Section: Anaesthesiology

Original Research Article

COMPARING THE EFFECT OF 0.5% HYPERBARIC BUPIVACAINE WITH DEXMEDETOMIDINE AND WITHOUT DEXMEDETOMIDINE IN SPINAL ANAESTHESIA FOR ELECTIVE CAESAREAN SECTION – A RANDOMISED CLINICAL STUDY

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Abstract

Background: Spinal anaesthesia is preferred for caesarean sections owing to its immediate onset, low failure rates, and motor block. However, administration to obstetric patients is challenging because of maternal morbidity, mortality, and risks. This study compared the clinical effects of adding dexmedetomidine to Inj 0.5% hyperbaric bupivacaine in elective lower-segment caesarean sections. **Material and Methods:** This prospective, randomised, double-blind study was conducted on 60 Madras Medical College patients from March 2022 to February 2023. Sixty patients were divided into groups A (n = 30) and B (n = 30). This study investigated the effects of subarachnoid block by assessing sensory and motor blockade, sedation levels, and the time required for rescue analgesia. Postoperative pain was assessed using a visual analogue scale, and the time for the first rescue analgesic request was recorded. **Results:** There were no statistically significant differences in age, BMI, or duration of surgery between the groups. Most participants achieved a T4 dermatome after intrathecal dexmedetomidine and hyperbaric bupivacaine administration, while 50% achieved t3 alone. The onset of sensory blockade was significantly earlier in group A, followed by motor blockade and complete analgesia. Group A had a longer duration of motor block and more effective analgesia. Two-segment regressions showed significant differences between the groups. There were significant differences in the mean VAS scores from the 2nd hour to 12 hours in the postoperative period. **Conclusion:** Dexmedetomidine, combined with 0.5% hyperbaric bupivacaine, significantly improves sensory and motor blockade, postoperative analgesia duration, and rescue analgesia requirement in elective caesarean section surgeries.

INTRODUCTION

Spinal anaesthesia is the preferred method for caesarean sections because of its immediate onset, low failure rates, complete motor block, and avoidance of general anaesthesia drawbacks. Physiological and pharmacological principles now govern the choice of drugs and techniques used in anaesthesia, and understanding the patient's background helps clinicians make the best choice. Modern pain management focuses on the pharmacological principles of drugs used in the dorsal horn of the spinal cord, with regional anaesthesia suppressing nociceptive transmission at the first synaptic relay for minimal systemic side effects. However, the administration of anaesthesia in obstetric patients has always been a challenge due to maternal morbidity and mortality, risks associated with general anaesthesia, failed intubation and ventilation, aspiration of gastric contents, oral cavity soft tissue trauma, dental injury, delayed breastfeeding initiation, and sedative effects on the neonate.[1,2]

The choice of local anaesthetic agent depends on the required quality of blockade and procedure duration. Lignocaine, the first amide-group local anaesthetic drug, was clinically used in the 1950s and is currently used for regional anaesthesia. However, owing to transient neurological symptoms, it is no

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longer used for spinal anaesthesia. Bupivacaine, the first long-acting amide local anaesthetic, remains the most used in clinical practice, producing prolonged and intense blockade, significant sympathetic blockade, and excellent surgical relaxation.[3,4] However, the usual dosage used for regional anaesthesia causes many side effects.[5] Lowering the dosage limits the spread of spinal blockade and produces a comparatively rapid recovery.[6]

In the past few decades, adding adjuvants to local anaesthetic drugs for spinal anaesthesia has increased and is gaining popularity. These additive agents reduce the unwanted and untoward haemodynamic effects of subarachnoid blockade or spinal anaesthesia by lowering the dose of the local anaesthetic required. It also provides a good, satisfactory blockade and, together with the intrathecal local anaesthetic, has a synergistic antinociceptive effect during intraoperative and postoperative periods by prolonging the duration of analgesia.[7-9]

Dexmedetomidine is a highly selective α-2-agonist that has been used in mechanically ventilated patients as a short-term sedative in the intensive care unit. Recently, it has been used as an adjuvant drug for patients undergoing caesarean section under the subarachnoid block and as an additive drug for labour analgesia because of its stable haemodynamics and potent intraoperative and prolonged postoperative analgesic properties with a lower incidence of maternal and neonatal complications.[10] Because the properties of dexmedetomidine are suitable for parturients with altered physiology in the post-delivery period, this study was designed to compare the clinical effects of adding dexmedetomidine to Inj 0.5% Hyperbaric Bupivacaine in elective lower segment caesarean section (LSCS).

Aim

This study aimed to compare and understand the analgesic efficacy of intrathecal dexmedetomidine as an additive to 0.5% hyperbaric bupivacaine in parturients undergoing elective caesarean section.

MATERIALS AND METHODS

This prospective, randomised, double-blinded study was conducted on 60 parturients who were scheduled to undergo elective LSCS (lower uterine segment caesarean section) under subarachnoid block at the Institute of Obstetrics and Gynecology, Madras Medical College, Chennai, from March 2022 to February 2023.

Inclusion Criteria

Patients in the 20- and 40-year-old age groups with ASA Class I and II physical status, planned for an elective Caesarean section, and provided valid informed consent.

Exclusion Criteria

Patients aged < 20 years and > 40 years, scheduled for emergency caesarean section, patient's refusal, morbid obesity, complicated pregnancy, intrauterine foetal compromise, known hypersensitivity to amide local anaesthetic drugs, coagulopathy, bleeding diathesis, and any liver or renal disease were excluded.

After obtaining institutional ethical committee approval (EC Reference No (DHR). EC/ NEW/INST/2021/1618; date 02.03.2022) and by applying inclusion and exclusion criteria, sixty parturients of ASA I and II classes were enrolled into the study. The purpose and methodology of the study were explained to every patient in their language and informed written consent was obtained from all patients. The documentation strictly included a detailed history, complete physical examination, and investigations, such as haemoglobin, blood sugar, renal function parameters, and ECG for all patients. Each patient was randomised into one of the groups using the sealed envelope technique.

Group A (30 patients) received 10 mg of 0.5% hyperbaric bupivacaine (2.0 ml) + 5 µg dexmedetomidine (0.5 ml). Total 2.5 ml volume. Group B (30 patients): 10 mg of 0.5% hyperbaric bupivacaine (2.0 ml) + 0.9% saline (0.5 ml), total 2.5 ml volume. Dexmedetomidine solution was prepared by diluting the drug (0.5 ml of the drug containing 50 mcg to 4.5 ml of 0.9% saline. Then 0.5 ml of this diluted solution, which contained 5 µg dexmedetomidine, was added to a syringe containing 2.0 ml of 0.5% hyperbaric Bupivacaine. The test drugs for both groups were prepared by someone unrelated to the study. A subarachnoid block was performed by an adequately trained resident or consultant anaesthesiologist, and data were collected using the prescribed format in an Excel sheet.

The patient was immediately placed supine, with the table lying flat horizontally, and a wedge was placed under the right hip. Supplemental oxygen was provided with a Hudson face mask. The time taken to perform the subarachnoid block was recorded. The study recorded parameters, such as the onset of motor blockade, time for complete motor blockade, and onset of sensory blockade after intrathecal injection. Sedation scores were assessed every 30 min intraoperatively and hourly during the postoperative period for the first 6 hours. The time required for the two segments of sensory regression (TSRT) was also measured. Intraoperative haemodynamics were measured at baseline, incision, before and after delivery, and at the end of surgery. Postoperative pain was assessed using a visual analogue scale, and the time for the first rescue analgesic request was recorded. Neonatal APGAR scores were recorded at 1 and 5 minutes.

After delivering the neonate, all patients were administered 10 units of Inj Oxytocin intravenously in 500 ml of normal saline. Upon completion of the surgery, the patients were shifted to the PACU for further monitoring and observation. The patient was transferred to the respective postoperative ward after

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stabilising the haemodynamic parameters and complete regression of the motor blockade. Postoperative haemodynamics were monitored at 0, 2, 4, 8, 12, and 24 h. Fifty milligrams of intramuscular tramadol were administered when the patient complained of pain in the postoperative period, as evidenced by VAS scores >3, and the time of rescue analgesia was noted.

This study investigated the effects of subarachnoid block by assessing sensory and motor blockade, sedation levels, and the time required for rescue analgesia. The onset of sensory blockade, determined by the loss of cold sensation at the T6 dermatome using cotton swabs, and the duration of the sensory blockade to its maximum level were examined. Additionally, the time required for two-segment sensory regression was measured. Motor blockade onset and maximal blockade were assessed using the Modified Bromage Scale. Sedation levels were evaluated using the Ramsay sedation score. The time from the spinal injection to the first complaint of subjective pain defines the need for rescue analgesia.

Statistical Analysis

Data analysis for statistical comparison was performed with the help of a computer using MS Excel Office version 2019 and SPSS software v28.0. Frequencies, percentages, ranges, means, and standard deviations were calculated. The chi-square test, Friedman test, and t-test were performed. Statistical significance was set at $p < 0.05$.

RESULTS

Age distribution was 25% in 21-25 years, 41.63% in 26-30 years, 28.3% in 31-35 years, and 5% in 36-40 years, and p=0.91 showed no statistically significant association between age and groups and were comparable. BMI (kg/m2) with groups was t-value=1.576, p=0.12, which showed no statistically significant difference and was comparable. There was no statistically significant difference between the surgery duration (min) and the groups (p = 0.41). [Table 1]

The height of the sensory dermatome after a subarachnoid block was compared between the study groups. Most 70% of the parturients achieved a T4 dermatome following intrathecal dexmedetomidine as an adjunct to hyperbaric bupivacaine, while 50% achieved t3 following intrathecal bupivacaine alone. Sensory dermatomal levels ranged from t3 to t6, which was statistically significant.

The onset of sensory blockade showed a significant difference (p = 0.0018). Group A had a significantly earlier onset of action than Group B. Sensory blockade (seconds) showed a statistically significant difference ($p < 0.0001$) between the groups. Group A had a significantly earlier onset of maximal sensory blockade.

The onset of motor blockade (p=0.0001) showed a high statistically significant difference between the groups. Group A had a significantly earlier onset of complete motor blockade. Two-segment regressions show a $p<0.0001$, which indicates a statistically significant difference between the groups. Group A had significantly delayed two segment regressions than group B.

The duration of motor blockade in minutes ($p<0.001$) showed a statistically significant difference between the groups. Group A had a significantly longer duration of motor block. The duration of complete analgesia in minutes ($p<0.001$) showed a very high statistically significant difference between groups. Patients in group A had a significantly longer duration of complete analgesia. The duration of effective analgesia in minutes ($p<0.0001$) showed a very high statistically significant difference between groups. Group A had a significantly longer duration of effective analgesia than group B. [Table 2]

There were significant differences in the mean VAS scores from the 2nd hour to 12 hours in the postoperative period. Patients in Group A had lower VAS scores than those in Group B over a longer period. There were no significant differences in the mean APGAR scores at both 1st and 5th minute after birth. The bradycardia, PONV, and postoperative shivering were not statistically significant between the groups. [Table 3]

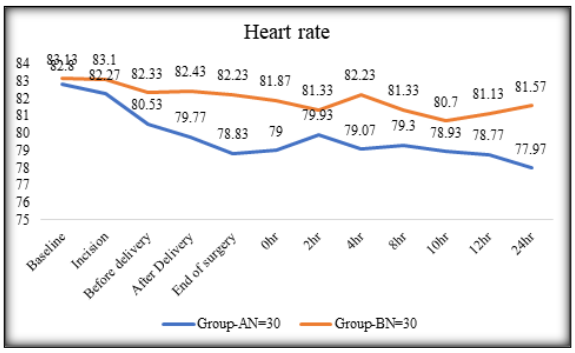

Figure 1: Comparison of heart rate with groups

The heart rates were relatively lower in group A, with a p-value >0.05, which was not statistically significant or comparable. [Figure 1]

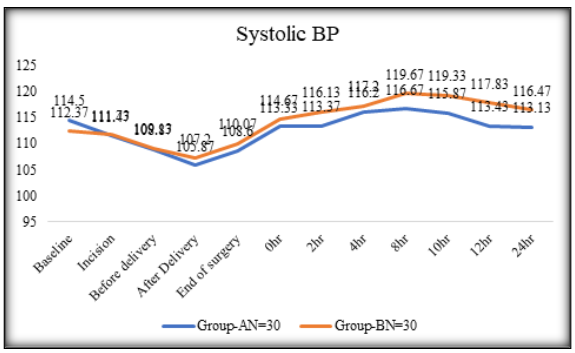

Figure 2: Comparison of systolic BP with groups

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The SBP was relatively lower in group A (p >0.05), which was not a statistically significant difference or comparable. [Figure 2]

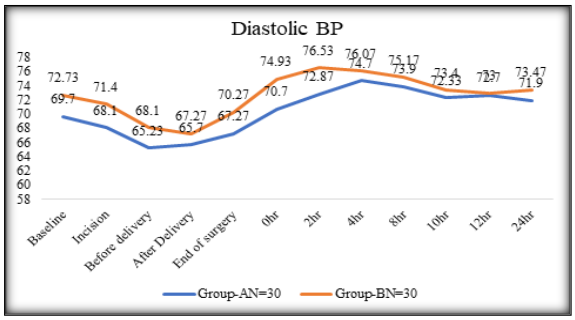

Figure 3: Comparison of diastolic BP with groups

Diastolic BP with groups by DBP was relatively lower in group A, with a p-value >0.05, which was not a statistically significant difference nor comparable. [Figure 3]

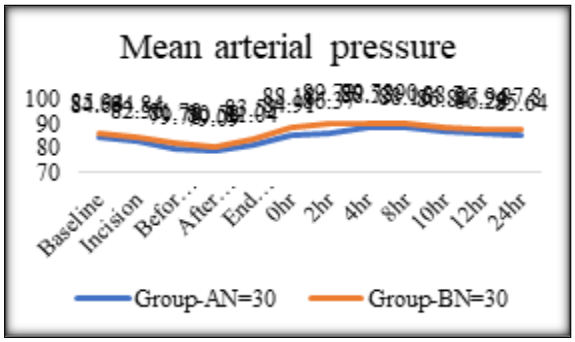

Figure 4: Comparison of mean arterial pressure with groups

MAP was relatively lower in group A, with a p-value >0.05, which was not a statistically significant difference and was not comparable. [Figure 4]

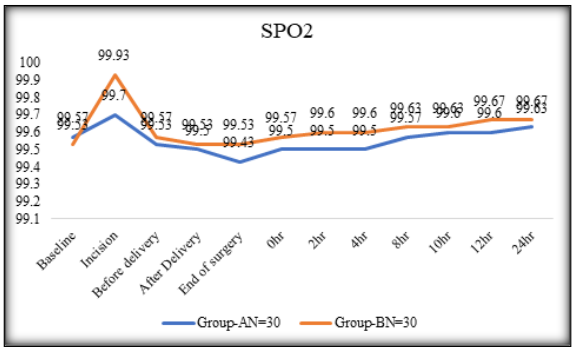

Figure 5: Comparison of SPO2 with groups

Spo2 with Groups by a p-value >0.05, which was not a statistically significant or comparable difference (Figure 5).

Table 1: Demographic data of the study

		Group A	Group B	P-value
Age (years)	21–25	7	8	0.91
	26-30	13	12	
	31-35	8	9	
	36-40	2	1	
Age (mean)		27.97±3.62	28.63±3.88	0.5
BMI		25.88±3.73	27.75±5.32	0.12
Duration of surgery		52.83±5.97	53.67±8.60	0.66

Table 2: Comparison of height, onset (sensory), duration (sensory), onset (motor), time for 2-segment regression, duration of motor blockade, duration of complete analgesia (min), and duration of effective analgesia between the groups

		Group A	Group B	P-value
Height of dermatomal block	T3	4(13.3%)	15(50%)	0.01
	T4	21(70%)	9(30%)	
	T5	3(10%)	4(13.3%)	
	T6	2(6.7%)	2(6.7%)	
Onset (Sensory)		223.33±32.20	256±44.38	0.0018*
Duration (Sensory)		334.67±44.39	398.33±36.96	<0.0001*
Onset (Motor)		4.7±0.79	5.63±0.89	0.0001 *
Time for 2-segment regressions		122.83±5.83	100.83±8.82	<0.0001*
Duration of motor blockade (minutes)		208.83±18.65	152±6.64	<0.0001
Duration of complete analgesia (minutes)		192.17±22	137.50±13.57	<0.0001*
Duration of effective analgesia (minutes)		256.67±21.96	207.33±14.84	<0.0001*

Table 3: Comparison of visual analogue scores, APGAR scores, complications between the groups

		Group A	Group B	P-value
Visual analogue scores	0 hour	0.03±0.18	0.13±0.35	0.17
	2 hours	0.27±0.45	0.70±0.53	0.0013

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	4 hours	1.07±0.58	1.93±0.64	<0.0001
	8 hours	3.10±0.84	2.60±0.62	0.011
	12 hours	3.73±0.78	4.18±0.95	0.049
	24 hours	4.57±0.94	4.53±0.68	0.85
APGAR scores	1 minute	7±0.79	7.03±0.76	0.88
	5 minutes	9±0	9±0	1
Complications	Bradycardia	4	-	0.11
	PONV	1	4	0.35
	Shivering	0	2	0.49

DISCUSSION

The demographic parameters compared in the study were age range distribution, mean age, and body mass index, which were comparable in both groups. The mean duration of surgery was comparable between the two groups. The mean duration of surgery in Group A was 52.83±5.97 minutes, while it was 53.67±8.60 minutes in Group B. At our institute, 7.5-12 mg of 0.5% bupivacaine will be routinely used based on the patient's characteristics, such as height. As the addition of an adjunct was planned, we used 10 mg of bupivacaine in all patients. Mahdy et al. conducted a similar study using 10 mg of 0.5% bupivacaine in ninety parturients undergoing caesarean section for which 0.5 ml of Adjunct was added, making the total volume 2.5 ml.11 Kanazi et al. compared Dexmedetomidine 3 mcg and Clonidine to hyperbaric bupivacaine and found no significant changes in the effects.12 5mcg of dexmedetomidine was used as an adjunct in the studies done by Mahdy et al., Xia et al., Gupta R et al., and Mohamad et al.[11,13,14,15]

In this study, the onset of sensory blockade was 223.33±32.2 seconds with dexmedetomidine and 256±44.38 seconds without dexmedetomidine. The onset of sensory blockade was significantly longer with the addition of 5mcg µg dexmedetomidine as an adjunct to 10 mg 0.5% bupivacaine. Nethra et al. and Abdelhamid et al. noticed a similar significant onset of sensory and motor blockade after adding 5 mcg of dexmedetomidine to hyperbaric bupivacaine.[16,17] Gupta et al.. found no significant effects on the onset of sensory blockade. It was 288 seconds with dexmedetomidine and 280 seconds with normal saline.[14]

In our study, the time to maximum sensory blockade was 334.67±44.39 seconds with dexmedetomidine and 398.33±36.96 seconds without dexmedetomidine. The difference in the early onset of sensory blockade was statistically significant. The maximum height of sensory blockade achieved was T4 in 70% of the patients in group A, while it was T3 in 50% of the patients in group B. Gupta R et al. reported the maximum duration of the sensory blockade as 11.7 minutes after adding dexmedetomidine to 0.75% ropivacaine.[14]

In our study, the onset of complete motor blockade was 4.7±0.79 minutes with dexmedetomidine and 5.63±0.89 minutes without dexmedetomidine. The onset of motor blockade was significantly longer with the addition of 5mcg µg dexmedetomidine as an adjunct to 10 mg 0.5% bupivacaine. The two-segment regression time was 122±5.83 minutes with dexmedetomidine and 100.83±8.82 minutes without dexmedetomidine. The two-segment regression time was significantly longer with the addition of 5mcg µg dexmedetomidine as an adjunct to 10 mg 0.5% bupivacaine. Abdelhamid et al. also reported a similar two-segment regression time of 120.3±138 minutes after 3.5ml of bupivacaine with 5mcg Dexmedetomidine, while it was 92.3±9.9 minutes with bupivacaine without any adjuncts.[17] Gupta et al. showed a similar prolongation of the two-segment regression time as 468.3±36.8 minutes, which is significantly longer with the addition of 5mcg dexmedetomidine to 0.75% Ropivacaine.[14]

In our study, the groups showed no statistically significant changes in haemodynamic parameters (heart rate, blood pressure, and oxygen saturation). However, intrathecal DEX was added to group A. Both parameters were within 20% of the baseline values. The fall in heart rates with dexmedetomidine 5mcg was like the study by Kanazi et al,[12] Similarly, Das et al. compared the effects of two doses of dexmedetomidine (5 and 10 mcg) to bupivacaine in patients undergoing abdominal hysterectomy.[18]

Although there were instances of bradycardia (<60 beats per minute), none of the patients required atropine supplementation. A similar trend was observed for blood pressure (systolic, diastolic, and mean arterial pressure). Blood pressure in group A was lower than that in group B. However, these differences were not statistically significant. Although the decrease in diastolic pressure was higher than that in systolic blood pressure, none of the patients in either group required ephedrine supplementation. Abdelhamid et al. showed a biphasic blood pressure response, a short, hypertensive response (lasting 5-10 minutes) followed by a hypotensive response in the blood pressure.[17] Al-Ghanem et al. reported stable hemodynamics in the dexmedetomidine group compared to the fentanyl group. Both groups were comparable in oxygen saturation.[19]

In our study, the duration of motor blockade was significantly longer when dexmedetomidine was added as an adjunct to intrathecal hyperbaric bupivacaine. The duration of motor blockade was 208.83±18.65 minutes with dexmedetomidine, while the same was 152±6.64 minutes with bupivacaine alone. Nethra et al. showed that the duration of motor blockade with dexmedetomidine was 323.05±54.58 minutes, much longer than the current

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study.16 a Significantly prolonged duration of motor blockade was also seen in the studies done by Xia et al. (0.75% ropivacaine with 5mcg dexmedetomidine).[13]

Our study's VAS scores were comparable in the immediate postoperative period. Subsequently, the scores were lower in group A until 12 hours postoperatively. The VAS scores were statistically significant and lower in group A 2-, 4-, 8-, and 12-hour periods. The VAS scores were 0.27, 1.07, 3.10, 3.73 and 4.57 in group A at 2, 4, 8, 12, and 24 h, and 0.70, 1.93, 2.60, 4.18 and 4.53 in group B at the same observation periods. Mohamad et al. documented the VAS scores at 8 hours (2.40), 12 hours (2.03) and 24 hours (2.26), which were significantly lower by the addition of dexmedetomidine to 0.75% ropivacaine.[15]

In our study, there were no statistical differences in the neonatal outcomes as measured by the APGAR scores 5 and 10 min after delivery. The adverse events observed included postoperative nausea and vomiting, shivering, and bradycardia. The study showed no hypotension, total or high spinal blockade, or failure of spinal sight. The incidence of bradycardia was 13.3% in group A and was not seen in any patient in group B; PONV was seen in 3.3% of the patients in group A and 13.3% of patients in group B and shivering (0% in group A and 6.7% in group B). However, the incidence of bradycardia and PONV was not statistically significant.

In this study, Nethra et al. reported the incidence of PONV and bradycardia as 5% each after adding 5 mcg of dexmedetomidine to 6 mcg of buprenorphine.[16] Gupta et al. reported 3.3% PONV, 6.6% bradycardia and 6.6%hypotension in the dexmedetomidine group, and 3.3 each for shivering and hypotension and 6.6% PONV without dexmedetomidine.[14] Mohamad et al. reported a 13.3% incidence of PONV in the Dexmedetomidine group.[18] Abdelhamid et al. reported hypotension (25.8% with dexmedetomidine and 19.4% without dexmedetomidine), bradycardia (25.8% with dexmedetomidine and 0% without dexmedetomidine), and shivering (6.5% with dexmedetomidine and 41.9% without dexmedetomidine).[17]

CONCLUSION

We conclude that, for elective caesarean section surgeries, dexmedetomidine, when added as an adjuvant to intrathecal 0.5% hyperbaric bupivacaine, was superior to 0.5% hyperbaric bupivacaine administered alone in terms of onset and duration of sensory and motor blockade. In addition, it increases the duration of postoperative analgesia and reduces the need for rescue analgesia. The quality of anaesthesia, haemodynamics, and sedation scores were comparable, with no significant maternal or neonatal side effects.

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