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ORIGINAL RESEARCH

A Comparative Study of Intrathecal Dexmedetomidine with Buprenorphine as Adjuvant to Bupivacaine in Spinal Anaesthesia

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ABSTRACT

Background:Aim: To evaluate and compare the following factors in two groups – intrathecal dexmedetomidine and intrathecal buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine for lower abdominal surgeries and lower limb surgeries.

Materials and Methods: A clinical study was undertaken to compare the effects of intrathecal Buprenorphine and dexmedetomidine as additives to 0.5 % hyperbaric bupivacaine for spinal anaesthesia. This prospective, randomized, Double blind study was conducted on 60 adult patients of ASA physical status 1 and 2 in the age group of 18 to 60 years, posted for elective lower abdominal surgeries at Osmania Medical college Hospital, Hyderabad from the period 2017 – 2020. Patients were randomly allocated into two groups namely, Group BB and Group BD of 30 each. Patients in Group BB received 60mcg of Buprenorphine with 0.5% bupivacaine 15mg intrathecally. Patients in Group BD received 5mcg of Dexmedetomidine with 0.5% bupivacaine 15mg intrathecally. After connecting monitors, the required preloading done to all patients. Subarachnoid block was carried out under aseptic precautions. Pulse rate, respiratory rate, arterial blood pressure and oxygen saturation were recorded at 0, 2, 5 minutes and thereafter every 10 minutes up to 90 minutes intraoperatively.

Results: The following parameters were observed - onset and duration of sensory block and motor block, time for sensory regression to S1, degree of sedation, hemodynamic stability and any side effects associated with these drugs. Collected data were analysed using appropriate statistics. Demographic datas were not statistically significant. The onsets of sensory and motor blockades were not statistically significant. The duration of sensory blockade was prolonged in dexmedetomidine group (51%) compared to buprenorphine group. The Motor blockade, sensory regression to S1 were also got prolonged in Dexmedetomidine group Hemodynamic parameters were comparable between the groups. In our study The onsets of sensory and motor blockades were not statistically significance between the groups. The duration of both sensory and motor blockades were prolonged in dexmedetomidine group compared to buprenorphine group with the best statistical significance. Both groups had stable and comparable hemo dynamics during the study. Compared to buprenorphine, intrathecal administration of dexmedetomidine as additive to hyperbaric bupivacaine was associated with fewer side effects.

Conclusion: Our study concludes that dexmedetomidine as an adjuvant to intrathecal bupivacaine prolongs both sensory and motor block duration with fewer side effects compared to buprenophine.

Keywords: Buprenophine, Dexmedetomidine, spinal anaesthesia, Bupivacaine.

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INTRODUCTION

Spinal anaesthesia with local anaesthetic agents is extensively used for lower abdominal surgeries. It provides the excellent pain relief as compared to intravenous or epidural route.

There are many advantages for spinal anaesthesia over general anaesthesia which makes it the anaesthesia of choice in current surgical practice. Many clinical studies support the fact that Postoperative morbidity and mortality may be reduced when neuraxial blockade is used either alone or in combination with general anaesthesia.

Since it decreases the stay, it is cost effective for both patient and hospital. It is suitable for patients with respiratory diseases and helps in preventing intubation related problem like laryngospasm. It is also helpful in maintaining the airway patency and reducing the blood loss.

Early return of gastro intestinal function following surgery can be considered as an added advantage. Other advantage may be reduced hypercoagulable state associated with surgery, increased tissue blood flow due to sympathectomy, decreased splinting which improves oxygenation, enhanced peristalsis, and reduced stress response to surgery due to suppression of neuroendocrine system.[1]

Apart from the theoretical risk of infection to the brain, difficulty in finding the space in old age and bony abnormalities can pose a challenge to the anaesthesiologist. The complications associated with sub arachnoid blockade includes bradycardia, hypotension, prolonged motor block and high spinal is related to the sympatholytic effect of local anaesthetic agents.

If the level of the block is higher, the sympatholytic effect will be more and leads to more serious complications. Though these effects cannot be abolished completely, they can be considerably minimized by using either low dose or low concentration of local anaesthetics.

One of the main disadvantages is the limited duration of block achieved with local anaesthetics. To overcome this, various adjuvants have been tried and used successfully.[2-4]

Buprenorphine is centrally acting lipid analogue of alkaloid THEBAINE. It exhibit analgesic property both at spinal and supra spinal levels.[5]. It has been used for various surgeries at different doses for the past few decades. It has consistently proven to prolong the duration of anaesthesia.[6-8] At higher doses, it causes pruritus, drowsiness, nausea and vomiting.

Dexmedetomidine is a specific α-2 adrenergic agonist.[9] It has been extensively used as premedicant, for sedation in the Intensive Care Unit and for awake fibreoptic intubation

It was first used intrathecally in humans for transurethral resection of prostate. It prolongs both sensory and motor block and has nociceptive action for both visceral and somatic pain. It is being evaluated now as a potential adjuvant to local anaesthetic agents.

This research is designed to study the efficacy of such combination in our setup and compare the results with the previous studies done at other institutions.

Aim & Objectives

To evaluate and compare the following factors in two groups – intrathecal dexmedetomidine and intrathecal buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine for lower abdominal surgeries and lower limb surgeries with respect to:

1. Sensory and motor blockade – Onset and duration.
2. Haemodynamic changes
3. Duration of analgesia
4. Adverse reactions

MATERIALS & METHODS

Study design: Double blinded randomised case control study.

After obtaining approval from the institutional ethical committee, Osmania medical college, Hyderabad, the study was conducted in 60 ASA grade 1 or 2 patients undergoing elective lower abdominal surgeries like Hernia repair, hydrocele, Total abdominal hysterectomy, and lower limb surgeries under spinal anaesthesia. Before including the patients for the study, all patients were explained about the procedures and a written informed consent was obtained.

Inclusion criteria:

1. Adult patients aged 18 - 60 years of either sex
2. ASA 1 and 2 patients.
3. Patients undergoing elective lower abdominal surgeries
4. And lower limb surgeries

Exclusion criteria:

1. Patients with known contraindication for spinal anaesthesia.
2. Patients with coagulation disorders or on anticoagulation therapy.
3. Patients with cardiac disease, heart blocks and dysrhythmias
4. Patients with beta blockers and alpha antagonists

Preoperative preparation:

After routine preoperative assessment at the patients‟ waiting room in the OT, basal line readings of the vital parameters were recorded. Intravenous line started. The patients were randomly allocated into two groups of 30 each by using closed cover technique.

In the operating room, appropriate equipment for airway management and emergency drugs were kept ready. The horizontal position of the operating table was checked. Patients were shifted to the operating room and positioned.

Non-invasive blood pressure monitor, pulse oximeter and ECG leads were connected to the patient. Preoperative baseline systolic and diastolic blood pressure, mean arterial pressure, pulse rate, respiratory rate and oxygen saturation were recorded. Patients were preloaded with 10ml/kg of ringer lactate 15minutes prior to the subarachnoid block. On sitting position, the skin over the back was prepared with antiseptic solution and draped with sterile towel.

BD Group

Patients received 3ml 0.5% bupivacaine (15mg), Dexmedetomidine (5µg) in 0.5 ml normal saline.

BB Group

Patients received 3ml 0.5% bupivacaine(15mg), 0.5ml Buprenorphine (60µg) Total volume of the injected solution was 3.5ml in both groups.

After skin‟s infiltration with 2% lidocaine, 25G Quincke‟s needle was inserted at the L3/4 interspace in the midline. After confirming free flow of CSF, the prepared solution was injected. The patients were made to lie supine immediately after injection and the time at which the spinal anaesthesia performed was noted.

The following parameters were noted:

1. Time of injection of subarachnoid block.
2. Time of onset of sensory block at T8 level.
3. Time of onset of motor block (modified bromage3)
4. Duration of sensory block.
5. Duration of motor block.
6. Duration of analgesia

Mean arterial pressure and pulse rate were recorded at 0, 2nd , 5th ,10th min and thereafter every 10 minutes up to 60 minutes and 90 mins of the procedure.
Hypotension was said to have occurred if the MAP fell less than 60 mmHg and treated with 100% O2, increasing the infusion rate of IV fluids and Inj. Mephentermine in incremental doses of 6mg at interval of 2 minutes.
Bradycardia was defined as heart rate less than 50/min and was planned to be managed with intravenous atropine in incremental doses.
Any discomfort like nausea, vomiting, shivering, pruritus and adverse events such as hypotension, bradycardia respiratory depression and ECG changes were noted.
Vomiting was planned to be managed with Inj.Ondansetron 4mg intravenously.
On completion of surgery, patient was shifted to post anaesthesia care unit for observation. Patients were transferred to postoperative ward after complete resolution of motor blockade and stabilization of blood pressure.
Vital signs and oxygen saturation were recorded until recovery of patients from anaesthesia.
Injection Diclofenac sodium 75mg was given intramuscularly when the patient complained of pain in the postoperative period (rescue analgesic).
Patients were followed up for one week postoperatively for headache, dysaesthesia in thighs, buttocks or lower limbs.

Sensory Block
The onset of sensory block was defined as the time between the injection of anaesthetic solution and the absence of pain at the T8 dermatome. Sensory block was assessed by loss ofsensation to pin prick using 25G sterile needle bilaterally along the midclavicular line. This assessment started immediately after turning the patient to supine position and continued every minute till loss of sensation to pinprick at T8 level was noted.
duration of sensory block was defined as the time between the intrathecal administration of anaesthetic solution and the time for regression of sensory block to S1 level.

Motor Block
Motor block was assessed bilaterally using Modified Bromage scale.
Modified Bromage Scale
0- No block. Able to raise extended legs against gravity.
1- Unable to raise extended legs, but just able to flex knees.
2- Unable to flex knees but able to flex ankles.
3- Total block. Inability to flex ankle/ move leg.

Assessment of motor block was started immediately after turning the patient to supine position and continued every minute till Bromage score of 3 was reached.
Onset of motor block was defined as the time to achieve Bromage score of 3 from the time of intrathecal injection.
Duration of motor block was taken as the time from intrathecal injection to return of Bromage score of 0 (complete recovery).

Duration of Anaelgesia
The duration of effective analgesia was defined as the period from spinal injection to the first occasion when the patient complaints of pain in the postoperative period.

RESULTS
All 60 patients in two groups completed the study without any exclusion. Inter group analysis was done and the results were as followed.

The collected data were analysed by chi square test and results obtained in the form of range, mean and standard deviation.
The probability value „p" of less than 0.05 considered statistically significant.
Patient demographic data that includes age, sex, etc between two groups were comparable.

Table 1: Age distribution

Age group	**Age in years**			
	Group BB		**Group BD**	
	No.	**%**	**No.**	**%**
Below30years	6	20	8	26.7
31 – 40	9	30	6	20
41 – 50	6	20	9	30
Above50	9	30	7	23.3
Total	30	100	30	100
Range	19 – 60 years		18 – 60 years	
Mean	42.33		40.57	
SD	12.88		13.22	
pvalue	0.875 Not significant			

The age distribution was in the range of 18-60 in Group BB and 18-60 in Group BD. The p-value for mean age was not statistically significant (p value = 0.875).

Table 2: Sex distribution

Sex	**Group BB**		**Group BD**	
	No	**%**	**No**	**%**
Male	25	83.3	23	76.7
Female	5	16.7	7	23.3
Total	30	100	30	100
P value	0.752Not significant			

Though male and female ratio is not equal in either group, statistics between the groups for sex distribution was not significant. The p value is 0.752.

Table 3: Time of onset of sensory block

Parameter	**Time of onset of sensory block (in minutes)**	
	Group BB	**Group BD**
Range	3-4	2-3
Mean	3.47	2.57
SD	0.507	0.504
p value	0.629NotSignificant	

The time of onset of sensory block was slower in Group BB (3.47± 0.507) when compared with Group BD (2.57± 0.504) and the p value was statistically not significant (0.629 > 0.05).

Table 4: Time of onset of motor block

Parameter	**Time of onset of motor block (in minutes)**	
	Group BB	**Group BD**
Range	3-5	3-5
Mean	3.83	4.13

SD	0.817	0.78
p value	0.775Not Significant	

The average time taken for the onset of motor block was 3.83 minutes in Group BB and 4.13 minutes in Group BD. It was statistically not significant (p value 0.775 > 0.05).

Table 5: Duration of sensory block

Parameter	**Time of sensory regression to S1 (in minutes)**	
	Group BB	**Group BD**
Range	250-299	389-409
Mean	272.27	398.1
SD	15.39	6.50
p value	0.001 Significant	

The time of sensory regression to S1 was shorter in Group BB (272.27 ± 15.39) when compared with Group BD (398.1 ± 6.50). It was statistically significant (p value = 0.048 < 0.05). There was a delay in sensory regression of approximately 1/3 times (30%) in Group BD comparing to Group BB.

Table 6: Duration of motor block

Parameter	**Duration of motor block (in minutes)**	
	Group BB	**Group BD**
Range	293-360	413-460
Mean	298.63	432.33
SD	35.79	12.74
p value	0.000Significant	

The mean duration of motor block was shorter in Group BB (298.63 ± 35.79) when compared with Group BD (432.33 ± 12.74). It was statistically significant (p value =0.00 < 0.05). The mean duration of motor block in Group BD is about approximately 44% longer than Group BB.

Table 7: Duration of analgesia

Parameter	**Duration of analgesia (in minutes)**	
	Group BB	**Group BD**
Range	303-360	480 – 520
Mean	332	502.13
SD	18.81	12.27
p value	0.005Significant	

The mean duration of analgesia was shorter in Group BB (332 ± 18.81) when compared with Group BD (502.13 ± 12.27). It was statistically significant (p value= 0.00 < 0.05). The mean duration of sensory block in Group BD is approximately 51% longer than Group BB.

Haemodynamic Variables

Table 8: Mean arterial Pressure

Time Interval	**BB Group**	**BD Group**	**P value**
	(Mean ± SD)	**(Mean ± SD)**	
0 min	81.23±10.45	80.17±10.45	0.963

2 min	80.57±13.35	80.90±10.47	0.089
5 min	75.63±14.47	80.33±13.79	0.854
10min	78.60±13.71	83.20±12.63	0.897
20min	75.07±11.96	78.97±12.75	0.337
30min	81.17±13.09	79.53±13.21	0.780
40 min	79.60±10.83	79.60±10.61	0.958
50 min	74.50±10.86	76.97±11.53	0.406
60 min	82.13±12.96	83.47±11.56	0.222
90 min	77.60±10.93	76.43±11.08	0.663

The mean arterial pressure was monitored from preoperative basal to 90thminute of the procedure (10 intervals). None of the intervals had statistical significance.

Table 9: Heart rate

Time Interval	**BB Group (Mean ± SD)**	**BD Group (Mean ± SD)**	**P value**
0 min	78.93±12.21	77.43±9.16	0.035*
2 min	81.47±13.37	74.27±9.13	0.000*
5 min	80.63±12.79	81.07±11.55	0.360
10 min	78.37±13.96	80.33±11.89	0.769
20 min	77.73±15.92	77.80±12.18	0.083
30 min	79.23±13.13	82.40±13.49	0.806
40 min	79.77±12.05	78.57±12.43	0.668
50 min	80.93±12.50	79.87±12.58	0.684
60 min	79.90±11.72	78.17±11.21	0.584
90 min	79.70±12.15	80.73±11.36	0.442

In this study, heart rate less than 50 beats was considered as bradycardia while collecting the data. Heart rate was recorded in 10 intervals, out of which only 2 intervals (0 and 3rd minute) were statistically significant (*).

Table 10: Adverse effects

Adverse effects	**Group BB**		**Group BD**	
	No	**%**	**No**	**%**
Hypotension	8	27	0	0
Bradycardia	6	20	2	7
Shivering	3	10	0	0
Nausea &Vomiting	3	10	0	0
Total caseswithadverseeffects	20*	67	2	7
Total caseswithoutadverse effects	10*	23	28*	93
Total	30*	100	30*	100

* More than one adverse effect was present in one case in each group

In Group BB, 8 patients (27%) had hypotension and received mephentermine

In Group BD, none of the patients had hypotension as an event. But these episodes were not statistically significant.

DISCUSSION

Subarachnoid block with bupivacaine has been most extensively used for lower abdominal surgeries and lower limb surgeries because of its simplicity, speed, reliability and minimal

exposure to depressant drugs. However, a single intrathecal injection of bupivacaine alone provides analgesia for only 2 – 2.5 hours. Most patients require further analgesia during post operative period.

This double blinded, prospective, randomised study was conducted in Osmania medical college, Hyderabad with an aim to compare the effects of intrathecal Dexmedetomidine and Buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine.

The study included 60 patients belonging to the age group of 18-60 years of both sexes of ASA grade 1 and 2 scheduled to undergo elective lower abdominal surgeries and lower limb surgeries.

One of the study drugs, Buprenorphine, a highly lipophilic and centrally acting partial opioid agonist has rapid onset of action following intrathecal administration. It has been found recently that prolonged duration of action of buprenorphine is due to its local anaesthetic action. The lesser side effects in post op period are due to its high lipid solubility.[10] Because of its high lipophilic nature, it diffuses quickly into the neural tissue and decreases the chance of rostral spread.

Another drug in the study, Dexmedetomidine which is a specific α2 adrenergic agonist, being used in recent times as an additive to intrathecal hyperbaric bupivacaine to prolong the quality and duration of analgesia. The mechanism for the prolongation of the duration of sensory and motor blockade produced by dexmedetonidine is not clearly known.[11]

It is attributed that α 2 adrenergic agonist (Dexmedetomidine) acts by binding to post synaptic dorsal horn neurons and to the C- fibres in the pre synaptic region. The prolonged analgesicaction of intrathecal α2 agonist is by decreasing the release of C-fibres neurotransmitters and by causing hyperpolarisation of neurons in the post synaptic dorsal horn.[12]

Even though there are lot of adjuvants, the above mentioned two adjuvants were considered for this study because there were only very few studies in the literature comparing the benefits and side effects of buprenorphine and dexmedetomidine as an adjuvants to bupivacaine for lower limb and lower abdominal surgeries. Also, they are pharmacologically different drugs but their effects are similar in terms of hemodynamic stability, onset of sensory and motor block and adverse effects.[13]

Hala EA Eid et al,[14] studied the effects of dexmedetomidine on a dose related manner (control, 10 µg and 15µg) and confirmed the prolongation of duration of analgesia. Many studies have chosen 5µg of dexmedetomidine as an additive to intrathecal hyperbaric bupivacaine with proven efficacy.[15]

Hence in our study we chose 5µg dexmedetomidine as an additive to hyperbaric bupivacaine. Few studies have been conducted with a higher dosage of buprenorphine.

Mahima gupta et al,[13]and sapkal Praveen S et al,[16]have chosen 60µg of buprenorphine as an additive to intrathecal bupivacaine and showed to have a significant prolonged duration of analgesia along with nausea and vomiting that were not statistically significant.

Onset of Sensory and Motor Block

The mean onset of sensory block in buprenorphine group was 3.47 minutes whereas in dexmedetomidine group it was 2.57 minutes. It was not statistically significant.

The mean onset of motor block in buprenorphine group was 3.83 minutes whereas in dexmedetomidine group, 4.13 minutes. It was not statistically significant.

Though the values of onset of motor blockade is similar to Mahima gupta et al,[13]and others, the onset of sensory blockade of dexmedetomidine group was clinically faster than buprenorphine group in our study which could not be explained.

Duration of Analgesia

Duration of analgesia was taken from the time of intrathecal injection of drugs to the first supplementation of rescue analgesic when patient complained of pain. In our study, the mean duration of analgesia was 332 minutes in buprenorphine group and 502.13 minutes in dexmedetomidine group.

the mean duration of analgesia in the buprenorphine group in the studies conducted by Shaikh and Kiran et al,[8] 475 minutes and 430 minutes respectively which is very high than our study. This gross difference might be explained by the geriatric group of patients in Capogna et al and lower limb surgeries included in Safiya et al as noted by Mahima gupta et al.[13]

The duration of analgesia in the dexmedetomidine group in the study conducted by Mahima gupta et al,[13] was 493 minutes and the study conducted by Shah et al,[11] was 474 minutes. The duration of analgesia was significantly prolonged in the study done by Rajni Gupta et al,[9] (478 minutes). In our study, the mean duration of analgesia was 502.[13] minutes in dexmedetomidine group which was similar to above mentioned studies. Also, the study done by Hala E A Eid et al,[12] showed that duration of analgesia with dexmedetomidine Group was proportional to its dose.

In this study, Dexmedetomidine group had prolonged duration of analgesia compared to Buprenorphine group which was 51% higher than the later.

Mahima Gupta et al,[13] have shown similar results. The prolonged analgesic action of intrathecal α2 agonist is by decreasing the release of C- fibres neurotransmitters and by causing hyperpolarisation of neurons in the post synaptic dorsal horn.[12]

Duration of Motor Block

The duration of motor block was taken from time of intrathecal drug administration to the time taken to attain modified bromage 3. The mean duration of motor block in Buprenorpine group was 298.6 minutes and in dexmedetomidine group was 432.33 minutes (p value 0.00).

This was similar with the study conducted by Mahima gupta et al,[13] where the duration of motor block in dexmedetomidine group was 413.4 minutes and in the study conducted by Rajni Gupta et al,[9] the duration of motor block was 421 minutes.

In our study itself, motor blockade in dexmedetomidine group was about 45% prolonged than Buprenorpine group. Such a prolongation of motor blockade may not be liked by many patients who have undergone surgeries that would end by one hour. In this perspective, Buprenorphine would be a better adjuvant. Also, the duration of pure sensory blockade (after the wear of motor blockade effect) in dexmedetomidine group was twice that of buprenorphine group (70 Vs 34 minutes). Still, Dexmedetomidine is a better drug as it would spare the rescue analgesic requirements.

Time For Sensory Regression to S1

The mean duration for sensory regression to S1 in buprenorphine group was 272.27 minutes and in dexmedetomidine group, 398.1 minutes.

In a study conducted by Mahima gupta et al,[13] the mean duration for sensory regression to S1 in buprenorphine group was 225.9 min which was lower than the same group in our study. But in dexmedetomidine group it was 451.4 min that was higher than the same group in our study.

Subhi M Al-ghanem et al,[17] showed that the mean duration for sensory regression to S1 dermatome was 274.8 minutes in dexmedetomidine group which was lower than our study. This may be because of the higher volume (3 ml) of a hyperbaric solution probably prolonged the regression time comparing to the lower volume (2ml) of isobaric solution in their study.

Rajni gupta et al,[9] have shown that the mean time for sensory regression to S1 was 476 min in dexmedetomidine group which is higher than our study. This may be because either the

usage of higher concentration(0.75%) of isobaric ropivacaine or due to the potentiation of intrathecal ropivacaine by intrathecal dexmedetomidine.

In this purview, in our study dexmedetomidine is superior to buprenorphine in having prolonged duration of sensory block, duration of motor block and anaelgesia.

Haemodynamic Stabilty

Al-Ghanem et al,[17] in their study noted that the use of intrathecal dexmedetomidine to be associated with decrease in blood pressure and heart rate.

In the present study, it was noted 2 cases of bradycardia and nil cases of hypotension in dexmedetomidine group whereas 6 cases of bradycardia and 8 cases of hypotension in buprenorphine group. They were managed successfully with the use of atropine 0.6 mg I.V and inj.mephentermine in incremental doses of 6 mg.

Bradycardia at 0- and 2-minute interval in dexmedetomidine group had the statistical significance.

Mahima gupta et al,[13] in their studies also shown incidence of bradycardia was more in dexmedetomidine group. Dexmedetomidine causes bradycardia but the effect is more prominent when administered intravenously and with a higher dose.[19]

Adverse Events

The incidence of nausea and vomiting were more in buprenorphine group as compared to dexmedetomidine group which is similar to the study conducted by Mahima gupta et al and also observed more number of nausea and vomiting in buprenorphine group. Similar observations were seen by sapkal et al.[16]

Talke et al,[20] in their study observed that α2 adrenergic agents have anti shivering property. In the present study we have not encountered any case of shivering. This is in contrast to Mahima gupta et al,[13] study where the incidence of shivering was more in dexmedetomidine group when compared to buprenorphine group.

CONCLUSION

Our study concludes that dexmedetomidine as an adjuvant to intrathecal bupivacaine prolongs both sensory and motor block duration with fewer side effects compared to buprenophine.

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