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Original Article

Anaesthesia Section

Intraperitoneal Ropivacaine versus Levobupivacaine for Postoperative Analgesia in Laparoscopic Surgeries: A Randomised Controlled Trial

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ABSTRACT

Introduction: Management of postoperative pain in laparoscopic surgeries remains challenging, often necessitating multimodal analgesic strategies to enhance patient comfort and recovery. Intraperitoneal Local Anaesthetic (IPLA) administration offers a promising approach for pain control while minimising systemic opioid use and associated side-effects. Ropivacaine and levobupivacaine are commonly used long-acting amide local anaesthetics with favourable safety profiles.

Aim: The present aimed to compare the efficacy of intraperitoneal ropivacaine versus levobupivacaine for postoperative analgesia in patients undergoing elective laparoscopic surgeries.

Materials and Methods: In the present double blinded, randomised controlled study, 48 patients {American Society of Anaesthesiologists (ASA) I-II, aged 18-65 years} undergoing elective laparoscopic surgeries were randomly allocated into two groups. Group R (n=24) received 20 mL 0.25% ropivacaine and group L (n=24) received 20 mL 0.25% levobupivacaine intraperitoneally before trocar removal. Postoperative pain was assessed using Visual Analog Scale (VAS) scores over 12 hours. Haemodynamic parameters, rescue analgesic requirements, and side-effects were monitored. Data were analysed using Statistical Package for Social Sciences (SPSS) version 26, with independent t-tests for normally distributed numerical variables and Chi-square tests for categorical variables, with statistical significance set at $p<0.05$.

Results: Both groups were comparable in demographic characteristics with mean (SD) age being 35.42±10.4 and 35.04±10.8 years in group L and group R, respectively. VAS scores were similar until five hours, after which group L showed significantly lower scores upto 10 hours. Rescue analgesia requirements peaked at five hours (group L: 20.8% vs group R: 16.7%, $p<0.001$) with no requirements after six hours in either group. Haemodynamic parameters remained stable except for significantly lower Systolic Blood Pressure (SBP) in group L at specific time points. The side-effects were minimal. Most patients in group L (87.5%) and group R (79.2%) had no side-effects. Nausea was the same in both groups (12.5%), but vomiting (8.3%) happened only in group R.

Conclusion: Both ropivacaine and levobupivacaine provide effective postoperative analgesia when administered intraperitoneally in laparoscopic surgeries. Levobupivacaine demonstrated superior pain control after five hours, making it a potentially preferable option.

Keywords: Local anaesthetics, Postoperative pain, Rescue analgesia, Visual analog scale

INTRODUCTION

Laparoscopic surgery has revolutionised modern surgical practice by offering numerous advantages over traditional open procedures, including reduced postoperative pain, shorter hospital stays, and improved cosmetic outcomes [1]. However, patients undergoing laparoscopic procedures often experience significant postoperative pain, particularly in the first 24-48 hours, which can delay recovery and hospital discharge [2]. Post-laparoscopic pain is multifactorial, arising from three primary sources: incisional pain (somatic), deep intra-abdominal pain (visceral), and shoulder pain (referred visceral pain) [3]. The visceral component, caused by peritoneal inflammation and local tissue trauma, contributes significantly to early postoperative discomfort [4]. This has led to increasing interest in IPLA administration as an effective method for post-laparoscopic pain management.

The use of long-acting local anaesthetics for intraperitoneal instillation has gained considerable attention in recent years. Among these, ropivacaine and levobupivacaine have emerged as promising agents due to their favourable safety profiles and prolonged duration of action [5]. Ropivacaine, an amide local anaesthetic, was specifically developed to reduce cardiac and central nervous system toxicity while maintaining effective sensory block with minimal motor blockade [6]. Similarly, levobupivacaine, the S-enantiomer of bupivacaine, offers comparable analgesic efficacy with an enhanced safety profile compared to its racemic parent compound [7]. Despite the theoretical advantages of these agents, comparative studies evaluating their relative efficacy in intraperitoneal administration remain limited. Previous research has predominantly focused on their use in regional anaesthesia, with fewer studies specifically addressing their role in laparoscopic surgery [8,9]. Additionally, the optimal timing, concentration, and volume of administration remain subjects of debate in the current literature [10].

The present study aimed to compare the analgesic efficacy of intraperitoneal ropivacaine versus levobupivacaine in patients undergoing laparoscopic surgery. The primary objective includes evaluating postoperative pain scores, the number of patients requiring analgesia, and the rescue analgesia requirements between group D and group K at different postoperative time points. Secondary objectives included assessing the haemodynamic parameters and adverse effects. The findings of this study may contribute to the growing body of evidence regarding optimal pain management strategies in laparoscopic surgery and may help establish evidence-based guidelines for IPLA administration.

MATERIALS AND METHODS

The present double blinded (investigator and patient), randomised controlled study was conducted at a Dr. DY Patil Medical College,

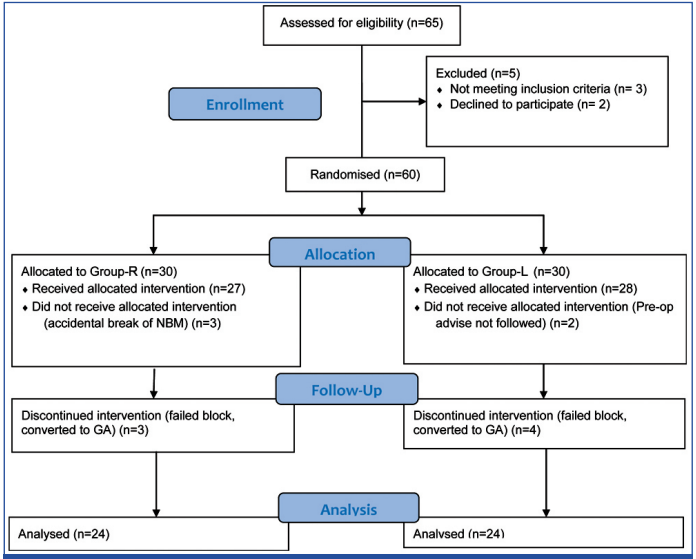
Hospital and Research Centre in Pune, Maharashtra (India), from March to August 2024 following ethical approval (IESC/FP/12/2022) with prior informed consent. The trial was registered on The Clinical Trials Registry- India (CTRI/2024/06/069370).

Sample size calculation: The sample size of 48 patients (24 per group) was calculated based on previous studies by Acharya R et al., and Honca M et al., considering mean VAS scores at 1-hour postoperation (ropivacaine: 1.83±0.54; levobupivacaine: 3.6±1.8), with 5% significance level, 80% power, and 20% non-inclusion rate [11,12].

Inclusion and Exclusion criteria: ASA grade 1-2 patients aged 18-65 years of either sex undergoing elective laparoscopic surgeries were included. Patients with ASA grade ≥3, emergency cases, major systemic diseases, coagulation abnormalities, or drug allergies were excluded.

Study Procedure

Preoperative assessment included detailed history, physical examination, and routine investigations. Patients were randomly allocated using a computer-generated table into [Table/Fig-1].



[Table/Fig-1]: CONSORT diagram.

- Group R (n=24): Received 20 mL 0.25% ropivacaine
- Group L (n=24): Received 20 mL 0.25% levobupivacaine

The random allocation sequence was generated by an independent statistician using a computer-generated randomisation table. Participant enrolment was performed by the study's principal investigator and co-investigators, who assessed eligibility based on inclusion and exclusion criteria. Assignment of participants to interventions was conducted by an independent Anaesthesiologist not involved in patient care or data collection, who prepared and administered the blinded study medications using coded syringes to maintain the double-blind design.

Premedication included glycopyrrolate (0.004 mg/kg), midazolam (0.02 mg/kg) and fentanyl (2 µg/kg). Induction was done with propofol (2 mg/kg). Intubation was facilitated with succinylcholine (2 mg/kg) if not contraindicated, followed by vecuronium (0.1 mg/kg) for maintenance. After confirmation of position and before incision all patients received 1g Inj. paracetamol. The assigned local anaesthetic was administered intraperitoneally through the trocar before its removal. Following surgery, reversal was achieved with neostigmine (0.05 mg/kg) and glycopyrrolate (0.008 mg/kg).

Postoperative pain assessment was conducted using the VAS, where 0 indicated no pain and 10 represented the worst possible pain. Pain scores were recorded each hourly postoperatively till 12 hours.

Rescue analgesia (tramadol 50 mg with ondansetron 0.1 mg/kg) was administered for VAS scores >/=5. Throughout the study, patients were closely monitored for adverse effects or complications. Vital haemodynamic parameters, pain scores, rescue analgesic requirements, and any adverse events were recorded in a standardised data collection form.

To minimise potential bias, a double-blind (Investigator and patient) approach was implemented. An independent Anaesthesiologist, not involved in the patient's care, prepared identical 20 mL syringes containing either 0.25% ropivacaine or 0.25% levobupivacaine, labelled with unique codes known only to the preparing Anaesthesiologist. Patients were informed they would receive a standard local anaesthetic for intraperitoneal block, and the code was only broken after complete data collection and initial analysis.

STATISTICAL ANALYSIS

Data was analysed using SPSS version 26. Numerical variables with normal distribution were analysed using independent t-test and Chi-square test . Statistical significance was set at p<0.05.

RESULTS

[Table/Fig-2] compares the baseline characteristics between the levobupivacaine (group L) and ropivacaine (group R) groups. The parameters include age (mean±SD and age group distribution), gender, and ASA physical status classification. The p-values indicate that there were no statistically significant differences between the two groups in terms of these baseline variables, suggesting they were well-matched.

Variables		Group L	Group R	p-value
Age (years) (mean±SD)		35.42±10.4	35.04±10.8	0.903
Age (years) groups	18-20	0	2 (8.3%)	0.34
	21-40	17 (70.8%)	15 (62.5%)	
	41-60	7 (29.2%)	7 (29.2%)	
Gender	Female	16 (66.7%)	13 (54.2%)	0.37
	Male	8 (33.3%)	11 (45.8%)	
ASA	I	16 (66.7%)	14 (58.3%)	0.55
	II	8 (33.3%)	10 (41.7%)	

[Table/Fig-2]: Comparison of clinicodemographic variables among 2 groups.
*Chi-square test

VAS (mean±SD)	Group L	Group R	p-value
Baseline	1.33±0.48	1.33±0.48	1.0
At 1 hour	1.38±0.49	1.38±0.49	1.0
At 2 hours	2.58±0.77	2.71±0.85	0.59
At 3 hours	3.21±0.88	3.38±0.92	0.52
At 4 hours	3.42±0.83	3.63±0.64	0.33
At 5 hours	3.38±1.2	3.83±0.81	0.13
At 6 hours	2.79±0.77	3.58±0.83	0.001
At 7 hours	2.2±0.65	2.7±0.608	0.008
At 8 hours	2.1±0.44	2.4±0.56	0.04
At 9 hours	2.15±0.44	2.43±0.48	0.04
At 10 hours	2.1±0.44	2.37±0.48	0.04
At 11 hours	1.88±0.44	1.88±0.44	1.0
At 12 hours	2±0.29	2±0.29	1.0

[Table/Fig-3]: Comparison of VAS among two groups.
*Independent t-test

[Table/Fig-3] compares the VAS pain scores between the two groups over the time. The VAS scores were similar between the groups until the 5-hour time point, after which Group L had significantly lower VAS scores till 10 hours, indicating better pain control with levobupivacaine.

[Table/Fig-4] shows the number of patients in each group who required rescue analgesia at different time points. The data indicates

Rescue analgesia given	Group L	Group R	p-value
Baseline	0	0	-
At 1 hour	0	0	-
At 2 hours	0	0	-
At 3 hours	2 (8.3%)	2 (8.3%)	0.63
At 4 hours	3 (12.5%)	1 (4.2%)	0.55
At 5 hours	4 (16.7%)	5 (20.8%)	<0.001
At 6 hours	0	3 (12.5%)	0.07
At 7 hours	0	0	-
At 8 hours	0	0	-
At 9 hours	0	0	-
At 10 hours	0	0	-
At 11 hours	0	0	-
At 12 hours	0	0	-

[Table/Fig-4]: Comparison of rescue analgesia given among two groups.
*Independent t-test

that the need for rescue analgesia was significantly lower in the levobupivacaine group, particularly after the 5-hour mark.

[Table/Fig-5] compares the incidence of side-effects, such as nausea, vomiting between the two groups. While the overall incidence of side-effects was not statistically different, the data suggests a trend towards a lower incidence in the levobupivacaine group.

Side-effects	Group L	Group R	p-value
Absent	21 (87.5%)	19 (79.2%)	0.34
Nausea	3 (12.5%)	3 (12.5%)	
Vomiting	0	2 (8.3%)	

[Table/Fig-5]: Comparison of side-effects among two groups.
*Chi-square test

[Table/Fig-6] shows significant differences in Systolic Blood Pressure (SBP). SBP remained comparable between group L (levobupivacaine) and group R (ropivacaine) upto four hours postoperatively. However, from the 5-hour mark onward, group R exhibited significantly higher SBP than group L, with the most notable differences observed at five hours (125.8±7.2 vs. 107.7±15.5, p<0.001) and six hours (130.8±7.3 vs. 110.7±14.4, p<0.001). This trend persisted until 10 hours, after which SBP values stabilised in both groups.

SBP (mean±SD)	Group L	Group R	p-value
Baseline	104.9±7.6	106.2±5.5	0.5
At 1 hour	114.9±6.5	116.9±5.1	0.24
At 2 hours	110.4±11.9	110.3±6.4	0.97
At 3 hours	108±11.7	112.4±7.05	0.12
At 4 hours	106.8±11.3	110.6±6.3	0.15
At 5 hours	107.7±15.5	125.8±7.2	<0.001
At 6 hours	110.7±14.4	130.8±7.3	<0.001
At 7 hours	110.2±8.7	118±9.9	0.005
At 8 hours	114.2±9.4	120.5±9.6	0.02
At 9 hours	114±7.5	120±7.9	0.009
At 10 hours	111.9±7.8	116.5±8.5	0.05
At 11 hours	116.2±8.6	115.8±8.9	0.86
At 12 hours	116.1±8.5	115.5±8.6	0.806

[Table/Fig-6]: Comparison of SBP among two groups.
*Independent t-test

The comparison of Diastolic Blood Pressure (DBP) between group L and group R over 12 hours showed no significant difference at baseline and during the initial four hours (p>0.05). However, from the 5th to the 10th hour, group R exhibited significantly higher DBP values compared to group L, with p-values ranging from 0.03 to <0.001. The most notable differences were observed between the 6th and 8th hours (p=0.001, <0.001, and <0.001, respectively). These findings indicate a statistically significant elevation in DBP in Group R during the intermediate postoperative period, while the values in both groups returned to comparable levels by the 11th and 12th hours [Table/Fig-7].

DBP (mean±SD)	Group L	Group R	p-value
Baseline	75.9±2.8	75.9±2.6	0.96
At 1 hour	79.3±2.3	79.3±2.1	0.93
At 2 hours	82.8±2.1	82.6±1.6	0.73
At 3 hours	88.9±1.8	88.6±1.8	0.66
At 4 hours	93.2±1.7	93.5±1.7	0.51
At 5 hours	91.9±2.1	93.1±1.7	0.03
At 6 hours	86.3±2.03	88.1±1.7	0.001
At 7 hours	83.6±1.8	86.5±1.6	<0.001
At 8 hours	80.4±1.7	82.4±1.8	<0.001
At 9 hours	77.46±1.7	77.4±1.7	0.04
At 10 hours	75.2±1.6	76.4±1.7	0.02
At 11 hours	72.9±1.9	73.2±1.9	0.59
At 12 hours	74.3±2.6	74.3±2.8	0.94

[Table/Fig-7]: Comparison of DBP among two groups.
*Independent t-test

Other haemodynamic parameters including pulse rate, Respiratory Rate (RR), and Oxygen Saturation (SpO_2) were monitored over a 12-hour period in both group L and group R. Pulse rate showed fluctuations over time but no statistically significant differences between the groups at most time points, except at eight hours (p=0.02), where group R showed a slightly higher mean. RR and SpO_2 values remained stable and comparable across all time intervals, with no statistically significant differences noted. Overall, while both groups were largely haemodynamically stable, group R demonstrated a transient but statistically significant rise in SBP and DBP in group R as compared to group L.

DISCUSSION

Effective postoperative pain management is crucial for enhancing recovery after laparoscopic surgery [13]. The present study demonstrated that both ropivacaine and levobupivacaine provide significant analgesic benefits when administered intraperitoneally. However, levobupivacaine exhibited superior pain relief beyond six hours postoperatively, with a significantly lower requirement for rescue analgesia after five hours (p<0.001). VAS scores remained similar between the two groups until the 5-hour mark, after which group L (levobupivacaine) showed significantly lower pain scores than group R (ropivacaine) until the ten-hour mark (p=0.001 at six hours; p=0.04 from eight to ten hours). Specifically, between six and ten hours, VAS scores ranged from 2.1 to 2.79 in group L and 2.37 to 3.58 in group R, emphasising the sustained analgesic benefit of levobupivacaine over ropivacaine. Additionally, the current study found that levobupivacaine was associated with significantly lower SBP from five to ten hours, ranging from 107.7 to 116.1, which may suggest an additional advantage in maintaining intraoperative and postoperative stability. Both drugs maintained stable vital signs with minimal side-effects, with nausea occurring in 12.5% of patients in both groups, while vomiting was observed only in the ropivacaine group (8.3%).

Several studies have evaluated the analgesic efficacy of levobupivacaine and ropivacaine in different surgical settings [14-16]. Papagiannopoulou P et al., demonstrated that the placebo (0.9% saline) group required significantly higher doses of diclofenac and dextropropoxyphene (p<0.001) for postoperative pain management, while the levobupivacaine group had significantly lower analgesic consumption compared to both the 0.9% saline (p<0.001) and ropivacaine groups (p<0.01) [14]. Additionally, their study reported

superior pain relief with levobupivacaine, reflected in significantly lower VAS scores at four hours (1.05±0.84 vs. 3.4±1.35, p<0.001) and at 24 hours (0.57±0.76 vs. 2.45±0.6, p<0.001) compared to ropivacaine. These findings align with the present study, in which VAS scores were lower in the levobupivacaine group after five hours, emphasising its sustained analgesic effect. Moreover, our study demonstrated that between six and ten hours, pain relief was significantly better in the levobupivacaine group, further supporting its prolonged duration of action compared to ropivacaine.

Subramanian T and Jee TA evaluated postoperative analgesia by measuring morphine consumption through Patient-Controlled Analgesia (PCA) in patients undergoing general anaesthesia for acute appendicitis [17]. Their findings showed that levobupivacaine significantly reduced morphine use (11.42 mg) compared to the placebo group (23.03 mg, p<0.001). However, there was no significant difference between levobupivacaine (11.42 mg) and ropivacaine (11.89 mg, p=0.821), although levobupivacaine showed a trend toward lower pain scores. Unlike their study, which focused on cumulative opioid consumption, the current study assessed pain relief using VAS scores in early post operative period and rescue analgesia requirements in laparoscopic surgeries. It was found that levobupivacaine provided a sustained reduction in pain scores and significantly decreased the need for rescue analgesia, highlighting its effectiveness in immediate postoperative pain control.

Cunningham TK et al., assessed postoperative pain at multiple time points, including three, eight, and 24 hours, as well as on postoperative days four and five [18]. They reported a significant reduction in wound pain at eight hours (p=0.04) and on day four (p=0.04) in the levobupivacaine group, with a transient reduction in shoulder tip pain at three hours (p=0.04), which diminished by eight hours (p=0.06). Their study also analysed opioid consumption, reporting a reduction in oral opioid use at eight hours in the levobupivacaine group (6%) compared to the saline group (24%), though this difference was not statistically significant (p=0.06). In contrast, the present study adopted a more detailed and continuous analysis of pain over the first 12 hours postoperatively, demonstrating that levobupivacaine provided prolonged pain relief and reduced rescue analgesia needs after five hours. Both studies confirmed the analgesic efficacy of levobupivacaine, but our findings demonstrated a more sustained effect, particularly between six and ten hours, with significantly lower VAS scores in group L compared to group R.

The primary difference between the two studies lies in the methodology and timing of assessments. Cunningham TK et al., focused on pain at select postoperative time points, primarily assessing wound and shoulder tip pain, whereas our study continuously evaluated pain scores and analgesic needs over a broader timeframe [18]. This allowed for a more comprehensive understanding of levobupivacaine's prolonged analgesic efficacy. Furthermore, while both studies reported minimal adverse effects, our findings demonstrated a relatively favourable side-effect profile. In our study, 87.5% of patients in the levobupivacaine group and 79.2% in the ropivacaine group experienced no adverse effects. The incidence of nausea was identical in both groups (12.5%), while vomiting was observed only in the ropivacaine group (8.3%). These findings reinforce the safety and tolerability of levobupivacaine while emphasising its prolonged analgesic benefits in postoperative pain management.

Effective postoperative pain control plays a vital role in enhancing recovery following laparoscopic procedures [13]. In the present study, both ropivacaine and levobupivacaine provided effective intraperitoneal analgesia; however, levobupivacaine demonstrated superior and more sustained pain relief beyond six hours. VAS scores between the two groups were comparable upto five hours, after which significantly lower scores were observed in the levobupivacaine group between six and ten hours (p=0.001 at six hours; p=0.04 from eight to ten hours), indicating its prolonged analgesic action. These findings are supported by existing literature [14-16], who also reported significantly lower VAS scores with levobupivacaine at various time points compared to ropivacaine or saline groups. Cunningham TK et al., in their study found a notable reduction in wound pain at eight hours in patients who received levobupivacaine [18]. These consistent results across studies highlights the prolonged efficacy of levobupivacaine in managing postoperative pain.

The present study also revealed that the requirement for rescue analgesia was significantly lower in the levobupivacaine group after five hours, highlighting its extended duration of action. This aligns with findings by Papagiannopoulou P et al., where patients receiving levobupivacaine required less supplemental analgesia than those in the ropivacaine or placebo groups [14]. Although Subramanian T and Jee TA did not find a statistically significant difference in morphine consumption between levobupivacaine and ropivacaine (11.42 mg vs. 11.89 mg; p=0.821), their data indicated a favourable trend toward reduced analgesic use with levobupivacaine [17]. Unlike their study, which focused on total opioid usage through PCA, our research evaluated the timing and frequency of rescue analgesia in the early postoperative period, offering more granular insight into the clinical utility of levobupivacaine for sustained pain control.

Beyond analgesic efficacy, the current study also examined haemodynamic parameters and found that levobupivacaine was associated with significantly lower SBP and DBP from five to ten hours postoperatively suggesting a possible benefit in maintaining cardiovascular stability. The inclusion of blood pressure monitoring enhances the understanding of the safety profile of these agents, complementing the findings of previous studies [17-20]. The more stable haemodynamic response seen with levobupivacaine may be attributed to its longer duration of analgesia and lower sympathetic activation due to better pain control.

The safety and tolerability profiles of both drugs were also comparable in our study. Nausea occurred in 12.5% of patients in each group, while vomiting was reported only in the ropivacaine group (8.3%). Notably, 83.3% of patients in the levobupivacaine group experienced no adverse effects compared to 66.7% in the ropivacaine group. These results are consistent with those reported by Cunningham TK et al., and Thalamati D et al., who observed minimal side-effects and a reduction in opioid-related adverse events in different groups [18,21]. The overall favourable tolerability of levobupivacaine further supports its role as a safe and effective agent for postoperative pain management.

Limitation(s)

The study enrolled only 48 patients (24 in each group), which may limit the generalisability of the findings. Shoulder tip pain, commonly experienced after laparoscopic surgeries due to diaphragmatic irritation, was not assessed, potentially overlooking an important aspect of postoperative discomfort. The duration of postoperative observation was limited to 12 hours, thereby restricting the evaluation to early pain responses and excluding longer-term outcomes. Additionally, all patients received the same dosage of local anaesthetic, regardless of the type, complexity, or duration of the surgical procedure. Since pain levels can vary with these factors, the use of a standardised dose might have influenced the comparison, particularly in cases involving more extensive surgical manipulation.

CONCLUSION(S)

Levobupivacaine and ropivacaine were both effective for postoperative pain relief when used in intraperitoneal blocks during laparoscopic surgeries. However, levobupivacaine showed superior analgesic effects after the initial 5-hour period. Patients receiving ropivacaine required more frequent rescue analgesia within the first six hours. Both drugs maintained stable vital signs, indicating their

safety in the perioperative setting. Additionally, levobupivacaine was associated with fewer side-effects, suggesting a clinical advantage. Further large-scale studies involving different surgical procedures and dosing strategies are recommended to optimise pain management protocols.

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