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Original Article

Embolization of arterial gastrointestinal hemorrhage with Fuaile medical adhesive

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Abstract

Background: To investigate the safety and effectiveness of Fuaile medical adhesive (FAL) with superselective catheterization in endovascular embolotherapy for the treatment of gastrointestinal hemorrhage (GIH) that was unresponsive to internal medicine treatment and gastroscopy management.

Methods: A total of 25 patients with GIH, confirmed using angiography but with failed results after internal medicine treatment or gastroscopy were retrospectively analyzed. A mixture of lipiodol and FAL (1:1) was used to embolize the bleeding vessels. In the follow-up, the operation time, FAL amount, technical success rate, clinical success rate, postoperative complications, and survival conditions were compared and analyzed.

Results: Among the 25 patients with GIH, FAL was applied alone in 23 patients and microcoil combined with FAL was applied in two patients. Hemostasis was successfully achieved in all patients. Two patients treated with embolotherapy experienced relapse of bleeding within 30 days but achieved successful hemostasis with FAL. Four patients died during follow-up: three patients died of advanced cancer and one patient died of severe infection induced by necrotizing pancreatitis. Three patients developed postoperative intestinal ischemic symptoms, which resolved spontaneously in two patients. In one patient, abdominal pain progressively aggravated. This patient underwent surgical resection, which confirmed the presence of colonic neoplasms. The intraoperative view revealed obvious ischemia of the local normal bowel near the tumor; however, the patient finally recovered and was discharged after surgery. The remaining patients exhibited good survival during the postoperative follow-up.

Conclusion: FAL embolotherapy has a high success rate for arterial GIH that was unresponsive to internal medicine treatment and gastroscopy management, with low postoperative rates of bleeding and complications; thus, this method has a high cost-efficacy.

Keywords: Complications; Embolism; Fuaile medical adhesive; Gastrointestinal hemorrhage

1. Introduction

Gastrointestinal hemorrhage (GIH) is a common medical emergency, and can be categorized into upper GIH (UGIH) and lower GIH (LGIH) based on the distance of the bleeding tract from the Treitz ligament. Studies have shown that the annual incidence of UGIH is 40−150 per 100,00 persons,[1] and the annual mortality rate is 10%−35%.[2] Of patients with LGIH, 25% may experience relapse of hemorrhage after

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internal medicine treatment, among whom 1%–10% die.[3] The treatment methods for GIH can be divided into three categories, namely, conservative and endoscopic therapy, surgery, and endovascular embolization. Conservative and endoscopic therapies are still the first-line treatment methods.[4] Patients with GIH have high surgical risks, including postoperative complications and mortality.[5] Thus, interventions that can resolve the problem with a higher success rate and lower mortality are desired.[6,7] Although endoscopy can clearly identify the location, nature, and cause of the lesion and stop the bleeding, there is a 30% probability of recurrent bleeding after endoscopic treatment.[8] The mortality rate of endoscopic treatment for acute UGIH is about 10%,[9,10] and the mortality rate in patients converted to surgical treatment after the failure of conservative or endoscopic treatment is about 20%–40%.[5] LGIH accounts for 20%–30% of the total GIH cases,[11–14] and the mortality rate of surgery can be as high as 30%.[15] Since Rösch et al.[16] successfully used transcatheter arterial embolization (TAE) for the treatment of UGIH in 1972, TAE has been widely applied in the treatment of nonvenous bleeding that was unresponsive to endoscopic therapy, especially in high-risk patients. TAE has more advantages over surgical treatment[17–21]; therefore, many medical centers consider TAE as the first-line treatment of GIH after the failure of endoscopic treatment.[5,22,23]

Currently, various types of embolic agents are available. Solid embolic agents have less efficacy when used in conditions such as complex collateral vessels, tortuous vessels, vasospasm, or coagulation disorders.[24] For such conditions, n-butyl cyanoacrylate (NBCA) can compensate for the insufficiencies solid embolic agents and be a good choice as a liquid embolic agent.[3,22] Our medical center (located in Beijing, China) uses Fuaile medical adhesive (FAL), which has similar embolization characteristics to NBCA, as a liquid embolic agent without the need for a specific catheter. Moreover, FAL is cheaper than NBCA. In this study, we retrospectively analyzed the clinical data of patients who received FAL embolotherapy for arterial GIH that was unresponsive to internal medicine treatment and gastroscopy management, and preliminarily investigated the efficacy and safety of this treatment method.

2. Methods

2.1. Background

The data of patients with GIH, who underwent interventional embolotherapy at our hospital, were collected. Interventional embolotherapy was administered to patients who met the certain criteria: (i) failed results after conservative or endoscopic therapy; (ii) inability to tolerate surgery; (iii) refusal of open surgery by the patient or family members; (iv) GIH due to rupture of the artery, not the vein. The criteria for study inclusion were: (i) presence of direct signs of GIH on intraoperative angiography, and (ii) simple application of FAL for embolotherapy or supplementary embolotherapy. The conditions in which FAL was selected as the embolic agent were: (i) the bleeding vessel was tortuous or slim, making it difficult for the surgeon to decide whether microcoil or gelatin sponge can achieve effective embolization; (ii) the patient had coexisting coagulation abnormalities; (iii) the patient showed unstable vital signs and needed immediate hemostasis; (iv) the patient needed medical adhesive application for supplementary embolization; (v) the patient or the family members were willing to adopt FAL as the first step of treatment after receiving an explanation of the method.

2.2. Patient information

A total of 25 patients treated between October 2012 and May 2015, who met the above criteria, were included in this retrospective study. The included patients comprised 17 men and eight women, aged 26–75 years (mean age, 53.5 years). According to the anatomical localizations, 19 patients had UGIH and six patients had LGIH. Etiological analysis revealed five patients had gastric ulcer, seven had duodenal ulcer, six had tumorous bleeding, four had postoperative bleeding, one had severe pancreatitis-induced vascular hemorrhage, and two had bleeding due to unknown causes. Eighteen patients exhibited various degrees of intraoperative blood coagulation abnormality, and only seven patients exhibited normal blood coagulation function.

2.3. Procedure of embolotherapy

All patients first underwent angiography with 5F catheters (Terumo, Japan) targeting the celiac trunk, as well as the superior and inferior mesenteric arteries. After identifying the bleeding vessels, coaxial catheterization was performed with a micro-catheter (2.7F; Terumo, Japan) combined with a microguidewire (0.014 in; Terumo, Japan), for superselective catheterization of the bleeding vessels. Thereafter, the target vessels were subjected to microcatheter-based uniform angiography to sufficiently reveal the lesions. If the target vessels cannot be effectively reached, the catheter tip was placed as close as possible to the target vessels. When the microcatheter has reached the target site as confirmed with angiography, 5% glucose solution was used to repeatedly wash the catheter, in order to maintain a non-ionic state inside the microcatheter. This was done to avoid embolization failure induced by intra-catheter medical adhesive polymerization during the injection. Before injection, FAL was mixed with lipiodol (Laboratoires Andre Guerbet, Aulnay-sous-Bois, France) in a 1:1 ratio for good visibility and polymerization time. When reflux signs appeared, embolization was immediately stopped and the catheter was quickly withdrawn. The entire injection procedure was monitored under fluoroscopy to ensure the safety of embolotherapy. After the microcatheter and the 5F catheter were withdrawn from the vessels, 5% glucose was applied in vitro for repeated washing to maintain catheter patency. Target artery angiography was later performed to confirm the embolization results, and if the results were poor, the above steps can be repeated for supplementary embolization.

2.4. Follow-up evaluation

After embolization, the operation time, FAL amount, and technical success rate were analyzed, and the clinical success rate, surgery-related complications, and survival condition were followed-up. The operative time was defined as the duration from the successful insertion of the 5F catheter into the gastrointestinal tract for angiography to the repeat angiography after complete embolization. Technical success was defined as the disappearance of lesions and lack of contrast agent extravasation on full angiography immediately after embolization. Clinical success was defined as the absence of re-bleeding in the re-embolization region within 30 days after embolotherapy. The definitions of treatment-related complications were determined according to international embolotherapy guidelines.[25]

3. Results

3.1. Radiography

Among the 25 patients, angiography revealed contrast agent extravasation in 24 patients and pseudoaneurysm in one patient. The bleeding vessels were the gastroduodenal artery in 12 patients, the left gastric artery in three patients, the superior mesenteric artery in five patients (Fig. 1), the mesenteric artery in three patients, the right gastric artery in one patient (Fig. 2), and the pancreaticoduodenal branch artery in one patient (Table 1, Fig. 3).

3.2. Embolization

In 23 patients, superselective catheterization targeting the bleeding vessel was successfully performed; however, superselective catheterization failed in two patients (nos. 13 and 18) because of the tortuous shape of the bleeding blood vessels, and thus, the microcatheter was placed into the upper level vessel. Among the 25 patients, 18 patients exhibited coagulation disorders; 23 patients preferred FAL whereas two patients preferred microcoil embolization, which was supplemented with FAL upon hemostasis failure. Embolization was successful in all patients, with a technical success rate of 100%. The amount of FAL and lipiodol mixture was 0.3–09 mL (average, 0.6 mL). The operation time was 12–28 min (average, 19.4 min). The average cost of FAL was 75.4 USD (range, 65–130 USD; cost of glue: 65 USD per vial). Two patients with tumor experienced re-bleeding (26 days later in patient no. 4 and 14 days later in patient no. 15), which was confirmed with angiography. Successful supplementary embolization with FAL was done in our department. The overall clinical success rate was 92% (23 of 25).

3.3. Complications

Three patients were converted to surgery when their bleeding stopped, and they were all discharged after healing. Among these three patients, one patient (no. 13) exhibited postoperative abdominal pain in the embolization area that progressively aggravated for three days, which was considered to be intestinal ischemia. Thus, this patient underwent local surgical excision. The postoperative pathology suggested intestinal tumor, and the normal local intestinal tract 5 cm close to the tumor area exhibited significant ischemia, which was also resected simultaneously. The other two patients exhibited mild abdominal pain; however, no special treatment was performed before the abdominal pain resolved spontaneously. Four patients died of disease progression during follow-up; however, no surgery-related death occurred. No other surgery-related complications, such as femoral artery puncture or visceral vascular injury (excluding the target vessels), occurred.

4. Discussion

This study showed that embolization with FAL injection to control GIH can be safe and effective. The treatment of different diseases requires different types of embolic agents to address specific conditions effectively. The arterial vasculature of the digestive tract is normally characterized by complex collateral vessels, tortuous vessels, vasospasm, or coagulation disorders, and the bleeding site is usually at the terminal branch vessel; thus, the embolization material need to be deployed more proximally to the bleeding site. In this study, FAL injection with the coaxial technique and microcatheterization achieved precise localization, embolization, and fewer complications.

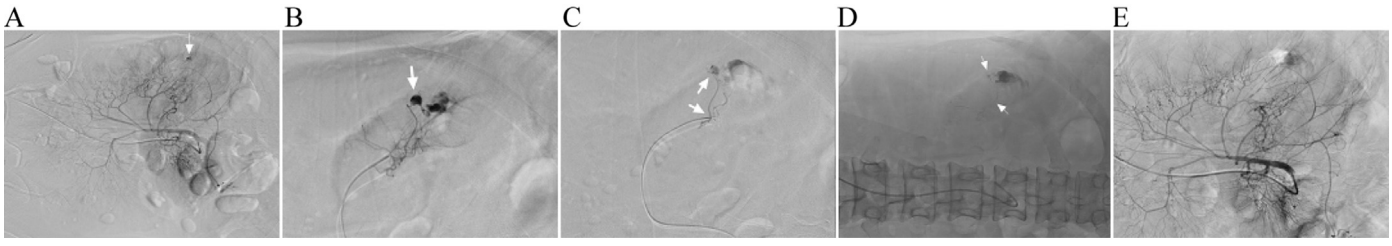

Fig. 1. NO22, male, 45 years old, admitted for 1-day unexplained hematochezia. A. The 5F catheter is hooked on the superior mesenteric artery, and the subtraction suggests the right hemicolonic peripheral arterial branch ruptures, and the contrast flows out (arrow); B. The microcatheter is superselectively inserted into the target vessel for angiography, and further determines the bleeding vessel (arrow); C. The microcatheter is superselectively inserted into the target vessel for FAL embolotherapy (arrow); D. Oneshot photography clearly shows the perfect shaping of FAL in the target vessel in the embolization region (arrow); E. Re-5F catheter angiography shows the signs of target vessel and contrast extravasation disappear.

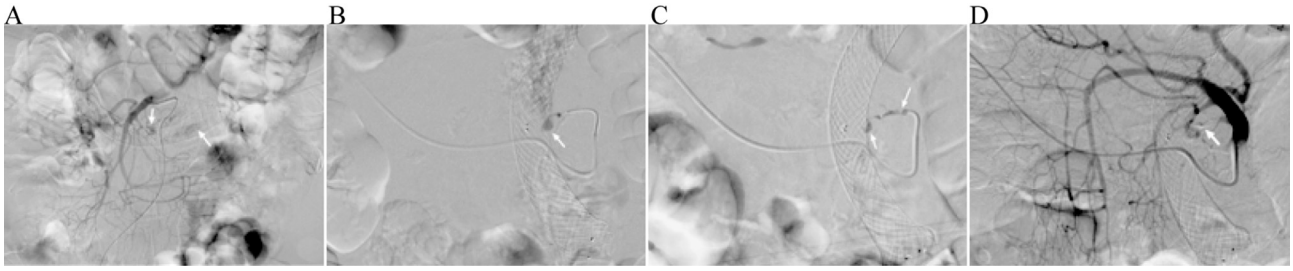

Fig. 2. NO4 male, 53 years old, patient with pancreatic cancer, admitted due to intermittent hematochezia within 3 months after duodenal stent implantation. A. The 5F catheter is hooked on the superior mesenteric artery, and the angiography shows the distal pancreaticoduodenal artery branch enlargement (arrow), and partial contrast agent enters the intestinal stent (arrow); B. The microcatheter is superselectively inserted into the pancreaticoduodenal branch, and the angiography shows contrast extravasation into the intestine (arrow); C. FAL embolization (arrow); D. Re-5F catheter angiography shows the perfect shaping of FAL in the target vessel (arrow) and no sign of contrast extravasation.

The choice of embolic material is usually dependent on the underlying pathology, vascular anatomy, availability of the embolic agent, and preference of the surgeon. Currently, various interventional embolic materials are available. Different embolic materials are used for different diseases and different body parts. Therefore, familiarization with the nature of the embolic material is an essential requirement for the surgeon. Each embolic agent has its advantages and disadvantages. First, solid embolic agents, such as microcoils, have good visibility, different specifications, simple operation, and similar features for surgical ligation. Thus, they are easy to apply when the target blood vessel is in a relatively good condition; however, release of the embolic agent is difficult to achieve accurately and effectively in tortuous and slim vessels.[23] Meanwhile, the selection of microcoil and catheter tip fixation during the release of the microcoil are bigger problems.[26] Intraoperative problems, such as too large microcoils or microcoil injection-induced catheter tip rollback will be difficult to overcome, thus easily leading to ectopic embolization. Second, gelatin sponge particles are relatively cheaper, have good diffusion properties, and can embolize multiple vessels simultaneously; however, their poor visibility and controllability may easily lead to ectopic embolization. Furthermore, as the embolus is absorbable, late revascularization may be a future problem.[27] In addition, all solid embolic agents are based on the mechanism of mechanical embolization to promote thrombosis and stop bleeding. Consequently, they have some common shortcomings: (i) when the coagulation function is poor, thrombosis is difficult to detect after embolization, which results in a high rate of post-embolization recurrent bleeding, and (ii) as collateral vessels cannot be effectively embolized, the bleeding cannot be stopped completely. On the other hand, medical adhesive liquid embolic agents have certain advantages: (i) as the embolization mechanism is based on strong polymers generated by the polymerization of the agent and ions, the purpose of thrombosis prevention will not be affected by the coagulation function; (ii) the effects of embolization are exact because the flow properties are good and the embolization is permanent, the embolic agent can effectively enter slim and tortuous target vessels and collateral vessels, and revascularization will be difficult; (iii) when mixed with lipiodol, liquid embolic agents have good visibility and good controllability.

Our research center uses Chinese-made FAL, which is composed of *N*-octyl-α-cyanoacrylate (NOCA; purity >99%) and NBCA (ratio 1:4), has a polymerization time ranging from two to 6 s, and forms very stable and strong polymers in vivo.[28] NBCA and Onyx are medical adhesives with similar embolic mechanisms; thus, they have similar clinical applications. However, the price of FAL is only 1/7 that of NBCA ($65 vs. $485) and 1/17 that of Onyx ($65 vs. $1129). However, as the injection of FAL does not need a special catheter, its cost-efficacy is higher. Animal experiments have revealed that the mixture of FAL and lipiodol in a ratio of 1:1 can achieve instant embolization, and this mixture has been successfully applied in the clinic.[28]

On the basis of our experience, the success rate of using FAL for the treatment GIH can be improved and its complications can be reduced with some operational considerations. (i) The surgeon should be extensively trained before performing the operation individually; first, in vitro tests should be performed to understand its features; second, success should be achieved in animal experiments; third, progressive embolization should be performed based on the degree of the risk of different surgical sites, and the embolization of parenchymal organs should be practiced under the guidance of experienced doctors, and further applied in UGIH first and LGIH later when sufficient skill has been achieved. (ii) The amount of FAL should be accurately calculated using the formula: total amount = amount injected into the lesion + catheter volume + remaining amount. The injection amount can be arrived at through repeated angiographic evaluations targeting the lesion; injection speed should be uniform to avoid regurgitation. Owing to the different characteristics between the mixture of medical adhesive-lipiodol and the contrast agent, the injection speed and injection amount are slightly smaller than those used during angiography. (iii) The ratio of FAL to lipiodol can be changed according to the vascular anatomic conditions; the lower the proportion of FAL, the longer the polymerization time will be, which may be useful for embolizing the distal end of blood vessels. However, based on clinical experience, the ratio of 1:1 can usually achieve effective and satisfactory embolization. (iv) The increased risk of intestinal necrosis when embolizing four

Table 1
Patient information.

No	Sex/age	Bleeding reason	Angiographic appearance	Coagulation disorders	Target vessel	Embolotherapy material
1	F/48	GU	E	Yes	GDA	FAL
2	F/73	DU	E	Yes	GDA	FAL
3	M/62	Stomach cancer	E	Yes	LGA	FAL
4	M/53	Pancreatic cancer	E	Yes	PD-arcade	FAL
5	M/62	DU	E	Yes	GDA	FAL + Coil
6	M/38	Pancreatitis	E	Yes	SMA	FAL
7	M/41	GU	E	Yes	GDA	FAL
8	M/37	DU	E	Yes	GDA	FAL
9	F/75	Rectal cancer	E	No	IMA	FAL
10	M/42	GU	E	No	GDA	FAL
11	M/68	After gastroenterostomy	P	Yes	SMA	FAL
12	F/35	DU	E	Yes	GDA	FAL
13	M/59	Colonic cancer	E	No	SMA	FAL
14	M/53	DU	E	Yes	GDA	FAL
15	M/69	Stomach cancer	E	No	GDA	FAL
16	F/58	After rectal cancer surgery	E	Yes	IMA	FAL + Coil
17	M/59	After gastroenterostomy	E	No	LGA	FAL
18	M/69	NA	E	No	SMA	FAL
19	M/34	Colic polyp	E	No	IMA	FAL
20	F/50	DU	E	Yes	GDA	FAL
21	M/68	Stomach cancer	E	Yes	LGA	FAL
22	M/45	NA	E	Yes	SMA	FAL
23	F/74	DU	E	Yes	GDA	FAL
24	M/26	GU	E	Yes	RGA	FAL
25	F/39	GU	E	Yes	GDA	FAL

No	Amount of FAL and lipiodol (ml)	Operation time (min)	Rehaemorrhagia	Follow-up results
1	0.8	15	No	Discharged 10 days later
2	0.6	18	No	Discharged 15 days later
3	0.6	25	No	Transferred to surgery, discharged after surgery
4	0.5	28	26 days	Supplemented embolization, died 3 months later
5	0.4	26	No	Discharged 7 days later
6	0.6	20	No	Died 20 days later
7	0.7	16	No	Discharged
8	0.7	22	No	Discharged 5 days later
9	0.5	12	No	Transferred to surgery, discharged after surgery
10	0.9	18	No	Discharged 8 days later
11	0.3	22	No	Discharged 17 days later
12	0.7	17	No	Discharged 5 days later
13	0.6	25	No	Transferred to surgery 4 days later, discharged after surgery
14	0.8	20	No	Discharged 11 days later
15	0.5	23	14 days	Supplemented embolization, died 5 months later
16	0.6	14	No	Died 12 months later
17	0.6	20	No	Discharged 18 days later
18	0.4	17	No	Discharged 20 days later
19	0.3	13	No	Discharged 11 days later
20	0.6	16	No	Discharged 6 days later
21	0.7	28	No	Discharged 15 days later
22	0.5	22	No	Discharged
23	0.8	17	No	Discharged 3 days later
24	0.6	18	No	Discharged 4 days later
25	0.7	14	No	Discharged 5 days later

GU = gastric ulcer; DU = duodenal ulcer; RGA = right gastric artery; GDA = gastroduodenal artery; LGA = left gastric artery; IMA = inferior mesenteric artery; SMA = superior mesenteric artery; PD arcade = pancreaticoduodenal branch artery; FAL = Fuaile.

or more intestinal branch vessels was once reported[29] (especially in the lower gastrointestinal tract[30]); thus, the catheter tip should enter or be close to the target vessel as much as possible, and the injection should be stopped immediately when embolization occurs and signs of reflux appear. (v) After embolization, the microcatheter and 5F catheter should be withdrawn quickly to prevent adhesion between the catheter and the vessel, and 5% glucose should be used for repeated washing in vitro. Washing should be avoided in vivo in cases where the intracatheter adhesive enters the intestinal vessels and results in ectopic embolism. After the cleaning, the catheter can secure the corresponding blood vessel for angiography to confirm the embolization effects. (vi) In some special cases, such as high-flow bleeding, embolic agents should be comprehensively

Fig. 3. NO24 male, 26 years old, patient with gastric ulcer, admitted due to sudden hematemesis. A. The 5F catheter is hooked on the superior mesenteric artery, and the angiography shows the right gastric artery ruptures, as well as contrast extravasation (arrow); B. The microcatheter is superselectively inserted into the right gastric artery for angiography and FAL embolization (arrow); C. Re-5F catheter angiography shows the perfect shaping of FAL in the target vessel (arrow) and no sign of contrast extravasation.

used, and medical adhesive embolic agent alone may be rapidly washed away by the bloodstream, thus leading to incomplete embolization or ectopic embolization. At this time, microcoil embolization can be used first to reduce the flow rate, followed by supplementary embolization with medical adhesive. Taking the results together, FAL embolization is a relatively safe procedure. In this study, one patient developed severe intestinal ischemia and had to undergo surgery because of highly tortuous target vessels, which made the exact placement of the catheter tip at the target vessel difficult, leading to the embolization of more than four branch vessels. All other patients showed no serious treatment-related complications. Technical success was achieved in all patients, and compared with previously reported embolization efficiencies of NBCA in GIH (75.3%–96.4%),[10,31–33] the success rate of FAL in this study was 92%.

Compared with embolization with NBCA and Onyx, FAL embolization is more difficult owing to its short injection time (NBCA injection rate: 0.1 mL/min). However, this problem can be solved through the above-mentioned operational considerations. As FAL has better cost-efficacy, it is a good choice for patients with economic difficulties. Therefore, FAL is a reasonable choice as an embolic agent for some patients and surgeons compared with other embolic materials.

Jiang et al.[34] reported that NOCA and NBCA exhibit significant adhesion and the risk of the microcatheter adhering to blood vessels. Moreover, their aggregation effects may produce heat. In comparison, FAL has an appropriate polymerization speed, low polymerization heat, and desirable diffusion. Thus, FAL is safe for human use.

However, our study has several limitations. First, this study included a small number of patients and had a retrospective design. Second, the use of FAL was operator dependent. Third, there was no evidence to prove that the effect of the use of FAL alone has any statistical difference with that of the use of other embolic agents.

In conclusion, by developing proficiency in the use as medical adhesive, FAL can be safely and effectively applied in GIH, especially in cases in which solid embolic agents cannot reach the lesion or when the patient has coagulation dysfunction. FAL has similar features to NBCA, and the same safety and efficacy. Furthermore, FAL has the added advantage of being much more cost-effective.

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