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Original Research Article

An evaluation of hyperbaric ropivacaine with magnesium as an adjuvant in lower abdominal surgeries among the north Indian subjects: a double-blind randomized trial

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ABSTRACT

Background: An evaluation of intrathecal hyperbaric ropivacaine without adjuvant and with adjuvant magnesium for lower abdominal surgeries.
Methods: This was a prospective, randomized, double-blind study conducted among the patients aged 18 to 60 years planned for lower abdomen surgeries under spinal anaesthesia and ASA grade I or II. Patients were randomly allocated to two groups (30 in each): ropivacaine Group (R group): spinal anesthesia with 3ml of 0.6% hyperbaric ropivacaine (18mg)+ 0.5ml NS. hyperbaric ropivacaine + Magnesium Group (R+M group): spinal anesthesia with 3ml of 0.6% hyperbaric ropivacaine (18mg) + 0.5ml magnesium sulphate (50 mg). All the patients scheduled for operation were given oral tablets ranitidine 150 mg and Alprazolam 0.25mg in the night before surgery.
Results: There was no significant difference in the basic characteristics between the groups. The mean HR, MAP and SpO2 in both the groups decreased over the periods as compared to baseline. However, the trend of HR over the periods remains similar in both R and R+M groups. The bromage levels were significantly (p=0.0001) higher among the patients of Group R compared with R+M. The 2 segment sensory regression (min), Sensory regression S2 (hr), motor recovery (hrs) and long term mobilization after spinal anesthesia were significantly (p=0.0001) lower among the patients of Group R compared with R+M. The complications were lower in Group R+M than R.
Conclusions: Magnesium may be more suitable drug in surgeries in which muscle relaxation has greater value in lower abdominal surgeries.

Keywords: Abdominal surgeries, Hyperbaric ropivacaine, Magnesium, Spinal anesthesia

INTRODUCTION

Spinal anaesthesia is commonly given for lower abdominal surgeries. Various studies have found spinal anesthesia to be superior to general anaesthesia as it is associated with less blood loss, less need of blood transfusion, less risk of pneumonia, early recognition of signs and symptoms in TURP syndrome, early return of gastrointestinal function following surgeries, blunting of stress response due to surgery, lower incidence of deep vein thrombosis, reduce cost, early ambulation thus reduces the hospital stay.[1,2] It also reduces the perioperative morbidity and mortality in high risk patient with respiratory diseases and old age.[3] It also reduces the amount of analgesics in the immediate post-operative period.

Ropivacaine is the pure s (-) enantiomer of propivacaine and it is the new long-acting amino amide local anaesthetic agent. It produces effects similar to other

local anaesthetics via reversible inhibition of sodium ion influx in nerve fibers. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade. Thus, ropivacaine has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable. The reduced lipophilicity is also associated with decreased potential for central nervous system toxicity and cardio toxicity.[4] Intrathecal use of hyperbaric local anesthetic (LA) agents have become more popular as they produce predictable block characteristics.[5] Presently only isobaric preparations of ropivacaine are commercially available for the reason of difficulty in maintaining the pharmacological stability of hyperbaric solutions for clinical use.

Magnesium is found predominantly in bone but also substantially in muscle and neuronal tissue. It has antinociceptive effects in animal and human models of pain. Its effects are primarily based on physiological calcium antagonism, that is voltage-dependent regulation of calcium influx into the cell, and noncompetitive antagonism of N-methyl-D-aspartate (NMDA) receptors. The safety of intrathecal magnesium has been extensively evaluated in animals and humans. Studies in which intrathecal magnesium was given to various different groups of patients found that none had symptoms suggestive of neurotoxicity, nor did they exhibit signs of systemic toxicity such as hypotension, arrhythmias, somnolence or weakness, during the study.[6] Intrathecal (IT) magnesium 50 mg was found to be safe and effective. The addition of IT magnesium sulphate (50 mg) to spinal anaesthesia induced by bupivacaine and fentanyl significantly delayed the onset of both sensory and motor blockade, but also prolonged the period of anaesthesia without additional side-effects.[7] Addition of magnesium sulphate 50 mg to the intrathecal combination of bupivacaine and fentanyl prolongs the duration of analgesia and reduces postoperative analgesic requirements without additional side effects.[8]

METHODS

This prospective, randomized, double-blind, comparative study was done after obtaining the approval from the institutional ethical committee. The patients who were ASA (Amercian society of anaesthesia) grade I or II, age 18 to 60 years planned for lower abdomen surgeries to be done under spinal anaesthesia were selected in the study. The study was carried in various Surgical Department between August 2011-12, KGMU Erstwhile CSMMU, Lucknow, UP. Informed consent was obtained from all the patients.

The inclusion Criteria were age 18 to 60 years, either Male/Female, ASA grade I, and II, the patient who undergoing lower abdominal surgeries under spinal anesthesia and weight ±20% of ideal body weight. The exclusion criteria were patients for whom central neuraxial block was contraindicated, those with history of adverse reaction to any study medication, cardiovascular diseases, pulmonary diseases, chronic use of cardiovascular medications (β blocker, ACE inhibitor etc), history of analgesic use, chronic pain syndrome, where communication difficulties preventing reliable assessment, history of allergic drugs with study medication and pregnant and lactating females

Patients were randomly allocated to three groups 30 patients in each group using the computer generated random table to one of the following groups:

Ropivacaine Group (control group or R group): spinal anesthesia with 3ml of 0.6% hyperbaric Ropivacaine (18mg)+0.5ml NS.

Magnesium Group (R+M group or M group): spinal anesthesia with 3ml of 0.6% hyperbaric Ropivacaine (18mg) + 0.5ml magnesium sulphate (50 mg).

All patients scheduled for operation were given oral tablets ranitidine 150 mg and Alprazolam 0.25mg in the night before surgery. All patients were nil per orally for 6 hours. After arrival in operating room intravenous access was secured and standard monitoring with noninvasive blood pressure, electrocardiography and pulse oximetry was done. All the patients in the study group were catheterized. Baseline heart rate (HR), Mean arterial pressure and oxygen saturation were recorded.

Drugs were prepared by anaesthetics who were not involved in study after the drug preparation. After taking adequate aseptic preparation drugs were made. Solution for control group was prepared by taking 4ml of 0.75% ropivacaine (30mg) in syringe and mixing it with 1ml of 25% dextrose to make it 0.6% hyperbaric ropivacaine (5ml), 2ml of this solution was discarded 3ml of this 0.6% hyperbaric ropivacaine (18mg) was mixed with ½ ml of 0.9% normal saline to make the final solution of 3.5ml of 0.6% hyperbaric ropivacaine (18mg). The specific gravity of solution was 1.010.

Solution for magnesium group was prepared by taking 4ml of 0.75% ropivacaine (30mg) in syringe number 1 and mixing it with 1ml of 25% dextrose to make it hyperbaric ropivacaine, 2 ml of this solution was discarded. Then in syringe number 2, 2ml of magnesium sulphate 50% w/v was taken and mixed it with 9ml of 0.9% normal saline to make the total volume 10 ml. Now solution contains 100mg magnesium sulpahte per ml, ½ ml of this solution from syringe number 2 is mixed with 3ml of hyperbaric ropivacaine to make the final solution 3.5ml of 0.6% hyperbaric ropivacaine, (18mg) + 50mg of magnesium sulphate. The specific gravity of solution was 1.020.

Patients were preloaded with Lactated ringer solution 10ml/kg body weight in 15 mins. With all aseptic precautions, spinal anaesthesia was given in sitting

position at the level of L2-L3 with 25 G pencil point needle (Pancan, B. Braun, Melsungen, Germany) and the anesthetic solution was injected without barbotage or aspiration at the beginning or at the end of injection. All injections were made with hole in the spinal needle facing upward. The injection was made over a span of 15 seconds and the patients were returned to supine position immediately after completion the block. Sensory and motor assessment methods were described to all patients before starting of anaesthesia. Sensory level was assessed using Pinprick testing in midclavicular bilaterally and time taken to reach T10, T8 and peak sensory level was recorded. Time taken to Two segment sensory regression; time taken to sensory regression at S2 was also recorded.

Motor blockade was determined using Modified Bromage Scale:

1=complete motor blockade; 2=almost complete motor blockade, the patient is able only to move the feet; 3=partial motor blockade, the patient is able to move the knees; 4=detectable weakness of hip flexion, the patient is able to raise the leg but is unable to keep it raised; 5=no detectable weakness of hip flexion, the patient is able to keep the leg raised for 10 s at least; 6=no weakness at all, the patient is able to perform partial knee bend while lying supine. Hemodynamic data, including mean arterial pressure and heart rate were recorded every 2 min in the first 15 min. after spinal anesthesia, then every 5 min. till 90 min. The anesthesiologist recording the data, the surgeon, the patients, and the nursing staff were all blind to patient group assignment. Complications during surgery were treated as Hypotension (defined as a mean arterial pressure of <65 mm Hg) was treated with adequate fluids and increments of 6mg mephentramine, Bradycardia (defined as a heart rate of <50 bpm) was treated with 0.4 mg of atropine, Oxygen desaturation (defined as pulse oximetry oxygen saturation <94% on room air) was treated with oxygen via Hudson's face mask, If a patient complained about discomfort or pain, midazolam and fentanyl by anaesthetics in titrated doses, In the event of inadequate spinal block (defined as pain severe enough to interfere with the surgical procedure, General anesthesia was administered, Nausea/ vomiting was treated by fluid, oxygen and ondansetron 4mg i/v, Shivering was treated by tramadol 0.5mg/kg body weight. In the post-anesthesia care unit, pain was treated with intravenous injection of paracetamol 1000 mg titrated to patient comfort. In case of breakthrough pain, rescue analgesia was given using injection tramadol 25-100mg in titrated dose. The surgeon's and patients's satisfaction was recorded on 5-point Likert scale.

The amount of tramadol administered, paracetamol administered after operation, time to first analgesic dose and the occurrence of any intraoperative or postoperative adverse events, including (but not limited to) nausea, vomiting, itching, respiratory depression (defined as a respiratory rate <12 bpm) and postdural puncture headache, were documented and treated accordingly.

Statistical analysis

Continuous data were summarized as Mean±SD while discrete (categorical) in %. The primary outcome measures (HR, MAP and SpO2) of two groups over the periods (time) were compared by repeated measures two factor (Groups and Periods) analysis of variance (ANOVA) using general linear models (GLM) followed by Tukey's post hoc test. Groups were compared by unpaired t-test. The categorical variables were compared by chi-square ($\chi 2$) test. A two-sided ($\alpha=2$) $p<0.05$ was considered statistically significant. All analyses were performed on STATISTICA (window version 6.0).

RESULTS

The basic characteristics viz. age, gender, weight, height and ASA grade of the two groups at admission (baseline) are summarized in Table-1. There was no significant difference in the basic characteristics between the groups.

Table 1: Basic characteristics of three groups.

Characteristics	Group R (n=30)	Group R+M (n=30)	p value
Age (years)	43.10±11.24	42.43±12.74	0.83
Sex			
Males	20 (66.7%)	21 (70.0%)	0.78
Females	10 (33.3%)	9 (30.0%)	
Height (cm)	159.13±8.69	157.83±8.94	0.57
Weight (kg)	62.53±6.17	61.80±4.92	0.61
ASA physical status			
I	23 (76.7%)	25 (83.3%)	0.638
II	7 (23.3%)	5 (16.7%)	

The mean HR in both the groups decreased over the periods as compared to baseline. However, the trend of HR over the periods remains similar in both R and R+M groups (Figure1).

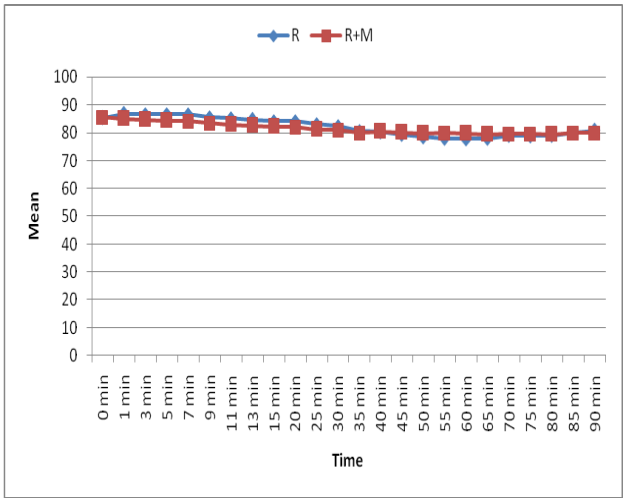

Figure 1: Mean heart rate at different time.

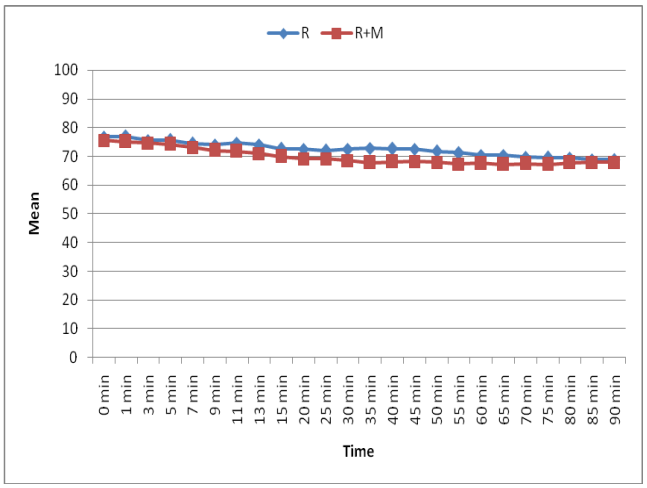

Figure 2: Mean MAP rate at different time.

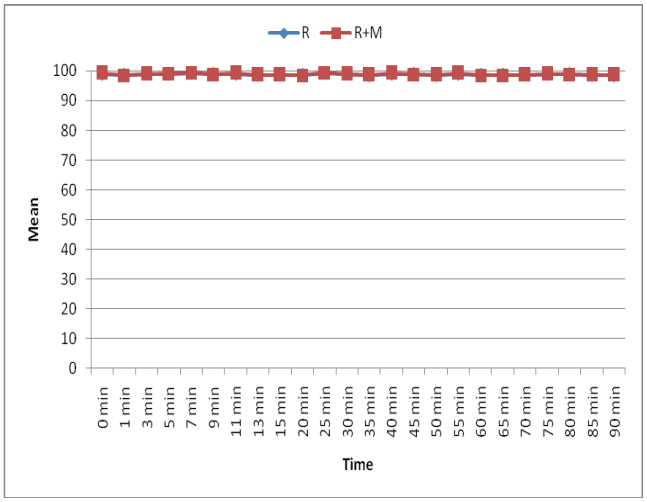

Figure 3: Mean SpO2 rate at different time.

The mean MAP and SpO2 in both the groups also decreased over the periods as compared to baseline (Figure 2 and 3).

The onset sensory levels were significantly (p=0.0001) higher among the patients of Group R compared with R+M. The bromage levels were significantly (p=0.0001) higher among the patients of Group R compared with R+M.

The 2 segment sensory regression (min), Sensory regression S2 (hour), Motor recovery (hours) and long term mobilization after spinal anesthesia were significantly (p=0.0001) lower among the patients of Group R compared with R+M. The surgeon's and patient's satisfaction were higher in Group R+M than Group R (Table-2). The complications were lower in Group R+M than R (Table-3).

DISCUSSION

This prospective, randomized, double-blind, comparative study was done on the patients who were ASA grade I or II age 18 to 60 years planned for lower abdomen surgeries to be done under spinal

anaesthesia. In this study, we have taken 18 mg of hyperbaric ropivacaine because it is safe in spinal anaesthesia and does not cause major side effect, improves the quality and prolong the duration of analgesia, early mobilization as in a study the addition of fentanyl 25 mg to hyperbaric ropivacaine 18 mg for spinal anesthesia in patients undergoing TURP may significantly improve the quality and prolong the duration of analgesia, without causing a substantial increase in the frequency of major side-effects.[9]

Bigat Z et al, found that that 10 mg of 0.66% hyperbaric ropivacaine is preferred to 7.5 mg of 0.5% hyperbaric bupivacaine because it provides a more selective unilateral block and a faster recovery in outpatient knee arthroscopy.[10] Fettes et al also observed that addition of glucose 50 mg/ ml to ropivacaine 5 mg/ ml increases the speed of onset, block reliability, duration of useful block for perineal surgery, and speed of recovery. Plain solutions are less reliable for surgery above a dermatome level of L1.[11]

In our study, we have taken 50 mg intrathecal magnesium sulphate because this dose is safe in spinal anesthesia without additional side effects, prolongs the duration of analgesia and reduces postoperative analgesic requirements. Jabalameli et al, found that that addition of 50 mg magnesium sulfate provides safe and effective anesthesia, but 75 mg of this drug was enough to lead a significant delay in the onset of both sensory and motor blockade, and prolonged the duration of sensory and motor blockade, without increasing major side effects.[12]

In these studies, we observed that there was significantly ($p<0.001$) decrease in mean arterial pressure and heart rate in magnesium group in comparison to R

(ropivacaine) group but patients were hemodynamically stable. In the present study, both the groups had significantly (p<0.001) decrease in HR and mean arterial pressure in comparison to baseline over a period. This decrease in heart rate was higher in magnesium group in comparison to ropivacaine group. This finding was similar to study conducted by Sultan et al.[13]

Table 2: Secondary outcome measures summary (Mean±SD, n=30) of three groups.

Secondary outcome measures	Group R	Group R+M	p value[1]
Onset sensory level			
T10	5.17±0.87	3.20±0.55	0.0001*
T8	7.17±0.87	4.80±0.81	0.0001*
T6	10.43±1.41	6.80±1.00	0.0001*
T4	13.30±2.26	9.10±1.65	0.0001*
Bromage			
B1	12.43±2.11	10.53±1.50	0.0001*
B2	9.13±0.94	7.67±0.96	0.0001*
B3	6.43±0.94	5.33±0.88	0.0001*
B4	3.87±0.57	2.97±0.56	0.0001*
B5	2.30±0.53	1.77±0.50	0.0001*
B6	0.73±0.74	0.50±0.51	0.16
2 segments sensory regression (min)	28.43±2.21	36.40±2.01	0.0001*
Sensory regression S2 (hour)	2.03±0.39	3.53±0.57	0.0001*
Motor recovery (hours)	1.83±0.37	3.29±0.54	0.0001*
Long term mobilization after spinal anesthesia (hours)	2.28±0.41	4.44±0.54	0.0001*
Total amount of vasopressor given (mephentremine) (mg)	9.33±3.16	7.20±2.68	0.22
Total amount of atropine given (mg)	0.48±0.04	0.43±0.06	0.17
Surgeon's satisfaction for intra-operatively sedation analgesia and motor blockade (7 point likert like verbal rating scale)	3.47±0.51	5.30±0.47	0.0001*
Patient's satisfaction for intra-operatively sedation analgesia and motor blockade (7 point likert like verbal rating scale)	3.60±0.50	5.17±0.38	0.0001*

1Unpaired t-test, *Significant.

Table 3: Distribution of complications of three groups.

Complications	R (n=30)	R+M (n=30)	p value
Nausea	3 (10.0%)	1 (3.3%)	0.30
Vomiting	4 (13.3%)	1 (3.3%)	0.16
Postdural puncture headache	0 (0.0%)	0 (0.0%)	NA
Hypotension	8 (26.7%)	5 (16.7%)	0.34
Bradicardia	6 (20.0%)	3 (10.0%)	0.27
Respiratory depression	0 (0.0%)	0 (0.0%)	NA
Urinary retension	0 (0.0%)	0 (0.0%)	NA
Itching	0 (0.0%)	0 (0.0%)	NA
Shivering	5 (16.7%)	0 (0.0%)	NA
Long term complications in follow up of patients (6 weeks to 6 months)	0 (0.0%)	0 (0.0%)	NA

This study observed that there was no significant (p>0.05) difference in SpO2 in all the groups. Jabalameli et al, found that the addition of 50, 75, or 100 mg magnesium sulfate provides safe and effective anesthesia intrathecally without increasing major side effects.[12] Our study shows significantly (p<0.001) rapid onset of peak sensory and motor blockade in magnesium group in comparison to ropivacaine group (p<0.001). It might be because we have used hyperbaric ropivacaine and following studies used hyperbaric bupivacaine.

It was in contrast to following studies. In a study among the patients undergoing lower extremity surgery, the addition of IT magnesium sulphate (50 mg) to spinal anaesthesia induced by bupivacaine and fentanyl significantly delayed the onset of both sensory and motor blockade.[7] In another study, 75 mg of intrathecal

magnesium sulphate was enough to lead a significant delay in the onset of both sensory and motor blockade, and prolonged the duration of sensory and motor blockade, without increasing major side effects.[12]

In these studies, we also found addition of magnesium causes significant ($p<0.001$) prolongation of two segments sensory regression (S2) in comparison to control group. Dayioğlu et al, found that the addition of intrathecal magnesium (50 mg) to spinal anesthesia prolonged the time for regression of two segments in the maximum block height and time to L2 regression. Jabalameli et al, observed that 75 mg of intrathecal magnesium sulphate was enough to lead a significant delay in the onset of both sensory and motor blockade, and prolonged the duration of sensory and motor blockade, without increasing major side effects. In the present study, it was observed that two segment sensory regression was significantly ($p<0.001$) higher in magnesium group in comparison to control group.[12,14]

Authors observed addition of magnesium sulphate significantly ($p<0.001$) delays the time taken for sensory regression S2 and complete motor recovery in comparison to control group and prolongs the duration of sensory and motor blockade and delays in mobilization compared with ropivacaine group. Ozalevli et al, found that addition of IT magnesium sulphate to bupivacaine-fentanyl in spinal anaesthesia results in prolonged duration of sensory and motor blockade. Dayioğlu et al, concluded that addition of intrathecal 50 mg magnesium sulfate with 6mg bupivacaine 0.5% results in prolong time to ambulation.[7,14] Overall in these study we observed there is significantly ($p<0.001$) high duration of sensory and motor blockade in magnesium group in comparison to ropivacaine group.

Malleeswaran et al, studied the effect of adding intrathecal magnesium sulphate to bupivacaine-fentanyl spinal anaesthesia in patients with mild preeclampsia undergoing caesarean section and concluded that, the addition of magnesium sulphate 50 mg to the intrathecal combination of bupivacaine and fentanyl prolongs the duration of analgesia and reduces postoperative analgesic requirements without additional side effects. In this study, authors observed that total amount of atropine and vasopressor (mephentrimine) given to patients was least in magnesium group.[8]

It is now, well-established that physical properties such as specific gravity, density and baricity of drug related to cerebrospinal fluid (CSF) determines the intrathecal spread of the drug, compared with plain solutions. Khaw et al, compared plain and hyperbaric ropivacaine for cesarean delivery in a dose of 25 mg with or without glucose 8.3% intrathecally. They observed faster onset and recovery, extensive spread and greater success rates with hyperbaric ropivacaine. They observed specific gravity of plain ropivacaine 1.0092 and that of hyperbaric ropivacaine to be 1.0345 at 37°C.[15]

Kulkarni et al, observed that bupivacaine ropivacaine group had good sensory block, favorable recovery profile of sensory/motor blockade and shorter time to first micturition. Ropivacaine is less lipophilic than bupivacaine and that, together with its stereo selective properties, contributes to ropivacaine having a significantly higher threshold for cardiotoxicity and CNS toxicity than bupivacaine in animals and healthy volunteers.[16,17] The lower lipophilicity of ropivacaine versus bupivacaine correlated with the lesser cardio depressant effects of both ropivacaine isomers than of the bupivacaine isomers in animal studies.[16]

In these studies, authors observed nausea, vomiting and shivering in all the groups but significantly ($p<0.001$) high in ropivacaine group. Incidence of vomiting was lower in magnesium group than ropivacaine group. Christopher Lysakowski et al, concluded that Perioperative magnesium supplementation prevents postoperative hypomagnesaemia and decreases the incidence of postoperative shivering.[18] Qian et al, concluded incidence of shivering and vomiting were high in ropivacaine group compared with ropivacaine sufentanil group.[19] In these study, authors observed that surgeons and patient satisfaction for intra operative sedation analgesia and motor blockade significantly higher in magnesium group as compared to ropivacaine group.

CONCLUSION

Magnesium is a better alternative drug and hemodynamic changes requirement of atropine; vasopressor requirement is less with magnesium. It is a good option for patients in whom less hemodynamic variations are needed like geriatric patients.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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