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A prospective study of risk factors for in-hospital mortality in patients with malignant obstructive jaundice undergoing percutaneous biliary drainage

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Abstract

Background: The in-hospital mortality rate in patients undergoing percutaneous transhepatic biliary drainage (PTBD) for malignant obstructive jaundice (MOJ) is high. There are few reports on the risk factors associated with hospital death after MOJ, with most of them being retrospective analyses of single factors. Therefore, this study aimed to assess pre-, intra-, and post-procedure risk factors that were independently associated with increased in-hospital mortality in MOJ patients who underwent PTBD.

Methods: One-hundred fifty-five patients with MOJ who underwent initial PTBD were included in this study. A total of 25 pre-, 4 intra-, and 6 post-procedure factors potentially related to in-hospital mortality were assessed by univariate and multivariate analyses.

Results: The in-hospital mortality rate was 16.8% (26/155). Of 25 pre-procedure variables analyzed, Child-Pugh classification C, creatinine level ≥6.93 μmol/L, and quality-of-life score (≤30) were found to be significant in univariate and multivariate analyses. Increased mortality was observed in patients with 2 or more risk factors, which was significantly different from patients with no risk factors or one risk factor ($P < .01$). None of the intra-procedure factors were important in identifying patients at risk of death. Multivariate analysis indicated post-PTBD cholangitis and unsuccessful drainage as post-procedure risk factors that correlated with in-hospital death.

Conclusion: It was identified that in-hospital mortality was associated with 3 pre-procedure and 2 post-procedure risk factors, such as the liver function classification, quality-of-life score of cancer patients, creatinine level, PTBD-associated biliary duct infection, and unsuccessful drainage.

Abbreviations: MOJ = malignant obstructive jaundice, PTBD = percutaneous transhepatic biliary drainage.

Keywords: in-hospital mortality, malignant obstructive jaundice, percutaneous biliary drainage

1. Introduction

Malignant obstructive jaundice (MOJ) comprises a group of diseases caused by obstruction of the intrahepatic or extrahepatic bile duct owing to the growth of malignant tumors, such as from the primary and secondary malignancies of liver, bile duct, gallbladder, pancreas, or periampullary area.[1] Generally, surgical resection is the primary treatment for MOJ; however, it is not always feasible owing to the low number of patients suitable for surgical procedures and to the higher incidence of postoperative complications. Therefore, urgent treatment is required to improve hepatic function in patients who are unable to undergo surgery.

Recently, percutaneous biliary drainage (PTBD) has evolved to become a safe and effective palliative treatment technique for patients in whom surgical procedures cannot be performed,[2,3] but the rate of in-hospital death in patients undergoing PTBD was still high, at approximately 9% to 20%.[4–6] However, only a few studies have reported the risk factors associated with hospital death after MOJ, most of which were retrospective analyses of single factors.[7–9] These results may not really represent the risk factors for hospital death after PTBD surgery.

Therefore, the purpose of this study was to evaluate independent risk factors associated with hospital death after PTBD surgery using prospective multifactor analysis. The analysis of these risk factors can provide scientific clues for doctors in the adequate treatment of MOJ to better reduce the mortality rate in the future.

2. Subjects and methods

2.1. Subjects

This was an observational cohort study that included all patients with MOJ who underwent the first PTBD in our hospital from January 2009 to June 2016, after receiving approval from the

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The authors declare that they have no conflict of interest.

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The inclusion criteria were as follows: patients who were clearly diagnosed with malignant tumors by pathological or imaging examination but did not undergo surgery owing to personal reasons or tumor invasion; patients with primary and secondary malignancies of the liver, bile duct, gallbladder, pancreas, or periampullary area malignant tumors; age ≥18 years; and patients with a history of first PTBD surgeries for MOJ. In addition, patients who were automatically discharged, those who refused testing, and those who did not report for the follow-up were excluded. Of the 196 patients recruited, only 155 completed the study. A flowchart of the study is presented in the flow diagram (Fig. 1). All patients signed an informed consent form.

2.2. Methods

We used the method described by Zhai et al for PTBD.[10] When total bilirubin reduces markedly, some patients who were expected to have a survival period of more than 6 months undergo biliary stent implantation. This surgical treatment was performed by 3 senior doctors, and every patient who underwent operation was randomly scheduled for surgery by a senior interventional physician.

Two junior physicians reviewed the literature and identified the following risk factors. The preoperative risk factors in this study included 13 clinical risk factors and 13 laboratory risk factors. Clinical risk factors included age, sex, primary tumor, cirrhosis, Child-Pugh classification, quality-of-life score of cancer patients, Karnofsky functional score, obstruction site, preoperative cholangitis of PTBD, liver metastasis, duration of jaundice, operation time or intraoperative or intraoperative period, and the history of retrograde pancreatic cholangiography. Laboratory risk factors included hemoglobin, white blood cell count, coagulation time, aspartic acid aminotransferase, alanine aminotransferase, alkaline phosphatase, γ-glutamotransferase, total bilirubin, albumin, blood urea nitrogen, creatinine, CA199, and CA125; the last 2 laboratory results were collected within 1

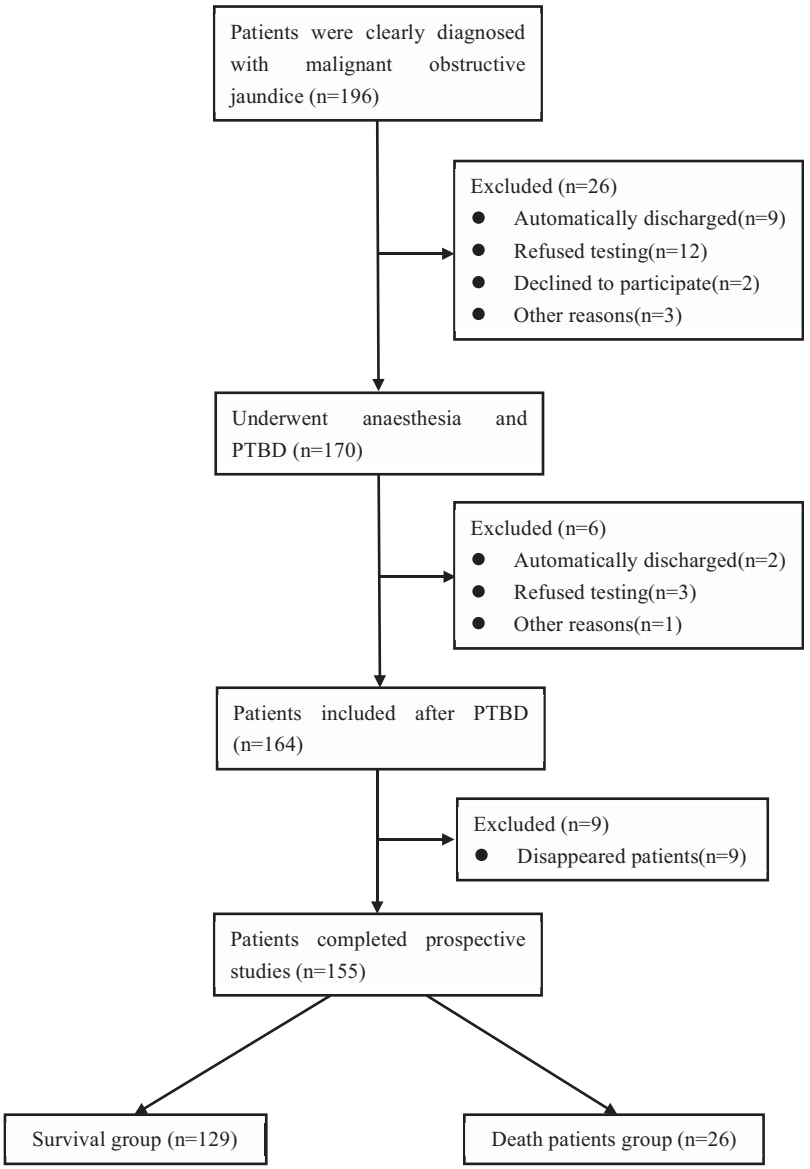

Figure 1. Flow diagram.

Table 1

Primary etiology of 2 groups of malignant obstructive jaundice.

	Biliary cancer	Pancreatic cancer	Gastric carcinoma	Hepatocarcinoma	Carp carcinoma	Cholecyst cancer	Duodenal cancer	Hepatic metastatic tumor	Lymph node metastasis	Total
Hospital deaths	11	4	2	4	1	1	0	1	2	26
Survival	50	35	15	8	6	6	3	2	4	129

week before PTBD, and the remaining 11 laboratory results were collected within 48 hours before PTBD, on the 3rd and 7th day after PTBD, and on the day of discharge.

Intra-operative risk factors included the mode of bile duct drainage, the surgical experience of senior doctors, the times liver puncture, and the type of drainage tube. Postoperative risk factors included post-PTBD-associated cholangitis, post-PTBD-associated pancreatitis, unsuccessful drainage, renal failure, pulmonary embolism, and gastrointestinal bleeding. Two junior doctors gathered information under the guidance of a superior physician.

2.3. Definitions

High obstruction was defined as the obstruction of Bismuth type II, III, and IV; low obstruction was defined as Bismuth type I, when the obstruction site was far away from the porta hepatis. Hospital deaths and early complications were defined as deaths and complications that occurred within 30 days after PTBD. Successful drainage was defined as a decrease in total bilirubin of more than 30% within 1 week after surgery or a total decrease in bilirubin in the later period close to normal level.[11] The following symptoms were diagnosed as biliary tract infection, including postoperative fever, white blood cell elevation ($\geq 10 \times 10^9$/L), positive bile culture, aggravated jaundice or upper abdominal pain, and no other infection. Pancreatitis was defined as presence of abdominal pain and serum amylase level exceeding 3 times the upper normal limit within 24 hours after surgery.

2.4. Data collection

To reduce selection bias, 2 highly trained junior physicians separately collected all information of all groups of patients and entered the clinical data of each patient into a pre-designed case report form (CRF table). The follow-up time was calculated from the PTBD operation day to the 30th day after the operation. To eliminate follow-up bias, all the patients' conditions after discharge were assessed by the hospital's special follow-up department by clinic visits or via telephone. All postoperative complications, causes, and times of death were recorded.

2.5. Statistical analysis

Patients who died within 30 days after PTBD surgery were classified into the hospital death group, and the remaining patients were classified into survival groups. A sample size of 155 was determined to be required for a power of 0.8 and an α value of 0.1. For 25 potential preoperative risk factors, a single-factor analysis was performed, classification variables were applied to X^2 test, and continuous variables were applied to t test. This study involved hospital deaths within 30 days after surgery, and thus the single-factor analysis screened possible risk factors using the progressive multi-factor logistic analysis model. In bilateral tests, $P < .05$ was considered to be statistically significant. The statistical analysis for 4 potential intraoperative risk factors and 6 potential postoperative risk factors was performed using the X^2 test; $P < .05$ was considered to be statistically significant.

3. Results

Initially, a total of 196 patients were recruited in the study, of whom 41 patients were lost to follow-up. Therefore, 155 cases were finally included, comprising 100 men and 55 women. The age range was 26 to 87 years and the median age was 65 years. Of the 155 cases included in this study, 109 were treated only with PTBD and 46 were treated via PTBD combined with biliary stent implantation. In all, 26 patients (16.8%) died within 30 days after PTBD, and the remaining 129 patients were classified into the survival group. No cases of intraoperative death occurred. The causes of death included 10 cases of cancer cachexia or multiple-organ failure, 7 cases of acute biliary duct infection combined with sepsis, 4 cases of renal failure, 2 cases of gastrointestinal bleeding, 1 case of liver cancer rupture and hemorrhage, 1 case of pulmonary embolism, and 1 case of liver function failure. The primary cause of MOJ is shown in Table 1. The primary tumor had no significant effect on the incidence of hospital death ($X^2 = 3.666$, $P = .300$).

3.1. Preoperative risk factors associated with in-hospital death

The preoperative clinical and laboratory data of the patients are shown in Table 2. Single-variable analysis showed that age, Child-Pugh classification, quality-of-life score of cancer patients, Karnofsky functional score, cirrhosis, alanine transaminase, albumin, blood urea nitrogen, and creatinine were associated with increased in-hospital mortality. After multivariate analysis, it was found that the odds ratio (OR) of Child-Pugh C patients was 4.024 and the 95% confidence interval (95%CI) was 1.432–11.307, $P < .05$; quality-of-life score of cancer patients was ≤ 30, the value of OR was 8.688, and 95% CI was 2.788 to 27.079, $P < .05$; and the creatinine was $\geq 69.3\,\mu$mol/L, OR was 5.102, 95%CI was 1.798–14.478, $P < .05$, and they were independent risk factors for in-hospital death after PTBD surgery.

The number of risk factors (Child-Pugh classification, cancer patient quality-of-life score, and creatinine) in each patient was significantly related to the patient's mortality rate in the hospital. At the same time, the above 3 risk factors were present in 8 cases, of which 7 cases were in-hospital deaths. In all, 22 patients had 2 of these factors, of whom 11 died (50%), and only 6 cases of 49 patients with 1 risk factor died (12.2%). Of the 76 patients with no risk factors, 2 died (2.6%). We found that the nosocomial mortality rate increased significantly in patients with 2 or 3 risk factors ($X^2 = 28.423$, $P < .01$).

Table 2

Single-factor analysis for preoperative clinical and laboratory risk factors of patients.

	Number of patients	Age (yr)	Sex		Child-Pugh		Quality of life score	Kamofsky functional score	White blood cell count	Hemoglobin
			Male	Female	C	B				
Hospital deaths	26	70±10	20	6	16	10	32±5	40±12	7.53±3.14	114.77±18.35
Survival	129	63±13	80	49	26	103	37±4	53±10	7.17±2.70	112.05±15.89
Statistics		2.765	2.101*		18.759*		−5.644	−5.559	0.611	0.774
P		<.05	>.05		<.05		<.05	<.05	>.05	>.05

		Aspartic acid transaminase (U/L)	Alanine transaminase (U/L)	Alkaline phosphatase (U/L)	γ-glutamotransferase (U/L)	Total bilirubin (umol/L)
Hospital deaths	26	132.04±88.18	69.08±42.75	539.35±286.86	593.88±476.16	352.43±189.38
Survival	129	134.50±94.42	13.50±94.42	592.88±355.82	719.25±467.50	298.18±154.24
Statistics		−0.122	−4.09	−0.772	−1.224	−1.552
P		>.05	<.05	>.05	>.05	>.05

		Albumin (g/L)	Coagulation time (s)	CA199 (kU/L)	CA125 (ug/L)	Creatinine (umol/L)	blood urea nitrogen (mmol/L)
Hospital deaths	26	23.02±4.02	15.15±4.30	1278.91±2332.23	159.14±164.61	109.17±117.32	7.63±7.40
Survival	129	26.51±5.12	12.29±2.12	2687.62±3492.95	112.17±309.09	61.35±22.73	4.20±1.75
Statistics		−3.276	3.306	−1.976	0.752	2.070	2.351
P		<.05	<.05	>.05	>.05	<.05	<.05

			Cirrhosis of liver		Hepatic metastatic tumor		Preoperative biliary tract infection		Obstruction site		ERCP & Cholecal anastomosis	
		Jaundice time before PTBD (d)	Y	N	Y	N	Y	N	H	L	Y	N
Hospital deaths	26	26.42±34.28	5	21	5	21	3	23	14	12	3	23
Survival	129	19.82±15.33	7	122	21	108	10	119	59	70	11	118
Statistics		0/963	4.022*		0.006*		0.016*		0.571*		0.013*	
P		>.05	<.05		>.05		>.05		>.05		>.05	

* Was the value of X^2, the others were *t* value.

3.2. Intraoperative and postoperative risk factors associated with nosocomial death

The univariate analysis showed that there was no significant correlation between the 4 potential intraoperative risk factors and nosocomial death. Among the 6 potential postoperative risk factors, PTBD-associated biliary duct infection, unsuccessful drainage, and renal failure were significant risk factors in the univariate analysis (Table 3). Multivariate analysis showed that PTBD-related biliary duct infection (OR = 6.239, 95%CI = 2.289–16.999, $P < .05$) and unsuccessful drainage were independent risk factors (OR = 7.467, 95%CI = 2.481–22.475, $P < .05$).

4. Discussion

In the past 30 years, many studies have reported risk factors for inpatient mortality after MOJ.[7,12–15] Most of these studies included a variety of treatment models, and few studies had been conducted on risk factors related to the incidence of inpatient death after PTBD. Recent advances in technology and equipment and the results of previous studies did not fully represent the risk factors associated with the in-hospital mortality rate after PTBD treatment.

4.1. Analysis of preoperative potential risk factors of PTBD

The Child-Pugh classification was often used to evaluate the prognosis of patients with cirrhosis.[16,17] It not only evaluates liver reserve function[18] but also reflects the patient's multiorgan function. Multivariate analysis in this study showed that the probability of nosocomial death in patients with Child-Pugh C increased 4 times compared to that in patients with Child-Pugh B. The patients with Child-Pugh C had poor liver reserve function

Table 3

A single factor analysis of postoperative risk factors in patients with hospital death and survival group.

		Bile duct drainage		Surgeon experience		Biliary puncture times		Number of drainage tubes		Postoperative infection		Postoperative pancreatitis		Insuccessful drainage		Renal failure		Gastrointestinal bleeding		Pulmonary embolism	
		External	Internal and external	Senior physician	Low seniority physician	5	≤4	1	≥2	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Hospital deaths	26	17	9	12	14	6	20	1	25	19	7	4	22	14	12	4	22	2	24	1	25
Survival	129	87	42	56	73	35	94	11	118	37	92	16	113	10	109	1	128	1	128	4	125
X^2		0.041		0.066		0.183		0.170		18.481		0.009		19.209		7.722		2.419		0.039	
P		>.05		>.05		>.05		>.05		>.05		>.05		<.05		<.05		>.05		>.05	

and poor nutritional status, and hyperbilirubinemia and hypoproteinemia led to a significant decline in the patient's cell and hormone immunity; therefore, it was more likely to lead to in-hospital death. In addition, some studies had found a significant correlation between hypoproteinemia and nosocomial death after treatment for MOJ.[7,9,12,19] In this study, it was found that hypoproteinemia and thrombocytosis have obvious significance in univariate analysis, and there was no obvious correlation between these 2 laboratory indicators in multivariate analysis. It may be due to the appearance of interference variable liver function classification that weakens the connection between coagulation time and albumin. The results further emphasized the important role of liver function classification in predicting the in-hospital mortality rate after PTBD. Therefore, preoperative improvement of liver function through albumin supplementation and improved coagulation function can help reduce the incidence of hospital death after PTBD surgery.

MOJ was often associated with endotoxemia, which can easily lead to renal insufficiency, the degree of which depends on the degree of biliary obstruction.[20] Patients with liver and kidney syndrome tend to have a significantly higher in-hospital mortality rate.[21] The study showed that the increase in blood urea nitrogen was an important risk factor for postoperative mortality in patients with MOJ, and creatinine was not an obvious risk factor.[7] In this study, single-variable analysis showed that blood urea nitrogen and creatinine were both risk factors, whereas in the multivariate analysis only creatinine was an independent risk factor. Because both the risk factors were indicators for evaluating renal function, it was considered that creatinine has a more powerful effect on the dependent variables, resulting in the loss of significance of blood urea nitrogen in multifactor analysis. Therefore, the author believed that in patients with creatinine $\geq$69.3 μmol/L, adequate rehydration and application of diuretics before PTBD surgery may help improve renal function and reduce the in-hospital mortality rate.

A study of one form of esophageal cancer showed that the postoperative mortality rate significantly increased in patients with a low quality of life. The quality-of-life score of cancer patients was an independent risk factor for increased mortality in the hospital after PTBD, as determined by multivariate analysis. The quality-of-life score was a comprehensive assessment of the physiological, psychological, and social factors for the patients. In this study, the in-hospital mortality rate increased significantly in patients with MOJ with a quality-of-life score $\leq$30, indicating that the patient's own status and social and family factors had a significant impact on the patient's prognosis. Karnofsky functional score was only meaningful in single-factor analysis. Considering that the quality-of-life score was more suitable for the patient's comprehensive physical condition, this score was more useful in multivariate analysis than the Karnofsky functional score.

Some researchers applied endoscopic technology to reduce the bilirubin caused by MOJ. They found that hyperbilirubinemia was related to the increase in the in-hospital mortality rate after the PTBD for MOJ in multivariable factor analysis,[8,14] whereas in other studies the hyperbilirubinemia and mortality rate were not considered to be related.[7,9] The results of this study were consistent with those of the latter. The decolorization treatment before PTBD surgery in patients with MOJ was controversial, because the reduction of total bilirubin did not reduce the incidence of postoperative complications and deaths.[22] The single-factor analysis showed that alanine transaminase was lower in the survival group than in the mortality group, which indicated that alanine transaminase increased liver function damage. However, on multifactor analysis, it was found that alanine transaminase had no effect on the in-hospital mortality rate. It was considered that the Child-Pugh classification system was more accurate in assessing the degree of liver damage, resulting in alanine aminotransferase losing its significance in multifactor analysis. Consistent with the results of the study by Dixon et al and those of other studies,[13] alanine aminotransferase cannot be an independent risk factor for predicting hospital death after PTBD surgery.[13] In the single-factor analysis, we found that cirrhosis was also a risk factor for hospital death,. The consideration was due to the fact that liver function classification was mostly Child-Pugh C in patients with combined cirrhosis and MOJ, which made it meaningless in multi-factor analysis.

4.2. Analysis of potential risk factors during and after PTBD

In this study, no correlation was found between the risk factors and the increased in-hospital mortality rate. However, as animal experiments have shown that the use of both internal and external drainage technology results in lower incidence of endotoxemia and mortality of the MOJ patient, it was recommended to use internal and external drainage more often instead of external drainage only.[23] However, the study did not describe the impact of the 2 drainage methods on the in-hospital mortality rate of patients. In future, after PTBD surgery, there may be fewer complications caused by external drainage and the time taken for endotoxemia to have a significant effect on the patient may be longer.

In terms of postoperative risk factors, multifactor analysis showed that biliary tract infection and unsuccessful drainage after PTBD were associated with nosocomial death.[2] The most common complication after PTBD surgery was biliary tract infection. Biliary duct infection can cause damage to the liver and renal function as well as multiple-organ failure, leading to death. In this study, the direct cause of death in 7 patients was biliary duct infection and sepsis. Preoperative biliary duct infection had no obvious effect on the in-hospital mortality rate, considering that infection in most patients can be effectively controlled through active anti-inflammatory agents and drainage treatment. For patients with unsuccessful drainage, the total bilirubin did not decrease significantly or even continued to increase, and the liver and renal function damage continued to increase. Due to the presence of fungus in the bile duct, patients were easily susceptible to biliary duct infection.[23–25] All of these can cause multiple-organ failure, resulting in death of the patient.

4.3. Correlation between the number of preoperative risk factors in patients and in-hospital mortality rate

The author believed that for patients who have 3 risk factors at the same time, the risk of hospital death after PTBD surgery was extremely high; therefore, the best support treatment should be the first choice for this group of patients. For patients with 2 risk factors at the same time, PTBD should be treated with caution. Preoperative supplementation of albumin to improve coagulation function as well as adequate rehydration and diuresis were conducive to improving liver and renal function and reducing the incidence of hospital death.

4.4. Limitations

A major limitation of the present study was that no long-term follow-up data were collected after surgery; therefore, whether postoperative PTBD was related to increased mortality was unknown. Furthermore, the small sample size might cover up the differences between the variables. Additionally, our study was conducted at a single tertiary hospital. In addition to being a single-center project, there are some other possible conditions limiting generalizability.

5. Conclusion

In summary, the hospital mortality rate was still high for patients with malignant obstructive jaundice after PTBD. Through multivariate analysis, liver function classification, quality-of-life score, and creatinine were found to be independent preoperative risk factors that helped to select more suitable interventional treatment for patients. The potential risk factors associated with the operation did not affect the patient's hospital death; PTBD-associated biliary duct infection and unsuccessful drainage were independent postoperative risk factors, suggesting that we should actively control infection and reduce bilirubin to reduce the impact on liver and renal function. The results of this study may provide scientific and reasonable advice to clinicians in the treatment of MOJ. In the future, studies with a larger number of samples, a longer follow-up time, and in multiple centers should be conducted.

Author contributions

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