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Original Research Article

Effect of the WHO labour care guide on cesarean delivery and intrapartum interventions: a randomized controlled trial

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ABSTRACT

Background: The World Health Organization (WHO) Labour Care Guide (LCG) promotes individualized intrapartum care. This trial compared caesarean delivery and maternal and neonatal outcomes among women monitored with the LCG versus the modified partograph.

Methods: In this single-center randomized controlled trial, 266 low-risk women with singleton, term, cephalic pregnancies in spontaneous labour were allocated to LCG or modified-partograph monitoring (133 per group). The primary outcome was caesarean delivery. Risk ratios (RRs) with 95% confidence intervals (CIs) were calculated for binary outcomes.

Results: Caesarean delivery occurred in 41/133 (30.8%) women in the LCG group and 39/133 (29.3%) in the modified-partograph group (RR 1.05, 95% CI 0.73-1.52; $P=0.894$). Active labour was longer with the LCG (mean difference 1.4 hours, 95% CI 0.92-1.88; $P<0.001$). Oxytocin augmentation (18.0% vs 39.1%; RR 0.46, 95% CI 0.30-0.70) and amniotomy (6.0% vs 55.6%; RR 0.11, 95% CI 0.05-0.22) were less frequent with the LCG (both $P<0.001$). Neonatal intensive care unit admission was similar (16.5% vs 19.5%; $P=0.633$).

Conclusions: The LCG did not reduce caesarean delivery but was associated with fewer intrapartum interventions and longer active labour, without evidence of worse short-term neonatal outcomes.

Keywords: WHO labour care guide, Caesarean delivery, Labour monitoring, Modified partograph, Randomized controlled trial

INTRODUCTION

Caesarean delivery is an essential, potentially lifesaving intervention when clinically indicated. However, caesarean rates have increased in many settings, including countries where population-level use already exceeds the level expected to provide additional mortality benefit.^{1,2} Unnecessary caesarean delivery exposes women to operative morbidity, longer recovery, and risks in subsequent pregnancies, while also increasing resource use.^{2,3} Monitoring the pattern of caesarean use and

reducing avoidable primary procedures are therefore important components of quality obstetric care.⁴

The partograph has been used for decades to document labour progress and maternal and fetal observations. Evidence that routine partograph use alone improves clinical outcomes is limited, and rigid application of historical cervical-dilatation thresholds may encourage premature diagnosis of labour dystocia.⁵ Contemporary data show considerable physiological variation in cervical dilatation, challenging the assumption that all women in active labour should progress at 1 cm per hour.⁶ In 2018,

World Health Organization (WHO) issued recommendations for a positive childbirth experience, including a later threshold for the active first stage and greater emphasis on respectful, supportive, woman-centered care.⁷

WHO subsequently introduced the Labour Care Guide in 2020.⁸ The LCG records labour progress alongside maternal and fetal wellbeing, supportive care, medications, and shared decision-making. It replaces alert and action lines with evidence-informed reference thresholds for each centimetre of cervical dilatation and prompts clinicians to assess the whole clinical picture before intervening.^{8,9} Its development incorporated feedback from maternity-care providers, and its intended purpose extends beyond documentation to improving the consistency and quality of intrapartum care.^{10,11}

Early evaluations have produced differing estimates of effect. An open-label, individually randomized trial from India reported lower caesarean and oxytocin use with the LCG.¹² In contrast, a large stepped-wedge cluster-randomized pilot trial in four Indian hospitals found no statistically significant reduction in caesarean delivery, although crude oxytocin augmentation was lower after LCG implementation.¹³ Additional evidence is needed because the effect of a monitoring tool may vary with the population, staff training, baseline intervention rates, and institutional decision-making practices.

The present trial therefore compared the WHO LCG with the modified partograph among low-risk women in spontaneous term labour at a tertiary-care center. The primary objective was to determine whether LCG use reduced caesarean delivery. Secondary objectives were to compare mode of delivery, intrapartum interventions, maternal complications, and short-term neonatal outcomes.

METHODS

Study design and setting

This was a single-center, parallel-group randomized controlled trial conducted in the labour ward of the Department of Obstetrics and Gynaecology, Karnataka Institute of Medical Sciences (KIMS), Hubballi, a tertiary-care teaching hospital. Recruitment and follow-up occurred from April 2023 through October 2024. The report has been structured according to CONSORT guidance, and participant flow is shown in Figure 1.

Ethics approval

Before recruitment, the Karnataka Institute of Medical Sciences, Hubballi Ethics Committee (registration no. ECR/486/Inst/KA/2013/RR-16) approved the study at meetings held on 29 and 30 March 2023 (approval no. KIMS: ETHICS COMM:864:2022-23; certificate dated 30 March 2023). The approval certificate identifies Dr

Chidananda S. Vaidya as the investigator. All participants provided written informed consent. Participant confidentiality was maintained, and the study was conducted in accordance with the Declaration of Helsinki.

The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.

Participants

Women admitted in spontaneous labour were screened. Eligible participants had a singleton pregnancy at 37+0 to 40+0 weeks, cephalic presentation, spontaneous onset of labour, and no recognized medical or obstetric complication at enrolment. Women were excluded for hypertensive disorders, diabetes mellitus, renal or pulmonary disease, multiple gestation, malpresentation, previous caesarean delivery, adverse obstetric history, preterm or post-term pregnancy, antepartum complications, intrapartum epidural analgesia, or refusal of consent.

Sample size

Sample-size calculation

The sample size was calculated for two independent proportions using caesarean-delivery rates of 1.5% with the LCG and 17.8% with the modified partograph reported by Pandey et al.¹² At a two-sided significance level of 5% and 99% power, 121 participants were required per group. Allowing 10% for attrition yielded a target of 133 participants per group (266 overall).

Randomization, allocation concealment, and blinding

Sequence generation

The random-allocation sequence was generated using a computer-generated random-number method. Participants were assigned in a 1:1 ratio to either the WHO Labour Care Guide group or the modified-partograph group. The sequence was prepared by an independent statistician who was not involved in participant recruitment, treatment allocation or clinical management.

Allocation concealment and implementation

The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes prepared by an investigator who was not involved in participant recruitment or clinical management. After confirming eligibility and obtaining written informed consent, the recruiting investigator enrolled the participant. The next envelope in sequence was then opened to reveal the assigned group. The allocation sequence remained inaccessible to the recruiting and treating teams until assignment.

Blinding

This was an open-label trial. Blinding of participants, treating clinicians, outcome assessors and the statistician was not undertaken because the allocated labour-monitoring charts were visibly different and formed part of routine clinical documentation. To reduce assessment bias, outcomes were defined in advance and extracted using a standardized data-collection form.

Interventions and data collection

Participants allocated to the intervention group were monitored using the WHO LCG; those in the control group were monitored using the modified partograph. At admission, investigators recorded demographic and obstetric characteristics and completed a clinical examination. During labour, maternal pulse and blood pressure, uterine contractions, cervical dilatation, descent of the presenting part, and fetal heart rate were documented according to the allocated tool. Oxytocin augmentation, amniotomy, operative vaginal delivery, and caesarean delivery were undertaken when clinically indicated by the treating obstetric team. Mode of delivery, indications for caesarean delivery, postpartum hemorrhage (PPH), maternal fever, obstetric anal sphincter injury, episiotomy wound gaping, Apgar scores, NICU admission, and the reason for NICU admission were recorded.

Intervention implementation

Before participant recruitment, obstetricians, resident doctors and nursing personnel working in the labour ward received standardized training on the completion and interpretation of the WHO Labour Care Guide and modified partograph. Participants allocated to the intervention group were monitored using the WHO Labour Care Guide, whereas those in the control group were monitored using the modified partograph. Maternal condition, fetal wellbeing, labour progress, medications and supportive care were recorded at the recommended intervals. Oxytocin augmentation, amniotomy and caesarean delivery were undertaken only when clinically indicated according to institutional protocols. Postpartum hemorrhage, maternal fever, fetal distress and non-progression of labour were defined according to the study protocol. Completed monitoring charts were reviewed periodically by the investigators to assess completeness and adherence to the allocated monitoring tool.

Outcomes

The primary outcome was caesarean delivery. Prespecified secondary outcomes were duration of active labour; overall mode of delivery (spontaneous vaginal, instrumental vaginal, or caesarean); oxytocin augmentation; amniotomy; indication for caesarean; PPH; maternal fever; obstetric anal sphincter injury; episiotomy wound gaping; Apgar score; and NICU admission.

Statistical analysis

Analyses included all randomized participants in their allocated groups. Categorical variables were summarized as number (percentage) and compared using the chi-square test or Fisher exact test, as appropriate. Continuous variables were summarized as mean (standard deviation) and compared using the independent-samples t test when distributional assumptions were satisfied. For binary outcomes, risk ratios (RRs) with 95% confidence intervals (CIs) were calculated. All tests were two-sided, and $P < 0.05$ was considered statistically significant. Analyses were performed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA). No adjustment was made for multiple secondary comparisons; these results are exploratory.

Data quality assurance

Before analysis, the dataset was checked for completeness, duplicate records, out-of-range values, and inconsistencies. Denominators, percentages, effect estimates, 95% CIs, and P values were independently cross-checked against the final statistical output; discrepancies were resolved against source records.

RESULTS

Participant flow and baseline characteristics

A total of 266 women were randomized, with 133 allocated to each group. All participants received the allocated monitoring method, completed follow-up, and were included in the analysis (Figure 1). Age-group and parity distributions were similar between groups (Table 1).

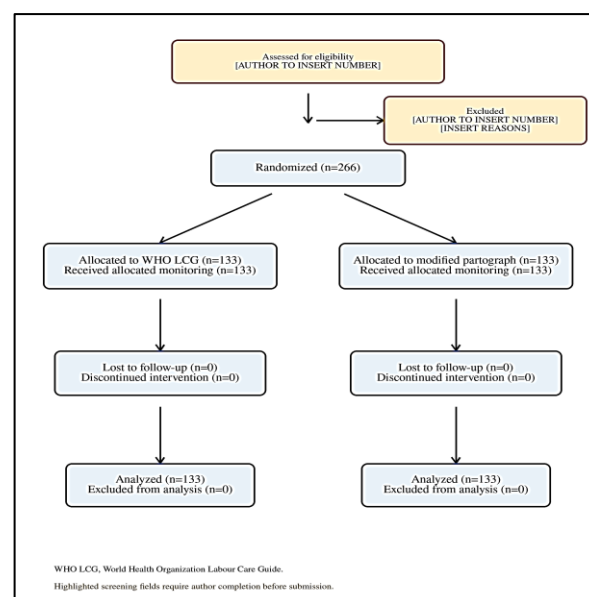


Figure 1: CONSORT flow diagram of trial participants. WHO LCG, World Health Organization Labour Care Guide.

Highlighted screening fields require author completion before submission.

Table 1: Baseline age and parity distributions.

Characteristics	WHO LCG (n=133)	Modified partograph (n=133)	P value
Age group, years	-	-	0.866
20-25	46 (34.6)	42 (31.6)	-
26-30	47 (35.3)	50 (37.6)	-
31-35	40 (30.1)	41 (30.8)	-
Parity	-	-	0.462
Primigravida	70 (52.6)	64 (48.1)	-
Multigravida	63 (47.4)	69 (51.9)	-

Data are n (%). P values are from chi-square tests.

Primary outcome and mode of delivery

Caesarean delivery occurred in 41/133 (30.8%) participants monitored with the LCG and 39/133 (29.3%) monitored with the modified partograph (RR 1.05, 95% CI

0.73-1.52; absolute risk difference 1.5 percentage points, 95% CI -9.5 to 12.5; P=0.894). The distribution of spontaneous vaginal, instrumental vaginal, and caesarean delivery did not differ between groups (overall P=0.807) (Table 2).

Table 2: Baseline age and parity distributions.

Outcome	WHO LCG (n=133)	Modified partograph (n=133)	Effect estimate (95% CI)	P value
Mode of delivery	-	-	-	0.807
Spontaneous vaginal	84 (63.2)	88 (66.2)	-	-
Instrumental vaginal	8 (6.0)	6 (4.5)	-	-
Cesarean	41 (30.8)	39 (29.3)	RR 1.05 (0.73-1.52)	0.894
Oxytocin augmentation	24 (18.0)	52 (39.1)	RR 0.46 (0.30-0.70)	<0.001
Amniotomy	8 (6.0)	74 (55.6)	RR 0.11 (0.05-0.22)	<0.001
Active labour duration, mean (SD), hours	9.2 (2.1)	7.8 (1.9)	MD 1.4 (0.92-1.88)	<0.001

Data are N (%) unless stated otherwise. Active-labour duration is mean (SD). CI, confidence interval; MD, mean difference; RR, risk ratio. The overall mode-of-delivery P value is from the chi-square test; binary-outcome P values are from Fisher exact tests; active-labour duration was compared using the independent-samples t test.

Table 3: Recorded indications among participants who underwent caesarean delivery.

Indication	WHO LCG (n=41)	Modified partograph (n=39)	Total (n=80)
Mode of delivery	-	-	-
Spontaneous vaginal	84 (63.2)	88 (66.2)	-
Instrumental vaginal	8 (6.0)	6 (4.5)	-
Cesarean	41 (30.8)	39 (29.3)	RR 1.05 (0.73-1.52)
Oxytocin augmentation	24 (18.0)	52 (39.1)	RR 0.46 (0.30-0.70)
Amniotomy	8 (6.0)	74 (55.6)	RR 0.11 (0.05-0.22)

Intrapartum interventions

The mean (SD) duration of active labour was 9.2 (2.1) hours with the LCG and 7.8 (1.9) hours with the modified partograph (mean difference 1.4 hours, 95% CI 0.92-1.88; P<0.001). Oxytocin augmentation was less frequent with the LCG (24/133, 18.0%) than with the modified partograph (52/133, 39.1%; RR 0.46, 95% CI 0.30-0.70; P<0.001). Amniotomy was also less frequent (8/133, 6.0% vs 74/133, 55.6%; RR 0.11, 95% CI 0.05-0.22; P<0.001) (Table 2).

Indications for caesarean delivery

Among women who had a caesarean delivery, fetal distress was the most frequent recorded indication in the LCG group, whereas non-progression of labour was most frequent in the modified-partograph group. The overall distribution of recorded indications did not reach statistical significance (p=0.066) (Table 3).

Maternal and neonatal outcomes

PPH was recorded in 6/133 (4.5%) participants in the LCG group and 16/133 (12.0%) in the modified-partograph

group (RR 0.38, 95% CI 0.15-0.93; $P=0.043$). Because the number of events was small and no multiplicity adjustment was applied, this secondary finding should be interpreted cautiously. Maternal fever did not differ significantly (2.3% vs 6.8%; $P=0.137$). No obstetric anal sphincter injury or episiotomy wound gaping was reported. NICU

admission was similar between groups (16.5% vs 19.5%; RR 0.85, 95% CI 0.51-1.42; $P=0.633$). Among admitted neonates, respiratory distress was recorded in 14/22 (63.6%) and 16/26 (61.5%), respectively. No neonate had a 5-minute Apgar score below 7 (Table 4).

Table 4: Recorded indications among participants who underwent.

Outcomes	WHO LCG (n=133)	Modified partograph (n=133)	RR (95% CI)	P value
Postpartum hemorrhage	6 (4.5)	16 (12.0)	0.38 (0.15-0.93)	0.043
Maternal fever	3 (2.3)	9 (6.8)	0.33 (0.09-1.20)	0.137
NICU admission	22 (16.5)	26 (19.5)	0.85 (0.51-1.42)	0.633
Apgar score <7 at 1 minute	0	1 (0.8)	Not estimable	1.000
Apgar score <7 at 5 minutes	0	0	Not estimable	-
OASIS	0	0	Not estimable	-
Episiotomy wound gaping	0	0	Not estimable	-

Data are n (%). CI, confidence interval; NICU, neonatal intensive care unit; OASIS, obstetric anal sphincter injury; RR, risk ratio. P values are Fisher exact tests.

DISCUSSION

In this single-center randomized trial of 266 low-risk women in spontaneous term labour, the WHO LCG did not reduce the primary outcome of caesarean delivery compared with the modified partograph. The point estimate was close to the null, and the confidence interval included both a potentially meaningful reduction and increase. Oxytocin augmentation and amniotomy were markedly less frequent with the LCG, although active labour was longer by a mean of 1.4 hours. Short-term neonatal outcomes, including NICU admission and 5-minute Apgar score, were similar between groups.

The absence of a detectable reduction in caesarean delivery differs from the individually randomized trial by Pandey et al which reported caesarean rates of 1.5% with the LCG and 17.8% with the modified partograph.¹² Differences in inclusion criteria, timing of randomization, management of caesareans performed during the latent phase, clinician behavior, and baseline institutional practice may contribute to the discrepant estimates. Of particular relevance, Pandey et al. excluded women who underwent caesarean delivery in the latent phase from the labour-outcome analysis, whereas the present report includes all randomized participants in the denominators.¹²

The present primary-outcome result is more consistent with the multicenter stepped-wedge pilot trial by Vogel et al., which found a nonsignificant crude absolute reduction in caesarean delivery among women in Robson Group 1 after introduction of an LCG implementation strategy.¹³ That study also observed substantially lower crude oxytocin use after implementation, although its adjusted estimate was imprecise because of between-hospital and between-period variability.¹³ Taken together, these findings suggest that the LCG may influence labour-management processes more consistently than it changes

caesarean delivery, which is determined by multiple clinical and organizational factors.

Lower use of augmentation and amniotomy is biologically and operationally plausible. The LCG adopts contemporary evidence on the variability of labour progression, begins active-phase monitoring at 5 cm, and removes the historical 1-cm-per-hour expectation.⁷⁻⁹ It also prompts assessment of supportive care, maternal wellbeing, fetal wellbeing, and labour progress before action.^{8,10,11} These features may reduce intervention triggered solely by a perceived delay in cervical dilatation. Continuous labour support itself can reduce caesarean delivery and improve childbirth experience, although the degree to which supportive-care components were delivered in this trial was not reported.¹⁴

The magnitude of the difference in amniotomy was especially large: approximately 6% of the LCG group underwent the procedure compared with 56% of the control group. The longer active-labour duration with the LCG is consistent with less intervention and greater tolerance of physiologic variation, but it may also affect workload and patient experience. Because amniotomy and oxytocin may be used sequentially or together, their effects are not independent. Reporting the timing, indication, cervical dilatation at intervention, combined augmentation, and time from intervention to delivery would clarify whether the LCG appropriately avoided intervention or shifted practice patterns.

The lower observed PPH frequency in the LCG group merits further study but should not be interpreted as definitive evidence of protection. Only 22 PPH events occurred, PPH definitions and severity were not provided, and multiple secondary outcomes were compared without adjustment. Maternal fever was numerically lower but not statistically significant. Similarly, the trial was not powered for uncommon maternal or neonatal harms.

Larger trials should use standardized outcome definitions and report absolute effects with confidence intervals.

The primary-outcome estimate also illustrates why a nonsignificant result should not be interpreted as proof of equivalence. The 95% CI around the RR ranged from 0.73 to 1.52, and the confidence interval for the absolute difference ranged from approximately 9.5 percentage points fewer to 12.5 points more cesarean deliveries with the LCG. Thus, the study excludes neither a clinically relevant benefit nor clinically relevant harm. A formal noninferiority or equivalence conclusion would require a prespecified margin and a design powered for that purpose. The appropriate interpretation is that this trial did not demonstrate superiority of the LCG for reducing cesarean delivery.

Indications for caesarean delivery differed descriptively: fetal distress was recorded more often in the LCG group and non-progression more often in the modified-partograph group. The overall difference did not reach statistical significance. These diagnoses may be sensitive to local definitions and documentation practices; future work should prespecify diagnostic criteria and, where feasible, use blinded adjudication. Application of the Robson classification would also improve comparison with institutional and international caesarean-delivery patterns.⁴

From a clinical perspective, fewer procedures do not automatically mean better care; the central question is whether avoidable interventions can be reduced without delaying indicated treatment. In this study, the large reductions in augmentation and amniotomy were not accompanied by a detectable increase in NICU admission or low 5-minute Apgar score. This pattern is reassuring but incomplete because the study did not report cord blood gases, hypoxic-ischemic encephalopathy, severe maternal morbidity, length of stay, or longer-term outcomes. Implementation should therefore retain clear escalation criteria and ongoing audit of balancing measures, including emergency caesarean timing, fetal compromise, PPH, infection, and neonatal morbidity.

Woman-centered care is another important domain that was not measured. The LCG includes prompts for companionship, oral intake, mobility, pain relief, preferred birth position, and shared decision-making.⁸ A reduction in procedures would be more meaningful if accompanied by improved experience, respectful communication, and freedom of movement without compromising safety. Conversely, completion of the LCG form does not establish that supportive care was delivered. Future evaluations should combine clinical outcomes with validated measures of childbirth experience and respectful maternity care, along with provider acceptability and completion quality. This would test the full intervention rather than treating the LCG only as a replacement chart.

Tertiary-care context may have affected both the intervention and control pathways. Decisions about augmentation and operative delivery reflect staffing, supervision, workload, local protocols, fetal-monitoring resources, and clinician tolerance of slower labour. The LCG is intended to support clinical judgment rather than function as a stand-alone rule. Training should therefore cover the rationale for revised labour-progress thresholds, consistent recording, supportive care, recognition of deviations from normal, and timely action when maternal or fetal findings warrant intervention. Audit and feedback can help distinguish genuine changes in care from incomplete chart documentation.^{8,13}

Generalizability should also be considered in relation to the study population. Restriction to uncomplicated singleton, cephalic, term pregnancies reduce clinical heterogeneity and focuses the comparison on women for whom spontaneous vaginal birth is generally expected. However, it does not establish effectiveness in women with induction of labour, previous caesarean delivery, multiple pregnancy, malpresentation, preterm birth, medical comorbidity, or evolving intrapartum complications. Even within a low-risk cohort, parity can modify labour duration and intervention risk. Stratified estimates for nulliparous and multiparous women would therefore be informative, particularly because the Robson classification separates these populations when assessing caesarean use.⁴

The study has practical relevance because it evaluates an intervention designed for routine labour care in a busy tertiary setting. All randomized participants were included in the reported outcome denominators, and the groups were similar in the reported age and parity distributions. Computer-generated sequence allocation, sealed-envelope concealment, standardized staff training, and periodic chart review strengthened implementation. Nevertheless, the open-label design and the use of the same clinical environment for both groups may have influenced clinician behavior or introduced contamination.

Future trials should be multicenter and prospectively registered, publish or make the protocol and statistical analysis plan accessible, and use concealed allocation with blinded outcome adjudication where feasible. They should prespecify a core set of maternal, perinatal, process-of-care, and childbirth-experience outcomes; record adherence to each component of the LCG; and report results by relevant Robson groups. Process evaluation is particularly important because an LCG form can be introduced without changing supportive care or decision-making. Cluster designs may reduce contamination when the same clinicians care for both groups, whereas individually randomized designs can provide greater statistical efficiency if protocol separation is credible. Economic and implementation outcomes, including training burden, completion time, documentation quality, acceptability, and sustainability, would help determine

whether observed clinical effects translate into routine practice.

Strengths and limitations

This trial was conducted at one tertiary-care center and included only low-risk term pregnancies, limiting generalizability to high-risk populations and other models of care. The sample size was based on a large effect from an earlier single-center trial and was not powered for uncommon maternal or neonatal outcomes. Participants, treating clinicians, outcome assessors, and the statistician were not blinded. Quantitative adherence data were not reported, and several outcome definitions were not reproduced in the manuscript. The numbers assessed for eligibility and excluded, with reasons, remain necessary to complete the CONSORT flow diagram. Finally, multiple secondary outcomes were analyzed without adjustment, so statistically significant secondary findings require cautious interpretation.

CONCLUSIONS

In this trial, the WHO Labour Care Guide did not reduce cesarean delivery compared with the modified partograph. It was associated with substantially less oxytocin augmentation and amniotomy, but active labour was longer. Short-term neonatal outcomes were similar. The observed reduction in PPH is hypothesis-generating because event numbers were small. Adequately powered multicenter trials with complete CONSORT reporting, standardized outcome definitions, and implementation-fidelity assessment are needed.

In a tertiary-care labour ward, the WHO LCG reduced the use of oxytocin augmentation and amniotomy without a detected increase in short-term neonatal morbidity. These findings support careful implementation of the LCG as a woman-centered monitoring tool, while emphasizing that its effect on caesarean delivery remains uncertain.

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