

Prevention of preterm birth in patients with symptoms of preterm labor—The benefits of psychologic support

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OBJECTIVE: The aim of this study was to assess the effectiveness of psychologic support against preterm delivery in pregnant women with symptoms of preterm labor.

STUDY DESIGN: The study, which involved two cohorts of women identified during two successive periods in the same maternity ward, included 309 women in the experimental group and 323 in the control group. The women in the control group were followed up according to the usual therapeutic procedures, whereas additional psychologic support was offered to the experimental group. The analysis, conducted "in intent to treat," was based on the estimation of the relative risk by a multivariate logistic regression adjusting for confounding factors.

RESULTS: A significant decrease in the preterm birth rate was observed in the experimental group (12.3%) compared with the control group (25.7%), with an adjusted relative risk of 0.37 (95% confidence interval 0.30 to 0.47).

CONCLUSION: This study confirms the feasibility of this kind of intervention and the effectiveness of psychologic support on the risk of preterm delivery. (*Am J Obstet Gynecol* 1997;177:947-52.)

Key words: Preterm birth, preterm labor, prevention, psychologic support, epidemiologic assessment

Preterm birth is more than a major cause of neonatal mortality and morbidity; it is a serious international public health problem. Although risk factors of a personal, medical, social, or occupational nature have been well described¹ and in spite of use of preventive or therapeutic measures aimed at treating this condition, no continued reduction in the rate of preterm birth has been observed in France since 1990, after the marked reductions of the 1970s and 1980s, when new legislation for medical care was introduced.

However, clinical observations and epidemiologic studies suggesting the existence of a relationship between psychologic factors and pregnancy outcome began to call attention to certain features of the personality of women who gave birth prematurely.²⁻⁸ These factors are related to the affective experiences^{2,5} or mental functioning (most often anxiety and depression)^{6,8} of the women and the role of life events or environmental stresses during pregnancy.^{3-5,7}

Although these studies put forward new hypotheses,

they raise methodologic problems of sample size,^{4,8} retrospective design,^{4,5} and a high rate of nonresponding women in one prospective study.⁷ Moreover, certain authors often were forced to use scales developed in quantitative psychiatry because of the lack of tools to measure psychologic dimensions in a population of pregnant women.⁶⁻⁸ In this respect, we showed that a scale such as HSCL90 (Hopkins Symptom Check List) allowed measuring the psychologic changes caused by pregnancy but not predicting preterm delivery.⁹

For our part, we hypothesized that different psychologic dimensions may be associated with different outcomes of pregnancy, so specific questionnaires should be developed for each outcome of pregnancy.¹⁰ We built up a specific method based on two successive psychologic and epidemiologic approaches. The psychologic approach was carried out by de la Bastie¹¹ and aimed at pinpointing the feelings and attitudes toward pregnancy of women who had just had a preterm delivery: difficulty adapting to changes in body image, inadequate or poorly developed feelings of fulfillment during pregnancy, a hectic daily lifestyle or a proactive attitude towards expected events, insufficient paternal involvement, poor family ties, and an excessive reliance on superstitions and popular beliefs. Then, the epidemiologic approach was based on a broad prospective study, confirming that women who were delivered prematurely exhibited the traits raised by the psychoanalytic approach more often than others who did not. Simply stated, about 12% of

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pregnant women have psychologic difficulties during pregnancy; the risk of preterm delivery is twice as high for these women as for those women who have no such problems.¹⁰

These results open up a new dimension for prevention of preterm birth and suggest that it might be useful to offer psychologic support to women who have such difficulties in their pregnancies, to prevent preterm delivery.

Recent data, provided by the French Maternity Ward Sentinel Network,¹² documented that 40% of preterm births followed spontaneous onset of preterm labor, so it is mostly important to attempt to prevent preterm delivery in women with preterm labor. Among the previous studies Newton et al.⁴ observed a relationship between psychosocial stress and the onset of premature labor and Omer et al.⁸ showed that psychopathologic tendencies were linked to preterm labor and premature contractions.

After these observations, we hypothesized that preterm labor is the somatic expression of a psychologic difficulty related to pregnancy and built up a study aimed at assessing the degree to which psychologic support prevents preterm delivery in women with symptoms of preterm labor.

Subjects and methods

The protocol of this experimental study had the following characteristics.

Target population. The target population included pregnant women with premonitory symptoms of preterm labor appearing between the eighteenth and thirty-fifth weeks of pregnancy regardless of whether the clinical condition necessitated hospitalization. The symptoms of preterm labor included signs of uterine maturation (cervix shorter than 2 cm, patent internal cervical os, signs of engagement, or ballooning of the lower segment) or painful contractions. All had been described and validated in the description of the Haguenau study of preterm labor and delivery.¹³

Study design. The study included two successive cohorts from the same maternity ward. The first comprised women who were followed up with use of the usual therapeutic procedure ("control group"); the second group was offered additional psychologic support ("experimental group").

Assessment criterion. The effectiveness criterion of the intervention was deemed the rate of preterm delivery (i.e., delivery before the thirty-seventh week of gestation) in the "experimental group" (regardless of whether the women met the psychologist and agreed to have psychologic support) compared with the "control group."

Number of subjects required. The number of women required to demonstrate the intervention effectiveness was calculated on the basis of a 25% preterm birth rate in

the control group and an expected reduction by half to 12.5% in the experimental group. With α and β risks of 0.05 and a two-tailed test, the number of patients required for each group was 270.

Inclusion of patients and follow up. Patients with symptoms of preterm labor, hospitalized or not, were included in this study on the basis of the obstetric inclusion criteria described above. The following initial characteristics were recorded on at inclusion: sociodemographic data, previous obstetric history, pathologic events during the current pregnancy (related to preterm delivery or not), gestational age at the time of occurrence of the first signs of preterm labor, presence of painful contractions (recorded or not), and, finally, signs of cervical maturation (cervix shorter than 2 cm, patent internal cervical signs, signs of engagement, or ballooned lower segment).

The routine therapeutic management was the same in the two periods. In hospitalized patients with contractions at entry (recorded on external tocodynamometry and occurring at a frequency of at least one per 10 minutes) associated with at least one cervical sign, β -sympathomimetics were prescribed (perfusion of salbutamol 10 mg/L, 20 to 30 ml/hr during 12 to 48 hours). Each 12 hours the dose and rate were adapted to decreases or increases in contraction. When the contractions were stopped, the perfusion was replaced by oral β -sympathomimetics (2 mg salbutamol tablets). In hospitalized patients with cervical signs at entry without contractions recorded on external tocodynamometry and in outpatients, only myorelaxing therapeutics or bed rest were prescribed.

At each follow-up visit or hospitalization the complications of pregnancy and the prescribed treatments were noted: prescription of β -sympathomimetic agents or other myorelaxing therapeutics or of rest or leave from work.

The women in the experimental group were offered psychologic support and a meeting with the psychologist in charge of the study.

Description of the intervention. The intervention was designed on the basis of psychoanalytic concepts described some time ago by several psychoanalysts. Racamier et al.¹⁴ characterized pregnancy as an identity crisis comparable to that of adolescence; Bibring¹⁵ considered pregnancy as a condition bordering on psychopathologic diagnoses. After these authors, Bydlowski^{16, 17} more recently described pregnancy as a "crisis through which one passes awakening latent anxiety and conflicts"; she also developed the notion of "psychical transparency," a specific mode of psychic functioning of pregnant women that suggests that psychotherapeutic work can be effective in this population, even if performed over a very short time.

The therapeutic intervention was constructed as a

Table I. Baseline characteristics of patients in experimental and control groups

	Experimental group (n = 309) (%)	Control group (n = 323) (%)	Statistical significance
Age			
<20 yr	3.2	2.8	
20-34 yr	87.1	86.0	NS
≥35 yr	9.7	11.2	
Family status			
Married	70.6	67.1	
Live-in couple	24.9	27.2	NS
Single	4.5	5.7	
Work during pregnancy	66.0	60.4	NS
Parity			
0	47.6	40.6	
1	35.0	39.0	NS
≥2	17.4	20.4	
Previous obstetric pathologic features	47.2	46.1	NS
Current gravidic complications related to preterm delivery	14.2	16.8	NS
Gestation			
<27 wk	26.5	33.5	
27-31 wk	51.5	47.5	NS
≥32 wk	22.0	18.9	
Cervical signs			
Cervical length <2 cm	18.4	19.2	NS
Patent internal os	13.9	15.8	NS
Ballooned lower segment	25.9	20.1	NS
Signs of engagement	8.7	6.0	NS
At least one cervical sign	52.4	51.1	NS
Contractions experienced as painful	76.7	62.9	<i>p</i> < 0.05

NS, Not significant.

period of psychologic support for women who had difficulties at some time in the pregnancy. Thus the first interview, with a psychoanalytic orientation, allowed study of the somatic experiences of pregnancy and preterm labor, the associated subjective experiences, and the wish to have a child, the place of the child in the family structure and its filiation, and the familial and obstetric histories. After this interview, depending on whether the patient requests it or the nature of the problem observed by the psychologist, a specific support program adapted to each woman was proposed. Programs included regular psychotherapeutic interviews, telephone contacts, and eventual follow-up at home. Parallel to this direct intervention, self-analysis and co-operation were implemented by the nursing staff, in collaboration with the psychoanalyst, in an attempt to build a protective framework in which patients were able to regain a feeling of safety and confidence in their ability to complete the pregnancy.

Statistical analysis. The analysis was performed as an "intent to treat" to test the effectiveness of the offer of psychologic support made to all women, regardless of whether they actually met the psychologist and accepted the psychologic support. As a matter of fact, the women who did not meet the psychologist or who refused the psychologic support obviously would be different from those who did. As a result, restricting the experimental

group to the women who had benefited from the intervention would have led to a selection bias.

The results are expressed as the crude relative risk of preterm birth in the experimental group compared with the control group and as the adjusted relative risk of preterm birth after the prognostic factors were controlled for in a logistic regression model. A specific analysis was also performed in the subgroup of patients with spontaneous deliveries.

Results

Inclusion of patients and follow-up. The study dealt with two successive cohorts of 323 women included between Jan. 1, 1992, and July 30, 1993, who only received usual therapeutic management and 309 women included between Nov. 1, 1993, and May 31, 1995, who received the same therapies plus an offer of psychologic support. Of the 309 women in the second sample, 196 (63.4%) met the psychologist (79% for hospitalized women and 48% for outpatients). Of these 196 women, 92% accepted the psychologic support (94% of hospitalized women, 90% of outpatients). The number of interviews ranged from one to eight.

Comparison of initial patient characteristics. Tables I and II show that the initial demographic characteristics of both groups were similar; the occurrence or absence of pathologic events in relation to preterm delivery were

Table II. Course of pregnancy in experimental and control groups

	Experimental group (n = 309) (%)	Control group (n = 323) (%)	Statistical significance
Hospitalization when signs occur	27.5	24.3	NS
Hospitalization when signs occur or later on	50.2	49.2	NS
In hospitalized patients			
Contractions at entry	91.0	79.4	$p < 0.05$
At least one cervical sign at entry	80.4	83.9	NS
Perfusion of β -sympathomimetics	38.7	43.0	NS
In outpatients			
Rest or sick leave	56.0	53.6	NS
Home care by midwives	26.2	30.7	NS

NS, Not significant.

Table III. Estimate of relative risks of premature birth in experimental group compared with control group after adjustment for prognostic factors in total sample, in sample including only patients with spontaneous deliveries, and in sample including only hospitalized patients with severe preterm labor

	Relative risk	95% Confidence interval	Statistical significance
Total sample			
Experimental/control group			
Before adjustment	0.48	0.34-0.67	$p < 0.001$
After adjustment*	0.37	0.30-0.47	$p < 0.001$
Sample including only patients with spontaneous deliveries			
Experimental/control group			
Before adjustment	0.55	0.36-0.83	$p < 0.02$
After adjustment*	0.43	0.33-0.56	$p < 0.01$
Sample including only hospitalized patients with severe preterm labor†			
Experimental/control group			
Before adjustment	0.50	0.28-0.89	$p < 0.02$
After adjustment‡	0.47	0.25-0.89	$p < 0.02$

*After adjustment for contractions and gestational age at occurrence of signs and hospitalization at any time after occurrence of signs.

†Patients with cervical signs and contractions at entry.

‡After adjustment for gestational age at entry.

not different for the women of the two groups. The gestational age at the time of occurrence of the first clinical sign also was equally distributed between the two groups, as were clinical signs: short cervix, patent internal os, ballooned lower segment, and signs of engagement. However, contractions experienced as painful were slightly more frequent in the experimental group than among controls. The course of pregnancy was not different between the two groups in terms of hospitalization frequency, prescription of β -sympathomimetic agents in case of hospitalization, rest or leave from work, or home care by midwives.

Effectiveness of intervention in the whole sample. As specified in the study design, the effectiveness of intervention was tested "in intent to treat" by comparing the preterm birth rate observed in the experimental and control groups, including all the women of the former group, whether they actually had benefit from psychologic support.

On the whole, the preterm delivery rate observed among the women of the experimental group was 12.3% versus 25.7% in the control group ($p < 0.01$). In the subgroup of hospitalized women these figures were, respectively, 18.7% versus 39.6% ($p < 0.01$) and in the subgroup of outpatients 5.8% versus 12.2% ($p < 0.05$).

If these results are expressed as a relative risk of preterm birth in the experimental group compared with the control group, the estimate of crude relative risk is of 0.48 (95% confidence interval 0.34 to 0.67) across the whole sample. Stated another way, the risk of preterm delivery among the women in the experimental group is one half that of the control group (Table III).

These results are valid after accounting for the following potentially confounding prognostic factors: existence of painful contractions among the first signs (a variable that was variably distributed between the two groups), gestational age at the time of the first signs (a major prognostic factor), and hospitalization (therapeutic prac-

tice indicating the severity of the preterm labor). Because the intervention could potentially be less effective in the group of women who were not hospitalized, an "Intervention \times Hospitalization" interaction term was introduced in the logistic regression model; it turned out to be nonsignificant. This allowed us to carry on the analysis without taking it into account. The logistic regression model led to an estimation of the adjusted relative risk of 0.37 (95% confidence interval 0.30 to 0.47) in the whole sample (Table III).

Effectiveness of intervention in the subgroup of women with spontaneous deliveries. Because a number of preterm deliveries were induced for medical reasons (10% in the control group and 3% in the experimental group), it was deemed important to check the effectiveness of intervention in women who were delivered without medical induction. There was a significant decrease in the risk of preterm delivery in this subgroup, with a crude relative risk of 0.55 (95% confidence interval 0.36 to 0.83). As before, these results were validated after taking into account the gestational age at the occurrence of symptoms, the existence of painful contractions, and hospitalization. The application of a logistic regression model produced an estimated adjusted relative risk of 0.43 (95% confidence interval 0.33 to 0.56) in this group of women with spontaneous deliveries (Table III).

Effectiveness of intervention in the subgroup of women with severe preterm labor. Because of the wide inclusion criteria, certain patients were potentially not in "true preterm labor," so it is interesting to test the effectiveness of the intervention in women hospitalized with contractions recorded on tocodynamometry and at least one cervical sign. After taking into account the gestational age at the occurrence of symptoms and contractions, the adjusted relative risk was 0.47 (95% confidence interval 0.25 to 0.89). Then, the intervention was beneficial in women with severe preterm labor (Table III).

Comment

This experimental study deals with two cohorts observed during two successive periods in the same maternity ward. Although this type of study may be viewed by some as less desirable than a controlled randomized trial, we chose this recruitment method to avoid a contamination bias that would be inevitable in an intervention involving all the maternity staff in addition to the psychologist in charge of the interviews. Indeed, excellent comparability of the initial characteristics of women in both groups was achieved, because no changes occurred in the patient recruitment pattern and in the inclusion criteria for the population of women followed up in the maternity ward in the two periods.

The psychologic support was very well accepted by the women (92%) after they met the psychologist, although

this first meeting was difficult to organize for outpatients so that only 50% of this subgroup had an initial contact with the psychologist. Our observation on this point accentuates the feasibility of this kind of intervention in hospitalized patients and corroborates the difficulty in the outpatient population.

In this study we obtained a significant decrease in the preterm delivery rate in the experimental group (12.3%) compared with the control group (25.7%). Results were globally positive, regardless of whether the women were hospitalized, with a significant adjusted relative risk of 0.37. However, because the preterm delivery rate was markedly different between the two subgroups, the gain in terms of avoided preterm deliveries was greater in the subgroup of hospitalized patients.

Our wide inclusion criteria (contractions or cervical signs with or without hospitalization) can be debated. In the subgroup of outpatients, we hoped to inhibit contractions and to avoid severe preterm labor to prevent subsequent preterm delivery. Omer¹⁸ suggested a possible psychologic mechanism of preterm labor on the basis of an increase in catecholamine levels under the effect of stress and anxiety, leading to increased uterine activity. He concluded that "anxiety-reducing interventions may reduce catecholamine levels and thus help to inhibit contractions."¹⁹ However, to prevent questions about our inclusion criteria, we performed a complementary analysis in the subgroup of women hospitalized with contractions and cervical signs and obtained a significant adjusted relative risk of 0.47. Then the intervention appeared positive even in women with serious preterm labor.

To our knowledge, no study in the international literature deals with the evaluation of an intervention on the basis of a psychotherapeutic approach. In spite of this, various works report about studies or experimental trials aimed at preventing the risk of preterm delivery through a psychosocial rather than psychologic approach. Four studies have been devoted to prevent preterm delivery in women with a high risk of preterm labor, by use of an educational program or psychosocial support.²⁰⁻²³ Another two studies have aimed to prevent preterm birth in women with preterm labor by a hypnotic relaxation technique.^{24, 25}

Dyson et al.²⁰ included a group of women at high risk for preterm delivery in an educational program on the identification of preterm labor symptoms and observed a significantly lower rate of preterm delivery (before 36 weeks) in this group than in the control group. In a large randomized controlled trial including women at high obstetric risk divided into two groups of which one received social support (home visits and telephone calls by midwives), Bryce et al.²¹ failed to demonstrate a significant decrease in the preterm delivery rate in the experimental group compared with the control group.

Oakley et al.²² used the same method to measure the effect of social support, in addition to standard care, for women who previously had a low birth weight baby and obtained the same preterm delivery rate in both groups. In a large randomized multicenter trial, Villar et al.²³ also tested the effectiveness of additional social support in women at high obstetric or social risk and concluded that psychosocial support has no beneficial effect.

On the other hand, Omer et al.,²⁴ in a small number of patients, observed the effectiveness of a hypnotic relaxation technique to extend the period elapsing between the onset of preterm labor and the date of delivery in women with early contractions or cervical modifications. In a clinical study without a control group, Mehl²⁵ also described the benefits of a hypnotic technique in women with preterm labor.

In view of these questionable results about the possible benefits of social support for women at high risk for preterm delivery, we used a support program based on psychotherapeutic interviews that operated in two ways.

First, the psychotherapeutic work enabled women to express some psychic conflict or trauma that seemed to have an outlet only through the current symptoms. The interviews thus gave the women the opportunity to verbalize painful or feared effects to see them objectively and make them less harmful. This psychic elaboration turned out to be particularly valuable for women with a previous poor obstetric history or those who had experienced stressful or traumatizing events during pregnancy, which is thus pervaded by these painful affects. The interviews let the patients revive emotions related to previous events and allowed them to complete pregnancy peacefully.

Second, the analysis of interviews has shown that preterm labor often occurs when women fail to find in themselves or in their environment the support required for their psychic safety, and then they lose confidence in their own capacity to fulfil their pregnancy. Regular interviews with the psychologist fostered the creation of reassuring therapeutic ties, which was used as a support to help these women regain a more self-assured vision of the pregnancy and the birth of the child.

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