

# A TRIAL OF "PROTAMYL" IN OBSTETRIC ANALGESIA

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Ever since, 1847, when Sir J. Y. Simpson administered chloroform to Queen Victoria, almost every known analgesia and anaesthetic drug has been tried at one time or the other during labour.

By now, bromides, chloral hydrate, chloroform, ether, morphia with scopolamine, pethidine, nitrous oxide, trichlor ethelene, conduction anaesthesia local infiltration, pudendal nerve block and low spinal anaesthesia are advocated with varied response. Pethidine was used in the first stage of labour (Paterson and Prescott, 1944; Barnes, 1947). Though pethidine does not fulfill all the criteria of a perfect obstetric analgesia but with the advent of nalorphine (Plaza) and its systemic use by Eckenhoff *et al* (1953) seems to have changed the whole concept of analgesia in the first stage of labour. Bullough (1957), Baker (1957) and Gupta *et al* (1966) conducted similar clinical trials and found the incidence of respiratory depression of the new-born reduced comparatively.

With the advent of so called "tranquillizers", obstetricians looked with a new hope. Reports of the use of chlorpromazine in sedation and analgesia during labour are now numerous (Hershenson

1954, Anz and Smith 1956, Schaffer 1956, Norton *et al* 1956, Harer 1956). These authors described, their experiences and the risk of precipitous fall in blood pressure and other toxic side effects. Kuntze and Sison (1957), Wergyn and Mark (1958) administered promazine hydrochloride during labour and consider it to be a superior and safer analgesia. Shah and Sathe (1966) used it along with pethidine and found it to be a very efficacious one.

In the present study a combination of Amyl barbitone with promethazine marketed by May & Baker as "Protamyl" was tried orally during labour to clinically evaluate the efficacy of the drug as analgesic and sedative during parturition. Each tablet of "Protamyl" contains Promethazine hydrochloride (I. P.) 12.5 mgm and Amylobarbitone (I.P.) 50 mgm.

## Material and Method

The study was carried out on 300 patients admitted for confinement in the Kamla Nehru Memorial Hospital, Allahabad. The patients were divided in the following groups:

1. Control Group			
Primigravidae	..	..	25
Multigravidae	..	..	75
2. Study Group			
Primigravidae	..	..	74
Multigravidae	..	..	126

A thorough history was taken with special reference to age, parity, time of on-

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set of true labour pains and in multigravidae the nature of previous labour was ascertained. A general examination was carried out and mental make up of the patient was studied in great detail.

A thorough clinical examination was done. Vaginal examination was also performed and dilatation of the cervix was determined. For all practical purposes the duration of the first stage was calculated from 4 cm dilatation of the cervix to full dilatation. It was very difficult to determine the actual onset of the first stage. As no patient gave a correct history of the onset of true labour pains we had to depend upon the finding of the vaginal examination.

Four tablets of "Protamyl" were given to the cases of the study group when the cervix was 4 cm dilated. The dose of protamyl was repeated at 6 hourly intervals, depending upon the subjective and objective relief of pain and also on the dilatation of the cervix.

The duration of the second stage of labour, duration of the third stage, blood loss in the third stage, condition of the baby and apgar score were noted.

#### Observation

The youngest age in the control group

and study group was 15 years and the oldest 40 years. There is hardly any difference of effect of the drug in different age groups. The duration of the gestation varied from 36 to 40 weeks.

Seventy-four cases of the study group were primigravidae and 126 had borne one or more children.

*Mental Make-up and Psychology:* Depending upon mental make-up and psychology, the mothers were graded as A and B. Number of cases in each grade are as shown in Table I. The patients who were frightened and apprehensive were graded as B and required larger amount of protamyl alone or in combination with pethidine, with appreciably less subjective relief, though the cooperation of the patient during delivery was better as compared to the control group. In the present series other sedation as I/M injection of 100 mgm pethidine was needed in 6 cases (8.10%) in primiparae, 2 (1.67%) cases in multiparae while in grandmultiparae no other sedation was required. The combined sedation was needed in grade 'B' cases.

The average dose of protamyl required in different grades of patients is shown in Table II.

TABLE I  
No. of Cases in Each Grade of Study And Control Groups

Group of Cases	Grade A		Grade B	
	No.	%	No.	%
1. Control Group				
Primipara .. .. .	16	22.22	9	32.14
Multipara .. .. .	56	77.88	19	67.85
2. Study Group				
Primipara .. .. .	39	32.23	35	44.30
Multipara .. .. .	82	67.77	44	55.69



TABLE II  
Showing Average Dose of Protamyl In Different Grade of Patients

Grade of Patients	Total Dose of Protamyl				Other Sedation Required
	4 Tablets	8 Tablets	12 Tablets	16 Tablets	
1. Grade A					
—Primi	20	15	4	—	—
—Multi	50	30	2	—	—
2. Grade B					
—Primi	8	16	10	1	6
—Multi	30	14	—	—	2

TABLE III

Average Duration of First Stage of Labour From 4 cm to Full Dilatation

Group	Primi para	Multi para
Control Group	9.2 Hrs.	5.4 Hrs.
Study Group	8.6 Hrs.	5.1 Hrs.

The average duration of the first stage of labour is shown in Table IV.

Sedation in the First and Second Stage of Labour: The relief of pain by protamyl alone or in combination, as assessed by amount of sedation, is depicted in Tables V and VI.

The condition of the babies at the time of delivery was assessed by apgar scoring is shown in Table VII.

Type of Delivery

Out of 74 primigravidae normal spontaneous delivery with live babies occurred in 65 (87.83%) cases, breech 1 case (1.35%) and instrumental delivery in 8 cases (10.8%). Out of these 8 cases L. S. C. S. was done in 3 cases—two for cephalopelvic disproportion and one for uterine inertia in the first stage. In the rest 5 cases forceps was applied, two for uterine inertia in second stage, two for mild cephalopelvic disproportion and one for mild outlet contraction. All multigravidae and grandmulties delivered normally. Three babies were premature (4.05%) in primiparous group and rest (95.94%) cases were mature. Out of 119 babies born to multigravidae, 5 (4.20%) were premature and 114 (95.79%) were

TABLE IV  
Sedation in First Stage of Labour

Amount of Sedation	Primipara		Multipara*		Grand Multipara	
	No.	%	No.	%	No.	%
Excellent	36	48.7	50	42.74	5	62.5
Good	29	39.1	54	46.15	3	37.5
Fair	9	12.1	12	10.25	—	—
Nil	—	—	1	0.85	—	—

\* Out of 118 cases of multigravidae, one case was of pre-eclamptic toxæmia who was given injection of Largactil and Phenargan 50 mgm. 4 hourly after initial dose of protamyl, so that case is not included here.

TABLE V  
Sedation in the Second Stage of Labour

Amount of Sedation	Primiparae*		Multiparae**		Grandmulti	
	No.	%	No.	%	No.	%
Excellent	11	15.7	20	17.09	2	25
Good	34	48.6	51	43.58	4	50
Fair	19	25.7	29	24.80	2	25
Nil	7	10.0	17	14.52	—	

\* Out of 74 primigravidae L.S.C. section was done in three cases—two for mild cephalopelvic disproportion and one for prolonged 1st. stage because of hypotonic uterine inertia. These cases are not included here.

\*\* One case was given Largactil and Phenargan 50 mgm. I/M 4 hourly alternatively for preeclamptic toxæmia in addition to initial dose of protamyl which is not included here.

TABLE VI  
Showing Apgar Scoring

No. of Score	Babies of Primigravidae		Babies of* Multigravidae		Babies of Grandmulties	
	No.	%	No.	%	No.	%
10	55	74.32	102	85.71	4	50
9	9	12.17	6	5.04	2	25
8	5	6.75	3	2.52	1	12.5
6	1	1.35	3	2.52	—	
4	2	2.70	4	3.36	—	
2	1	1.35	—	—	—	
0	1	1.35	1	0.84	1	12.5

\* Out of 118 cases of multigravidae one was a twin delivery, therefore babies born to multigravidae were 119.

mature. Two babies (25%) were premature and 6 (75%) were mature in grand multigravidae group. All patients except one delivered normally in the control group. Midcavity forceps was applied to one primigravida for uterine inertia.

There was no adverse effect of protamyl on uterine action. None of the cases developed hypertonic uterine inertia. Incidences of hypotonic uterine inertia was almost equal in the study and in the control groups i.e., 1.5% and 1% respectively.

**Blood Pressure:** In all cases the variation in blood pressure, during active la-

bour was within normal limits. It rose by 10 to 20 mm of Hg. during active contractions. No fall in blood pressure was noted in any case.

**Foetal Heart Rate:** Except in three cases the foetal heart rate was regular and remained within normal limits, ranging from 124 to 160 with an average of 146. In 2 cases it was because of cephalopelvic disproportion and in one because of prolonged first stage of labour. None of these causes could be attributed to "Protamyl". The three cases where foetal distress occurred cannot be accounted due



to this particular drug as in control group one case also developed foetal distress.

**Blood Loss:** In 192 cases the blood loss was estimated at 100 to 200 c.c. with an average of 150 c.c. which is within normal limits. Out of 8 cases where operative interference was done average blood loss was 500 c.c. Amongst the control group one case had midcavity forceps, the estimated blood loss was 300 c.c.

**Result:** The response to the oral medication of protamyl was graded on amount of sedation—(a) Excellent, (b) good, (c) fair, (d) nil, and appgar scoring of the babies.

Thirty six cases (48.7%) in primiparae and 50 (42.74%) cases in multigravidae and 5 (62.5%) in grandmultigravidae had an excellent result. Regardless of the anxiety they exhibited before medication, these patients immediately became quiet and relaxed. Some slept soundly without being completely aroused by contractions and had little or no memory of the labour and delivery. Others dozed in between contractions and occasionally moved and turned on the sides during pains. This group included the cases who received a second dose of protamyl at an interval of 6 hours.

Twenty-nine (39.1%) primiparae, 54 (46.15%) multigravidae and 3 (37.5%) grandmultigravidae had good results. These patients became relaxed immediately and slept between the contractions, which usually awakened them. Some sighed, moaned or turned about with contractions. They had somewhat clearer memory of the labour, but usually little of the delivery room. On being interrogated on the first postpartum day they usually replied that the pain became less intense after about half an hour of giving protamyl, although they were aware of some of the contractions. Fair results were figured as 9 (12.1%) cases in primiparae

and 12 (10.25%) cases in multigravidae. In these cases delivery occurred within 1 to 2½ hours.

Seven (10.0%) cases in primiparae and 17 (14.52%) cases in multigravidae in the second stage of labour (Table 6) and 1 (0.85%) case multigravidae in the first stage or labour (Table 5) had no sedation.

**Foetal Response:** Foetal response was graded by Appgar Score. From 10 to 8 was graded as good, 7 to 5 as fair and below 5 as poor.

From: Table VI it can be seen that good response was noted in 69 (93.2%) primiparae, 111 (93.27%) multiparae and 7 (87.5%) grandmultiparae. Fair response was found in 1 (1.35%) primipara and none in grandmulti. Poor response was found in 3 (4.06%) primiparae, 4 (3.36%) multiparae and none in grandmultiparae. One baby was stillborn in each group. In primi and multi group the patient was admitted with absent foetal heart sound and in grand multi the stillbirth was because of congenital anomaly (anencephaly).

Reasons for the low score are shown in Table VII a and VII b.

**Response:** There was no nausea and vomiting during labour or delivery, and there was less postpartum emesis than usually seen after a general anaesthetic. Except one patient, no body showed disorientation or hyperactivity during uterine contractors, as is observed with barbiturate sedation.

All were able to respond appropriately to questions and instructions during labour, although they had little memory of such conversations afterwards. No confusion or excitement occurred in the postpartum period.

#### *Summary*

In this study the over all good results, obtained in 93.4% cases, are commend-

TABLE VII a

*Causes of Low Score in Primigravidae*

Apgar Score (Grade)	No. of Score	No. of Cases	Causes of Low Score.
1. Fair (7-5)	6	1	Asphyxia—Cord round the neck.
2. Poor (Below—5)	4	2	Prematurity (Hydramnios).
			Asphyxia (foetal distress, L.S.C.S. was done).
	2	1	Prolonged 1st stage.
	0	1	Admitted With absent F.H.S.

TABLE VII b.

*Causes of Low Score in Multigravidae*

Apgar Score (Grade)	No. of Score	No. of Cases	Causes of Low Score
1. Fair (7-5)	6	3	—Prematurity.
			—Placental insufficiency.
			—Asphyxia (Cord round the neck).
2. Poor (5 and Below)	4	4	—Prematurity
			—Prematurity (Hydramnios).
			—Cord round neck and shoulder.
			—Cord round neck.
	0	2	—Congenital anomaly.
			—Admitted with absent F.H.S.

able. These findings can be compared with those of Kuntz and Sison (1957), Wegryn and Marks (1958), Shah and Sathe (1966) who have reported excellent results in 75%, 55% and 82.5% respectively but they have eliminated barbiturates and combined promazine hydrochloride with pethidine. Moreover, besides promazine and pethidine they administered gas or spinal anaesthesia.

The results of protamyl on the newborn is also worth considering.

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