Original Research Article

DexmedetomidineVersus Clonidine as Adjuvant in Subarachnoid Block in Patients of Preeclampsia Undergoing LSCS.

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Abstract

Background: The aim of this study is to compare the duration and quality of analgesia with maternal and neonatal outcome following subarachnoid block with intrathecal hyperbaric bupivacaine with either dexmedetomidine or clonidine used as adjuvant in preeclampsia patients undergoing LSCS.**Material and Methods:** Patients with preeclampsia were drawn from those scheduled for operations requiring subarachnoid block for LSCS.100 ASA grade I & II patients are randomized into two groups.Group A:-Sub arachnoid block with [2ml 0.5% Bupivacaine heavy + 45 µg clonidine]Group B:-Subarachnoid block with[2ml 0.5% Bupivacaine heavy + 15µg dexmedetomidine]**Results:** Changes observed in systolic, diastolic and mean blood pressure were comparable in both the groups at different time points (P>0.05). Three patients in Group A and in Group B developed hypotension which responded to intravenous fluid therapy.SpO_2 remained stable and comparable in both the groups throughout the study period, (P>0.05).There was significant prolongation of analgesia in Group B where first rescue analgesic was required after 9 hours of subarachnoid blockade. Patients in Group A required rescue analgesic at 7 hours after subarachnoid blockade.There was statistically significant difference in duration of analgesia in two groups. Postoperative analgesia was significantly prolonged in Group B as compared to Group A.**Conclusion**: Clonidine and Dexmedetomidine as an adjuvant to Bupivacaine did not show significant difference in onset and peak of sensory blockade but Dexmedetomidine provided prolonged duration of sensory blockade and postoperative analgesia as compared to Clonidine group.

Keywords: Clonidine ,Dexmedetomidine , Intrathecal, Hyperbaric Bupivacaine, Adjuvant Preeclampsia

Introduction

The main stay of post operative pain relief is still the use of potent analgesics in the post operative period. It has proved difficult to find a drug which is a great improvement over-narcotics.Pregnancy-induced hypertension is a major cause of morbidity and mortality in obstetncs complicating 3% - 8% of pregnancies. Severe preeclampsia poses a dilemma for anesthesiologists, and there is some controversy about the best anesthetic technique for cesarean delivery in such cases. Because of the risks related to airway edema, difficulty with the airway or failed intubation, hypertensive response to direct laryngoscopy, and aspiration pneumonitis, general anesthesia is associated with more untoward outcomes in this particular group of patients. [1-4]When there is no contraindication for performing regional anesthesia, risk-benefit considerations strongly favor neuraxial techniques over general anesthesia for cesarean delivery in cases of preeclampsia. Regional anesthesia techniques have been widely used recently, however, spinal anesthesia, once considered contraindicated due to the common belief that the sudden and extensive sympathetic blockade following the subarachnoid block would result in severe hypotension and compromise uteroplacental blood flow in this group of patients.[2-4]

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Recent evidence has challenged this view, suggesting that spinal anesthesia may in fact be an appropriate choice for preeclamptic women when cesarean delivery is planned, as long as neuraxial anesthesia is not contraindicated (e.g., coagulopathy, eclampsia with persistent neurologic deficits). Although the relative safety of the subarachnoid block in these patients has been demonstrated, there are few studies that compare the differences in the hemodynamic changes and newborn well-being after single-shot spinal anesthesia in preeclamptic parturients.[5-6]Spinal anaesthesia is a popular technique for lower abdominal surgeries.Spinalanaesthesia has the advantage of simplicity of technique, rapid onset of action and reliability in producing uniform sensory and motor blockade. Its main disadvantage relates to its limited duration of action and hence, lack of long lasting post operative analgesia. To overcome this problem, administration of local anaesthetics in combination with different adjuvants is an excellent technique which not only relives postoperative pain but also refines the quality of sensory and motor blockade of subarachnoid block and hence, acts as synergistic to local anaesthetics with lower local anaesthetic requirement, decreased side effect and excellent post operative analgesia.The anesthetic and the analgesic requirement get reduced by the use of these two adjuvants because of their analgesic properties and augmentation of local anesthetic effects as they cause hyperpolarization of nerve tissues by altering transmembrane potential and ion conductance at locus coeruleus in the brainstem. The stable hemodynamics and the decreased oxygen demand due to enhanced sympatho-adrenal stability make them very useful pharmacologic agents.The safety of the use of dexmedetomidine on neonatal outcome is a very important issue. Others studied the transfer of clonidine and dexmedetomidine across the isolated

perfused human placenta and concluded that dexmedetomidine disappeared faster than from the maternal circulation, while even less dexmedetomidine was transported into the fetal circulation.Some case reports concluded that dexmedetomidine has no harmful effects during cesarean delivery.[2-8]This study examines and compares the usefulness and safety of dexmedetomidine versus conidine as an adjuvant to bupivacaine in subarachnoid block in LSCS in patients of preeclampsia.

Materials and Methods

Study design: A comparative prospective study

Setting: Present study of 100 patients was carried out in the Department of Anaesthesiology, Gandhi Medical College and associated Sultania Zanana Hospital, Bhopal during period from January 2019 to June 2020 after fulfilling the inclusion and exclusion criteria. Following is an attempt to summarize the observations of the study. Patients with preeclampsia were drawn from those scheduled for operations requiring subarachnoid block for LSCS.100 ASA grade I & II patients are randomized into two groups using envelope method.

Inclusion Criteria

Full term parturients with Pre-Eclampsia scheduled for LSCS.

Exclusion Criteria

1. Patients with severe Preeclampsia
2. Height less than 147 cm and more than 170 cm.
3. Weight >90 kg
4. Patients refusal,spinal deformity and any other contraindications to spinal anesthesia.

Anesthesia Technique

In the operating room, each patient had multi parameter monitor attached. Baseline pulse rate, non invasive blood pressure, oxygen saturation and respiratory rate were obtained and recorded before induction of spinal anesthesia and subsequently during the procedure. Maternal sedation was recorded using the 4 point ordinal sedation scale (l=wide awake and alert, 2=awake but drowsy, responding to verbal stimulus, 3=arousable, responding to physical stimulus, 4=not arousable, not responding to physical stimulus) every 15 min upto 6 hours post-operatively.

Quality of surgical anesthesia was noted at the end of procedure on a 3 point scale (Excellent: No supplementary sedative or analgesic required, Good: Only sedative required, Fair: Both sedative and analgesic required)

Ethical approval

Informed concent was taken from the patient and study protocol as decided by institutional ethical committee was followed.

Observations

Table 1:Demographic Profile Of Patients

Variables	Group A	Group B	P value
Age (years)	47.18 ±09.72	47.28 ± 10.14	0.9600
weight (in kg)	64.32 ± 04.54	65.46 ± 12*42	0.3897

Table showing demographic profile of patients in two groups according to age and weight.

Table 2:Comparison Of Sensory Characteristics Of Subarachnoid Block Between Two Groups

Variables		Group A	Group B	P Value
Highest sensory level achieved (range)		**$T_6 – T_8$**	**$T_6 – T_8$**	**0.1713**
Onset of sensory block (min)	At L_1 dermatome	01.4 ± 00.45	01.50 ± 00.40	0.2466
	At T_{10} dermatome	03.32 ± 01.17	03.59 ± 00.68	0.1703
	At highest sensory level	10.45 ± 01.91	10.99 ± 01.69	0.1364
Time to reach peak of sensory block (min)	L_1 dermatome	02.71 ± 00.84	02.9 ± 00.47	0.3591
	T_{10} dermatome	04.64 ± 01.36	04.81 ± 00.93	0.4555
	Highest sensory level	14.69 ± 01.36	16.26 ±0.72	0.1218
Time for regression of sensory block (min)	2 segment regression	120.9 ± 24.61	147.04 ± 32.09	<0.0001
	Complete regression	264.8 ± 38.87	325.76 ± 38.49	<0.0001

Values given in Mean ± SD.

Table 3:Showing Comparison Of Motor Characteristics Of Subarachnoid Block Between Two Groups

Variables	Group A (Mean ± SD)	Group B (Mean ± SD)	P Value
Time to achieve grade I motor block (min)	03.72 ±00.78	03.75 ±00.88	0.8582
Time to achieve grade II motor block (min)	05.95 ±01.13	05.92 ±01.15	0.8964
Time to achieve grade III motor block (min)	10.91 ±01.85	10.88 ±01.72	0.9335
Regression of motor block to previous grade	147.18 ± 24.94	161.38 ± 24.05	<0.0001
Time to complete regression of motor block	194.72 ± 22.57	213.44 ± 22.27	<0.0001

Inference: There was no statistically significant difference in onset of motor block in two groups. But there was statistically significant difference in regression of motor block. There was delayed regression of motor block in group B as compared to group A, **(P<0.0t)01).**

Table 4:Statistical Analysis Of Pulse Rate (Per/Min)

Pulse rate per minute at different time points.	Group A (Mean ± SD)	Group B (Mean ± SD)	P value
Baseline	84.66 ± 07.03	83.80 ±07.40	0.54
Just after block	84.66 ± 06.85	85.12 ±06.88	0.73
2 min after block	83.82 ± 06.65	84.22 ± 07.44	0.77
4 min after block	80.92 ± 06.43	82.82 ± 07.24	0.16
6 min after block	80.02 ±05.72	81.78 ±06.84	0.16
8 min after block	78.94 ±05.50	79.90 ±06.95	0.44

10 min after block	76.46 ±04.71	78.74 ±06,79	0.05
20 min after bloik	75.42 ±05.73	77.26 ±05.49	0.10
30 min after block	74.06 ± 04.70	/ 75.72 ±05.28	0.10
40 min after block	73.12 ± 05.56	74.98 ± 04.76	0.07
50 min after block	74.18 ± 04.89	74.40 ±05.29	0.82
60 min after block	72.28 ± 04.55	73.20 ±05.20	0.34
1 hr 10 min after block	71.08 ±05.09	72.86 ± 04.47	0.06
1 hr 20 min after block	71.18 ± 04.19	72.90 ± 04.86	0.06
1 hr 30 min after block	71.30 ±04.06	73.00 ± 04.70	0.05
1 hr 40 min after block	71.68 ±03.58	72.90 ±04.83	0.15
1 hr 50 min after block	71.12 ±03.52	72.30 ±09.74	0.42
2 hr after block	72.36 ± 02.95	73.76 ±04.20	0.05
2 hr 30 min after block	72.52 ± 03.14	73.90 ± 04.28	0.06

Table 5:Systolic Blood Pressure, Diastolic Blood Pressure And Mean Arterial Pressure

Blood Pressure at different time points	Systolic Blood Pressure			Diastolic Blood Pressure			Mean Arterial Pressure		
	Group A	Group B	P	Group A	Group B	P	Group A	Group B	P
Baseline	125.0 ± 05.94	122.3 ± 07.83	0.05	77.82 ± 04.60	77.20 ± 04.60	0.51	93.50 ± 03.65	92.10 ± 04.40	0.08
Just after block	125.2 ± 07.84	122.7 ± 07.19	0.09	77.62 ± 04.28	76.32 ± 06.24	0.22	93.34 ± 04.57	94.98 ± 25.11	0.65
2 min after block	121.4± 06.65	120.2 ± 07.26	0.41	75.30 ± 04.83	74.94 ± 05.80	0.74	90.72 ± 04.33	90.00 ± 05.06	0.44
4 min	119.6 ± 05.87	118.4 ± 06.95	0.33	74.42 ± 05.76	74.42 ± 06.89	0.99	89.04 ± 05.36	89.04 ± 05.95	0.99
6 min	117.3 ± 06.64	115.9 ± 07.79	0.35	74.16 ± 04.40	72.80 ± 07.34	0.26	88.44 ± 04.27	86.98 ± 07.46	0.23
8 min	113.2 ± 06.26	113.9 ± 07.82	0.62	72.16 ± 05.08	72.70 ± 06.80	0.65	86.04 ± 05.08	86.40 ± 06.52	0.76
10 min	111.6 ± 06.11	111.9 ± 08.29	0.82	72.12 ± 04.85	71.94 ± 06.27	0.87	85.14 ± 04.40	85.32 ± 05.88	0.86
20 min	110.7 ± 06.11	111.1 ± 07.99	0.76	71.66 ± 05.17	71.32 ± 06.01	0.76	84.72 ± 04.52	84*.64 ^ 05.73	0.93
30 min	108.2 ± 04.98	109.3 ± 08.40	0.41	70.44 ± 04.17	69.68 ± 05.38	0.43	83.06 ± 03.84	82.82 ± 05.26	0.79
40 min	105.6 ± 05.94	108.1 ± 08.16	0.08	70.86 ± 07.03	68.60 ± 05.80	0.08	82.42 ± 05.85	81.72 ± 05.25	0.53
50 min	106.7 ± 04.86	108.7 ± 09.97	0.21	70.02 ± 04.60	69.20 ± 05.80	0.43	82.26 ± 03.80	82.36 ± 05.93	0.92
60 min	108.9 ± 05.59	110.3 ± 08.32	0.32	7L62 ± 03.90	69.82 ± 05.63	0.06	83.92 ± 03.39	83.26 ± 05.17	0.45
1 hr 10Min	110.3 ± 05.61	111.5 ± 08.08	0.38	71.46 ± 05.25	70.18 ± 09.44	0.40	84.26 ± 04.31	83.98 ± 06.60	0.80
1 hr 20 min	112.9 ± 5.62	112.7 ± 07.89	0.88	71.74 ± 03.33	71.46 ± 04.04	0.64	85.38 ± 02.50	85.26 ± 04.29	0.86
1 hr 30 min	114.6 ± 05.64	114.6 ± 08.87	0.99	72.36 ± 03.89	71.96 ± 04.13	0.61	86.40 ± 03.30	86.18 ± 04.57	0.78
1 hr 40 min	114.5 ± 05.69	116.4 ± 08.71	0.19	71.98 ± 03.72	72.14 ± 04.33	0.84	86.12 ± 03.44	86.88 ± 04.87	0.37
1 hr 50 min	115.3± 16	116.5± 08.85	0.41	71.44± 03.87	72.80± 03.85	0.08	86.06 ± 03.65	87.52 ± 04.45	0.07
2hr	117.7 ± 05.74	116.6 ± 09.07	0.49	73.08 ± 03.96	72.76± 03.07	0.65	87.98 ± 03.66	87.42 ± 04.04	0.46
2hr 30 min	118.6 ± 06.65	116.6 ± 09.01	0.21	72.50 ± 03.78	72.30± 03.84	0.78	87.82 ± 03.41	87.08 ± 04.64	0.37

Table 6:Visual Analogue Scale

Time	Group A (Mean ± SD)	Group B (Mean ± SD)	P Value
1 hr after block	0	0	-
2 hr after block	0	0	
4 hr after block	0 .	0	-
5 hr after block	0	0	-
6 hr after block	3.5 ± 1.24	0.38 ±0.83	<0.0001
7 hr after block	5.26 ±0.12(rescue analgesic given)	1.96 ±0.32	<0.0001
8 hr after block	-	02.98 ± 0.62	-
9 hrafterblock	—	05.46 ± 0.54(rescue analgesic given)	

Table 7:Statistical Comparison Of Duration Of Effective Analgesia Between Two Groups

Variable	Group A (Mean ± SD)	Group B (Mean ± SD)	P value
Duration of effective analgesia (minutes)	401 ± 34.71	526.4 ± 27.38	<0.0001

Table 8:Complications in Two Groups

Complications	Group A	Group B
	No. of patients	No. of patients
	%	%

Hypotension	3	3
	06%	06%
Bradycardia	3	1
	06%	02%
N ausea-V omiting	4	6 .
	08%	12%
Headache	0	0
	00%	00%
Respiratory depression	0	0
	00%	00%
Neurological	0	0
Complication	00%	00%

Results

Patients characteristics in terms of age and weight were comparable in both the groups (P>0.05).[Table 1]There was no statistically significant difference in mean time for onset, peak of sensory block in two groups. But there was statistically significant difference in two segment and complete regression of sensory block. Regression of sensory block was prolonged in group B as compared to group A, (P<0.0001).There was no statistically significant difference in onset of motor block in two groups. But there was statistically significant difference in regression of motor block. There was delayed regression of motor block in group B as compared to group A.[Table 2,3]

The changes observed in heart rate were comparable in both the groups throughout the study period. Heart rate remained stable and comparable at different time points in two groups. Except three patients in group A and one patient in group B, no other patient in either group developed bradycardia.Changes observed in systolic, diastolic and mean blood pressure were comparable in both the groups at different time points (P>0.05). Three patients in Group A and in Group B developed hypotension which responded to intravenous fluid therapy.SpO_2 remained stable and comparable in both the groups throughout the study period, (P>0.05).[Table 4,5]

There was no significant difference in sedation score between two groups. Sedation started at 30 minutes of block with maximum sedation score reached between 1.5 - 2 hours in both groups. Sedation score decreased to 0 within 5 hours. At no time, sedation score exceeded 2 and no patient developed signs of respiratory depression.[Table 6]

There was significant prolongation of analgesia in Group B where first rescue analgesic was required after 9 hours of subarachnoid blockade. Patients in Group A required rescue analgesic at 7 hours after subarachnoid blockade.There was statistically significant difference in duration of analgesia in two groups. Postoperative analgesia was significantly prolonged in Group B as compared to Group A.[Table 7]

In Group A, three patients developed bradycardia and three patients developed hypotension where as in Group B, one patient developed bradycardiaand three patients developed hypotension. Four patients (8%) in Group A and six patients (12%) in Group B experienced nausea and vomiting, which was statistically not significant. No other complication was noted in either group.[Table 8]

Statistical Analysis

After getting the required information, the collected data were coded, tabulated and analysed. The various statistical techniques i.e. the mean, standard deviation and test of significance (t-test and chi-square-test) were used for drawing valid conclusions.Statistical analysis done using student t-test. SPSS 13.0 software was used to calculate p value.P<0.05 was taken as statistically A descriptive analysis was done on all variables to obtain a frequency distribution. The mean + SD and ranges were calculated for quantitative variables. Continuous variables were compared by the Student t test. Proportions were analyzed with the chi-square test

Discussion

Dexmedetomidine hydrochloride was introduced in clinical practice in the United States in 1999 and approved by the FDA only as a short-term (< 24 hours) sedative for mechanically ventilated adult ICU patients.Dexmedetomidine is now being used outside the ICU in variety of clinical settings, including sedation and adjunct analgesia in the operating room, sedation in diagnostic procedures and for other applications such as withdrawal/detoxification amelioration in adult and paediatricpatients.Though Clonidine, an older member of $a_2$adrenoceptor family, has well established record of efficacy and safety as an adjuvant to local anaesthetic in subarachnoid block , Dexmedetomidine is yet to be established for this purpose.Dexmedetomidine is recently being introduced in Indian market; hence to contribute the literature, we decided to study the efficacy and safety profile of Dexmedetomidine versus Clonidine in combination with local anaesthetic in subarachnoid block in patients of preeclampsia undergoing lscs.

Kothari et. al. recommended the dose of 15-45 microgram Clonidine for supplementation of spinal anaesthesia since this dose effectively prolongs the duration of spinal block with minimal sedation and side effects. Compared with Clonidine, the affinity of Dexmedetomidine to a receptor has been reported 10 times more than Clonidine. Moreover, Sethiet. al. reported 1:10 dose ratio between intrathecal Dexmedetomidine and Clonidine in animals. Hence we used 45 microgm. preservative free Clonidine with 10 mg Bupivacaine intrathecally in Group C.[9-10]The clinical studies about the use of intrathecal Dexmedetomidine in surgical patients are limited in the literature. Kanazi et al found that 3 ug Dexmedetomidine is equipotent to 30 µg Clonidine in prolonging duration of sensory and motor block with minimal side effects when added to 15 mg spinal Bupivacaine for urology surgery. From **Kanazi's** study and animal studies, we assumed that 3 - 5 ug Dexmedetomidine would be equipotent to 30- 45 (microgm Clonidine. Animal studies have used intrathecalDexmedetomidine at a dose ranged to 2.5 - 100 microgm.[11] Present study showed that the supplementation of 10 mg of spinal Bupivacaine with 45µg Clonidine or 5 µg Dexmedetomidine did not show significant difference in the time for onset and peak of sensory blockade.But addition of 5µ*g* Dexmedetomidine showed significantly prolonged two segment regression (147.04 ± 32.09 min) and total duration of sensory blockade (325.76 ± 38.49 min) as compared to Clonidine where time for two segment regression and total duration of sensory blockade was (120.9 ± 24.61 min) and (264.8 ± 38.87 min). Dexmedetomidine also showed longer postoperative analgesia period of 9 hours as compared to 7 hours in Clonidine group.In this study, the addition of 5 µg Dexmedetomidine to intrathecal Bupivacaine also did not show significant difference in time for onset of motor block but showed prolonged duration of motor block when compared with 45µ*g* Clonidine intrathecally with Bupivacaine.

Findings of this study are similar to the findings reported by G. E. Kanazi et al, Rampal Singh et al and Sarma et al where Kanazi et al and SolankiSLetal concluded that there was no significant difference in onset of sensory and motor block. Solanki SL et al also concluded

that total duration of sensory and motor block was prolonged with Dexmedetomidine as compared to Clonidine. Sarmaet al concluded that addition of Dexmedetomidine to intrathecal Bupivacaine produces longer post operative analgesia than Clonidine.This antinociceptive effect may explain the prolongation of sensory block when added to spinal anaesthetic.[11-13]

Sushruth MR **et al**. has shown that the intrathecal$a_2$adrenoceptor agonist can cause dose dependent decrease in motor strength in animals and prolongation of motor block of spinal anaesthetics due to addition of a_2 agonist may result from their binding to motor neurons in dorsal horn.In this study, addition of Dexmedetomidine did not cause significant fall in blood pressure intraoperatively and postoperatively. Three patients in Dexmedetomidine group and three patients in Clonidine group developed hypotension which responded to intravenous fluid therapy and is statistically not significant. Intrathecal local anaesthetics block the sympathetic outflow and reduce the blood pressure. Sympathetic block is near maximum with the doses of local anaesthetic used for spinal anaesthesia. The addition of low dose of a_2 agonist to high dose of local anaesthetics does not further affect the near maximal sympatholysis.[14] Intrathecally administered $a_2$adrenoceptor agonists have a dose dependent sedative effect. The dose of Dexmedetomidine and Clonidine selected in this study did not produce excessive sedation, as at no time, sedation score exceeded two and no patient developed respiratory depression or fall in $Sp0_2$. In fact, the sedation produced by Dexmedetomidine and Clonidine was found to be desirable as all the patients remained calm and quite in intraoperative and postoperative period. -The only side effect noted was nausea and vomiting but it was not clinically and statistically significant and its incidence was comparable in both the groups.Reddy VS et al did a randomized double-blind study on intravenous dexmedetomidine versus clonidine for prolongation of bupivacaine spinal anesthesia and analgesia.Kim JE etal in a similar study like us studied effects of intrathecal dexmedetomidine on low-dose bupivacaine spinal anesthesia in elderly patients undergoing transurethral prostatectomy. Mahendru V etal did a comparison of intrathecaldexmedetomidine, clonidine, and fentanyl as adjuvants to hyperbaric bupivacaine for lower limb surgery in a double blind controlled study.whereas Hanoura SE et al studied intraoperative conditions and quality of postoperative analgesia after adding dexmedetomidine to epidural bupivacaine and fentanyl in elective cesarean section using combined spinal-epidural anesthesia. Anesthesia, essays and researches. The results of all above studies are in conjunction with our studies.[15-18]

Conclusion

Dexmedetomidine in the dose of 5µg added to 10 mg o.5% Hyperbaric Bupivacaine in subarachnoid block for lower segment cesarian section surgery in partieunts with Preeclampsia provides comparable onset for sensory and motor blockade but significantly prolonged duration as compared to 45µg of Clonidine. Longer duration of postoperative analgesia with 5µg Dexmedetomidine makes it superior to Clonidine in respect to postoperative analgesia. Both the drugs produce desirable level of intraoperative and postoperative sedation, stable haemodynamics and minimal side effects.

Ethical approval

Informed concent was taken from the patient and study protocol as decided by institutional ethical committee was followed.

What this Study Add to Existing Knowledge

The anesthetic and the analgesic requirement get reduced by the use of these two adjuvants because of their analgesic properties and augmentation of local anesthetic effects as they cause hyperpolarization of nerve tissues by altering transmembrane potential and ion conductance at locus coeruleus in the brainstem. The stable hemodynamics and the decreased oxygen demand due to enhanced sympatho-adrenal stability make them very useful pharmacologic agents.

Limitation of Our Study

1. Small sample size
2. Chances of bias
3. Single center trial

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