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Safety and effectiveness of very-high-power, short-duration ablation in patients with atrial fibrillation: Preliminary results

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Abstract

Background: *Pulmonary vein isolation (PVI) is at the forefront of rhythm control strategies in patients with atrial fibrillation (AF). A very-high-power, short-duration (vHPSD) catheter, QDot Micro™ (Biosense Webster) was designed to improve the effectiveness of AF ablation within a shorter procedure time. The aim of this study was to compare the effectiveness and safety of PVI ablation between this vHPSD ablation mode and conventional ablation-index-guided ablation (ThermoCool Smarttouch SF catheter).*

Methods: *This single-center, retrospective, observational study enrolled 108 patients with AF, referred for catheter ablation between December 16, 2019 and December 3, 2021. In 54 procedures (mean age: 58.0 ± 12.3; 66.67% male), a QDot Micro™ catheter was used (vHPSD-group), and 54 patients (mean age: 57.2 ± 11.8; 70.37% male) were treated with a ThermoCool Smarttouch™ SF catheter (AI-group). The primary endpoint was freedom from AF 3 months after ablation.*

Results: *Atrial fibrillation was found to recur in 14.81% of patients in the vHPSD-group and in 31.48% of patients in the AI-group ($p = 0.07$). There was no difference in treatment-emergent adverse events between the two groups (6.3% vs. 0%; $p = 0.10$). One severe adverse event (a cerebral vascular accident) was observed in the vHPSD-group. The mean dose of remifentanil was reported to be lower during QDot Micro™ catheter-based PVI ($p < 0.001$). The vHPSD-based PVI was associated with shorter radiofrequency application time ($p < 0.001$), fluoroscopy time ($p < 0.001$), and total procedure time ($p < 0.001$).*

Conclusions: *This study suggests vHPSD ablation is safe, can reduce the dosage of analgesics during significantly shorter procedures and may enhance the success rate of catheter-based PVI.* (Cardiol J)

Key words: ablation, pulmonary vein isolation, atrial fibrillation, vHPSD, QDot Micro™

Introduction

Atrial fibrillation (AF) is the most common supraventricular arrhythmia, affecting more than 10% of the population aged 80 years or older [1]. Treatment of AF requires individualized therapeutic approaches that either control heart rate or restore and maintain sinus rhythm. According to guidelines, catheter ablation (CA) is a class I indication for AF patients with severe symptoms that are refractory to pharmacological therapy [2]. Pulmonary vein isolation (PVI) is a well-established rhythm control strategy for AF and is expected to gain further significance. Multicenter randomized controlled trials — CABANA and CASTLE AF — showed that CA is superior to any medication for

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improving quality of life in patients with AF, without increasing the rate of complications. The latter trial, dedicated to patients with AF and coexisting heart failure with reduced ejection fraction, demonstrated improved morbidity and mortality in the group assigned to CA in comparison to those treated with medications [3, 4].

Several studies evaluating the role of AF CA as a first-line therapy demonstrated that it was more effective and more economical than drug therapy [5–8]. The success rate of AF ablation varies depending on many factors, both patient- and procedure-related [9–13]. After a single procedure, the freedom from arrhythmia in patients with paroxysmal AF oscillated between 60% and 90% over 12 months of follow-up [13–15]. The constant development of new technologies improves the safety and long-term clinical outcomes of AF ablation as well as streamlines workflow in electrophysiology labs. It is believed that in conventional radiofrequency (RF) ablation, insufficient catheter stability and the predominance of the conductive phase, both resulting in tissue edema, are responsible for the majority of the recurrences [9, 16–18]. In recent years, there has been increased interest in the utility of the very-high-power, short-duration (vHPSD) mode, which enables up to 90 W of energy to be applied for only 4 s. This protocol is meant to reduce conductive heating, which is strongly dependent on the time of RF delivery, and to maximize immediate heating during the resistive phase, resulting in irreversible myocardial injury [18–24]. Delivering such high power requires a special generation of catheters which monitor accurately and are highly sensitive to temperature fluctuations. A next-generation open-irrigated, contact-force (CF)-sensing catheter, the QDot Micro™ (Biosense Webster), working according to the Qmode+ algorithm, was designed to improve the effectiveness of AF ablation and to allow better work management, mainly due to the shorter procedure time. The tip of the catheter, embedded with six superficial thermocouples, allows accurate real-time temperature control during RF application. The addition of extra microelectrodes optimizes high-density mapping by registering electrical potentials with resolution comparable to that of multielectrode mapping catheters [23, 24]. Importantly, the histological analysis of damaged tissue revealed that vHPSD is conducive to the formation of broader, more homogenous, and less hemorrhagic lesions with fewer steam pops [17, 18, 20–22].

This study compares vHPSD-guided PVI to the conventional ablation-index (AI)-guided PVI regarding procedural factors, treatment-related complications, and 3-month success rate.

Methods

Study design

This was a retrospective, observational, single-center study that evaluated the effectiveness and safety of vHPSD ablation utilizing a novel CF catheter, the QDot Micro. The study involved 108 patients who were referred for their first catheter-based AF ablation to the reference center, which performs approximately 600 ablation procedures per year. All PVIs were conducted between December 2019 and December 2021. The procedures performed with a QDot Micro catheter prior to November 2020 were not analyzed, as they were part of the operators' learning curve.

The inclusion criteria included an age of at least 18 years and symptomatic paroxysmal or persistent AF indicated for the first catheter-based ablation. Patients with a medical history of surgical or catheter ablation for AF were excluded from the study.

Patients attended routine post discharge appointment at the outpatient clinic and had a 24--hour Holter electrocardiogram (ECG) scheduled at 3 months post ablation. Additionally, telephone follow-up was collected a minimum of 3 months after the procedure.

The study was conducted in accordance with the Declaration of Helsinki's ethical principles. The protocol of the investigation was approved by the local Bioethics Committee (approval number: AKBE/127/2022). All patients signed informed consent to the processing of personal data.

Study population

Of the 57 patients that underwent vHPSD--guided PVI during the study period, 54 were enrolled in the vHPSD-group. The other 3 patients were excluded due to ineligibility for the follow-up interview. Of those, 1 patient did not consent to participate and 2 died of causes unrelated to treatment (exacerbation of plasmacytoma and sudden cardiac arrest of non-cardiac origin, 2 months after ablation). An equivalent number of consecutive patients who underwent AI-guided PVI constituted the AI-group.

Procedural workflow

Prior to ablation, transesophageal echocardiography (TEE) was performed in order to rule out intracardiac thrombus and to assess the possible

difficulties of transseptal puncture. Pain was controlled by an intravenously administered opioid, mainly remifentanil. In some patients additional sedation with midazolam boluses was introduced at the discretion of an operator. All catheters were inserted under local anesthesia through four femoral vein punctures. During the procedure, unfractionated heparin was infused according to the activated coagulation time (target: > 335 s); the first bolus dose (100 IU/kg) was administered before transseptal puncture. In most procedures, a three-dimensional reconstruction of the left atrium and pulmonary veins (PV) was created using rotational angiography. Bipolar voltage mapping was generated using either a 20-pole Nav Laso or a PentaRay™ catheter as well as a CARTO electroanatomic navigating system (Biosense Webster). PVI was determined to be successful when the acute durability of linear lines was confirmed after a 20-min waiting period, showing an entrance block with either the catheter or pacing maneuvers. In the event of a short-term PV reconnection, additional RF applications were delivered. Transthoracic echocardiography was performed immediately after the procedure and in the morning of the following day to rule out pericardial effusion and other intracardiac complications.

Study group

The vHPSD ablation (90 W, 4 s) was performed with a QDot Micro catheter according to the Qmode+ algorithm (temperature-controlled ablation). This algorithm calls for at least 2 s of pre-cooling and 4 s of irrigation flow at a rate of 8 mL/min during each RF application. The temperature cut-off limit was 55°C based on the thermocouple with the highest temperature. The maximum interlesion distance was 4.5 mm on the anterior wall and 5.0 mm in other regions.

Control group

The AI-guided PVI was conducted in accordance with the CLOSE protocol, using an open-irrigated, CF-sensing Thermocool Smarttouch Surround Flow catheter (Biosense Webster). AI comprises power, contact force, and time in a weighted formula. RF was delivered in a power-controlled mode with predefined settings: the RF power output was 35 W with a target AI of > 400 at the posterior and inferior wall of the left atrium and > 550 at the remaining sites. The target range for CF was 10–30 g, with an irrigation rate of 15 mL/min and a maximum interlesion distance of 6 mm. The maximum temperature cut-off point was 40°C.

Outcomes

The primary outcome was freedom from AF at 3 months post-ablation. The diagnosis of AF recurrence was based on the results of Holter ECG performed after a 3-month blanking period (an AF episode of at least 30 s) or ECG recorded any time within 3 months of discharge. The main secondary endpoints included the amount of opioids administered during the procedure and the incidence of early-onset treatment emergent adverse events (TEAEs). TEAEs were divided into serious adverse events and minor complications, occurring up to discharge. Serious adverse events were defined as death, myocardial infarction, cardiac tamponade, phrenic nerve palsy, cerebrovascular accident, transient ischemic attack, major bleeding, thromboembolic event, or other vascular complication. Minor complications were associated with vascular access and referred to groin hematoma, pseudoaneurysm, or arteriovenous fistula. Additionally, the duration of the procedure (the time from the first anesthetic injection to the removal of vascular sheaths, including a 20-min waiting period), the duration of ablation (the total time of all applications), the number of applications, the fluoroscopy time, and radiation dose were compared between the two groups. All aforementioned information was extracted from the medical records.

The follow-up interview was conducted via telephone, at least 3 months after ablation. By that time, patients had already undergone the 24-h Holter ECG monitoring. During the interview, they were asked whether they had experienced any heart palpitations. In cases of AF recurrence, the questions concerned the alleviation of post-ablation symptoms, the documentation of arrhythmia, and the precise time of its recurrence.

Data collection

All PVI ablations were performed by three electrophysiologists, who conduct more than 50 PVI a year [25]. The procedural and clinical data were extracted from medical records by a single independent investigator. The same investigator interviewed all patients at least 3 months post-ablation.

Statistical analysis

Distributions of continuous variables were assessed with the Shapiro-Wilk test. The results are presented as: mean and standard deviation for normally distributed continuous variables, median and interquartile range for non-normally distributed continuous variables and as percent-

Table 1. Patients' characteristics and the medications used.

Characteristics	vHPSD-guided (n = 54)	AI-guided (n = 54)	P-value
Paroxysmal AF	74.07% (40/54)	66.67% (36/54)	0.53
Persistent AF	25.93% (14/54)	33.33% (18/54)	0.53
Age (mean ± SD) [years]	58.0 ± 12.3	57.2 ± 11.8	0.72
Gender (male)	66.67% (36/54)	70.37% (37/54)	0.84
Body mass index (mean ± SD) [kg/m^2]	27.39 ± 0.53	28.00 ± 0.57	0.43
Hypertension	57.41% (31/54)	57.41% (31/54)	1.00
Diabetes type 2	9.26% (5/54)	11.11% (6/54)	1.00
Antiarrhythmic drugs in total	12.96% (7/54)	5.56% (3/54)	0.32
Propafenone	7.415 (4/54)	3.70% (2/54)	0.68
Amiodaron	5.56% (3/54)	1.85% (1/54)	0.62
Beta-adrenolytic	81.48% (44/54)	83.33% (45/54)	1.00
Bisoprolol	44.44% (24/54)	51.85% (28/54)	0.56
Metoprolol	24.07% (13/54)	18.52% (10/54)	0.64
Nebivolol	9.26% (5/54)	7.41% (4/54)	1.00
Anticoagulants	100% (54/54)	100% (54/54)	1.00
Apixaban	42.59% (23/54)	44.44% (24/54)	1.00
Rivaroxaban	7.41% (4/54)	11.11% (6/54)	0.74
Dabigatran	42.59% (23/54)	42.59% (23/54)	1.00
Acetylsalicylic acid	1.85% (1/54)	0% (0/54)	1.00
Clopidogrel	1.85%% (1/54)	0% (0/54)	1.00
Vitamin K antagonists	7.41% (4/54)	1.85% (1/54)	0.36

AF — atrial fibrillation; AI — ablation index; SD — standard deviation vHPSD — very-high-power, short-duration

ages for categorical variables. The Fisher exact test was used for comparing categorical variables and the Student t-test and Mann-Whitney U test were used for continuous variables. A p-value of < 0.05 was considered statistically significant. The Kaplan–Meyer survival curves were plotted for an analysis of the AF recurrences. The statistical analysis was performed using Statistical Analysis Software (Cary, NC, USA), version 9.4.

Results

Patient characteristics

The patient characteristics and medication data are summarized in Table 1. The groups were comparable in terms of mean age (58.0 ± 12.3 vs. 57.2 ± 11.8 years; p = 0.72) and sex (66.67% vs. 70.37% male; p = 0.84). The proportions of paroxysmal to persistent AF were similar in both groups (74.07% vs. 66.67% paroxysmal; p = 0.53). There were also no significant differences in body mass index or comorbidities between the groups. The antiarrhythmic drugs were prescribed at the discretion of the attending cardiologist, non-significantly more frequently in the vHPSD-group (12.96% vs. 5.56%; p = 0.32). The proportion of patients in sinus rhythm at the beginning of the procedure was comparable in the two groups (70.37% and 66.67%, respectively; p = 0.84). All patients were instructed to take antithrombotic medications for at least 2 months post-ablation.

Primary endpoint

Successful acute PVI was achieved in all patients. At the 3-month follow-up, AF was documented in 14.81% of the patients in the vHPSD group and in 31.48% of the patients in the AI-group (p = 0.07).

Three patients in the vHPSD-group (5.56%) and 2 in the AI-group (3.70%) experienced AF recurrence before discharge (p = 1.00). There was no difference between groups in AF recurrence within 7 days of discharge (9.26% vs. 7.41%; p = 1.00). Within 3 months of discharge, the recurrence of arrhythmia was non-significantly less frequent in the vHPSD-group (25.94% vs. 37.04%; p = 0.30).

Figure 1 presents the Kaplan–Meier curve, showing no difference in arrhythmia recurrence

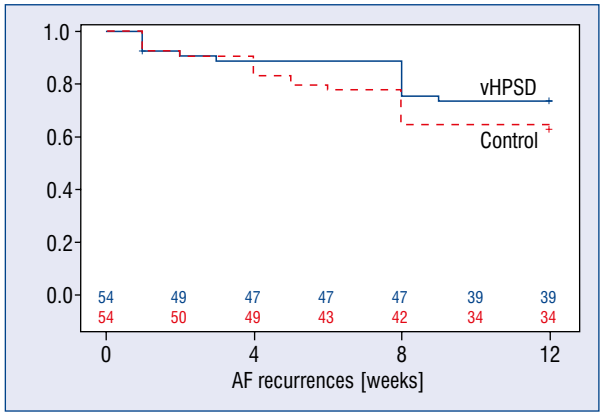

Figure 1. Atrial fibrillation (AF) recurrences over time in the very-high-power, short-duration-group (vHPSD) and ablation index-group (Control). The graph shows that there is no difference in when AF recurs (in weeks) depending on the ablation strategy used.

over time between the two groups. The follow-up outcomes concerning AF recurrence and symptom improvement are displayed in Table 2.

Secondary endpoints

During the procedure, in most cases the opioid used was remifentanil. However, fentanyl was administered during 7 procedures (1 in the vHPSD-group and 6 in the AI-group); those quantities were excluded from the calculations due to unrepresentative data for statistical evaluation. The analysis of the mean opioid doses during the procedure revealed that there was significantly lower demand for analgesics in the vHPSD-guided PVI (0.50 [0.40–0.60] vs. 0.70 [0.55–0.90]; $p < 0.001$).

There was no statistically significant difference in TEAEs between the vHPSD- and AI-groups (6.3% [3/54] and 0% [0/54], respectively; $p = 0.10$). Minor complications included 2 pseudoaneurysms and 1 arteriovenous fistula, all observed in the vHPSD-group. One severe adverse event (transient ST segment elevation in inferior leads directly after transseptal puncture, followed by left ventricle thrombus and cerebral vascular accident 2 days after PVI; there was no intracardiac thrombus detected in TEE prior ablation) was also reported in the vHPSD-group. No other serious adverse events were reported in either group. The reduction of symptom burden was similar in the two groups (90.74% vs. 87.04%; $p = 0.76$). In the vHPSD-group, 20.37% of the patients experienced lone heart palpitations (without AF recorded by ECG), as compared to 18.52% of those in the AI-group ($p = 1.00$).

The total number of RF applications required to completely isolate PV was higher in the vHPSD-group (77.5 [65.0–91.0] vs. 75.5 [67.0–97.0]; $p < 0.001$). In the vHPSD-group, the durations were significantly shorter for total procedure time (120 [95–140] vs. 145 [140–180] min; $p < 0.001$), total RF application time (312 [260–367] vs. 2109 [1835–2325] s; $p < 0.001$), and fluoroscopy time (399.0 [278.0–630.0] vs. 431.5 [317.0–620.0] s; $p < 0.001$). A comparison of safety outcomes and procedural factors between the groups is presented in Tables 3 and 4, respectively.

Discussion

The main finding of the study is that vHPSD ablation with a QDot Micro catheter is a safe and feasible procedure, with a success rate that is comparable to conventional AI-guided ablation with other open-irrigated CS-sensing catheters. Although the presence of AF at 3-month follow-up differed between the groups, it was not statistically significant.

The potential of the Qmode Plus algorithm to improve the effectiveness and safety of CA PVI is discussed. It is postulated that the vHPSD approach can affect the durability of linear lines,

Table 2. Follow-up data concerning atrial fibrillation (AF) recurrence and symptom improvement.

Outcome	vHPSD-guided (n = 54)	AI-guided (n = 54)	P-value
AF recurrence before discharge	5.56% (3/54)	3.70% (2/54)	1.00
AF recurrence within 7 days of discharge	9.26% (5/54)	7.41% (4/54)	1.00
AF recurrence within 3 months of discharge	25.93% (14/54)	37.04% (20/54)	0.30
Symptom improvement stated by patient	90.74% (49/54)	87.04% (47/54)	0.76
AF present 3 months after discharge	14.81% (8/54)	31.48% (17/54)	0.07

AI — ablation index; vHPSD — very-high-power, short-duration.

Table 3. Treatment emergent adverse events.

Adverse event	vHPSD-guided	AI-guided	P-value
Post-procedural pericardial effusion	0% (0/54)	0% (0/54)	1.00
Vascular complication	5.56% (3/54)	0% (0/54)	0.24
Pseudoaneurysm	1.85% (1/54)	0% (0/54)	1.00
Arteriovenous fistula	3.70% (2/54)	0% (0/54)	0.50
Cerebrovascular accident	1.85% (1/54)	0% (0/54)	1.00

AI — ablation index; vHPSD — very-high-power, short-duration

Table 4. Procedural factors.

Procedural factor	vHPSD-guided (n = 54)	AI-guided (n = 54)	P-value
SR at the beginning of ablation [%]	70.37 (38/54)	66.67 (36/54)	0.84
Procedure time [min]	120 (95–140)	145 (140–180)	**< 0.001**
Ablation time [min]	312 (260–367)	2109 (1835–2325)	**< 0.001**
Number of RF applications	77.5 (65.0–91.0)	75.5 (67.0–97.0)	**< 0.001**
X-ray time [min]	399.0 (278.0–630.0)	431.5 (317.0–620.0)	**< 0.001**
Remifentanil [mg]	0.50 (0.40–0.60)	0.70 (0.55–0.90)	**< 0.001**
Heparin [thousand units]	15.0 (13.0–20.0)	16.0 (14.0–20.0)	**< 0.001**

AI — ablation index; RF — radiofrequency; SR — sinus rhythm; vHPSD — very-high-power, short-duration

mainly by overcoming catheter instability and escalating resistive heating. Barkagan et al. [22] examined the transmularity and contiguity of lines by voltage mapping and pacing 1 month after PVI in a swine model, observing a higher chronic line integrity in the vHPSD group (90 W, 4 s) than in the control group (30 W, 30 s), with no evident PV stenosis. Similar results were also observed in other studies [18, 20, 21]. Although many authors have demonstrated the advantages of the vHPSD approach, there is little evidence that it significantly enhances the long-term effectiveness of AF catheter ablation over other strategies.

The QDot Micro is the first catheter to shorten the time of lesion formation to 4 s, through the application of uniquely high energy in a temperature-controlled mode. One of the main advantages of the novel QDot Micro catheter is that it incorporates contact force sensing with real-time temperature measurement. The importance of proper contact force during energy delivery has been proven by many studies [15, 16, 26, 27]. The Qmode Plus algorithm modifies power in response to real-time tissue temperature measurement. Accurate temperature feedback is essential, as it helps to predict when the lesion is transmural and protects surrounding tissues from overheating. It also contributes to a lower risk of steam pops, which is particularly important regarding the narrow safety and efficacy window of vHPSD [23, 24, 28–31]. Moreover, the use of very small microelectrodes substantially improves the registration of the near-field electrical signal, detecting even minor signal attenuation.

The safety of vHPSD ablation with a QDot Micro catheter was demonstrated by other studies [23, 29]. Leshem et al. [18] showed that such a reduction in RF time leads to substantially less collateral damage due to the reduced conductive heating. The current study confirmed that the vHPSD strategy using the QDot Micro catheter has an acceptable safety profile. Although TEAEs were more often observed among the vHPSD-group, the vascular access complications (pseudoaneurysm or atrioventricular fistula) were rather incident to the procedure as such and their higher prevalence in the vHPSD-group was due to factors unrelated to the ablation strategy or type of catheter.

Lower dosages of opioids are associated with reduced intraprocedural and immediate postprocedural adverse effects, such as hypotension, respiratory depression, and bradycardia. Also, a lower opioid dosage contributes to the patient's comfort, as they tend to be less confused and unsteady after sedation and rarely experience postoperative nausea, urinary retention, or constipation [32, 33].

Remifentanil, an ultra-short-acting opioid, has a particularly high potential to induce hyperalgesia and opioid tolerance. Both of these phenomena are certainly dose-dependent, so lower anesthetic demand is crucial for preventing them [34].

It is well known that highly symptomatic AF is closely related to impaired psychological well-being [35–37]. Many authors have highlighted the importance of AF ablation in combating the anxiety and depression linked with frequent arrhythmia episodes, especially when the symptoms are refractory to antiarrhythmic therapy [3, 4, 12, 38]. Fortunately, a strong reduction in arrhythmia burden was reported in both groups at the 3-month follow-up interview. This is a particularly important factor, as it reflects the primary aim of AF ablation — to restore quality of life [2, 10].

The study demonstrates that vHPSD has significantly shorter times of RF application, fluoroscopy, and the overall procedure, which helps optimize workload management. The lower radiation dosage certainly translates into improved workplace safety [39]. The total number of RF applications required to completely encircle the PV was higher in the vHPSD-group. This may be due to the operators being more prone to reduce interlesion distance while using a new, less tested, catheter.

The results are consistent with those of other studies regarding the clinical application of vHPSD mode for PVI [40–44]. Both the QDot Fast study and Fast and Furious study demonstrated that vHPSD-based ablation utilizing the QDot Micro catheter is associated with a low risk of complications and leads to remarkably shorter procedure times [23, 28]. The biophysical analysis of ablated tissue indicates that vHPSD forms a lesion of up to 4 mm deep, which is generally sufficient to create transmural myocardial necrosis in areas with a relatively thin (3–4 mm) cardiac wall, such as PV circumference [18, 21]. However, the insufficient lesion depth in areas of thicker tissue might have had an impact on AF recurrence in the vHPSD--group.

Limitations of the study

The study has several limitations. Firstly, as this was a non-randomized, observational study, potential biases cannot be excluded. Secondly, the fact that the study involves a relatively small cohort of patients from a single center should be considered before generalizing the results. Thirdly, the extensive inclusion criteria allowed for certain heterogeneity of patients' clinical characteristics, which was not evaluated in the study. Moreover, because the follow-up was collected from patients remotely, the information concerning AF recurrence and its documentation could have been misstated. Also, the recurrence of other arrhythmias besides AF was not taken into consideration. Additionally, there was a relatively short follow-up period, as the success rate was assessed after only 3 months. However, the long-term outcome will be further evaluated.

Conclusions

This study suggests that vHPSD ablation is safe and enables analgesic usage to be reduced during significantly shorter procedures. vHPSD mode may enhance the success rate of catheter-based PVI, though further research is required to provide additional evidence of its positive impact on long-term AF ablation outcomes.

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