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HOW-I-DO-IT ARTICLE

Endoscopic vacuum therapy (EVT) for early infradiaphragmal leakage after bariatric surgery—outcomes of six consecutive cases in a single institution

Bernhard Morell[1] · Fritz Murray[1] · Diana Vetter[2] · Marco Bueter[2] · Christoph Gubler[1]

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Abstract

Purpose Anastomotic leakages or staple line defects after Roux-en-Y gastric bypass (RYGB) and primary laparoscopic sleeve gastrectomy (LSG), respectively, with consecutive bariatric revisional surgery are associated with relevant morbidity and mortality rates. Endoscopic vacuum therapy (EVT) with or without stent-over-sponge (SOS) has been shown to be a promising therapy in foregut wall defects of various etiologies and may therefore be applied in the treatment of postbariatric leaks.

Methods We report the results of six consecutive patients treated with EVT (83% in combination with SOS) for early postoperative leakages in close proximity to the esophagogastric junction (EGJ) after LSG ($n = 2$) and RYGB ($n = 4$) from May 2016 to May2018.

Results All patients (2/6 male, median age 51 years, median BMI 44.2 kg/m^2) were treated successfully without further signs of persisting leakage at the last gastroscopy. The lesions' size ranged from 0.5 cm^2 to 9 cm^2, and the leaks were connected to large (max. 225 cm^2) abscess cavities in 80% of the cases. Median duration of treatment (= EVT in situ) was 23.5 days (range, 7–89). The number of endoscopic interventions ranged from 1 to 24 (median, $n = 7$), with a median duration between vacuum sponge replacements of 4 days.

Conclusion EVT is an effective and safe treatment for staple line defects or anastomotic leakage after bariatric surgeries and can therefore be adopted for the treatment of midgut wall defects. Further studies with a greater number of patients comparing surgical drainage alone or in combination with EVT versus EVT alone are needed.

Keywords Endoscopic vacuum therapy · Stent-over-sponge · Laparoscopic sleeve gastrectomy · Roux-en-Y gastric bypass · Anastomotic leakage · SEMS

✉ Christoph Gubler
christoph.gubler@usz.ch

Bernhard Morell
bernhard.morell@usz.ch

Fritz Murray
fritz.murray@usz.ch

Diana Vetter
diana.vetter@usz.ch

Marco Bueter
marco.bueter@usz.ch

[1] Division of Gastroenterology and Hepatology, University Hospital Zurich, Raemistrasse 100, 8091 Zurich, Switzerland

[2] Division of Surgery and Transplantation, University Hospital Zurich, Raemistrasse 100, 8091 Zurich, Switzerland

Abbreviations

LSG	Laparoscopic sleeve gastrectomy
RYGB	Roux-en-Y gastric bypass
GI	Gastrointestinal
SEMS	Self-expandable metal stent
EVT	Endoscopic vacuum therapy
SOS	Stent-over-sponge
EGJ	Esophagogastric junction
CT	Computed tomography

Introduction

Since 1975, the worldwide prevalence of obesity has nearly tripled [1] and is associated with substantial comorbidities and a noteworthy economic burden. Currently, laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass

(RYGB) comprise the most efficient therapies in treating morbid obesity.

Despite the relatively low incidence of postbariatric surgery leaks ranging between 1.5% and 4.9% [2–5], the growing number of bariatric surgeries leads to a significant increase of complications. It is commonly recognized that revisional bariatric operations are (i) technically demanding and (ii) associated with intra- and postoperative complications thereby carrying a severalfold increased risk of mortality [6, 7].

During the last decade, interventional endoscopy has become an invaluable alternative or addition to revisional surgery. Hitherto, the endoscopic placement of self-expandable metal stents (SEMS) has been regarded as the mainstay of the endoscopic management with postbariatric leak closure of up to 88% [8]. However, stent-related complications such as stent migration, local pressure necrosis, bleeding, mucosal ulcers, and strictures are frequently encountered adverse events. In the management of postbariatric complications, SEMS treatment is further hampered by the frequent requirement for supplementary abscess drainage to prevent or treat sepsis. Due to the mentioned limitations, SEMS has been challenged by endoscopic vacuum therapy (EVT) that was first introduced for the treatment of anastomotic leakage-complicating rectal resection [9, 10]. Vacuum therapy using a polyurethane foam has the ability to seal the leak, thereby decreasing bacterial contamination, promoting vascularity, and propagating the formation of granulation tissue [11, 12]. In fact, retrospective studies suggest that EVT may be superior to other treatment modalities [13–15]. In 2013, our group introduced the stent-over-sponge (SOS) treatment which combines EVT with SEMS placement [16]. In selected cases, this technique optimizes vacuum therapy by directing the vacuum force towards the defect which in our experience results in faster ingrowth of granulation tissue, thus promoting more rapid closure of the defect. Only scant literature, however, exists on EVT in bariatric patients [17, 18].

Material and methods

Patient selection

We herein describe the endoscopic treatment of six consecutive patients (2/6 male, median age 51.5 years, median BMI 44.3 kg/m^2, median preoperative weight 133.5 kg; for detailed patient characteristics see Table 1) that were treated with EVT for early postoperative anastomotic leakages after primary LSG ($n = 2$) and RYGB ($n = 4$) at our institution between May 2016 to May 2018. Four patients (# 1, 2, 5, and 6) were referred from other hospitals after the initial treatment of the postoperative leak had failed.

Endoscopic interventions

All endoscopies were conducted with Olympus single-channel gastroscopes (Olympus Medical Systems, Tokyo, Japan). The technical aspects of the endoscopic procedures (EVT and SOS) have been previously described [16, 19]. Briefly, the initial endoscopic assessment included an approximative assessment of the dehiscence dimensions in reference to standard biopsy forceps. The placement of the Eso-SPONGE® (B. Braun Melsungen AG, Melsungen, Germany) consisting of an open-pored polyurethane sponge fitted to a gastric tube was aided by a previous endoscopic placement of an overtube provided by the manufacturer. Using the Eso-SPONGE® pusher, the foam was directly placed into the wall defect, or in case of large perforations into abscess cavities (Fig. 1). In two patients, the sponge placement was complicated due to angulation of the opening towards the wound cavity. Hence, the insertion had to be performed applying the "backpack method", i.e., the sponge was pulled in to the cavity using a forceps after a suture loop was attached to the tip of the loop. After optimal placement, continuous negative pressure of 75 mmHg was applied over the sponge suction tube which was connected to a vacuum device (VAC Medela, Baar, Switzerland). In 83% of the presented cases, the stent-over-sponge (SOS) technique was applied at least once as described previously by our group [16]. In brief, after insertion of the foam into the wound cavity, a partially covered SEMS (Ultraflex Esophageal NG, Boston Scientific, Marlborough, MA, USA; or Hanaro Esophagus, M.I. Tech, Pyeongtaek, South Korea) was placed over the foam in order to avoid dislodging from the correct position. The SOS technique was applied if the wall defect was considered too large to be sealed by the sponge in order to prevent muddy reflux into the cavity or in case of smaller defects, the luminal placement appeared to be ineffective. A scheme of the described endoscopic interventions is shown in Fig. 2. The sponge was replaced every 3–5 days in order to prevent ingrowth of granulation tissue. Vacuum therapy was considered successful if no macroscopic evidence for a persisting dehiscence was visible after final sponge removal without subsequent need for any surgical intervention. All treatments were performed in accordance with previous institutional experiences aiming for a prospective analysis. All patients signed the written informed consent for the endoscopic treatment and consented the analysis and anonymized publication of their medical data.

Results

Patient characteristics

We retrospectively analyzed six consecutive patients who were treated endoscopically at our institution for leakage

Table 1 Patient characteristics

Patient	Sex; age (years)	Type bariatric surgery	Size and type of wall defect and abscess cavity	BMI (kg/m^2)	Number of postoperative days until diagnosis of leakage	Days from diagnosis of leakage until EVT	Type first-line treatment, if any	Number of endoscopies (= number of endosponge placements)	Median number of days between sponge exchanges	Number of SEMS implantations	Median number of days between SEMS exchanges	Total duration of EVT (days)	Additional interventional therapy during EVT	Duration of hospitalization (duration of stay on IMC/ICU) (days)	Therapeutic success
1	Female; 51	LSG	2 × 1 cm dehiscence, 10-cm-deep intraperitoneal abscess cavity	48	3	1	None	9	4	6	4	39	Laparoscopic lavage due to enlarging infradiaphragmatic abscess cavity 11 days after start of EVT	52 (1/0)	Yes
2	Female; 60	RYGB	1.5 × 1 cm dehiscence, 5-cm-deep abscess cavity	48.9	3	4	None	7	4	5	4	24	No	42 (1/0)	Yes
3	Male; 54	RVGB	1 × 0.5 cm dehiscence, 2-cm-deep cavity	40.6	9	1	Surgical repair	1	4	0		7	No	30 (0/2)	Yes
4	Female; 29	RYGB	1.5 × 1.5 cm dehiscence, no cavity	44.3	3	7	Surgical repair + SEMS	3	4	3	4	12	No	22 (0/0)	Yes
5	Male; 48	LSG	3 × 3 cm dehiscence, 15 × 15 cm abscess cavity	42.2	5	6	Laparoscopic lavage and drainage + 2 SEMSs	24	3	16	3	89	ECMO due to severe secondary ARDS with multiple organ failure; unsuccessful attempt to close fistula with Padlock Clip™	71 (0/40)	Yes
6	Female; 52	RYGB	3 × 3 cm dehiscence, 5 × 5 cm abscess cavity, fistula to remaining stomach	41.3	4	1	surgical repair + drainage of abscess	7	3	6	3	23	ECMO due to severe secondary ARDS	22 (7/10)	Yes

LSG laparoscopic sleeve gastrectomy, *RYGB* Roux-en-Y gastric bypass, *EVT* endoscopic vacuum therapy, *SEMS* self-expandable metal stent, *IMC* intermediate care unit, *ICU* intensive care unit, *ECMO* extracorporeal membrane oxygenation, *ARDS* acute respiratory distress syndrome

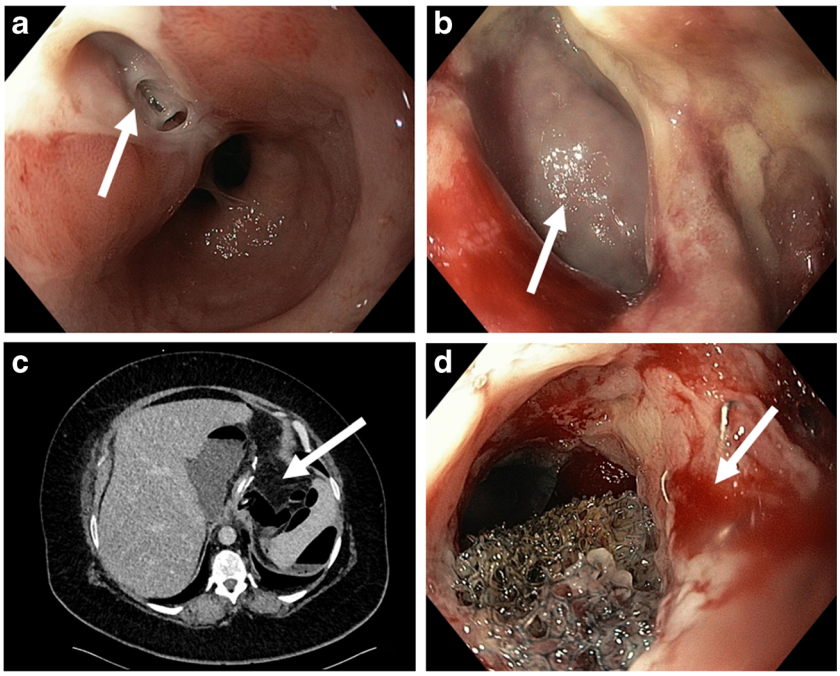

Fig. 1 Initial situation patient #1. **a** Initial dehiscence (gastroscopy #1). **b** Enlarged dehiscence with visualization of the spleen (gastroscopy #4, 11 days after initial EVT). **c** Exemplary CT image showing large fluid collection with entrapped air. **d** Eso-SPONGE® in defect (gastroscopy #6, 18 days after initial EVT)

in the upper gastrointestinal tract after bariatric surgery between 2016 and 2018. All treated complications were considered early occurring within a median of 3.5 postoperative days (range 3–9). In five of the six cases, diagnosis was made by computed tomography (CT). In the remaining case (1/6), a dehiscence was solely seen during diagnostic gastroscopy. In the patients undergoing LSG, an underlying defect staple line rupture was found (2/6). In case of the leaks post-RYGB (4/6), anastomotic leakage was detected. The median number of days between diagnosis of the anastomotic leakage and the beginning of EVT was 2.5 days (range 1–7), resulting in a median of 7.5 days (range 4–11) after the initial bariatric surgery. All leakages or defects were located distally to the diaphragm in close proximity to the gastroesophageal junction (EGJ) with an endoscopically measured distance to the teeth ranging from 39 to 50 cm. In 5/6 of the patients (83%), the leakages or staple line defects, respectively, were connected to considerably large (up to 15 × 15 cm) infradiaphragmatic abscess cavities. Prior to EVT, a total of three patients (# 3, 4, and 6) underwent surgical repair which was combined with the placement of a self-expandable metal stent (SEMS) in one case (patient #4). Another patient (#5) underwent SEMS placement along with laparoscopic lavage prior to EVT.

Clinical course and procedure-related complications

No therapy-related severe adverse events were observed. Of note, none of the patients operated at our institution developed

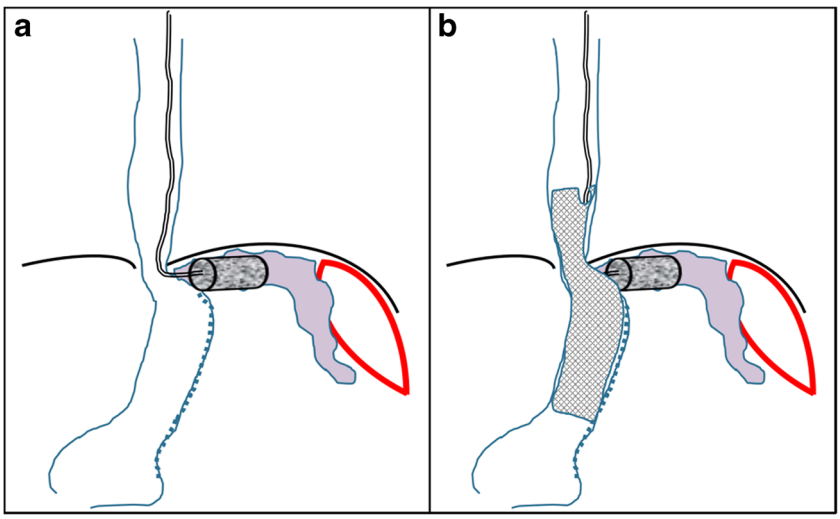

Fig. 2 Endoscopic vacuum therapy (EVT) as performed in patient #1. **a** Intracavitary EVT was initially applied. **b** Care was taken to avoid any contact with the spleen (exemplified by the red line). As the cavity diminished in size, the stent-over- sponge (SOS) method was used

sepsis nor needed to be referred to the intensive care unit. In one patient (patient #1), esophageal wall stripping occurred when the SEMS was extracted and an enlarging intraperitoneal abscess cavity with extension to the spleen had to be laparoscopically drained. In the same patient, great care was taken that the foam was not in contact with the spleen to prevent potential splenic hemorrhage. Over the course of the prolonged hospital stay with a total of nine sponge replacements, the patient was diagnosed with adjustment disorder, requiring psychiatric counseling. Two of the four patients that were referred to our hospital presented with secondary acute respiratory distress syndrome which required initiation of extracorporeal membrane oxygenation before referral to our institution. In one of these patients (#5), the application of Padlock Clip™ to close a fistula was ineffective after 16 sponge treatments had been performed. Subsequently, this patient underwent another eight EVTs which finally resulted in sustained closure of the defect. The other three patients did not receive any additional interventional therapy during the course of EVT. The decision to terminate EVT was based on visual conformation of a small contained wound cavity, lined by granulation tissue (Fig. 3). The median duration of EVT was 23.5 days (range 7–89) with a median number of 7 endoscopic interventions (range 1–24) conducted in a median of 4 days (range 3–4) in between sponge replacements. In 83.3% (5/6 patients) of the cases, EVT was combined with SOS. In these five patients, a median of 5.5 (3–16) SOS-replacements were performed. Representative images of the endoscopic procedures are shown in Figs. 1 and 2. During the course of EVT, all patients received broad spectrum antibiotics.

Discussion

A leak-complicating bariatric surgery represents still a life-threatening situation, and its management remains a major clinical challenge. The evidence published on EVT in bariatric patients, however, is extremely limited, and no guidelines embrace its implementation. To the best of our knowledge, this is the largest case series evaluating the clinical course of bariatric patients undergoing EVT due to anastomotic or staple line leakage. The rationale to apply EVT in bariatric patients is mainly derived by the favorable outcomes observed in the treatment of leakages of various other etiologies, such as anastomotic insufficiency secondary to esophagectomy, Boerhaave's syndrome, or iatrogenic perforations [13–15]. Considering the serious instability of two of our patients (# 5 and 6), the clinical outcome of our series with no mortality, low EVT-associated morbidity, and complete recovery is excellent. According to our experience, EVT may reduce the need for percutaneous drainage and serves as another argument to forgo routine use of an abdominal drain following bariatric surgery [21]. It needs to be emphasized, however, that significant EVT-related complications, such as severe hemorrhage due to eroded blood vessel [13] or dislodgement of the foam into the pharynx compromising respiration (personal observation beyond this study), occur. In addition to that, physicians need to be aware that repeat sponge replacements can lead to considerable psychological distress in affected patients. As a result, one patient undergoing 16 sponge placements over a period of 89 days developed adjustment disorder that made psychiatric counseling necessary. Whereas most publications on EVT in the upper GI tract focus on the treatment of supradiaphragmatic perforations, we herein

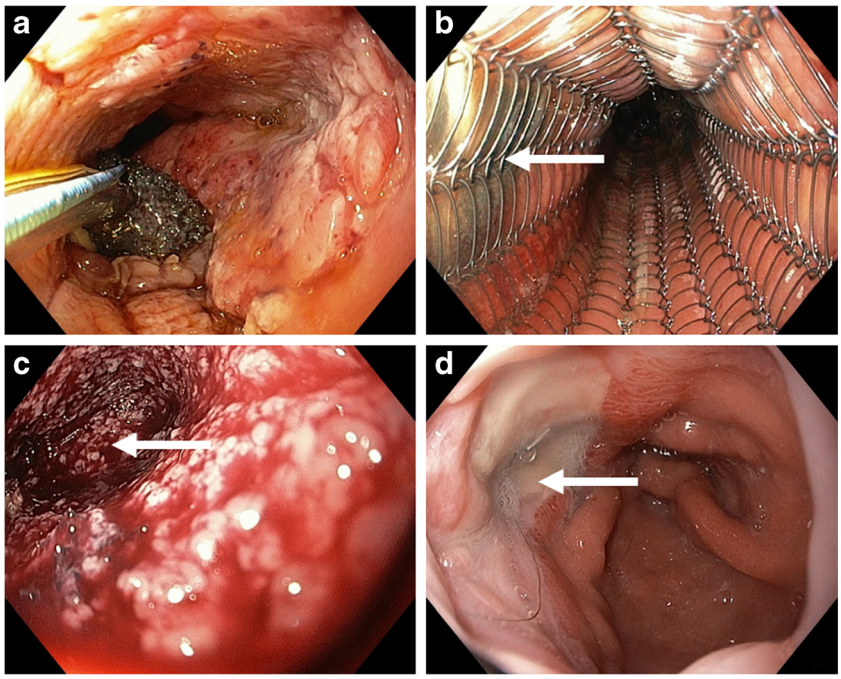

Fig. 3 Course of treatment patient #1. **a** Formation of granulation tissue with Eso-SPONGE® in situ (gastroscopy #7, 24 days after initial EVT). **b** Stent-over-sponge (gastroscopy #7, 24 days after initial EVT). **c** Granulation tissue in former cavity (gastroscopy #9, 31 days after initial EVT). **d** Final visualization of initial dehiscence with healed mucosa (gastroscopy #12, 40 days after initial EVT)

demonstrate the feasibility of EVT distally to the diaphragm in patients with extensive defects. By using the backpack method, overtube length did not preclude treatment of wall defects in the midgut, as they occur in anastomotic leakage of the gastrojejunostomy after RYGB.

As described above, partially covered SEMS were used instead of fully covered stents based on the rationale that the uncovered meshes of the stents may prevent migration [20]. Nonetheless, SEMS migration occurred in one patient.

Since timely treatment of postbariatric leaks is crucial, any treatment delay should be avoided. The lag between the diagnosis of the leakage and the initiation of EVT is mainly attributed to the fact that four patients (# 1, 2, 5, and 6) were referred from other hospitals. In patient #4, EVT was applied after a previous SEMS treatment over a period of 7 days did not result in clinical improvement.

Undeniably, our study has some limitations. The successful treatment of a limited number of cases does not rule out potential treatment failures. Additionally, the question of how to combine the various treatment modalities in the management of postbariatric leaks remains unsolved. Since repeat inpatient endoscopies are required during EVT, expenditures are of major concern, especially when combined with the SOS-principle. As mentioned above, SEMS placement represents another effective treatment option [20, 22, 23] with the potential advantage of (i) fewer endoscopies and (ii) outpatient treatment. Relating to the data published by Murino et al. [20], reporting on the outcome for 91 postbariatric patients, 74 patients could be successfully treated by SEMS application, thereof 36 were treated by a single SEMS placement. However, it needs to be emphasized that clinical success rate in the cited studies is less than 90% and treatment failure likely results in prolonged hospital stay generating additional costs. Therefore, the evaluation of other treatment modalities such as EVT appears to be justified. The significant costs generated by the application of the SOS-principle, however, should be carefully balanced against their potential benefits. To make an example, in patient #5 requiring 16 SEMS-placements, additional costs of approximately 40,000 Swiss francs were generated. It needs to be mentioned, however, that the same patient was critically ill needing treatment on ICU for 40 days.

We applied therefore the SOS-principle only when the clinical condition of the patient required aggressive treatment and either a mismatch between the size of the leak, the luminal diameter, and the size of the sponge was postulated or the defect was too large to be sealed by the sponge. By using the SOS method in turn, ineffective application of EVT could be reliably prevented.

Taking the various arguments together, EVT may be regarded as an effective alternative to SEMS placement in patients with large wound cavities that are amenable to sponge placement whereas the SOS-principle should be reserved for severely ill patients in whom sponge dislodgement is a major concern. Prospective studies are paramount to further elucidate the issue of cost-effectiveness, since growing number of postbariatric patients call for resource-sparing treatment algorithms that offer guidance in the choice of the optimal treatment strategy in relation to specific patient characteristics. Of note, pathophysiology and course of illness in patients with postbariatric leakage depend to some extent on the type of bariatric surgery. Leaks in patients undergoing LSG are usually located at the angle of His, and their treatment may be more time consuming [20, 24] because the sleeved stomach represents a high pressure system due to sphincters at both ends. Whereas the limited number of patients in our case series does not allow any conclusions to be drawn concerning this matter, trials evaluating EVT compared to transpyloric SEMS treatment in patients with leaks at the angle of His would be of great interest.

Finally, the role of endoscopic internal drainage (EID) by inserting pigtails into collections compared to EVT or SEMS treatment has not yet been defined. With respect to EVT, EID may be better tolerated and offers the advantage of outpatient treatment.

Conclusion

In summary, EVT is an effective and safe treatment for staple line or anastomotic leakage after bariatric surgeries and can be adopted for the treatment of midgut defects. Further studies with a greater a number of patients comparing surgical drainage alone or in combination with EVT versus EVT alone are needed.

Authors' contributions Study concept and design: Bernhard Morell, Fritz Murray, Christoph Gubler. Acquisition of data: Bernhard Morell, Fritz Murray, Marco Bueter. Analysis and interpretation of data: Bernhard Morell, Fritz Murray, Christoph Gubler. Drafting of manuscript: Bernhard Morell, Fritz Murray. Critical revision of manuscript: Marco Bueter, Diana Vetter.

Compliance with ethical standards

We (the authors) have nothing to disclose. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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