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Comparative feasibility of two World Health Organization partographs to predict prolonged labour: a randomized control trial

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ABSTRACT

Background: One of the major causes of maternal mortality is obstructed labor. Identification of abnormal labor at earliest and timely management can prevent prolonged labor and significantly reduce its sequel. Partograph is a useful tool in hands of labor care givers to monitor labor course. The study was done to compare feasibility of two WHO partographs a composite partograph including the latent phase with a simplified one without the latent phase to predict prolonged labor in randomized control trial.

Methods: A randomized controlled trial, with parallel arm design was conducted. Sample size was calculated as 404 pregnant women .They were randomly categorized in two groups, each group having 202 participants.

Results: labor had crossed the alert line in 108 (53.4%) cases monitored by composite partograph and 38(18.8%) cases monitored with simplified partograph. The calculated P value was <0.0001. The odds ratio calculate was 4.95 and 95% confidence interval was 3.16 to 7.76. Labor crossing the action line was found in 16 (7.9%) in composite partograph whereas in simplified partograph, labor had crossed the action line in 18 cases in simplified group. Calculated P value was 0.72 (>0.05). The odds ratio was 0.8793 and 95% confidence interval 0.43 to 1.77 which was not significant statistically .Most participants (70%) experienced difficulty with the composite partograph, but no participant reported difficulty while plotting the simplified partograph.

Conclusions: WHO simplified partograph was found to be as good as WHO composite partograph in identifying maternal and perinatal outcomes and was more user friendly.

Keywords: WHO composite partograph, WHO simplified partograph, Prolonged labor, Obstructed labor, Randomized control trial, Feto maternal outcome, Labor monitoring

INTRODUCTION

Partograph is a Greek word meaning "Labor Curve". The development of partograph started, when Emanuel Friedman developed cervicograph for the first time in 1954. It is a record of progress of labor in graphic form depicting the mother and fetal condition It has been used since 1970. It detects labor when it is deviating from normal course, indicates when augmentation of labor is required and identifies cephalo-pelvic disproportion before obstruction develops. It serves as an early warning system and assists in early decision-making on transfer,

augmentation and termination of labor. In 1970, Philpott's partograph developed from the original cervicograph of Friedman.³ An alert line was placed on cervicograph which was straight, not curved as in Friedman's graph. The next stage in the development of partograph by Philpott and Castle was the introduction of an action line.^{4,5}

As per WHO Global maternal mortality rate was 216 maternal deaths per every 100,000 live births in 2015 and developing regions accounted for 99% of global maternal deaths. One of the major causes of maternal mortality is

obstructed labor. Identification of abnormal labor at earliest and timely management can prevent prolonged labor, and significantly reduce the risk of postpartum hemorrhage and sepsis, obstructed labor, uterine rupture, and thereby reduce the maternal mortality.

Partograph is a useful tool in hands of labor care givers to monitor labor course. What is surprising perhaps is the use of the partograph itself was only rigorously evaluated 20 years after its introduction.^{6,7} It was only in 1987, that WHO introduced the composite partograph. It included a latent phase of Eight hours. It was an adaptation of the one formulated and described by Philpott and colleagues. Since the first publications on cervicography, the issue of the latent phase has been controversial, as there is always a risk of inappropriate interventions if undue attention is paid to the latent phase. Subsequently, in 2008 the WHO produced the modified partograph where the latent phase was removed, to make it simpler and easier to use. 8 The present study was aimed to analyze the usefulness of the two WHO partographs by a randomized control trial and compare the two WHO partographs (a composite one with a latent phase) (Figure 1) and a simplified one without a latent phase) (Figure 2). To analyse which partograph can better predict maternal and perinatal outcomes and is more user-friendly.

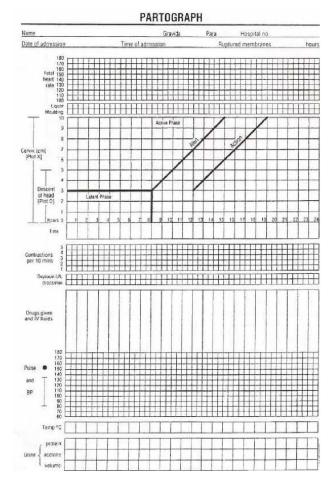


Figure 1: Composite WHO partograph.

PARTOGRAPH

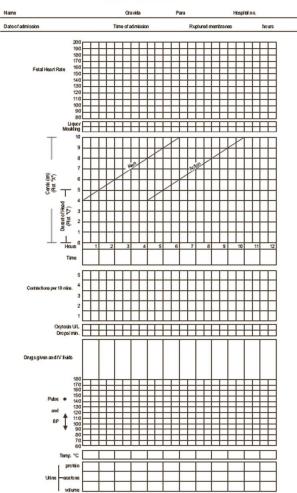


Figure 2: Simplified WHO partograph.

METHODS

A randomized controlled trial, with parallel arm design was done after obtaining Institutional Ethics committee approval at People's College of Medical Sciences and Research Centre, Bhopal, MP from October 2012 to July 2014. The CTRI registration done retrospectively (CTRI 2018/05/013836). The trial was conducted as per CONSORT guidelines 2010 (Figure 3).

Ethical concerns

All participants were explained the purpose of study in vernicular language and written informed consent was obtained. They were explained about there free will to withdraw from trial. No incentive was given to them. Confidentiality of data was strictly maintained. All the participants continued till the end detail observations were charted. None of particiapnt had withdrawn from trial after enrolment.

Two types of WHO partographs including composite partograph including latent phase and simplified partograph without latent phase were used as intervention

tools for labor monitoring. Both partographs have alert and action line which is drawn 4 hrs after alert line for early prediction and management of prolonged labour.

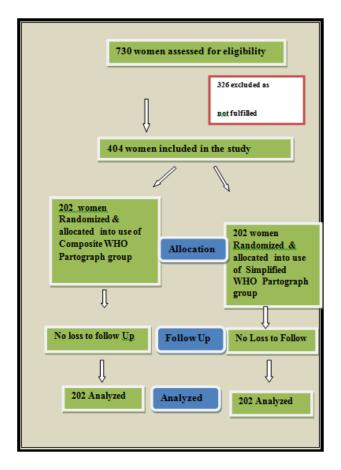


Figure 3: CONSORT flow diagram.

Inclusion criteria

Primigravida and multigravida women admitting with spontaneous labor, with a live, singleton pregnancy, cephalic presentation having 4 cm or less cervical dilatation and those willing to participate in the study were included.

Exclusion criteria

Women with intra uterine fetal death, pregnancies complicated by fetal malformation, multiple pregnancy, non-cephalic presentation, trial given outside our hospital were excluded.

Sample size

Sample size was calculated as 404 using formula $n=t^2\times p(1-p)/e^2$, where t=confidence interval (95%) standard value of t at 95% is 1.96, p=proportion (0.5), e=allowed error (5%=0.05). 404 pregnant women were randomly categorized in two groups, each group having 202 subjects.

Sequence generation was done by computer generated random number table was done by co-investigator. Patient allocation was done by allocation concealment was done by keeping partographs in sequentially numbered opaque, sealed, envelops by the same co-investigator. The principal investigator and all residents were kept blind to the sequence and allocation.

All pregnant women coming to the labor room of department of Obstetrics and Gynecology, People's College of Medical Science, Bhanpur, Bhopal Hospital and admitted for spontaneous onset of labor were examined after taking a detailed history. Women fulfilling the inclusion criteria and written informed consent were obtained. They were then allotted either of the two WHO partographs. The sequence was predetermined according to computerized randomization and partograph kept sealed in the numbered envelop was then opened and charted. The partographs were filled by 12 residents on rotational emergency duty. A two-hour sensitization session was taken for residence before initiating the study. The feasibility of charting was asked by residents at the end of partograph in the performa.

Partograph charting: cervical dilatation- in the centre of each partograph was a graph. Along the left side were numbers 0-10 against squares: each square represented 1 cm dilatation. Along the bottom of the graph were numbers 0-24, each square represented 1 hour. Dilatation was measured in centimeters. Dilatation of cervix is plotted against time in hours.

In simplified partograph, the first marking was at 4 cm. In composite partograph, latent phase was from 0-2.9 cm. The active phase was from 3 to 10 cm (full dilatation). When dilatation was 0-2 cm, plotting was started in the latent phase area of the cervicograph. When labor had entered the active phase, plotting was transferred by a broken line to the alert line, leaving the area between the transferred recording blank. The broken transfer line was not part of the process of labor.

In simplified partograph, latent phase was not included. Plotting was started at cervical dilatation of 4 cm.

Vaginal examinations were made every 4 hrs. 9,10 However, in advanced labor, women were assessed more frequently. Contractions, frequency and duration of the contractions were observed. Frequency was assessed by the number of contractions in a 10 min period. Duration of contractions was from the time, the contraction was first felt abdominally, to the time when contraction passed off, measured in seconds. The duration of contractions was shaded in three possible ways.

The maternal condition^{9,10}

Drugs and intravenous fluids were charted in the appropriate column just below the area for contractions. Pulse rate was recorded every half hourly. Blood pressure

was recorded and plotted once every 4 hours or more frequently (if indicated). Temperature was recorded once every 4 hourly or more frequently (if indicated).

Labor was monitored until delivery. The outcome was mentioned at the bottom of each partograph. Comparisons were done on the basis of labor crossing alert and action line, augmentation of labor, rate of cesarean section, perinatal outcome, user friendliness and maternal complications.

Fetal condition charted

Fetal heart rate was recorded at the top of the partograph, every half hourly with a dot. Each square represented half an hour. There were four different ways in which the state of liquor on the partograph was recorded, immediately below the fetal heart rate recordings. If the membranes were intact, recorded as letter "I". If membranes were ruptured and liquor was clear, recorded as letter "C". If membranes were ruptured and liquor was meconium stained, recorded as letter "M". If membranes were ruptured and liquor was absent, recorded as letter "A". Moulding showed how adequately the pelvis could accommodate the fetal head. Increasing moulding with the head high in the pelvis was regarded as an ominous sign of cephalopelvic disproportion. There were four different ways of recording moulding on the partograph, (immediately beneath those of the state of liquor). Bones were separated and the sutures could be felt easily, recorded as letter "O".

Bones were just touching each other, recorded as "+". Bones were overlapping, still separable, recorded as "++". Bones were overlapping severely and not separable, recorded as "+++".

Statistical analysis was done for the observations recorded using, 95% confidence interval, odd ratio, chisquare test and p value was calculated appropriate for study variables.

RESULTS

404 women who fulfilled the inclusion criteria were enrolled in the study from October 2013 to July 2014. Labor was monitored using either of the two WHO partographs. Parity (Table 1) shows the parity status of the laboring woman participants enrolled 60.3% were multigravida and 39.7% were primi gravida in composite group. 58.4% were muti gravida and 41.5% were primigravida in the simplified group.

Comparison of the two studies groups regarding various characteristics different characteristics of the participants were analyzed. Characteristics like mean duration of gestation, presence of co-morbidity during gestation, primigravida, multigravida, mean age (SD), history of booking, mean age (SD), mean station of head were found as similar in two groups. Mean duration of labor, mean systolic BP, mean diastolic BP, mean presentation were statistically dilatation at difference (Table 2).

Composite partograph Simplified partograph **Parity Total** Chi square P value (n=202)(n=202)N(%) N (%) Primigravida 80 (39.7) 84 (41.5) 164 0.164 0.685 Multigravida 122 (60.3) 118 (58.4) 240

Table 1: Number of participants in both the groups (n=404).

Table 2: Comparison of the two study groups in terms of the various study characteristics.

Parameter	Composite partograph group	Simplified partograph group	Test value	P value	Effect size
Mean duration of gestation	38.7	38.4	T=3.0150	0.0027	0.30
Presence of comorbidity during gestation	4.9%	4.9%	Z=0	1.00	-
Primigravida	80	84	Z=0.4087	0.6828	-
Multigravida	112	118	Z=0.406	0.6847	-
Proportion of women with h/o IUGR	0.9	0.9	Z=0	1.00	-
H/o booking	128	114	Z=1.4331	0.1518	-
Mean age (SD)	23.2	22.2	T=2.8646	0.0044	-
Mean duration of labor	12.3	11.8	T = 5.0249	< 0.0001	-
Mean SBP at presentation	123.7	121.2	T=25.1247	< 0.0001	-
Mean DBP at presentation	79.2	81.1	T=6.3649	< 0.0001	-
Mean dilatation at presentation	2.7	3.9	T=12.0599	< 0.0001	-
Mean station of head	1.88	1.93	T=0.5025	0.656	-

In the present study, labor had crossed the alert line in 108 (53.4%) cases monitored by composite partograph and 38 (18.8%) cases monitored with simplified partograph. The calculated p value was <0.0001. The odds ratio calculates was 4.95 and 95% confidence Interval was 3.16 to 7.76. Effect size

calculated is large (>3 odds ratio). This difference between the two groups was statistically significant. More number of cases was identified as crossing alert line by composite graph as compare to simplified graph. This aspect needs to be further evaluated as by including the latent phase as done in composite graph have more number of cases (Table 3).

Table 3: Labor crossing the alert line.

Types of partograph		Labor not crossing alert line	Chi square	P value	Odds ratio	95% CI
Composite	108 (53.4%)	94	52.6	< 0.0001	4.9586	3.1672 to 7.7632
Simplified	38 (18.8%)	164	52.6	<0.0001		

Table 4: Labor crossing the action line.

Types of partograph	Labor crossing the action line (n=16)	Labor not crossing the action line (n=18)	Chi square	P value	Odds ratio	95% CI
Composite	16	186	0.128	0.720	0.8793	0.4351 to 1.7771
Simplified	18	184	0.128	0.720		

Table 5: Requirement of augmentation of labor.

Partograph	stagraph Augmentation Parity		%	Augmentation	Chi	P	
Tartograph	needed	Primi gravida	Multi gravida	/0	not needed	square	Value
		N (%)	N (%)				
Composite	202	80 (39.6)	122 (60.3)	100	0	- 0.00	1.00
Simplified	202	84 (41.5)	118 (58.4)	100	0	0.00	1.00

Table 6: Number of successful vaginal delivery.

Type of partograph	Vaginal delivery done	Vaginal delivery not done	Chi square	P value	Odds ratio	95% CI
Composite	186	16	0.128	0.720	1.1372	0.5627 to 2.2984
Simplified	184	18	0.126	0.720	1.1372	0.3027 10 2.2904
	Cesarean	Cesarean section				
	section needed	not needed				
Composite	16	186	0.128	0.720	0.8793	0.4351 to 1.7771
Simplified	18	184	0.126			0.4331 t0 1.///1

Table 7: Difficulty in plotting the partograph.

Difficulty in plotting the partograph	Composite	Simplified	Z value	P value
Percentage (%)	70	0	14.75	< 0.0001

Labor crossing the action line was found in 16 (7.9%) patients for whom composite partograph were plotted whereas in patients monitored with simplified partograph, labor had crossed the action line in 18 (8.9%) cases. Calculated p value was 0.72 (p>0.05). The odds ratio was 0.8793 and 95% confidence interval 0.43 to 1.77. The effect size calculated was small. This difference was statistically not significant. The composite and simplified graph was found as similar in identifying the cases those crossed the action line (Table 4).

Augmentation of labor was required in 80 (39.6%) primigravidae and 122 (60.3%) multigravida cases who were

randomized to composite partograph group. In simplified group primigravidae 84 (41.5%) and multigravida 118 (58. 4%) patients required augmentation. The results were statistically not significant (Table 5).

92% women in composite partograph group and 91% in simplified group delivered vaginally. This was statistically not significant. The odds' ratio was 1.13 and 95% confidence interval was 0.56 to 2.29. The p value calculated was 0.72 (p>0.05) Out of 202 the patients, randomized to composite partograph, 16 (8.4%) underwent cesarean section. In patients with simplified partograph, cesarean section was done in 18

(10.3%) cases. The results were statistically not significant. The odds' ratio was 0.87 and 95% confidence interval was 0.43 to 1.77, the p value calculated was 0.72 (p>0.05). The effect size calculated was small. There was no difference between the cesarean section was done between composite group, and simplified group (Table 6).

Neonatal intensive care unit admissions were in composite partograph group 8 (4.4%) as compared to 17 (7.6%) in group monitored by simplified partograph. The p value calculated was 0.06. The odds' ratio was 0.44 and 95% confidence interval was 0.18 to 1.06. The effect size calculated was small. The results were statistically not significant. The NICU admission in composite group, and simplified group were similar. Majority of cesarean sections were due to prolong labor and fetal distress. Only 11.1% in composite group and 16.6% in simplified group were due to non-progress of labor. In composite partograph group 4 (1.9%) case and 5 (2.4%) in simplified partograph group was complicated with atonic postpartum hemorrhage which was not related to prolong and obstructed labor. No patient in both the groups had suffered from puerperal sepsis A total of 12 resident doctors working in 12 hour shifts at this teaching hospital was instructed to use the partographs as per sequence provided, according to computer randomization. Participants scored the two partographs for each of the following categories. Most participants experienced difficulty with the composite partograph, but no participant reported difficulty while plotting the simplified partograph (Table 7).

DISCUSSION

Kenchaveeriah et al reported in their study 54.8% were primigravida and45.14% were multigravida in composite group and 51.9% primigravida and 49.09% multigravida in simplified group. There was no statistical difference (p=0.42) in the parity status. Sethi et al reported primigravida in composite group were 56 primigravida and 44 multigravida simplified group 54 primi and 46 multigravida and was not statistically significant (p=0.776). 12

In our study the parity status of the laboring woman participants enrolled as 60.3% were multigravida and 39.7% were primi gravida incomposite group. 58.4% were mutigravida and 41.5% were primigravida in simplified group. The p value >0.5 (0.68) which was statistical not significant. Our study background was comparable with others as there was no significant difference in parity making a suitable background for conducting randomized control trial.

In the present study, labor had crossed the alert line in 108 (53.4%) cases monitored by composite parto-graph and 38 (18.8%) cases monitored with simplified partograph. The calculated p value was <0.0001. This difference between the two groups was statistically

significant. More numbers of cases were identified crossing the alert line by composite graph as compare to simplified graph. In the Sethi et al study 32/100 women crossed in composite group and 16 /100 women crossed in simplified group which was statistically significant difference. ¹²

In Ghanghoriya et al study, 94 (47%) out of 200 patients crossed the alert line, out of them 65/120 (65%) were primi and 29/80 (36.25%) were multi-gravida. ¹³ Kenchaveeriah et al also reported 98/350 cases crossed alert line in the composite group and 55 /393 cases monitored with the simplified partograph. ¹¹ It was statistically significant (p=0.0001). Our study results were similar to others as by excluding latent phase monitoring using simplified partograph reduced the number of cases crossing alert line. Early partograph charting in the latent phase of labor tends to cross alert line more.

Kenchaveeriah study reported labor crossing the action line was found in 40 patients for whom the composite partograph was plotted whereas in patients monitored with the simplified partograph, labor crossed the action line in 8 cases (p<0.05). 11 Sethi et al reported in the study 10/100 crossed action line in the composite group and 2/100 crossed in simplified group (p value 0.017 significant statistically). ¹² In our study labor crossing the action line was found in 16 (7.9%) patients for whom composite partograph were plotted whereas in patients monitored with simplified partograph, labor had crossed the action line in 18 (8.9%) cases. Calculated p value was 0.72 (>0.05, not significant). In our study the odds ratio was 0.8793 and 95% confidence interval 0.43 to 1.77. The result was statistically not significant. The reason for no difference could be the over watchfulness and augmentation. In study by Kenchaveeriah also reported augmentation was higher in patients in whom labor had crossed the alert and action lines.¹¹

ACOG suggested that the onset of active labour may occur in many women at 5-6 cm in contrast to earlier suggest latent phase of 4 cm. So, it is suggested to continue expectant management till maternal and fetal condition is re assuring.¹⁴

In Sethi et al study "68/100 vaginal delivery, Instrument delivery 9/100 in composite groups 90/100 and instrumental delivery 1/100 in simplified groups. 12 The difference was statistically significant 23/100 had CS delivery in composite group and 9/100 in simplified groups delivered by CS. Statistically significant difference present (p<0.001 for vaginal delivery, for CS p value 0.007). 12

Kenchaveeriah et al reported the success rate regarding vaginal delivery in their study as 76.08% in the composite group and 89.9% in the simplified group. 23.9% and 10.08% in the composite and simplified groups respectively underwent cesarean section

(p=0.001).¹¹ A study done by Alauddin et al had 149 (82.7%) of cases who delivered vaginally in the simplified group and 71 (71%) in the composite group (p value 0.05, significant).¹⁵

Windrim et al evaluate the effect of partogram use on the cesarean section and obstetric intervention rates conducted a randomized controlled trial of use of the partogram in 1932 primiparous women with uncomplicated pregnancies at term. 16 There was no significant difference between the groups in rates of cesarean section (partogram 24%, standard notes 25%), rates of other interventions, amniotomy, oxytocin use, or the mean cervical dilatation in labor. In this study, the use of a partogram without a mandatory management of labour protocol had no effect on rates of cesarean section other intrapartum interventions or healthy primiparous women at term.

In our study 92% in composite group and 91% in simplified group delivered vaginally. In composite, group 16 (8.4%) cases underwent cesarean section and in simplified group cesarean section was done in 18 (10.3%) cases (p value 0.720, not significant).

In our study there was no difference between the cesareans section was done between composite group, and simplified group as at our institute as cesarean sections as it was performed for obstetric indications also in addition to prolonged labor. In other studies' cesarean section are more in the composite group as early monitoring, and early augmentation in latent phase predisposes to more cesareans section but in our study there was no statistical. Kenchaveeriah et al reported in their study that in the composite group 126 cases required augmentation and 65 cases in simplified group were statistically significant (p<0.05). 11 Sethi et al reported augmentation was needed in 32 cases in comparison to only 15 cases in simplified group. It was statistically significant (p value=0.034). 12 Alauddin et al in their study reported labor augmentation was required in 17 (9.44%) in simplified partograph and 28 (28%) in composite partogarph. The difference was significant statistically (p<0.001). In the present study also augmentation was used in 25% in composite group and 10% in modified partograph group. The results were comparable to other studies. In Kenchaveeriah et al study reported augmentation of labor was needed in 126 cases in the composite partograph and in 65 patients subjected to the simplified partograph (significant statistically, p<0.05). 11 Sethi et al reported augmentation of labor was required in 32 cases in the composite partograph as compared to 15 in the simplified group was statistically significant).¹²

In our study neonatal intensive care unit admissions were in composite partograph group 8 (4.4%) as compared to 17 (7.6%) in group monitored by simplified partograph. The p value calculated was 0.06. The results were statistically not significant. The NICU admission in

composite group, and simplified group were similar.

Sethi et al reported in their study statistically significant difference in the number of infants admitted to NICU which was 15% and 3% in the composite and modified partograph groups respectively (p value=0.003). In Kenchaveeriah et al study NICU admissions were statistically significant in the composite partograph group 68 (19.4%) as compared to 35 (8.90%) in the simplified group (p value=0.05). In Our study results were different from other studies. Further, evidence is required in this aspect.

Cochrane systematic review reported the study included one trial were compared a partograph with the latent phase (including early stages of labour) and one without the latent phase, the caesarean section and oxytocin augmentation rates were higher in the partograph with a latent phase. There were no clear difference between groups for oxytocin augmentation, and Apgar score less than 7 at 5 minutes. Further, trial evidence was required to establish the efficacy of partograph use per se and its optimum design.

Mathews et al reported a trial conducted on 658 parturient women 18 physicians participated. The study concluded the simplified WHO partograph was more user-friendly, was more to be completed than the composite partograph, and was associated with better labor outcomes.

Singh et al reported in their study doctors working in hospitals with a policy of partograph use, demonstrated excellent skills using case scenarios for plotting partographs (p<0.01). And a positive attitude towards plotting partograph and its use as a decision support tool (p=0.000) as compared to doctor working in hospitals without a routine partograph plotting policy. They concluded "hospital policy of routine partograph plotting may positively influence utilization of partograph in tertiary care public hospitals in India."

CONCLUSION

In our study the WHO simplified partograph was found as equivalent to composite partograph in identifying prolonged labor. Also maternal and perinatal outcomes were equally identified by both types of partograph. Simplified one had fewer cases crossing alert line thus less early intervention was done and was reported as more user-friendly. Thus, our study supports use of simplified partograph over composite one.

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