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Programmed Labor for Optimizing Labour and Delivery – A multicentric Study

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ABSTRACT

To evaluate the efficacy of Programmed Labor protocol in providing shorter, safer and a relatively painless delivery. A multicentric study was conducted at three centres - two in Mumbai and one in Surendranagar (Gujarat). Each centre included two groups of 30 primigravidae each, the first group titled as ***study group*** *was treated as per the* ***Programmed Labour Protocol***[1]*. The second of matched primigravidae were treated conventionally and served as the* ***control group.*** *Labor outcome was analyzed in both groups and compared in terms of mean rate of cervical dilatation; mean duration of first, second and third stages of labor; average blood loss; mode of delivery; maternal and neonatal outcomes. Analysis of results revealed that-The mean rate of cervical dilatation in the study group was almost double that of the control group. There was marked shortening of all the stages of labor. Average blood loss was comparatively less in the study group. Women in the study group had significantly higher pain relief. Majority of women in the study group delivered vaginally. There was significant reduction in obstetric intervention. Babies born to these mothers had satisfactory Apgar Scores at birth, there was no perinatal mortality. Programmed labor protocol can safely lead to shorter labors with significant pain relief with a safe obstetric outcome for both the mother and the foetus.*

Key words: *Programmed Labour Protocol, Pain Relief, Safe Delivery*

INTRODUCTION

Labour is a physiological but painful event. The agony and stress a woman suffers is beyond description. The concept of providing relief from pain has been tardy in acceptance, however experience has shown that providing pain relief during labour reduces maternal stress and results in shorter labours and improved maternal outcome. Epidural analgesia has proved to be beneficial and has contributed significantly to pain relief and improved obstetric outcomes. However in India, wherein the majority of women are cared for in small community hospitals and private maternity homes, facilities for providing epidural analgesia continues to remain a distant dream. Obstetricians are trying to alleviate this misery and have an optimal outcome of labour, but there has always been great opposition by women activists as to why a natural phenomenon should be medicalized. After evaluating several alternatives, a protocol was developed by Daftary et al[1] to optimize the outcome of labour, ensuring smooth progress of labor resulting in the vaginal delivery of a healthy baby through judicious use of labour augmentation, appropriate obstetric analgesia regimen and partographic monitoring(1). A multicentric study was undertaken to establish the feasibility of its adoption and compare outcomes in diverse locales.

MATERIAL & METHODS

The present study was undertaken at three centres – Two in Mumbai and the third centre in Surendranagar, Gujarat. Thirty low risk primigravidae, presenting with induced or spontaneous onset of labour after 37 completed weeks of gestation, with a cephalic presentation and without any known medical or obstetric risk factors were selected for this study. Patients were enlisted in the study only after they entered the ***"Active Phase of Labour"*** (cervix 3 to 4 cm dilated at the time of inclusion in the study with 2-3 sustained contractions / 10 minutes). A ***routine*** amniotomy was performed to ensure the clear nature of liquor amnii and a satisfactory fetal heart rate at the time of inclusion in the study. A partogram was commenced alongside the "***Standard Nomogram***" and all labor events were charted on the partogram to guide the clinician in management of the patient. An intravenous line was started in every patient to ensure I.V.line access. A Ringer Lactate solution was set up to ensure adequate

hydration during labour. If the frequency of uterine contractions was not adequate, labour was augmented with Inj. oxytocin in doses of 2mIU/ml/min to a maximum of 8mIU/ml/min till at least 3 sustained contractions every 10 minutes were achieved. All patients included in the ***Study Group*** were given a low dose of sedation – 6mg Pentazocine with 2mg Diazepam diluted in 10ml of 5% dextrose administered slow intravenously as bolus. All these women then received Inj. Tramadol 50mg and Inj. Drotaverine intramuscular. The ***Pain Score*** (0 no pain, 1- mild pain, 2- moderately severe pain, 3- patient requesting for pain relief and 4 – severe unbearable pain) based on the severity of pain as perceived by the patient, was recorded at the beginning of the protocol, and ***Pain Relief Score*** (0 – no pain relief, 1 – some relief, but not enough pain relief, 2 – Satisfactory pain relief and 3 – Complete pain relief) after delivery. ***Active Management*** of third stage was carried out by injecting 125 mg carboprost intramuscularly routinely after delivery.

Partogram was plotted alongside the "Standard Nomogram", for assessing the progress of labour, detecting dystocia early and implementing timely corrective measures. Duration of all the three stages of labor was noted. Average blood loss was observed and assessed after delivery. Neonatal condition i.e. Apgar Score at 1 and 5 min were noted. Maternal and neonatal morbidity and mortality were noted. All the above parameters were compared with the obstetric outcomes of the low risk primigravidae taken as controls. Appropriate statistical analysis was undertaken wherever applicable using t-test and Fisher Exact test.

RESULTS

Table No. I Comparison of the Partographic Events

Centres of Study	(Mumbai – Ahmed Shaikh) and Daftary S.N.		(Mumbai – Nanak Bhagat) and Dr. Kartik Bhagat		(S' Nagar – M.Pandya)	
Number of cases included	n=30	n=30	n=30	n=30	n=30	n=30
MD-Cervical Dilatation (SD)	2.3(0.5) cm/hr	1.2(0.5) cm/hr	2.2cm/hr	1.5cm/hr	2.3 cm /hr	1.5cm/hr
MD -of first stage (SD)	4 (1)hrs	6 (2) hrs	3.1 (2.23)hrs	4.65(1.97)hrs	4 hrs	3.1 hrs
MD- of second stage (SD)	25 + 10 min	45 + 15 min	25 (17.15) min	35(16.78) min	25+10 min	35+10 min
MD- of third stage (SD)	3 - 5 min	5 min	4.67(2.47)min	8.30(4.98)min	3-5 min	8-10 min
Average blood loss (SD)	75(25)	175 (25) ml	86(48.96)ml	255.83(114.81)ml	75 ml	150ml
Apgar Score < 7 at 1 and 5 min	2	1	3	2	2	3
Perinatal Mortality	Nil	nil	Nil	nil	Nil	Nil

Table No. II Pain Relief Scores in the Study Group

Centres of Study

	Mumbai - Ahmed Shaikh		Mumbai - Nanak Bhagat		Surendranagar - M.Pandya	
Pain Relief Score	No.	%	No.	%	No	%
1	4	13.33	2	6.67	6	20.00
2	6	19.8	12	40	8	26.6
3	20	66.9	16	53.33	16	53.33

Table No. III Comparison of Mode of Delivery

Labour Outcomes in Primigravidae included in the Three Study Groups:

	Mumbai – Ahmed Shaikh		Mumbai – Nanak Bhagat		Surendranagar – M.Pandya	
Mode of Delivery	**Study Group**	**Control Group**	**Study Group**	**Control Group**	**Study Group**	**Control Group**
No. of Cases	30	30	30	30	30	30
Normal Vaginal Birth	27 (90.0%)	25 (83.3%)	23(76.67%)	14(46.67%)	25 (83.33%)	23(76.66%)
Low Forceps / Vento use	1 (3.3%)	2 (6.6%)	5(16.67%)	13(43.33%)	3(10.00%)	4(13.33%)
Cesarean Section	2 (6.6%)	3 (10%)	2(6.67%)	2(6.67%)	2(6.66%)	3(10.00%)

Analysis of Results and Clinical Interpretation:

Partographic events in labor were analyzed in the study group and compared with labour outcomes following routine protocols pursued in treating the control group of patients. Patients in the study group revealed that there was a marked reduction of the duration of the ***active phase of labor***. The mean rate of cervical dilatation was faster than in the control group in all the three centres resulting in shortening of the duration of both first as well as second stage of labor. (Table- I). This observation was found to be statistically significant ($p<0.001$). It was also observed that there was significant reduction in the duration of third stage, which was due to early separation of the placenta in the study group ($p<0.001$). Average blood loss was much reduced, 75 – 86 ml in the study group compared to 175 – 255 ml in the control group (Table I). The labour outcomes revealed that the incidence of normal vaginal delivery in the study group was comparable to that in the control group. So also the incidence of caesarean sections was comparable in the study and control groups, thus emphasized the fact that providing pain relief did not lead to any increase in the incidence of caesarean sections. The indication for caesarean section in the study group had essentially been cephalopelvic disproportion and fetal distress.

This is similar to the incidence of caesarean section in the control group. We observed in this study that 53 - 66% women had total pain relief in labor. Patients in the Study Group, when asked about their experience of labor, said they were aware that the medication provided for pain relief had taken the edge out of the pain, it was bearable and they were extremely thankful for the pain relief. 20 – 40 % of women had substantial relief while 6 – 13% had some relief but not as much as required/ expected. Pain relief scores in the study group compared to the controls revealed statistically significant results ($p< 0.001$). (Table - II). There was no statistically appreciable difference in the mode of delivery or obstetric intervention in terms of instrumental or operative deliveries and the APGAR scores in the study and control groups were comparable. (Table I). The third stage of labour was significantly shorter in the study group and amount of blood lost after delivery much less ($p<0.001$).

Tachycardia was the commonest maternal side-effect noted women in the study group. This was followed by nausea & vomiting, and mild fluctuations in blood pressure in occasional cases, however this was not of clinical significance.

DISCUSSION

Labor and childbirth are natural events. Childbirth should be an event of joy and satisfaction but many times it turns into a harrowing experience for the mother due to pain. Stress of pain disturbs the maternal autonomic functions and liberates catecholamines which predisposes to dysfunctional labor and compromise fetal oxygenation. Freedom from pain improves the environment for both mother and fetus and therapy improves obstetric outcome (2). 'Programmed Labor Protocol' (1), (9) provided relatively pain less, shorter and safer deliveries. The current study was undertaken in three different centres with the aim of evaluating the efficacy of programmed labor protocol in providing shorter, safer and a relatively pain less delivery in different locales. In the study group, mean rate of cervical dilatation was almost doubled; the duration of all the three stages of labor was markedly reduced; the average blood loss was less. Neonatal morbidity was similar to the control group. There was no fetal or maternal mortality. Chauhan et al(2), Daftary et al(1) and Jyoti M et al(3) also had similar observations.

The almost doubling of the rate of cervical dilatation and therefore, decrease first in the stage of labor can be attributed to the action of sedatives/ analgesics and drotaverine. Drotaverine is a quaternary muscarinic drug, considered to be a superior atropine substitute, mainly used in treatment of colics.(7) Studies have shown drotaverine to be a

superior cervical dilatation agent than other antispasmodics like epidosin or buscopan (4, 5).

Pain relief shortens the duration of first stage of labour by cutting the cycle of pain-fear-tension. Use of Sedatives / Analgesics in combination (sub-anaesthetic dosage) achieves synergism that ensures adequate pain relief without the obvious ill-effects each drug would have had in higher doses on the baby and the mother.

Pentazocine, a category C drug, is a benzo-morphan derivative with very potent action at kappa receptors in the spinal cord and weak antagonist action at the mu receptors. It is less effective compared to Morphine with a shorter duration of action. The incidence of Respiratory depression is less and it may raise the systolic and pulmonary arterial blood pressure slightly. It is metabolised extensively in the liver and excreted as a glucuronide. The adverse reactions include sedation, sweating, dizziness, nausea and hallucinations. The dose recommended for pain relief is 30 – 60 mg every 3 – 4 hours. In our "Opti-mising Labour Protocol" the dose of Pentazocine used was 6mg, which is $1/10^{th}$ of the recommended analgesic dose. (7) No side effects except a little dizziness and sleepiness was observed in the study population.

Diazepam is a Benzodiazipine derivative, used mainly as a Sedative and Anxiolytic. Its effective half-life is more than 24 hours. Its bedtime single hypnotic dose is 5 – 15mg and total daily Anxiolytic dose is 10 – 30mg. The adverse reactions are dose dependent and include CNS depression drowsiness, lethargy, ataxia, visual- motor in-coordination, daytime sedation, anterograde amnesia, behavioural changes and occasionally personality changes. Rarelydoes it produce leucopenia, allergy, photosensitisation, vertigo, headache and sexual dysfunction. Patients tend to develop tolerance to the sedative but not the anxiolytic action. If administered in high dose just before delivery, it may produce a Floppy Baby Syndrome where the newborn may get apnoeic spells, reluctance to feed, hypotonia and hypothermia. In our "Optimising Labour Protocol" the dose of Diazepam used was 2mg, which is $1/5^{th}$ the recommended single bedtime hypnotic dose. No newborns in the study had apnoeic spells or hypotonia due to the drug. In fact, all the babies in the study group were alert and capable of doing the breast crawl.(8)

Tramadol has been found to be an effective analgesic in labor without having a deleterious effect on the mother and the fetus(5). Tramadol is a synthetic codeine derivative, a Phenantherene alkaloid of opium. It is a weak agonist of mu receptors and exerts part of the analgesic activity by inhibiting noradenaline and serotonin uptake. It is rapidly absorbed in the liver to an active compound with analgesic action. Its half-life is 6 hours. It is as effective as Pethidine in mild to moderate pain. The common side effects are dizziness, sedation and nausea.

All the mothers were fully conscious and alert at the time of and after delivery and breastfed their babies easily.(1) Almost all the babies in the study group did the Breast Crawl and initiated breastfeeding in an hour of birth.(8) Average blood loss of women in the study group was also much less compared to those in the control group. This was attributed to the effect of Carboprost administered at the time of delivery of the anterior shoulder – active management of third stage. Daftary et al,(1) and Jyoti M et al(3) noted the same.

There was no major difference in the percentage of normal delivery in study as well as control groups. This was in accordance with the observations of Daftary et al,(1) and Jyoti M et al,(3). Majority of the patients had a good amount of pain relief, as reported in studies (1, 6). The incorporation of partogram into the protocol of programmed labor was found to be meaningful to most of the clinicians as it helped to eliminate the ill effects of prolonged labors, prompted earlier recognition of dystocia and implementation of corrective measures at the same time(6). The three centres reached a similar conclusion in this multicentric study. It can be safely concluded that the adoption of the programmed labour protocol should be of immense benefit to many clinicians, particularly in private maternity clinics and in areas where anaesthesiology services are not easily accessible. The procedure is cost effective and should be evaluated more widely.

CONCLUSION

"Optimizing Labor Protocol" or "Programmed Labor Protocol" leads to shorter labors; analgesia is quite effective and side effects of drugs are minimal and safe for the fetus as well; labor is cherished with pleasure and childbirth becomes a joyous event for the Mother. Clinicians in a private maternity set up can safely use it.

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