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Original Article

Anaesthesia Section

Effectiveness of Nebulised Dexmedetomidine for Treatment of Post Dural Puncture Headache in Parturients undergoing Elective Caesarean Section under Spinal Anaesthesia: A Randomised Controlled Study

THANKAM ABRAHAM RESHMA[1], RAVI SARAVANAN[2], KANTHAN KARTHIK[3], ANAND PUSHPARANI[4]

ABSTRACT

Introduction: Post Dural Puncture Headache (PDPH) following neuraxial anaesthesia is a common complication that can result in prolonged hospital stays. Central neuraxial anaesthesia remains the preferred technique for elective caesarean sections, and obstetric patients experience more intense PDPH compared to other patient categories.

Aim: To evaluate the efficacy of nebulised Dexmedetomidine (DEX), a novel modality of treatment for PDPH.

Materials and Methods: This double-blinded randomised controlled study was conducted at Department of Anaesthesiology SRM Medical College Hospital & Research Centre, Tamil Nadu, India. It was approved by the Institutional Ethics Committee and registered with the Clinical Trials Registry-India. After obtaining informed written consent from 60 patients, they were allocated into two groups. Group 1 received nebulisation with DEX, while Group 2 received nebulisation with 0.9% saline. Both groups received conservative management. Headache severity scores was compared as the primary outcome using a 5-point scale method, and the patient satisfaction scores as a secondary outcome using a Likert-type scale. One-way ANOVA, Student's t-test, Chi-square test, and two-tailed tests were used for statistical analysis.

Results: The age distribution, Body Mass Index (BMI), needle size, and the number of spinal attempts were comparable between both groups. Patients who received DEX nebulisation (Group 1) showed a considerable improvement in pain scores (mean±standard deviation: 0.67±0.48) compared to patients who received nebulisation with 0.9% saline (Group 2) (mean±standard deviation: 1.87±0.35). The patient satisfaction score was better in Group 1 (mean±standard deviation: 4.87±0.35) compared to Group 2 (mean±standard deviation: 3.33±0.48). Two patients in Group 2 required an Epidural Blood Patch (EBP) (p-value <0.001).

Conclusion: DEX nebulisation for PDPH was shown to be an effective treatment in reducing headache severity scores and alleviating PDPH symptoms in addition to conservative therapy, without causing side effects. Moreover, the DEX group displayed better haemodynamic stability compared to the placebo group.

Keywords: Blood patch, Cerebrospinal fluid, Conservative treatment, Epidural, Patient satisfaction

INTRODUCTION

PDPH is a common and severe complication following neuraxial anaesthesia, and obstetric patients experience a higher severity of PDPH compared to other categories [1]. The diagnosis of PDPH is made clinically by a history of dull throbbing pain, with symptomatic improvement upon lying down and worsening when sitting or standing [2]. According to the International Headache Society, PDPH is defined as a bilateral headache present within seven days of an intradural puncture, resolving spontaneously within 14 days [3]. Pathologically, PDPH is considered to arise from a cerebrospinal fluid leak through the dural puncture hole, resulting in decreased intracranial pressure and the tension effect on pain-sensitive structures. This aberrant vasodilation can trigger vascular headaches through the compensatory dilation of the intracranial vessels to maintain a constant volume [1].

Conservative management is the first-line treatment for PDPH, which mainly includes bed rest, hydration, caffeine, and analgesics. This traditional approach primarily focuses on symptom relief and supportive care. However, it often results in prolonged hospital stays and may be associated with lower patient satisfaction due to slower recovery.

Deep Inspiration Squeeze and Hold for 10 seconds (DISH10) is a non-invasive treatment for PDPH. It involves taking a deep breath, holding it, and squeezing the abdominal area. This manoeuvre helps to increase intrathoracic pressure and improve cerebrospinal fluid (CSF) circulation. While it provides temporary symptomatic relief, it is not a cure [4].

Epidural Blood Patch (EBP) is the second-line, gold standard treatment for PDPH, particularly when conservative measures fail. In this technique, a small amount of the patient's blood (usually 15-20 mL) is injected into the epidural space near the site of the dural puncture. The blood forms a clot that seals the hole in the dura, preventing further CSF leakage and restoring normal CSF pressure.

Sphenopalatine Ganglion Block (SPGB) blocks the sphenopalatine ganglion, which is involved in the regulation of blood flow and pain sensation in the face and head. This method can be effective in relieving pain, including headaches like PDPH. While both EBP and SPGB are more invasive methods recognised as effective treatments for PDPH, they carry a higher risk and may be less acceptable to patients due to the invasiveness of the procedures [5-7].

Consequently, less invasive treatments, such as inhaled DEX, have been investigated as alternatives for PDPH, presenting a novel modality of treatment [8]. DEX is a highly selective α2-adrenoreceptor agonist that provides cooperative sedation, anxiolysis, and analgesia with minimal respiratory depression [8]. It

can be administered through parenteral, nasal, and inhalation routes for various indications, such as premedication sedoanalgesia and postoperative analgesic actions.

DEX decreases Cerebral Blood Flow (CBF) through cerebrovascular vasoconstriction, which might be effective for reducing headaches [9,10]. However, the available evidence is limited, and some studies suggest that inhaled DEX may be a promising option for managing PDPH, offering a balance between effectiveness and patient comfort [11-14]. Owing to its desirable characteristics and multiple routes of administration, this study was designed to evaluate the efficacy of DEX nebulisation in PDPH following caesarean section patients under spinal anaesthesia.

MATERIALS AND METHODS

The present randomised double-blinded placebo-controlled study (both the patient and researcher were blinded) was conducted from July 2023 to January 2025 at the Department of Anaesthesiology, SRM Medical College Hospital & Research Centre, Tamil Nadu, India. The study was approved by our Institutional Ethics Committee (IEC-ST0723-767) and registered in the Clinical Trials Registry-India (CTRI/2023/12/060850). A written informed consent was obtained from each patient before participation.

Sample size calculation: The sample size was calculated based on the study conducted by Mowafy SMS and Ellatif SEA using the following formula, with the primary objective being pain scores, a 95% confidence interval, and an 80% power of the test [11]:

Formula:

$n=(Z_{1-\alpha/2}+Z_{1-\beta})^2\ p_1(1-p_1)+p_2(1-p_2)\ /\ (p_1-p_2)^2$

P1=Proportion of outcome from group -1, 3.72

P2=Proportion of outcome from group -2, 1.23

a=Level of significance, 10%

1-B=Power of test, 80%

ZI-a/2=Z value corresponding level of significance, 2.58

ZI-B=Z value corresponding to the level of power, 1.282

n=Sample size

n=(2.58+1.282) 2 (3.72×2.72)+(1.23×0.23)/(3.72-1.23)2

n=(3.962) 2× (10.1184+0.2829) / 6.2001

n=15.697×10.4013 / 6.2001

n=26.33

We obtained 26.33 as sample size, and we included 30 patients in each group to minimise the effect of data loss.

n1 =30, n2=30

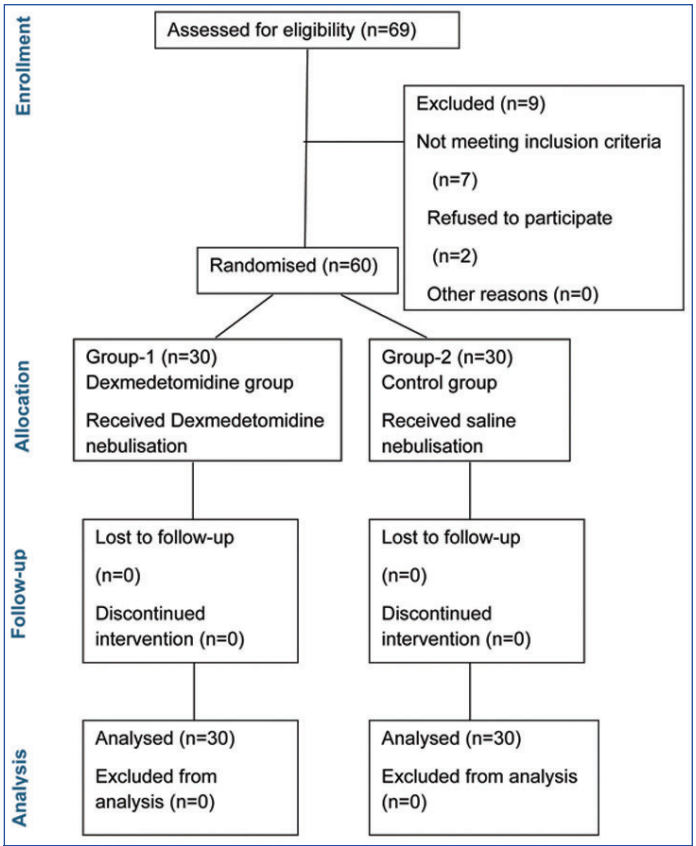
Inclusion criteria: Sixty patients with American Society of Anaesthesiology (ASA) status II, aged between 20-40 years, who presented with PDPH after elective caesarean section under spinal anaesthesia, were enrolled in our study.

Exclusion criteria: Patients who were unwilling to undergo the procedure, had undergone emergency caesarean sections, had hypertensive disorders of pregnancy, uncontrolled diabetes mellitus, a history of chronic headache or migraine, convulsions, cerebrovascular accidents, or who were on antidepressants were excluded from the study.

Study Procedure

A total of 60 patients were randomised into two groups using a computerised randomisation system, and allocation concealment was achieved using Sequentially Numbered Opaque Sealed Envelopes (SNOSE), which were opened only after participants' details were recorded[Table/Fig-1].

- Group 1 (DEX group): Received nebulisation with DEX 1 microgram/kg, diluted to 4 mL with 0.9% saline, twice daily from the time of PDPH diagnosis for three days [11].



[Table/Fig-1]: CONSORT diagram.

- Group 2 (control group): Received nebulisation with 4 mL of 0.9% saline, twice daily from the time of PDPH diagnosis for three days.

Both groups received conservative management, which consisted of bed rest in a supine position, adequate hydration (30 mL/kg/day) with oral/parenteral fluids, Inj. paracetamol 1 g IV every 6 hours, oral caffeine every 6 hours, and Inj. Diclofenac 75 mg in 100 mL NS infusion (as needed). EBP was considered in patients noted as treatment failures.

The severity of headache was evaluated at 0 (baseline), 24, 48, and 72 hours for both groups. The primary objective was to compare headache severity scores between the two groups. The secondary objectives included comparing patient satisfaction scores, hemodynamic parameters, the number of analgesic doses required, and the need for EBP between the two groups.

PDPH was diagnosed using the four criteria of the International Classification of Headache Disorders (ICH-III) guidelines, which include:

1. A postural headache that develops within five days after lumbar puncture,
2. Worsening within 15 minutes of sitting or standing,
3. Improvement within 15 minutes after lying down,
4. Associated with at least one of the following: neck stiffness, nausea, photophobia, or tinnitus. The headache resolves either spontaneously within one week or within 48 hours after effective treatment of the CSF leak.

The severity of PDPH was assessed using a 5-point scale:

- No headache: 0
- Mild: 1
- Moderate: 2
- Severe: 3
- Unbearable: 4[15].

Patient satisfaction was assessed using a Likert-type scale:

- Very satisfied: 5
- Somewhat satisfied: 4

- Neither satisfied nor dissatisfied: 3
- Somewhat dissatisfied: 2
- Very dissatisfied: 1

STATISTICAL ANALYSIS

Data were entered into an MS Excel spreadsheet (2010). The collected data were analysed using the statistical software Statistical Package for Social Sciences (SPSS) version 26. Continuous variables such as age, weight, BMI, headache severity score, patient satisfaction score, mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, and mean SpO2 were expressed as mean and standard deviation. Descriptive statistics for categorical variables, such as the size of the spinal needle, attempts or redirection of the spinal needle, number of diclofenac doses, and EBP, were expressed as frequency and proportion. Continuous variables were compared using the One-way ANOVA test and Student's t-test. Categorical variables were compared using the Chi-square test. A p-value of <0.05 was considered statistically significant, and a p-value of <0.001 was considered highly significant, using a two-tailed test.

RESULTS

Age, BMI, needle size, and the number of spinal attempts were compared between both groups and showed no statistically significant differences. However, when comparing the number of diclofenac doses, the control group received more doses than the DEX group, which was statistically significant. No patients in the DEX group required EBP, while two patients in the control group were indicated for EBP [Table/Fig-2]. PDPH severity was assessed in both groups using headache severity scores, showing no statistical significance in mean values at baseline readings. However, the mean values at 24, 48, and 72 hours were significantly lower in the DEX group compared to the control group [Table/Fig-3].

Parameters	Group 1 Mean±SD	Group 2 Mean±SD	p-value
Age, years	24.87±4.09	24.17±3.78	0.553
Body Mass Index (BMI), kg/m^2	23.39±2.18	23.01±2.84	0.559
Needle size (25G/26G)	14/16	12/18	0.602
Number of spinal attempts	1.17±0.38	1.2±0.41	0.712
Mean number of diclofenac doses	1.8±0.41	2.83±0.38	0.001**
Need for EBP	0/30	2/30	0.0001**

[Table/Fig-2]: Comparison between demographic data, total diclofenac doses and complications between study and control groups.
Data expressed in Mean±SD, were analysed by One-way ANOVA test and student t-test, data expressed in number, were analysed by Chi-square test; **p-value <0.001, statistically highly significant

Headache severity score	Group 1 Mean±sd	Group 2 Mean±sd	p-value
Before nebulisation	3.47±0.51	3.53±0.51	0.645
24 hours after nebulisation	2.17±0.38	3.2±0.41	0.001**
48 hours after nebulisation	1.8±0.41	2.77±0.43	0.001**
72 hours after nebulisation	0.67±0.48	1.87±0.35	0.001**

[Table/Fig-3]: Headache severity scores among two groups.
Analysed by One-way ANOVA test; **p-value <0.001, statistically highly significant

The patient satisfaction scores for both groups showed no statistical significance at baseline readings; however, they were statistically significant in the DEX group compared to the control group at 24, 48, and 72 hours [Table/Fig-4]. Additionally, hemodynamic parameters (heart rate, blood pressure, and oxygen saturation) were monitored between both groups. Heart rate and blood pressure showed no statistical significance at baseline readings, while their mean values were statistically significant at 24, 48, and 72 hours [Table/Fig-5,6]. Oxygen saturation at baseline, 24, 48, and 72 hours showed no statistically significant difference between the two groups.

Patient satisfaction score	Group 1 Mean±sd	Group 2 Mean±sd	p-value
24 hours after nebulisation	3.17±0.38	2.37±0.49	0.001**
48 hours after nebulisation	4.03±0.61	2.77±0.86	0.001**
72 hours after nebulisation	4.87±0.35	3.33±0.48	0.001**

[Table/Fig-4]: Patient satisfaction scores among two groups.
Analysed by One-way ANOVA test; **p-value <0.001, statistically highly significant

Heart rate	Group 1 Mean±sd	Group 2 Mean±sd	p-value
Before nebulisation	89.53±8.59	91.63±10.46	0.376
30 min after nebulisation	88.77±6.66	92.83±9.09	0.043*
60 min after nebulisation	79.87±8.85	85.03±11.43	0.043*
90 min after nebulisation	75.8±9.65	82.43±8.47	0.008*

[Table/Fig-5]: Comparison of heart rate between two groups.
Analysed by One-way ANOVA test; *p-value <0.05 statistically significant

Systolic BP	Group 1 Mean±sd	Group 2 Mean±sd	p-value
Before nebulisation	122.83±10.33	125.3±7.99	0.292
30 min after nebulisation	110.4±6.5	121.4±19.32	0.01*
60 min after nebulisation	109.17±6.76	115.07±8.95	0.005*
90 min after nebulisation	107.5±4.84	112.7±10.83	0.031*
Diastolic BP	**Group 1 Mean±sd**	**Group 2 Mean±sd**	**p-value**
Before nebulisation	84.6±4.23	86.93±7.49	0.113
30 min after nebulisation	73.8±7.34	80.37±9.46	0.007*
60 min after nebulisation	65.9±9.31	73.23±6.41	0.001**
90 min after nebulisation	66.53±8.93	79±8.26	0.001**

[Table/Fig-6]: Comparison of blood pressure between two groups.
Analysed by One-way ANOVA test;
*p-value <0.05 statistically significant, **p-value < 0.001, statistically highly significant

DISCUSSION

Spinal anaesthesia is the established standard of care for caesarean sections. It carries some risks, with post dural puncture headache (PDPH) being the most common. Symptoms of PDPH were first documented by August Bier in the late 19th century. Although several pharmacological medications and therapeutic options have been suggested, epidural blood patch (EBP) continues to be the most effective therapy for treating PDPH. However, EBP is an invasive procedure with serious risks, such as seizures and infection. Numerous studies are being conducted on the subject of PDPH treatment to identify effective pharmacological medications due to the lack of evidence-based treatment and the need for invasive procedures. Ahmadzade Z et al. found that the preventive administration of a combination of neostigmine and atropine is useful in reducing the severity and frequency of PDPH [16]. Yang CJ et al. stated that intraoperative intravenous infusion of aminophylline offers a lower incidence of PDPH [17]. Peralta FM et al. found that there is no difference in the onset, duration, and severity of headache when administering prophylactic intrathecal morphine after accidental dural puncture [18].

In anaesthesia and critical care, dexmedetomidine (DEX) is a powerful and highly selective α2-agonist that is currently in widespread use. Due to its neuroprotective, cardioprotective, and renoprotective features, DEX is preferred for use as a perioperative sedative in high-risk patients. Its application as a primary sedative and analgesic in intensive care unit patients is also becoming more widely accepted. Additionally, it has been shown that DEX possesses numerous desirable characteristics in the context of obstetric analgesia, including anxiolysis, an antinociceptive effect on visceral pain, maternal haemodynamic stability, and stimulation of uterine contractions. Furthermore, foetal bradycardia is less

common due to DEX's high lipophilicity and retention in placental tissue [19,20]. Alpha-2 adrenoreceptors are distributed throughout the body, with higher concentrations in the vascular smooth muscle and the main arousal areas of the central nervous system, such as the locus coeruleus. Thus, in addition to its established actions as an anxiolytic, analgesic, and sympatholytic, DEX may also cause cerebral vasoconstriction through the activation of vascular α2-receptors. Only a limited number of studies, mostly involving healthy human volunteers and varying doses of DEX, have assessed the drug's effects on cerebral haemodynamics. According to the current literature, there is a dose-dependent 30% reduction in cerebral blood flow (CBF) at clinically relevant DEX concentrations following DEX treatment due to cerebrovascular vasoconstriction [21].

Our study was undertaken to evaluate the effectiveness of nebulised dexmedetomidine (DEX) in treating post dural puncture headache (PDPH) after caesarean section under spinal anaesthesia. We conducted this study on a total of 60 patients undergoing elective caesarean sections who developed PDPH after spinal anaesthesia. All patients were divided into two groups: Group 1 and Group 2. Patients in Group 1 received DEX nebulisation, while those in Group 2 received a placebo (saline nebulisation) in addition to conservative management. All patients were monitored through the postoperative period for 72 hours.

Demographic characteristics: In our study, when comparing the two groups in terms of age, body mass index (BMI), spinal needle used, and the number of redirections or attempts, there were no statistically significant differences, and both groups were comparable.

Headache severity score: In the present study, we noted that after nebulisation with DEX, there was a significant improvement in headache scores in Group 1 patients. The findings are consistent with the study conducted by Mowafy SMS and Ellatif SEA, who evaluated the addition of nebulised DEX (1 µg/kg twice daily) with conservative treatment in 43 postpartum females with PDPH [11]. The study found significant reductions in the Visual Analog Scale (VAS) and Lybecker scores, indicating effective symptom relief.

Thomas J et al. reported two cases of PDPH in obstetric patients who were given DEX nebulisation, showing rapid and complete resolution of headache and pain (VAS-0) after a single dose [12]. Similarly, Soliman OM et al. conducted a study that demonstrated nebulisation with neostigmine/atropine and DEX resulted in a significant reduction in VAS compared to the saline placebo, with DEX showing promising results [13]. A study by Kumar A et al. compared nebulised DEX to fentanyl and saline in 90 obstetric patients with PDPH following caesarean section under spinal anaesthesia [14]. The results showed that DEX nebulisation significantly reduced pain scores at various time points and decreased the need for additional analgesic therapy compared to the other groups. Soni A et al. explored the use of intravenous DEX in treating PDPH, and the results showed a reduction in headache intensity and a decrease in the need for opioid analgesics [22].

Haemodynamic parameters: Our study showed significant haemodynamic stability in Group 1 patients compared to Group 2 patients. Kumar A et al. compared nebulised DEX to fentanyl and saline in obstetric patients with post dural puncture headache (PDPH) following cesarean sections under spinal anesthesia [14]. The results demonstrated that DEX nebulisation significantly reduced pain scores and showed marked results in haemodynamic stability. A study conducted by Soni A et al. explored the use of intravenous DEX in treating PDPH, revealing that DEX led to a mild reduction in blood pressure and heart rate, consistent with its known sympatholytic effects [22]. The drug's analgesic and sedative effects outweighed the mild haemodynamic changes. Mowafy SMS and Ellatif SEA conducted a randomised double-blind controlled trial involving 43 postpartum females with PDPH, assessing the effectiveness of nebulised DEX in addition to conservative treatment [11]. The study reported no adverse effects on haemodynamic stability.

Patient satisfaction score: We observed that patients who received DEX nebulisation had a higher satisfaction rate with the treatment compared to the control group. A study by Rashid A et al. evaluated the safety and efficacy of nebulised DEX in Endobronchial Ultrasound (EBUS). Results indicated that the patient satisfaction score in the DEX nebulisation group was notably higher than in the control group (lidocaine nebulisation) [23].

Analgesics consumption: We noted that the doses of diclofenac injection were reduced in the DEX group compared to the control group. The mean number of diclofenac doses used in Group 1 was 1.8±0.41, while in Group 2 it was 2.83±0.38. The p-value was 0.001, which is statistically significant. Kumar A et al., [14].demonstrated that nebulised DEX significantly reduced pain scores at various time points and decreased the need for additional analgesic therapy compared to other groups. Soni A et al. observed a decrease in the need for opioid analgesics with intravenous DEX [22].

Need for Epidural Blood Patch (EBP): In the control group, two patients needed an EBP; however, none of the patients in the DEX group required EBP. A review by Uluer H et al. discussed the potential benefits and challenges associated with DEX nebulisation for PDPH, including its analgesic effects [24]. The review suggests that DEX nebulisation may offer a non-invasive alternative to EBP for PDPH management. Soliman OM et al. demonstrated that nebulisation with neostigmine/atropine and DEX significantly reduced the need for additional interventions like EBP [13]. In the study conducted by Mowafy SMS and Ellatif SEA, EBP was required for two patients in the control group, while none of the patients in the DEX group needed EBP [11].

Limitation(s)

The study was conducted at a single center with a relatively small sample size (60 patients), which may limit the generalizability of our findings to broader populations. All patients included in our study were young and healthy, and those with uncontrolled systemic illnesses were not included. Future research should explore the dose titration of DEX for PDPH, which could potentially enhance patient outcomes.

CONCLUSION(S)

We conclude that DEX nebulisation (1 µg/kg twice daily) added to standard conservative therapy for PDPH was beneficial in reducing the severity of pain and PDPH symptoms without causing any side effects. DEX is an emerging, promising option for PDPH treatment due to its sedative, analgesic, and sympatholytic properties, without significant respiratory depression. It is a non-invasive adjunct to conservative care and can be considered before invasive techniques like EBP and SPGB.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Student, Department of Anaesthesia, SRM Medical College and Research Centre, Kattankulathur, Chennai, Tamil Nadu, India.
2. Professor, Department of Anaesthesia, SRM Medical College and Research Centre, Kattankulathur, Chennai, Tamil Nadu, India.
3. Associate Professor, Department of Anaesthesia, SRM Medical College and Research Centre, Kattankulathur, Chennai, Tamil Nadu, India.
4. Professor, Department of Anaesthesia, SRM Medical College and Research Centre, Kattankulathur, Chennai, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Ravi Saravanan,
Professor, Department of Anaesthesia, Room No. 1, B Block, SRM Medical College Hospital, SRM Nagar, Potheri, Kattankulathur, Chennai, Tamil Nadu, India.
E-mail: drcrsaravanan@gmail.com

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