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A randomized and clinical study comparing spinal anesthesia with hyperbaric bupivacaine with fentanyl and hyperbaric ropivacaine with fentanyl in cesarean sections

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ABSTRACT

Background: Hyperbaric bupivacaine (0.5%) is usually effective for spinal anesthesia and is being increasingly used in cases of patients undergoing lower segment cesarean section under neuraxial block. Addition of fentanyl to local anesthetic drugs such as bupivacaine and ropivacaine is associated with reduced doses of local anesthetic agents thereby decreasing side-effects of local anesthetic drugs. **Aims and Objectives:** The objectives of the study are as follows: (1) To compare the efficacy of with hyperbaric bupivacaine with fentanyl and hyperbaric ropivacaine with fentanyl in patients undergoing cesarean section. (2) To compare the side effects in both the groups. **Materials and Methods:** Patients were divided into two groups depending on whether they received hyperbaric bupivacaine with fentanyl (Group BF) or hyperbaric ropivacaine with fentanyl (Group RF). The onset and duration of motor as well as sensory blockade and duration of analgesia was noted. Hemodynamic parameters such as heart rate (HR) and systolic as well as diastolic pressure, respiratory rate, and SPO_2 were monitored. APGAR score at 1 min and 5 min was analyzed to know immediate neonatal outcome. Post-operative pain and adverse effects were compared in both groups. **Results:** Mean time for achieving highest level of sensory analgesia and duration of motor block and analgesia was found to be statistically significantly less in RF group as compared to BF group. Comparison of HR, SPO_2, and respiratory rates showed that these parameters were comparable in both the groups with no statistically significant difference ($P>0.05$). The mean systolic and diastolic blood pressures of BF group were lower as compared to RF group and the difference was found to be statistically significant ($P<0.05$). At 4 h and 6 h postoperatively, the severity of pain was found to be less in RF group as compared to BF group and the difference was found to be statistically significant ($P<0.05$). Overall incidence of side effects was found to be comparable in both the groups ($P<0.05$). **Conclusion:** Hyperbaric ropivacaine with fentanyl is a better alternative to hyperbaric bupivacaine with fentanyl in ASA II patients undergoing cesarean section.

Key words: Bupivacaine; Fentanyl; Hemodynamic stability; Ropivacaine; Visual analogue scale score

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INTRODUCTION

Caesarean sections are being increasingly done for maternal as well as fetal indications. The common indications for cesarean section include maternal indications such as cephalopelvic disproportion, chorioamnionitis, non-progression or obstructed labor, and previous caesarean sections.[1] The usual fetal indications include large for gestational age fetus, unfavorable lie, and fetal distress due to any cause. Lower segment cesarean section

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(LSCS) is routinely done under spinal anesthesia except in cases where either spinal anesthesia is contraindicated (such as patient refusal, injection site infections, severe thrombocytopenia, and uncorrected hypovolemia) or when LSCS under general anesthesia is indicated (such as in cases of emergency cesarean section where time for neuraxial block is not available and in cases where spinal anesthesia is contraindicated).[2] Spinal anesthesia is preferred over general anesthesia due to its easy technique, quick onset, and absence of complications associated with intubation.[3]

Bupivacaine, ropivacaine, and mepivacaine are the common drugs used for spinal anesthesia. The less commonly used drugs for spinal anesthesia for cesarean section include procaine, chloroprocaine, and lidocaine.[4] Hyperbaric bupivacaine (0.5%) is usually effective for spinal anesthesia and is being increasingly used in cases of patients undergoing LSCS under neuraxial block. Although usually considered safe, hyperbaric bupivacaine in some cases may cause sudden cardiac arrest due to extension of sympathetic blockade.[5]

Ropivacaine is another amide anesthetic agent which is similar to bupivacaine in pharmacodynamic qualities; however, it has a remarkable degree of separation, as compared to bupivacaine, as far as motor and sensory blockades are concerened.[6] Although many studies have found ropivacaine less potent than bupivacaine, one of the distinct advantages of ropivacaine over bupivacaine is that it does have a significantly less central nervous system affection and cardiotoxicity.[7]

Addition of low doses of opioids, such as fentanyl, as an adjuvant to local anesthetic drugs has become a standard anesthetic practice. Addition of fentanyl to local anesthetic drugs such as bupivacaine and ropivacaine is associated with reduced doses of local anesthetic agents thereby decreasing side-effects of local anesthetic drugs.[8] In cases of drugs such as bupivacaine which are known to cause central nervous system as well as cardiotoxicity, this become all the more important to reduce side effects. Addition of fentanyl to local anesthetic drugs such as bupivacaine and ropivacaine is reported to be not only effective in reducing the side effects but also causes enhanced analgesia thereby reducing the need for rescue analgesia.[9] Optimum analgesia in perioperative as well as post-operative period is an important aspect of maternal as well as neonatal well-being. Suboptimal analgesia may be associated with maternal as well as neonatal consequences. Pain in post-operative period may cause maternal effects such as poor control of blood pressure in cases of pre-eclampsia and failure or difficulty in establishment of breast feeding with its consequences in newborn baby such as neonatal hypoglycemia and hyperbilirubinemia.[10]

We conducted this study to compare the duration of action and onset as well total duration of sensory and motor blockade and hemodynamic parameters of patients undergoing LSCS and receiving equipotent doses of bupivacaine with fentanyl and ropivacaine with fentanyl. Maternal side effects and fetal outcome were also studied.

Aims and objectives

The objetives of the study are as follows:
(1) To compare the efficacy of with hyperbaric bupivacaine with fentanyl and hyperbaric ropivacaine with fentanyl in patients undergoing cesarean section. (2) To compare the side effects in both the groups.

MATERIALS AND METHODS

This was a comparative study conducted in the Department of anaesthesiology in Department of anaesthesiology FH Medical College, Etmadpur, Agra. Total 80 patients undergoing elective LSCS were included in this study on the basis of a predefined inclusion and exclusion criteria. The duration of the study was 12 months extending from January 2021 to December 2021. The Institutional Ethical Committee duly approved study. An informed and written consent was obtained from all the patients. Sample size calculation was done on the basis of pilot studies done for LSCS under spinal anesthesia. Keeping power (1-Beta error) at 80% and confidence interval (1-alpha error) at 95%, the minimum sample size required in each group was 60 patients; therefore, we included 80 patients (more than minimum required number of cases). Using simple random sampling method, patients were divided into two groups.

- Group BF: Received 10 mg hyperbaric bupivacaine with 20 microgram fentanyl
- Group RF: Received 15 mg hyperbaric ropivacaine with 20 microgram fentanyl.

A detailed history was obtained from all the patients with a particular emphasis to find out the indication for cesarean section, history of any surgery, and to exclude the possibility of any drug allergy. A thorough general as well as systemic examination was done including general as well as systemic examination to rule out presence of any systemic illness. Basic investigations such as complete blood count, coagulation profile, HBsAg, and HIV were done in all the cases if not already done. All patients were kept nil by mouth before surgery according to standard protocol. After shifting to the operation theater, venous access was secured with 20 G intracath and 500 ml ringers' lactate was started. Bladder catheterization was also done. Continues ECG monitoring, SPO_2, and non-invasive blood pressure monitoring were started. Spinal anesthesia was given using standard practice. All patients received 500 ml Ringer's lactate

and first dose of third generation of cephalosporin before giving spinal anesthesia. Patients either received bupivacaine and fentanyl or ropivacaine and fentanyl depending on the group they belonged. The onset and duration of motor as well as sensory blockade and duration of analgesia were noted. Hemodynamic parameters such as heart rate (HR) and systolic as well as diastolic pressure, respiratory rate, and SPO_2 were monitored. APGAR score at 1 min and 5 min was analyzed to know immediate neonatal outcome. Visual analog scale (VAS) score was determined, every 5 min then every 30 min up to 5 h, to assess severity of post-operative pain. The incidence of complications such as hypotension, bradycardia, nausea, vomiting, and shivering was noted.

Statistical analysis was done using SSPS 21.0 software. For quantitative data, unpaired t-test was used and for qualitative data, Chi-square test was applied. $P<0.05$ was taken as statistically significant.

Inclusion criteria

The following criteria were included in the study:

1. Those consented to be part of study and gave written consent
2. All patients undergoing elective cesarean section for any indication
3. ASA Grade II patients.

Exclusion criteria

The following criteria were excluded from the study:

1. Those who refused consent
2. ASA Grade III or Above
3. Patients in whom spinal anesthesia was contraindicated
4. Pre-operative hemodynamic instability, maternal heart disease, and severe anemia
5. History of allergy to local anesthetic or opioids.

RESULTS

The comparison of age, gender distribution, weight, height, and body mass index showed that all these parameters were comparable in both the groups. All the patients belonged to ASA Grade II as ASA Grade III and above were exclusion criteria. Duration of surgery was also found to be comparable in both the groups with no statistically significant difference ($P>0.005$) (Table 1).

The analysis of indications for cesarean section showed that the most common indication for LSCS in studied cases was fetal distress (18.75%) followed by cephalopelvic disproportion (12.5%), breech presentation (11.25%), failed induction (11.25%), premature rupture of membranes (8.75%), and non-progression of labor (8.75%) (Figure 1).

Patients in both the groups were analyzed for the difference in mean time for onset of sensory block, onset of motor block, maximum time taken for highest level of sensory analgesia, duration of motor block, and degree of motor block. Onset of sensory as well as motor blockade was found to be comparatively less in BF group as compared to RF and the difference was found to be statistically highly significant ($P<0.005$). Mean time for achieving highest level of sensory analgesia and duration of motor block and analgesia was found to be statistically significantly less in RF group as compared to BF group (Table 2).

Comparison of HR, SPO_2, and respiratory rates showed that these parameters were comparable in both the groups with no statistically significant difference ($P>0.05$). The mean systolic and diastolic blood pressures of BF group were lower as compared to RF group and the difference was found to be statistically significant ($P<0.05$) (Figures 2-6).

The comparison of mean VAS scores in post-operative period till 8 h postoperatively showed that there was no pain in patients of either group till 150 min after surgery. At 3 h, patients in Group BF were found to have less severe pain as assessed by VAS scores as compared to patients in Group RF but the difference was found to be statistically "not significant" ($P=0.224$). However, at 4 h and 6 h postoperatively, the severity of pain was found to be less in RF group as compared to BF group and the difference was found to be statistically significant ($P<0.05$). At 8 h postoperatively, the VAS scores were found to be comparable with no statistically significant difference ($P=0.424$) (Table 3).

Side effects in the form of nausea and vomiting, bradycardia, hypotension, respiratory depression, and pruritus were compared in both the groups (Figure 1). Respiratory depression was not seen in any patient in any of the groups. Although the incidence of nausea and

Table 1: Physical characteristics, ASA grades, and duration of surgery in studied cases

Characteristics	Group B (%)	Group R (%)	P-value
Mean age (years)	23.48±3.12	24.68±3.46	0.071 (Not Significant)
ASA Grade II	40 (100)	40 (100)	1 (Not Significant)
Weight (kg)	61.34±6.26	59.23±5.28	0.0715 (Not Significant)
Height (cm)	152.61±5.26	154.23±4.54	0.102 (Not Significant)
BMI (kg/m^2)	24.10±1.54	24.32±1.62	0.488 (Not Significant)
Duration of surgery (minutes)	58.12±6.12	56.20±4.92	0.087 (Not Significant)

vomiting as well as hypotension and bradycardia was seen in a greater number of patients in Group BF as compared to Group RF, the overall incidence of side effects was found to be comparable in both the groups (P>0.05) (Figure 7).

Immediate neonatal outcome was assessed by estimation of APGAR score at 1 and 5 min in neonates. The mean APGAR score at 1 and 5 min in Group BF and Group RF was found to be 8.3±0.42 and 9.0±0.25, respectively. In Group II, mean APGAR score at 1 and 5 min was found to be 8.3±0.53 and 9.8±0.40. The comparison of mean APGAR scores in both the groups showed that there was no statistically significant difference in both the groups (Table 4).

DISCUSSION

Bupivacaine as well as ropivacaine both are long-acting amide group local anesthetic agents commonly used for spinal anesthesia in various surgeries. Bupivacaine had been very popular for various surgeries given its long-acting local anesthetic profile. Its use, however, is associated with side-effects including central nervous system and neurotoxicity.[11] Ropivacaine in comparison is found to have a better safety profile and less likely to produce side effects such as urinary retention, bradycardia, and hypotension. Ropivacaine, as compared to bupivacaine, is less lipophilic and is known to not penetrate large myelinated motor fibers, causing a reduced motor blockade.[12] Ropivacaine is associated with comparatively better profile as far as cardiotoxicity and central nervous system affection is concerned. Moreover, it produces less motor block and equally effective, if not better, analgesia as bupicaine.[13] Given all these properties, ropivacaine is being increasingly preferred over bupivacaine for various surgeries under spinal anesthesia.

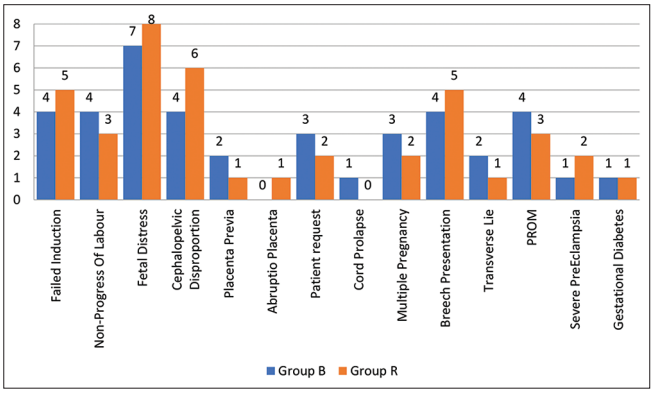

Figure 1: Indications for the lower segment cesarean section in studied cases

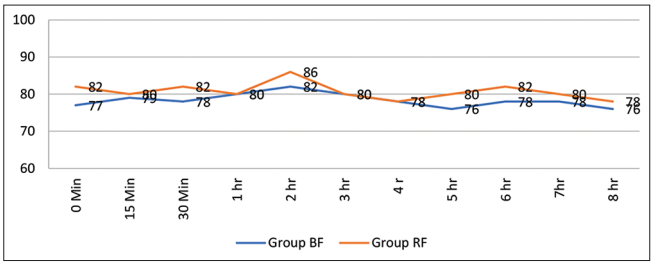

Figure 2: Comparison of mean heart rates in the studied groups

Onset of sensory as well as motor blockade was found to be comparatively less in BF group as compared to RF and the difference was found to be statistically highly significant (P<0.005). Mean time for achieving highest level of sensory analgesia and duration of motor block and analgesia was found to be statistically significantly less in RF group as compared to BF group.

Kulkarni and Patil conducted a study to compare the effect of ropivacaine-fentanyl and bupivacaine-fentanyl for labor analgesia.[14] For this purpose, the authors included 60 parturients who were divided into two groups of 30 subjects each. Group I received 10 ml of bupivacaine 0.1%+fentanyl 2 μg/ml and Group II received 10 ml of ropivacaine 0.1%+fentanyl 2 μg/ml by epidural catheter. The baseline and post-anesthesia systolic, diastolic blood pressure, HR, VAS score, degree of motor block, sedation, and APGAR score of the baby were recorded. The authors found that there was no significant difference in systolic/diastolic blood pressure in two groups except at 360 min where diastolic pressure was low in Group II. Significantly higher HR at 30 min (P=0.0003), 120 min (0.006), and 300 min (P=0.001) was observed in Group I subjects. VAS score was significantly less at 180 min (P=0.019) and 300 min (P=0.019) in Group II. Adverse effects such as fetal bradycardia, nausea/vomiting, and hypotension

Table 2: Mean time of onset of sensory and motor block, mean time for achieving highest level of sensory analgesia, and duration of analgesia and motor block

Parameters	Group BF	Group RF	P-value
Onset of Sensory block (sec)	152.8±16.62	186.32±22.16	<0.0001 (Significant)
Onset of motor block (sec)	324.2±30.12	362.54±38.24	<0.0001 (Significant)
Mean time taken to achieve highest level of sensory analgesia (sec)	334.33±24.54	382.68±28.62	<0.0001 (Significant)
Mean time to sensory regression (min)	132.54±10.18	98.12±8.62	<0.0001 (Significant)
Duration of motor block (min)	182.08±22.62	122.8±16.46	<0.0001 (Significant)
Duration of analgesia (min)	278.92±42.36	184.68±32.10	<0.0001 (Significant)

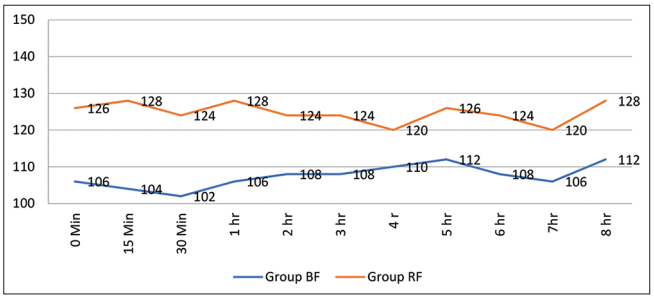

Figure 3: Comparison of systolic blood pressure in both the groups

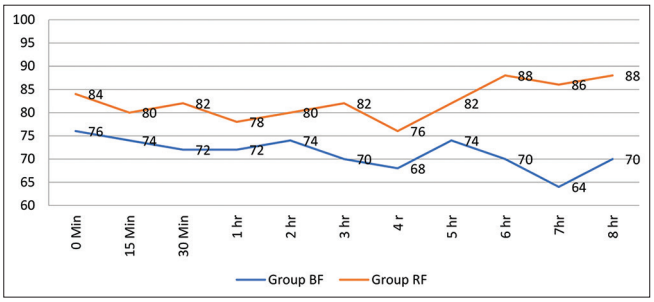

Figure 4: Comparison of diastolic blood pressure in both the groups

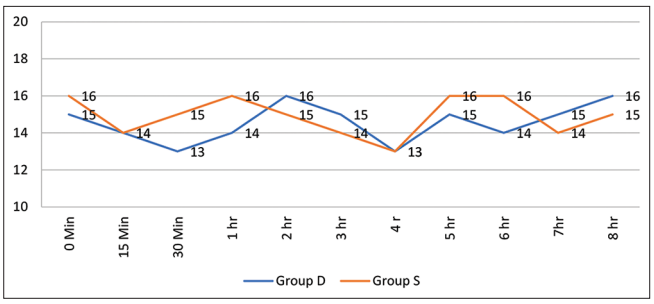

Figure 5: Comparison of respiratory rates in studied cases

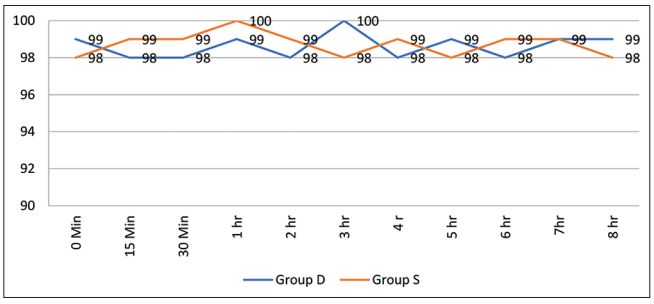

Figure 6: Comparison of SPO_2 in studied cases

observed were clinically insignificance when compared in two groups. On the basis of these findings, the authors concluded that ropivacaine can be used as a safe alternative to bupivacaine for labor epidural analgesia. Similar safety profile of ropivacaine was also reported by the authors such as Guo et al.,[15] and Danelli et al.[16]

In our study, comparison of HR, SPO_2, and respiratory rates showed that these parameters were comparable in both the groups with no statistically significant difference (P>0.05). The mean systolic and diastolic blood pressures of BF group were lower as compared to RF group and the difference was found to be statistically significant (P<0.05). This shows that bupivacaine has a more profound effect on hemodynamics as compared to ropivacaine. Olapour et al., conducted a study to compare clinical efficacy and safety between ropivacaine and bupivacaine during cesarean section.[17] In this study, 65 women undergoing elective cesarean delivery under spinal anesthesia were randomly allocated to receive either ropivacaine 1% (n=33) or bupivacaine 0.5% (n=32). Afterward, the differences in the anesthetic efficacy, vital signs, and hemodynamics of participants between the two groups were recorded. The authors found that duration of sensory block was shorter in the ropivacaine group than bupivacaine group (132.5±21.6 min vs. 175.8±26.2 min; P<0.001). Ropivacaine also produced a shorter duration of motor blockade than bupivacaine (124.8±20.2 min vs. 168.2±21.7 min; P<0.001). There was no difference between the two groups in terms of systolic and diastolic blood pressure, but the HR of patients in the bupivacaine group was significantly higher than the ropivacaine group. On the basis of these findings, the authors concluded that ropivacaine is a better choice due to little influence on the hemodynamics and shorter duration of sensory block and motor block which are useful for the recovery and also safe to the patients. Similar findings were also reported by the authors such as Diedhiou et al.,[18] and Memon and Pathak.[19]

Table 3: Comparison of mean VAS scores in studied cases

Time	Group BF	Group RF	P-value
Immediate post-operative period	00	00	--
30 Min	00	00	--
60 Min	00	00	--
90 Min	00	00	--
120 Min	00	00	--
150 Min	00	00	--
180 Min	1.22±0.48	1.36±0.54	0.224 (Not Significant)
4 h	2.12±0.64	2.92±0.72	<0.05 (Significant)
6 h	4.12±0.44	4.64±0.46	<0.05 (Significant)
8 h	5.12±1.10	5.34±1.34	0.424 (Not significant)

VAS: Visual analog scale

Table 4: Comparison of mean APGAR scores in studied cases

APGAR	Group I	Group II	P-value
APGAR at 1 min	8.9±0.44	9.05±0.49	0.153 (Not significant)
APGAR at 5 min	9.30±0.41	9.33±0.55	0.78 (Not Significant)

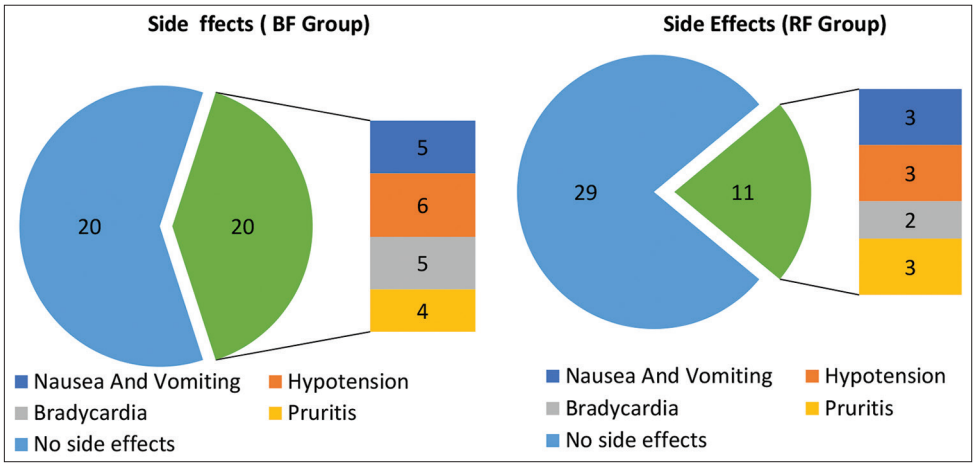

Figure 7: Side effects in BF and RF group

In our study, the incidence of nausea and vomiting as well as hypotension and bradycardia was seen in a greater number of patients in Group BF as compared to Group RF; however, the overall incidence of side effects was found to be comparable in both the groups. In a similar study, Wang et al., also concluded that ropivacaine is more recommended for little influence on the hemodynamic, shorter duration of sensory block and motor block, and low incidence rate of adverse reactions, which are conducive to the recovery and also safe to the patients.[20]

Limitations of the study

The limitation of this study was that we only included ASA Grade II cases. A study that also includes ASA Grade III patients would further give insights into the effects of these drugs in hemodynamically unstable patients.

CONCLUSION

Hyperbaric ropivacaine with fentanyl is a better alternative to hyperbaric bupivacaine with fentanyl in terms of hemodynamic stability, post-operative pain, and overall conduct of anesthesia in cases undergoing cesarean section

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Authors Contributions:
DH- Concept and design of the study, interpreted the results, prepared first draft of manuscript, and critical revision of the manuscript; **MB-** Statistically analyzed and interpreted, reviewed the literature, and manuscript preparation; and **NBK-** Design of the study, statistically analyzed and interpreted, preparation of manuscript, and revision of the manuscript; Concept and coordination of the overall study.

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