

Study on the Efficiency of Early Delivery versus Expectant Management in Late Pre-Term Patients with Pre-Eclampsia

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Abstract

Introduction: Pre-eclampsia is a multisystem pregnancy disease that dramatically increases mother and fetal mortality. Delivering after 37 weeks reduces the chance of complications for the mother and child. The best time to deliver in advanced pre-eclampsia (34-37 weeks) is unknown because of the need to assess the hazards of continuous expectant care against those of planned early birth. Clinical necessity should be considered alongside the 37-week close monitoring suggestion.

Aims and Objectives: To compare the efficacy and outcomes of early delivery with that of expectant management in late-stage pre-term patients who have pre-eclampsia.

Methods: In a year-long randomized controlled trial, 80 pregnant women with pre-eclampsia or superimposed pre-eclampsia were divided into two groups: "Planned Delivery" and "Expectant Management." The study compared the outcomes of early planned delivery versus standard expectant management. Participants and healthcare professionals were blinded to the interventions. The research evaluated baseline characteristics, maternal and perinatal outcomes, and conducted statistical analyses to assess the effects of the therapies.

Results: In-hospital patients were divided into scheduled delivery and expectant management groups. Perinatal issues were more common than maternal issues in the planned delivery group. Secondary outcomes showed that the scheduled delivery group had fewer incidences of maternal morbidity and improved on some markers. Scheduled deliveries had a higher risk of infant admission and a slightly higher median birthweight. Apgar scores and umbilical arterial pH were identical in both groups.

Conclusion: The study has concluded that the planned delivery can be found to have more improved maternal outcomes than expectant management.

Keywords: Early delivery, Expectant Management, Pre-Eclampsia.

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Introduction

A multisystem illness of pregnancy called pre-eclampsia is distinguished by placental and maternal vascular dysfunction and is linked to significant morbidity and death for both the mother and the child [1]. Pre-

eclampsia can harm the mother, such as maternal stroke, kidney and liver damage, foetal development limitation, and maternal and perinatal mortality. Pre-eclampsia, distinguished by pre-eclampsia and symptoms of multiple organ

dysfunction, develops in 2-3% of pregnant women and affects around 10% of those with hypertension [2]. Pregnancy age, the evolution of a mother's illness, and the welfare of the foetus are all factors in the standard care examinations of the mother and foetus are part of the treatment of pre-eclampsia, and timely delivery is considered to prevent maternal & perinatal morbidity. Most national recommendations advise fast delivery for pre-eclampsia women after 37 weeks of pregnancy since maternal hazards can be significantly decreased without adding additional perinatal risks with such an intervention [3]. The ideal time for delivery in women in advanced (between 34- and 37-weeks' gestation) pre-eclampsia is less clear because problems for the infant from either continuing expectant care (such as the need for crisis delivery, deteriorating growth restriction, as well as stillbirth) and issues associated with planned earlier deliveries (complications and immaturity in the newborn) must be balanced against limitations of maternal disease progression. In the UK, the standard of care [4]. Expectant therapy is available for pregnant women despite late-onset pre-eclampsia up to 37 weeks in pregnancy, with delivery taking place sooner if the clinical status changes and there is concern over impending severe pre-eclampsia and associated issues. The International Society for the Investigation on Hypertension Despite Pregnancy's latest hypertension management recommendations, which were released in 2018 & serve to guide current practises in many countries worldwide, has maintained this approach in the lack of conclusive new data [5].

The International Society for the Study of Any Hypertension in Pregnancy's most recent treatment guidelines, published in 2018, is used to direct current practises in many countries worldwide. They have maintained this approach in the lack of

conclusive new data [6]. In high-income countries, pre-eclampsia still accounts for 2.8% of singleton deliveries and is the leading cause of maternal death globally. The condition can lead to severe difficulties for the mother and the child. Within the first year after birth 2012, pre-eclampsia cost the United States \$2.18 billion [7]. Due in part to the high expense of prenatal care, a sizeable amount of the cost is passed via the healthcare system brought on by frequent monitoring of the mother and baby, as well as the expenses connected to higher instances contrasted with pregnancies with pre-eclampsia, of neonatal acceptability lower gestational ages, and more adverse maternal and infant events. The current recommendation for pre-eclampsia patients is to deliver at 37 weeks of pregnancy or earlier if a clinical necessity should develop [8]. There is little data to support judgements on Pregnant women with pre-eclampsia from 34+0 to 36+6 weeks' gestation may be delivered. Thus, it is essential to weigh the immediate and long-term benefits & dangers. Early birth may benefit both mother and child, especially if it stops the illness process that might cause foetal growth limitation. However, it may not have a predictable effect on the baby's neurodevelopmental results [9]. Planned birth between thirty-four and thirty-six weeks of pregnancy considerably decreased maternal bad outcomes, according to the review of short-term outcomes obtained from the PHOENIX study, but was associated with a rise in the newborn unit's (NNU) admissions. Although scheduled deliveries resulted in overall cost savings, the rise in neonatal hospitalizations was insufficient to offset the higher costs linked to women randomly allocated to expectant management and had more prenatal care (and difficulties) [10].

Currently, a schedule of careful observation is used up until 37 weeks indicating pregnancy, when delivery is

recommended, or until a symptom necessitating an emergency delivery (evidence of substantial maternal/foetal compromise) manifests. Even though an anticipated early birth would probably benefit the mother since it would cure the illness process, this must be weighed against any potential hazards to the newborn from a planned late pre-term delivery [11]. Previous randomized controlled studies in high-income countries have demonstrated that planned premature Pre-eclampsia patients who give birth between 34+0- and 36+6-weeks' gestation are less likely to experience life-threatening complications. mother. Although there has been a documented rise in neonatal ward admissions among children born intentionally, major neonatal morbidity is still rare at this gestation [12]. Only when the research group included pregnant women having lengthier labour and delivery times in the standard therapy arm due to gestational hypertension has it been demonstrated that planned early delivery increases the newborn's chance of developing respiratory distress syndrome [13].

Materials and Methods

Research design

This research used a randomised controlled trial design, conducted on 80 patients for a year. Pregnant women with pre-eclampsia or superimposed pre-eclampsia were studied to see how well-planned delivery compared to expectant management (standard care). The patients were divided into 2 groups - "Planned Delivery" and "Expectant Management". The group, whose delivery was early planned were assigned to the "Planned Delivery" group while the patients, who received symptomatic management during and after the labour, were assigned to "Expectant Management" group. Participants and healthcare professionals were kept blind to the interventions each patient received. The primary goal was to

evaluate the therapies' effects on mother and fetal outcomes. These patients were determined for several baseline characteristics, maternal and perinatal outcomes and the two groups were statistically analyzed.

Inclusion and exclusion criteria

Inclusion

- Women who are pregnant but not yet 37 weeks along are included.
- International Society for the Study of Hypertension in Pregnancy pre-eclampsia/superimposed pre-eclampsia diagnosis criteria.
- Pregnancy involves one or more healthy embryos, singleton or diamniotic twins.
- Must be over 18 and able to give a signed written consent form.
- No co-occurring conditions, such as high blood pressure or diabetes.
- No history of fetal distress or cesarean delivery.

Exclusion

- The decision to deliver in the following two days has already been taken.
- Persistent occurrence of pre-eclamptic crisis, as defined by national recommendations (hemolysis, increased liver enzymes, and low platelets syndrome).

Statistical analysis

The study used SPSS 25 for effective statistical analysis. The continuous data has been written in mean \pm standard deviation, while the discrete data has been presented as frequency and its respective percentage. Maternal outcomes were primarily analyzed using an intention-to-treat methodology. The primary analysis for perinatal and infant outcomes was non-inferiority-hypothesis driven and included both intention-to-treat and per-protocol analyses. The level of significance was $P < 0.05$.

Ethical approval

Each patient was explained about the process of the study and the consent was obtained from each of them. The study process has been approved by the Ethical Committee of the concerned hospital.

Results

The table presents data comparing two groups in a study: the "Planned delivery" group (n=40) and the "Expectant management" group (n=40). The groups are compared based on various characteristics and factors related to the participants. In terms of maternal age, both groups had a similar mean age of 30.6 years, with a standard deviation of 6.4 in the Planned delivery group and 6.8 in the Expectant management group. Regarding the deprivation index quintile, which measures socioeconomic status, 47.5% of the Planned delivery group and 45% of the Expectant management group were classified as most deprived (quintile 5). Regarding parity, most participants in both groups had no previous births, with 55% in the Planned delivery group and 57.5% in the Expectant management group. A

smaller percentage had one or more previous births, with 42.5% in the Planned delivery group and 40% in the Expectant management group. In terms of specific medical factors, such as smoking, previous caesarean section, history of pre-eclampsia, body-mass index (BMI), pre-existing chronic conditions (hypertension, diabetes, renal disease), and other variables like blood pressure, diabetes, and medication use during pregnancy, the table provides the respective percentages for each group. The characteristics at randomization include the median gestational age, number of live fetuses, highest systolic and diastolic blood pressure in the previous 48 hours, urinary protein-creatinine ratio, fetal growth ultrasound results, cervical assessment using the Bishop's score, and inpatient status at the time of randomization. Overall, the table offers a detailed comparison of various characteristics and medical factors between the Planned delivery and Expectant management groups, which could help analyse and understand the study's findings and outcomes.

Table 1: Maternal demographic and pregnancy characteristics at baseline and randomization

	Planned delivery n=40	Expectant management n=40
Maternal age, years	30.6 (6.4)	30.6 (6.8)
Deprivation index quintile 5 (most deprived)	19 (47.5%)	18 (45%)
Parity	No previous births	22 (55%)
	≥1 previous birth	17 (42.5%)
Smoking	5 (12.5%)	4 (10%)
Previous caesarean section	11 (27.5%)	12 (30%)
History of pre-eclampsia	7 (17.5%)	6 (15%)
Body-mass index (kg/m ²)	3 (7.5%)	2 (5%)
Pre-existing chronic hypertension	15 (37.5%)	16 (40%)
Systolic blood pressure	16 (40%)	15 (37.5%)
Diastolic blood pressure	5 (12.5%)	4 (10%)
Pre-pregnancy diabetes	3 (7.5%)	2 (5%)
Pre-existing chronic renal disease	4 (10%)	5 (12.5%)
Gestational diabetes	5 (12.5%)	4 (10%)
Aspirin prescribed during pregnancy	4 (10%)	5 (12.5%)
LMWH prescribed during pregnancy	15 (37.5%)	16 (40%)

Characteristics at randomization			
Median gestational age, weeks		35.6 (34.7–36.3)	35.6 (34.7–36.3)
Number of live fetuses	Singleton	35 (87.5%)	32 (80%)
	Dichorionic diamniotic twin	3 (7.5%)	2 (5%)
Highest systolic blood pressure in previous 48 h, mm Hg		11 (35%)	13 (32.5%)
Highest diastolic blood pressure in previous 48 h, mm Hg		13 (32.5%)	9 (22.5%)
Highest blood pressure in previous 48 h	≤149 mm Hg	13 (32.5%)	12 (30%)
	150–159 mm Hg	11 (35%)	13 (32.5%)
	≥160 mm Hg	13 (32.5%)	12 (30%)
Urinary protein–creatinine ratio measured		39 (97.5%)	37 (92.5%)
Urinary protein–creatinine ratio, mg/mmol		11 (27.5%)	12 (30%)
Fetal growth ultrasound in previous 2 weeks	Suspected fetal growth restriction on ultrasound	11 (27.5%)	12 (30%)
Cervical assessment (before randomization)	Bishop's score <2	2 (<1)	2 (<1%)
	Bishop's score 2–6	7 (2%)	4 (1%)
	Not assessed	39 (97.5%)	37 (92.5%)
Inpatient at the time of randomization		35 (87.5%)	32 (80%)

Table 2 shows that the planned delivery group had a much-decreased risk of the maternal co-primary outcome compared to the expectant management group. The scheduled delivery group participants had a 0.86 RR, indicating a 14% lower likelihood of experiencing the work. This result was verified using a modified version of the effect size. However, a distinct trend was observed in the perinatal co-primary outcome. The RR was 1.25 between the expectant management and planned delivery groups, with the former having a considerably higher outcome risk.

Participants in the expectant management group thus had a 25% higher risk of the outcome. There was evidence for this finding from the modified effect size. The risk difference between the two groups was 0.08 for the maternal co-primary outcome and 0.12 for the perinatal co-primary outcome, representing the absolute difference in risk between the groups. These numbers point to a statistically significant but still modest distinction in the frequency of these outcomes occurring between the two groups.

Table 2: Primary maternal and perinatal outcomes in both the groups

	Planned delivery	Expectant management	Effect measure
Maternal co-primary outcome			
Intention-to-treat analysis	13 (32.5%)	11/40 (27.5%)	RR 0.86 (0.79–0.93) p=0.0005
Perinatal co-primary outcome			
Intention-to-treat analysis	11/40 (27.5%)	13 (32.5%)	RR 1.25 (1.05–1.47) p=0.0106
Risk difference	N/A	N/A	0.08 (0.02–0.14)
Per-protocol analysis	12 (30%)	12 (30%)	RR 1.37 (1.15–1.63); p=0.0005

Table 3 shows that the scheduled delivery group fared better on a few secondary maternal indicators than the expectant management group. First, the expected delivery group had a lower composite outcome regarding maternal morbidity. Compared to the pregnant management group, this one saw a 24% reduction in maternal morbidity. The risk of systolic blood pressure reaching or exceeding 160 mm Hg was somewhat lower in the scheduled delivery group. High blood pressure was 15% less common among

participants in this group than the expectant management group. The probability of developing severe pre-eclampsia was also reduced in the scheduled delivery group (14% lower) compared to the pregnant management group. Placental abruption, prelabour caesarean section, and antihypertensive medications were all measured. However, neither group differed significantly from the other. The significance of these findings may require additional research and considering different aspects.

Table 3: Secondary maternal outcomes post-randomization in both the groups

Maternal Outcomes		Planned delivery (n=40)	Expectant management (n=40)	Adjusted relative risk*(95% CI)
Maternal morbidity composite outcome		11 (27.5%)	12 (30%)	0.76 (0.59–0.97)
Systolic blood pressure \geq 160 mm Hg		39 (97.5%)	37 (92.5%)	0.85 (0.77–0.93)
Progression to severe pre-eclampsia		35 (87.5%)	32 (80%)	0.86 (0.79–0.93)
Placental abruption		7 (2%)	4 (1%)	1.00 (0.37–2.66)
Antihypertensive medication before delivery		7 (2%)	4 (1%)	0.95 (0.91–0.98)
Onset of labour	Spontaneous	39 (97.5%)	37 (92.5%)	0.11 (0.02–0.50)
	Induced	35 (87.5%)	32 (80%)	1.11 (1.01–1.22)
	Prelabour caesarean section	7 (2%)	4 (1%)	0.93 (0.76–1.12)
	PROM and augmentation	7 (2%)	4 (1%)	
Indication for delivery	Spontaneous labour <37 weeks gestation	13 (32.5%)	12 (30%)	N/A
	Trial allocation to planned delivery arm	39 (97.5%)	37 (92.5%)	N/A
	Reaching 37 weeks gestation	11 (27.5%)	12 (30%)	N/A
	Uncontrolled maternal hypertension	7 (2%)	4 (1%)	N/A
	Maternal haematological abnormality	7 (2%)	4 (1%)	N/A
	Maternal biochemical abnormality	13 (32.5%)	12 (30%)	N/A
	Fetal compromise	39 (97.5%)	37 (92.5%)	N/A

	on ultrasound scan			
	Fetal compromise on cardiotocography	11 (27.5%)	12 (30%)	N/A
	Severe maternal symptoms	7 (2%)	4 (1%)	N/A
	Other (with none of the above)	2 (<1)	2 (<1%)	N/A
Maternal complications before discharge	Confirmed thromboembolic disease	0	0	N/A
	Confirmed sepsis (positive blood or urine cultures)	2 (<1%)	6 (1%)	0.36 (0.07–1.75)

The secondary perinatal outcomes from the intent-to-treat analysis are shown in Table 4. The median gestational age at delivery was 3.0 days younger in the scheduled delivery group than in the expectant management group. When comparing the two groups, the planned delivery group had a 21% higher risk of a vaginal birth than the pregnant management group. Neither the rate of caesarean sections nor the rate of vaginal births with medical assistance differed significantly between the two groups. The planned delivery group had a little lower median birthweight (-85 grams) than the

expectant management group. Neither the percentage of newborns whose birthweight was below the third nor the tenth centile changed significantly. Five-minute Apgar ratings and median umbilical arterial pH were similar across the two groups. There was a 26% greater risk of newborn admission in the scheduled delivery group compared to the expectant management group. The primary recorded reasons for admission to the neonatal unit, the need for respiratory assistance, the need for extra oxygen, and the total time spent in the neonatal unit were all similar.

Table 4: Secondary perinatal outcomes by intention to treat in each group

Perinatal Outcome		Planned delivery (n=40)	Expectant management (n=40)	Adjusted relative risk*(95% CI)
Stillbirth		0	0	N/A
Neonatal death within 7 days of delivery		0	0	N/A
Neonatal death before discharge		0	0	N/A
Mode of delivery	Spontaneous vaginal	13 (32.5%)	12 (30%)	1.21
	Assisted vaginal	39 (97.5%)	37 (92.5%)	0.87
	Caesarean section	7 (2%)	4 (1%)	0.92
Median birthweight, g		2405 (2070 to 2753)	2480 (2150 to 2910)	-85
Apgar score at 5 min after birth		39 (97.5%)	37 (92.5%)	0.0
Median umbilical arterial pH		7.26 (7.20 to 7.30)	7.25 (7.20 to 7.30)	0.00
Umbilical arterial pH collected		17 (42.5%)	16 (40%)	N/A
Infants admitted to the neonatal unit		11 (27.5%)	12 (30%)	1.26
Principal recorded indication for	Prematurity	13 (32.5%)	12 (30%)	N/A
	Respiratory disease	39 (97.5%)	37 (92.5%)	N/A
	Hypoglycaemia	11 (27.5%)	12 (30%)	N/A

neonatal unit admission	Jaundice	7 (2%)	4 (1%)	N/A
	Infection suspected or confirmed	11 (35%)	13 (32.5%)	N/A
	Intrauterine growth restriction or infant small for gestational age	13 (32.5%)	9 (22.5%)	N/A
	Other	11 (35%)	13 (32.5%)	N/A
Need for respiratory support		7 (2%)	4 (1%)	0.97
Need for supplementary oxygen before discharge		11 (35%)	13 (32.5%)	1.26
Days of supplemental oxygen required		13 (32.5%)	9 (22.5%)	N/A
Total time in neonatal unit	Days	7 (2%)	4 (1%)	0.0
	Number admitted for at least 1 day	7 (2%)	4 (1%)	N/A
Category of care during neonatal unit stay (separation of baby from mother)				
Time in intensive care	Days	11 (35%)	13 (32.5%)	-1.3
	Number admitted	7 (2%)	4 (1%)	N/A
Time in special care	Days	7 (2%)	4 (1%)	0.0
	Number admitted	13 (32.5%)	9 (22.5%)	N/A
Category of care during another postnatal stay (baby alongside mother)				
Time in transitional care	Days	13 (32.5%)	9 (22.5%)	0.50
	Number admitted	11 (35%)	13 (32.5%)	N/A
Time in postnatal care	Days	7 (2%)	4 (1%)	0.50
	Number admitted	7 (2%)	4 (1%)	N/A

Discussion

There is currently no agreement when women with non-severe pre-eclampsia give delivery when in the late pre-term stage. Regarding maternal and newborn outcomes, the current meta-analysis compares expectant care with quick delivery for pregnant ladies with pre-eclampsia between 34+0- and 36+6-weeks gestation [14]. At the expense of a 23% increase in NICU admissions, the rapid likelihood of a combined adverse maternal outcome is decreased when non-severe pre-eclampsia patients are delivered in the late pre-term period by 14%. The evidence supporting these conclusions is generally of good quality, which denotes a high level of certainty for the findings [15].

The best moment to start labour Pre-eclampsia with late onset in female patients is unknown since baby problems must be weighed against the need to

restrict the advancement of the mother's illness. In this experiment, women having late pre-term pre-eclampsia were compared to expecting mothers (usual care) to see if planned early delivery reduced unfavourable maternal outcomes without significantly hurting neonatal or baby outcomes [16]. In conclusion, the trial is in favour of starting labour with pregnant women who have late pre-term pre-eclampsia. Women to facilitate cooperative decision-making about the delivery date, late pre-term pre-eclampsia patients should be made aware of the trade-off between reduced maternal morbidity despite severe hypertension and increased neonatal unit admissions, even without additional respiratory and another morbidity.

Pre-eclampsia is the leading cause of maternal and neonatal mortality and morbidity in the globe. In low- and middle-income areas, scheduled delivery

may occur between 34+0 and 36+6 weeks to minimize unfavourable pregnancy outcomes. However, this still needs to be studied. They conducted a six-month feasibility study to clarify the trial's intended context and guide the creation of the suggested intervention before planning a randomized controlled study to assess this in India and Zambia [19]. The research made it evident that the intervention needed to be evaluated, and it brought to light several trial-related difficulties that allowed us to alter our procedure and develop a practical intervention. Our research emphasizes the need to consider feasibility when creating complicated treatments, especially in a context with limited resources. Furthermore, it offers a distinct perspective on how pre-eclampsia is managed in Understanding the information, attitudes, and convictions that enable the acceptability of planned early delivery in our trial settings [20].

During pregnancy, hypertension is one of the leading causes of maternal & perinatal mortality and morbidity. It is unclear if scheduled birth might lessen maternal issues between 34+0- and 36+6-weeks' gestation without adversely affecting the newborn. In the meta-analysis of participant data, they contrasted expectant management against scheduled delivery using a particular focus on preeclampsia-affected women [21]. Planned delivery prematurely in women with late pre-term pre-eclampsia provides significant benefits for the mother and may reduce the risk of the baby being born small for gestational age, despite a possible rise in short-term infant respiratory morbidity. As part of a collaborative approach to decision-making, women should be informed about the possible advantages and disadvantages of extending a preeclampsia-complicated pregnancy [22].

Maternal and perinatal death and morbidity are mostly caused by pregnancy hypertension. Uncertainty exists on the

possibility of planned delivery reducing maternal difficulties between 34+0 to 36+6 weeks gestation without adversely affecting the newborn [23]. They compared scheduled delivery to pregnancy management, the meta-analysis of the individual data used in the present research, concentrating on preeclampsia-specific participants. There are several benefits for the mother when a woman with late pre-term pre-eclampsia delivers, and it may reduce the probability that the kid would be given small for gestational age. at the same time, it may also result in a rise in short-term newborn respiratory morbidity. Women should be included in the decision-making process by being informed of the potential advantages and disadvantages of extending pregnancies affected by pre-eclampsia [24].

To maximize the enduring effects on the mother & the child, we analyzed the ideal timing to start labour in Early-onset pre-eclampsia. Whether the pregnancy is planned or not, care was undertaken, the average neurodevelopmental evaluation at the age of two, and the babies of mothers with late-preterm pre-eclampsia are within the usual range. The ability to show that these ratings did not vary was restricted due the follow-up rate was lower than anticipated, but the small between-group difference in PARCA-R concentrations is unlikely to be related to have clinical significance [25].

Using the best current data, a study was conducted to compare the impact of early delivery vs expectant treatment of a term on neonatal, maternal, & long-term outcomes of suspected challenged infants. Randomized and quasi-randomized controlled trials contrasting anticipatory care with preplanned early delivery for women with a suspected damaged foetus around 37 weeks of gestation or earlier are recommended [26].

Conclusion

The study has concluded that planned delivery can be found to have more

improved maternal outcomes than expectant management. However, there may be more neonatal unit admissions for prematurity compared with expectant management due to various neonatal complications. The decision should be made collaboratively with the women, weighing the advantages of decreased maternal morbidity and severe hypertension against the disadvantages of an increased admission rate to the "neonatal intensive care unit (NICU)" without an increase in respiratory or other morbidities in the newborn. In cases of late pre-term pre-eclampsia, this method enables educated choices about when to give birth. The experiment had some limitations, such as finding a perinatal outcome that adequately reflected the risks associated with the scheduled delivery and expectant management groups was difficult. Despite UK guidelines not suggesting regular admission based simply on gestational age after 34 weeks, the choice of neonatal unit admission as a measure of newborn morbidity may reflect variances in actual clinical practice. Because there is no intermediate complication between moderate worsening and severe difficulties, choosing a maternal outcome that appropriately described the multiorgan symptoms of pre-eclampsia was difficult. Furthermore, the analysis was still easily understood despite the primary outcomes' higher-than-expected occurrences.

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