4%, repectively). These results confirm previous analyses executed by Ekman, on the different reponses between these two groups [17].

Even the number of applications of prostaglandins necessary to obtain labor influenced the type delivery: if vaginal deliveries are more greatly represented in the group given a single administration, they are replaced by cesarean sections in the group requiring repeated administrations (Table 8).

Table 11 represents the existing correlation between the Bishop score and parity. There were no substantial changes toward the right of the graph of the pluriparous patients as was anticipated which is probably due to the different gestational ages represented in the two groups. In the cases of 42 weeks and over, there was in fact, a noted prevalence of nulliparous patients, with a relation of 3:1 (37 nulliparous versus 13 pluriparae).

The relationship existing between clinical evolution and parity reconfirms the importance of this anamnestic factor: 97.7% of the pluriparous patients went into labor, while 80% of the nulliparous patients did not.

The time necessary for induction (elapsed time from the application of the gel to a dilation of 3 cm) and labor was greater, as expected, in the second group. This time increase, a sign of greater difficulty, can probably be translated as an increase in cesarean sections (26% of the nulliparous patients versus 4.6% of the pluriparous patients). In numerical terms, the average time from induction to delivery in the nulliparous patients was 12 hours and 44 minutes and 9 hours and 8 minutes in the pluriparous patients. These times are superimposed with other studies that report averages of 11 hours and 50 minutes and 7 hours and 50 minutes, respectively [18].

The Bishop score also seems to have played an important role as a predictive factor in the induction of labor. By sub-dividing the studied population in to two classes, Bishop score <=4 and >=4, it is evident that the second group had a higher percentage of success.

The conclusion of our work is synthetically shown in the last table, which illustrates the frequency of pluriparous versus nulliparous vaginal deliveries in correlation with the Bishop score (greater than or less than 4) (Table 16).

We can therefore conclude that regardless of the gestational age and the indication that causes induced labor with prostaglandins, 91% of the pluriparous patients with favorable cervical scores had a vaginal delivery, in absence of any maternal or fetal-neonatal complications. Moreover, even the group exhibiting less favorable conditions for induced labor (nulliparous with a Bishop score <4) achieved a vaginal delivery in more that 70% of the cases a cesarean section was given, due to non-induction, in only 16.2% of the cases (11 out of 68).

Therefore, taking into consideration the cost of the method (certainly greatly inferior to those of a single day of hospital recovery prescribed in general to patients with high obstetric risk that are not labor-induced) we retain that choosing an active position is valid, respecting the criteria of eligibility for the induction of labor described above along with the optimal compliance of the patients undergoing this method.

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