Original Article

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The Role of a Clinical Pharmacist in Lifestyle Modification in type 2 Diabetic Patients with Peripheral Neuropathy in Erbil, Iraq

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Abstract

Background: This study was designed to evaluate the effectiveness of clinical pharmacist intervention in lifestyle modification to improve glycemic control and diabetic peripheral neuropathic (DNP) symptoms in type 2 diabetic patients. *Methods:* One-hundred diabetic peripheral neuropathic patients were randomly assigned into two groups, intervention and usual care group. The intervention group has received the three month's lifestyle modification program by a clinical pharmacist. The usual care group was provided with standard medical services. Lifestyle modification was assessed by using summary of diabetes self-care activity (SDSCA) scale while the Morisky scale was used to assess medication adherence. Douleur Neuropathique 4 (DN4), Neuropathic Pain Scale (NPS), and Brief Pain Inventory (BPI) were used to assess diabetic peripheral neuropathy. *Results:* Intervented patients had significant positive effects of self-management education on self-reported dietary habits, physical activity and foot care. The percentage of patients scoring moderate and high adherence scores in the intervention group were 40.7% and 14.8% respectively after three months follow up. After lifestyle modification, significant reduction in the percent of response of patients feeling electric shock, tingling, and pin needle were observed in the intervention patients. Lifestyle modification significantly improved all assessed pain qualities, except of feeling cold to a greater extent than the usual care group. Significant reductions in pain interference were observed in intervention group after the three months of follow up. *Conclusion:* The provision of lifestyle modification has positive effects on glycemic control and clinically effective approach for patients with DPN that improves severity in peripheral neuropathic symptoms and pain interference.

Keywords: Diabetic Peripheral Neuropathy; Clinical Pharmacist; Lifestyle Modification.

Introduction

Type 2 diabetes mellitus is a chronic disease that, if left uncontrolled, may cause microvascular and macrovascular complications in the long term, which are the main causes of increased morbidity and mortality and decreased health-related quality of life among patients [1]. Although the existence of effective therapies and the established benefits derived from tight control of blood glucose and other cardiovascular risk factors, such as blood pressure and serum lipids, evidence shows that the achievement of recommended objectives for these factors remains suboptimal among patients with type 2 diabetes [2]. This is because diabetes globally has been highly linked to the increasing rates of obesity, metabolic syndrome, westernized dietary patterns and physical inactivity [3], in addition lack of adherence to therapy and other recommendations might explain these findings, given that more than 50% of chronically treated patients do not take the prescribed pharmacotherapy [4].

Diabetic peripheral neuropathy (DPN) is a complex and frequent complication of diabetes that

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affects nearly 50% of diabetic patients [5]. It affects the quality of life and often inhibits daily activities and work and is associated with duration of diabetes, poor glycemic control and metabolic syndrome [6]. On the other hand, there is no pharmacological disease-modifying therapy available for diabetic peripheral neuropathy to reverse pathogenesis and progression and are thus aimed largely at pain control [7]. It is well established that diabetes and related complications as peripheral neuropathy can be prevented by tightly regulating blood glucose and lifestyle intervention which involve diet, exercise and medication adherence [8]. Diet improves neuropathic pain by improving glycemic control, blood lipid concentrations and blood pressure [9].

Patients with DPN are more probably lead a sedentary life style and to have low daily walking distances [10]. Exercise contributes to improve glucose control, which slows or stops the progression of diabetic neuropathy [11]. In addition, effective exercise interventions have been correlated with improvement in neuropathic symptoms, gait, stability, quality of life and sensory function [12].

Because of their knowledge in pharmacotherapy and their availability in the community, pharmacists are able to create strong relationships with patients and become a dependable source of information [13]. Consequently, pharmacists can provide patient education, monitor and boost adherence to self-care and therapeutic plan, which have a positive influence on achieving therapeutic outcomes in diabetes [14].

Patients and Methods

This study was conducted at the Leila Qasm Diabetic Centre, Erbil, Iraq from October 2015 to August 2016. Patients included in the study were aged 18 years or older, diagnosed with type 2 diabetes at least one year earlier, taking at least one medication for diabetes. Patients diagnosed with diabetic peripheral neuropathy based on clinical examination by physician and level of urea and creatinine within normal to exclude nephropathy. Patients were excluded from the study if they had history of alcohol consumption, thyroid gland disorder, any kidney disorder, any conditions that could confound assessment of pain due to diabetic peripheral neuropathy, and pregnant females or those who are plaanning to become pregnant during the study period.

One hundred diabetic peripheral neuropathic patients were randomly assigned into two groups, intervention and usual care group (50 patients in each group). The intervention group has received the three months lifestyle modification programme by a clinical pharmacist. The usual care group was provided the standard medical services.

The patients who met with the inclusion criteria and agreed to participate in the study were asked to sign a consent form. A specific questionnaire forum was designed to obtain the demographic characteristics and clinical data from each patient.

Glycemic levels (glycated hemoglobin (HbA1c) values and fasting blood glucose, blood urea, serum creatinine, blood pressure and BMI were measured.

Peripheral neuropathic pain was measured using three pain measurement scales: Douleur Neuropathique 4 questionnaire (DN4), Neuropathic Pain Scale (NPS) and part of The Brief Pain Inventory (BPI) [15,16,17].

Lifestyle modification was assessed using summary of diabetes self-care activity (SDSCA) while the Morisky scale was used to assess medication adherence [18,19].

All biochemical parameter and scales were determined at baseline and after three months follow up.

The patients in the intervention group were provided with lifestyle education sessions about the diet and exercise following ADA guidelines [10]. The goal of these sessions were to recommend dietary changes based on the personalized diet analysis and determination of dietary behavior that is threatening for blood glucose control. Also, present physical activity levels were assessed by ADA exercise goal (150 minutes of light aerobic exercise each week) and initiation of an exercise plan as per that could be incorporated into the patient's daily schedule. Self-monitoring of glycemic control by counseling the patients was advised to check their blood glucose levels daily. General foot self-care education to patients and importance of foot examination was taught. Adhererence to antidiabetic therapy as prescribed by physician was followed and they were asked about any problems that they had faced with respect to taking their medication. Finally, weekly direct and indirect contacts were made for three weeks by the clinical pharmacist to each intervention patient to emphasize the importance of adherence to diet, exercise, treatment plan, and to answer patient questions. Patients in the usual care group received the usual care provided by the medical staff, which included standard medical services.

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 19). Chi-square test

of association was used to compare between the groups. When the expected count of more than 20% of the cells of the table was less than 5, Fisher's exact test was used. McNemar test was used to compare groups of the same sample (before and after the intervention). For 3X3 tables, McNemar-Bowker test was used (also for same sample, before and after the intervention). Student's t test was used to compare means of the two study groups. The p value of d" 0.05 was considered statistically significant.

Results

Around half (43%) of the studied sample were in the age group 50-59 years and ourof them 75% of the total samples were females. Twenty-six percent were illiterate and 26% were of primary schools graduates. No significant differences were detected between different categories of the two study groups viz. age, sex, educational level and smoking and non-smoking.

Table (1) showed that lifestyle modification made significant reduction (P<0.01) on biochemical (FBG, HbA1c) parameters and BMI in intervention group. While the usual care group did not show significantly change in the tested parameters after three months of follow up except FBG and HbA1c parameters, which were significantly increased.

Table 2 represents means of diabetic self-care activity scale at baseline visit and after three months. In the intervention group, significant increases in the means of all parameters of the mentioned scale were detected except for blood sugar testing, which remained same. In the usual care group, only the mean of exercise has increased significantly (p = 0.05).

Table 3 showed that in the intervention group, there was significant difference between the adherence to medications before and after the lifestyle modification. The result also showed that there were 27 patients with low adherence to medications, whereas 40.7% and 14.8% of them had moderate to high adherence respectively (p< 0.01).

Table 4 represents DN4 scale. In the intervention group, there was significant reduction in the percent of response of patients feeling; electric shock (76% to 60%), tingling (80% to 66%), and pin needle ssensation (78% to 60%) after the lifestyle modification (p = 008, 0.016, 0.004) respectively, whereas the other symptoms (cold, numbness, itching, hypoesthesia to touch, hypoesthesia to prick and brushing, remained same or decreased non significantly.

Table 1: Mean scores of some of the studied variables at baseline and after three months visit in the study groups

Variables	Intervention group		P	Usual care		P
	Pre Mean ± SD	Post Mean ± SD		Pre Mean ± SD	Post Mean ± SD	
FBG	196.18 ± 87.41	148.82 ± 45.67	< 0.001	207.44 ± 72.25	227.54 ± 78.92	0.043
HbA1c	9.04 ± 2.08	7.70 ± 1.54	< 0.001	9.04 ± 1.73	9.66 ± 1.34	< 0.001
BMI	31.06 ± 4.96	30.54 ± 4.72	< 0.001	31.87 ± 6.91	31.76 ± 6.99	0.288
SBP	133.60 ± 15.88	131.60 ± 17.07	.236	132.70 ± 15.75	130.20 ± 17.78	0.208
DBP	83.80 ± 6.74	81.80 ± 7.74	0.042	81.60 ± 9.28	79.50 ± 8.88	0.077
Mean BP	100.40 ± 8.77	98.40 ± 8.60	0.032	98.63 ± 10.44	96.40 ± 10.60	0.059
Pulse pressure	49.80 ± 12.97	49.80 ± 16.84	1.000	51.10 ± 11.84	50.70 ± 14.32	0.838

P < 0.05 when compared to its baseline.

Table 2: Mean scores of diabetic self-care activity scale in each of the studied groups

DM self-care Activity	Intervention group		P	Usual care group		P
	Before Mean ± SD	After Mean ± SD		Before Mean ± SD	After Mean ± SD	
General diet	3.26 ± 2.46	4.81 ± 2.23	< 0.001	2.8 ± 2.4	2.8 ± 1.7	0.788
Specific diet	3.56 ± 1.72	5.02 ± 1.42	< 0.001	3.6 ± 1.7	3.5 ± 1.4	0.520
Exercise	2.99 ± 1.81	4.93 ± 1.86	< 0.001	2.3 ± 2.1	2.6 ± 2.0	.006
Blood sugar testing	2.68 ± 2.71	2.86 ± 2.73	0.376	1.9 ± 2.4	1.6 ± 2.1	0.209
Foot care	4.61 ± 2.88	5.65 ± 2.15	< 0.001	4.0 ± 2.9	4.2 ± 2.8	0.149

*P<0.05 when it's compared to its baseline

Table 3: Adherence to treatment according to Morisky scale before and after the intervention in each of the study groups

Adherence before intervention	Adherence according to Morisky scale after the intervention						Total (No.)	P*
	High		Moderate		Low			
	No.	%	No.	%	No.	%		
Intervention group								
High	6	100	0	0	0	0	6	<0.001
Moderate	9	52.9	8	47.1	0	0	17	
Low	4	14.8	11	40.7	12	44.4	27	
Usual care group								
High	10	83.3	1	8.3	1	8.3	12	0.572
Moderate	1	10	6	60	3	30	10	
Low	0	0	1	3.6	27	96.4	28	

Table 4: Comparison of the percentages of responses (to DN4 scale items) at baseline and after three months follow up, in each of the intervention group and the usual care group

DN4 scale items	Intervention group		P*	Usual care group		P*
	Response %			Response %		
	Pre	Post		Pre	Post	
Burning	78	74	0.5	72	72	1
Cold	34	30	0.5	42	42	1
Electric shock	76	60	0.008	64	62	1
Tingling	80	66	0.016	76	72	0.5
Pin needle	78	60	0.004	70	68	1
Numbness	48	48	1	50	48	1
Itching	48	42	0.25	52	52	1
Hyposthesia to touch	4	4	1	8	8	1
Hyposthesia to prick	6	6	1	28	30	1
Brushing	10	10	1	22	22	1

*By McNemar test

Table 5: Mean scores of neuropathy pain scale at baseline and after three months follow up, in each of the intervention group and the usual care group

NPS	Intervention		P	Usual care		P
	Before Mean ± SD	After Mean ± SD		Before Mean ± SD	After Mean ± SD	
Intense	5.78 ± 2.22	4.60 ± 2.37	< 0.001	6.16 ± 2.49	6.52 ± 2.30	0.035
Sharp	4.30 ± 3.40	3.26 ± 3.05	< 0.001	4.44 ± 3.51	4.72 ± 3.39	0.061
Hot	5.08 ± 3.11	3.36 ± 2.75	< 0.001	4.54 ± 3.55	4.56 ± 3.39	0.931
Dull	3.38 ± 3.12	2.56 ± 2.70	< 0.001	3.08 ± 3.47	3.10 ± 3.47	0.811
Cold	2.46 ± 3.51	2.12 ± 2.99	0.094	2.94 ± 3.79	2.86 ± 3.69	0.681
Sensitive	4.36 ± 3.04	3.82 ± 2.81	0.001	4.10 ± 3.30	4.30 ± 3.45	0.032
Itchy	2.44 ± 2.96	1.74 ± 2.42	0.002	3.28 ± 2.85	3.58 ± 2.93	0.149
Unpleasant	5.64 ± 2.31	4.34 ± 2.55	< 0.001	6.20 ± 2.19	6.38 ± 1.96	0.276
Deep pain	5.38 ± 2.60	4.42 ± 2.60	< 0.001	5.36 ± 2.72	5.48 ± 2.70	0.204

*P<0.05 when compared to its baseline

Table 6: Mean scores of brief pain inventory scale at baseline and after three months follow up, in each of the intervention group and the usual care group

Brief pain inventory scale	Intervention group		P	Usual care group		P
	Pre Mean ± SD	Post Mean ± SD		Pre Mean ± SD	Post Mean ± SD	
General activity	4.56 ± 2.89	3.04 ± 2.70	< 0.001	3.88 ± 2.48	4.20 ± 2.49	0.051
Mood	5.50 ± 3.22	3.70 ± 2.84	< 0.001	4.22 ± 3.07	4.36 ± 2.79	0.431
Walking ability	3.94 ± 2.85	2.38 ± 2.72	< 0.001	3.62 ± 2.57	3.90 ± 2.51	0.070
Normal work	3.72 ± 2.59	2.38 ± 2.69	< 0.001	3.60 ± 2.37	3.68 ± 2.33	0.542
Relations	0.76 ± 1.73	0.42 ± 1.25	0.02	.68 ± 1.45	0.74 ± 1.56	0.322
Sleep	5.16 ± 2.85	3.28 ± 2.65	< 0.001	4.90 ± 2.75	5.52 ± 2.56	0.011
Enjoyment	1.30 ± 1.96	0.94 ± 1.49	0.015	2.12 ± 2.33	2.30 ± 2.30	0.095

*P<0.05 when it's compared to its baseline

Table 5 represents NPS. In the intervention group, there was significant improvement in the mean scores of the parameters of neuropathy pain scale after the lifestyle modification, except for feeling of cold sensation which was non-significantly reduced. While in the usual care group, the changes in the mean scores of all parameters of the scale were found to be non significant, except for intense and sensitive sensation, which showed an increase in the mean scores after three months.

Table 6 represents BPI. There was significant decrease in the means of the parameters of brief pain inventory scale after the three months in the intervention group. While in the usual care group, no significant changes were detected except for sleep parameter, which was aggravated significantly (p=0.011).

Discussion

Patient education has recently become an important domain of medicine to enforce therapeutic outcomes [21]. Many studies have shown the role of pharmacists in educating patients and improve their understanding about the disease, importance of adherence to medication schedule and lifestyle modifications, which decreases the morbidity and mortality rate in patients [22,23,24].

This randomized controlled study provided evidence of the efficacy of lifestyle modification for patients with diabetic peripheral neuropathy. The intervention that consisted of individualized self-management education, adherence support, and regular contact follow-up lead to significant betterment in HbA1c and the primary outcome parameters in this study.

Although of blood- glucose levels changes due to a series of internal and external factors, maintenance of an normal blood glucose is depends on patient's active disease management [25].

The findings of this study indicated that the baseline mean of HbA1c values was higher in the intervention group than the mean of HbA1c for the usual care group. Moreover, the results of this study showed that the mean of HbA1c was significantly reduced for intervention group, while it was increased in the usual care group with significance differences between the two groups after 3 months follow up period. This reduction of HbA1c was consistent with previous research findings of Farsaei*et et al* [26] and Jarab*et et al* [27]. The improvements in HbA1c in the present study might be due to the clinical pharmacists interventions with regard the compliance to the prescribed medications, improving adherence to diet, physical activity, and regular telephonic follow-up.

The present study indicated a significant reduction in FBG levels in the intervention group patients when compared with the usual care group patients over the 3-month study period. This result is consistent with previous findings of Farsaei *et al* [26], and in agreement with the study of Jarab *et al* [27]. This major impact on glycaemia is consistent with significant improvement in self-management which include significant improvements in physical exercise, healthy diet and medication adherence, which is expressed by morisky scale and diabetic self-management education scale.

Weight loss has long been a recommended plan for obese adults with diabetes [28]. Modest weight decline may provide clinical benefits (improved blood pressure, lipids and glycemia) in some individuals with diabetes, especially those early in the disease process [29]. The challenge for every obese person is to keep up in lifestyle changes that will permit him or her to preserve the weight loss [30]. Results revealed that intervention group achieved significant reduction in BMI while the usual care group showed an increase in BMI values over the 3-month study period. This weight loss achieved in this study was a successful outcome for patients with diabetic peripheral neuropathy and suggests that subjects, who lose weight, and who met physical activities and dietary fat goals, could reduce their risk of diabetes and its complications as peripheral neuropathy.

The common coexistence of high blood pressure and high lipid profile in diabetic neuropathic patients needs monitoring of metabolic parameters to guarantee successful health outcomes [29]. When a patient has both high blood pressure and hyperglycemia, the risk of vascular complications is increased by 66 to 100% as compared with those with only one of these conditions [31]. In the current study, lifestyle modification had minor effects in lowering SBP, DBP and mean blood pressure among patients with diabetic peripheral neuropathy.

Good knowledge about medications adherence, diet, exercise and self-monitoring of blood glucose is essential for effective self-management of diabetes. However, knowledge alone does not guarantee required behavior modifications or effective self-management. The inclusion of assessment tools is an important consequence measure in diabetes education programs [32].

Non-adherence to medications has been reported as the primary factor responsible for unscheduled

referral and hospitalizations among diabetic patients [33]. Therefore, correct medication and adherence is necessary for treatment success among diabetic patients. The achievement of good glycemic control requires treatment with anti-diabetic medications as well as strict medication adherence [34]. Adherence is a complex integral part of treatment that is influenced by several factors directly related to patient, health care providers, their interactions and treatment components. In the present study, regular interaction between the clinical pharmacists and patients in intervention group reflected a great deal in improving the patient medication adherence behavior. This improvement was tailored by education of the patient regarding diabetes care, correcting misunder standings and erroneous ideas regarding diabetes treatment, establishing a treatment plan to foster medication adherence and sometimes engaging family members support. To summarize the results, self-reported medication adherence was sub-optimal for diabetic patients.

Many randomized controlled trials have been conducted to evaluate the impact of Diabetic self-management education (DSME) on clinical outcomes in individuals with T2DM [35,36].

The significant improvement in dietary habits in intervention patients at the end of the present study due to the influential content of the educational material that provides guidelines to follow a healthy diet plan. This result is consistent with findings of Jarab*et et al* [27] who reported that pharmacists were successful at increasing the number of days per week that patients spent engaging in healthy diet by helping basic meal scheduling, explain misunderstanding, and/or provide reinforcement of the nutrition programme developed collaboratively by the registered dietitian nutritionist and the patient.

It is well known that patients with high physical activity levels have improved glycaemia because exercise therapy induces glucose and free fatty acid utilization by skeletal muscles and ameliorates insulin resistance [31]. It is worth mentioning that this study included not only walking, but also other forms of aerobic exercise, such as bicycling or running. Also in this study, the patients have advised to walking at a moderate intensity, 120–150 minutes/week.

In the present study, patients who received the clinical pharmacist services had significantly better self-reported physical activity than did patients in usual care. Patients in usual care group showed an increase in mean number of days in performing exercise but this increase was found to be non-significant. For patients with diabetic peripheral neuropathy, this improvement in physical activity was beneficial on glycemic control and to reduce neuropathic symptoms.

Self-monitoring blood glucose (SMBG) plays a significant role in glycemic control and is part of the therapeutic strategy in both type 1 and type 2 diabetes mellitus [37]. Many studies have confirmed the role of SMBG in providing better glycemic control in patients with diabetes, Farham, B. [38] suggested that clinical management of diabetic patients who committed self-monitoring of blood glucose levels have significant reduction in HbA1c compared with those patients who do not have self-monitoring blood glucose.

The poor feet wear gives rise eventuallyto neuropathic foot ulceration andhigher HbA1c levels itself results to neuropathy again, causing a vicious circle for pathology to develop again and again [39]. The significant improvement in foot care in the intervention patients of this study was most probably attributed to information provided by clinical pharmacist about the foot care.

In this study, the presence of painful diabetic peripheral neuropathy was determined using the Douleur Neuropathique 4 questionnaire (DN4). After lifestyle modification, the result of this study showed improvements in neuropathic pain symptoms in intervention group. Improvement in burning, cold, electric shock, tingling, itching and pin and needles sensation, without any improvement in numbness, hypoesthesia to touch, hypoesthesia to prick and brushing symptoms.

At baseline, the patients in this study had DPN of varying severity and showed that intense pain was the most common while the least common was itching. Nearly all patients had more than one type of pain, which boosts the complication to any clinical evaluation. This may be proposed that the mechanism of pain is most possible from small nerve fibers, rather than from large fiber dysfunction. Previous clinical and electrophysiological studies also reported that neuropathic pain in diabetic polyneuropathy is not related with the degree of involvement of large diameter sensory fiber or diabetes severity [40].

Persons with neuropathic pain generally represent differential treatment effects on the various pain qualities they suffer. For this cause, neuropathic pain scale (NPS) items can be a more sensitive and clinically effective measure of neuropathic pain treatment effects than a single measure of total pain intensity.

This study using NPS scale demonstrates that the self-management education palliates most of the

usual pain qualities related with neuropathic pain. Three months of intervention in patients with peripheral neuropathy resulted in significant reductions in the mean of neuropathic pain qualities except for feeling cold.

In this study, improvement in the scales of peripheral neuropathy suggested that the lowering HbA1c and meaningful changes in adherence behaviors to medications in addition to healthy lifestyle (diet and exercise) have had real effects in intervention group which may be due to improved insulin sensitivity resulting to good glucose control [9].

Exercise was another important part of self-management of diabetic peripheral neuropathic patients. It is clear that routine exercise may be a highly effective means of promoting the recovery from, and improving some of the suffering symptoms associated with, peripheral neuropathy [41]. Routine exercise has been shown to both preserve and promote the function of the peripheral nerves [42].

Chronic neuropathic pain generally restricts patient's ability to accomplish important daily activities, thereby boosting the negative impact of pain. At baseline visit, patients experienced substantial diabetic peripheral neuropathy pain-related interference in normal work, walking ability, enjoyment of life, sleep, general activity and mood. The walking distance was of a special care, being one of the main indicators of physical health of diabetic patients [43]. It has been proposed that the level of neuropathic pain severity is associated with the experience of sleep problems, mood and walking [44].

The present study showed significant reductions in diabetic neuropathic pain conflicted in intervention patients with their daily activities including normal work, walking, relationships with others, and sleep. This significant reduction in mean of pain interference scale exhibits that the lifestyle modification may have played a role in declining the impact of pain on quality of daily life.

Conclusions

The engagement in diabetes self-management education results in a significant improvement in glycemic control, significant improvement in Douleur Neuropathique 4 (DN4) questionnaire -based DPN, reduced the intensity of general neuropathic pain qualities associated with peripheral neuropathic pain conditions, improvement in perceived neuropathic pain interference that is positively correlated with the extent of neuropathic pain relief. The present study has established the importance of clinical pharmacist in lifestyle modification for patients with diabetic peripheral neuropathy in Erbil. Further research is also needed to evaluate which intervention elements contribute the most to these observed effects. Also clinical pharmacists should be integrated into healthcare team to deliver an educational programme to improve patient safety, compliance with prescribed medications, create awareness on a healthier lifestyle and high quality responsive clinical care.

Limitation

First, this study was based on self-report and this may subject to recall bias and human error. Second, this study evaluate outcomes only after 3 months, and longer follow up is important to ascertain if the short term outcomes are attributed due to clinical pharmacist intervention.

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