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Comparative Interchangeability Assessment of Commercially Available Marketed Brands of Levothyroxine by Serum Thyroid-Stimulating Hormones in Pakistan

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Abstract

Background: Oral levothyroxine (LT 4) is the standard recommended treatment of hypothyroidism, and multiple brands are available on the market. Comparative interchangeability through serum thyroid-stimulating hormones is still debatable due to patient compliance. This study aimed to assess the potential clinical interchangeability of several brands of LT4 prompted by a lack of available brands by analyzing the thyroid-stimulating hormone (TSH) levels in patients utilizing different LT4 brands.

Materials and methods: Randomized cross observational research recruited 168 individuals with primary hypothyroidism utilizing a designated endocrinology outpatient department. Brands were chosen from community and hospital pharmacies. The study comprised four groups: a parent generic and three distinct brands (two global and one local), employing two-sample t-tests and analysis of variance.

Results: Of the 168 patients, 69 were male (41.1%) and 99 were female (58.9%). The data collection indicated that the 36-45 age group was overrepresented, with 54 people (32.1%) of the overall sample population. The age segment of 26 to 35 appeared as the second most prevalent demographic with hypothyroidism. Thyroxine was the predominant brand among all others; 75.59% of patients utilized thyroxine. Edema occurred in 55 cases (32.7%), and dry skin in 77 cases (45.8%), representing the most prevalent adverse effects across all brands.

Conclusion: Interchangeability of all groups, either patent or generic drugs or multinational and local pharmaceutical companies, was equivalent as per serum TSH, and there was no difference between them (shortage and storage are the constant factors of all the groups).

Introduction

Hypothyroidism is a thyroid disorder characterized by the impairment of the thyroid gland and its hormonal functioning(Salman et al., 2024). Primary hypothyroidism is a prevalent disorder, with an estimated occurrence in the general population between 0.3% and 3.7%(Muñoz-Ortiz et al., 2020).In the United States (USA), 8 million people are thyroid-deficient(Haymart & Papaleontiou, 2022). Clinical and subclinical hypothyroidism affects up to 4.1% of adults and 5.4% of children in Pakistan. Females are more likely than men to have both hypo- and hyperthyroidism(Shah et al., 2021). Consequently, a significant fraction of the adult population undergoes lifelong thyroid hormone therapy. The conventional management of hypothyroidism is the daily oral intake of synthetic levothyroxine (LT4)(Gottwald-Hostalek & Razvi, 2022). The dosage is adjusted to attain physiological plasma levels of thyroid-stimulating hormone (TSH)(Van Uytfanghe et al., 2023).

LT4 possesses a limited therapeutic index, necessitating TSH monitoring, as incorrect dosing might result in significant side effects. TSH measurement is advised following LT4 therapy, regardless of whether the replacement is under or over the same brand(Gunasekaran & Tan, 2024; Liu et al., 2023). It was emphasized that two brands of LT4 sodium are no longer bioequivalent. Various variables influence TSH levels, including stomach absorption and the transition between different brands (Liu et al., 2023). Medicine shortages, together with alterations in packaging and cost, are the primary reasons for brand switching(Shukar et al., 2021).In recent years, the issue of

the interchangeability of brand-name vs generic LT4 has garnered significant attention and remains contentious(Nagy et al., 2021).

In recent years, European nations have encountered recurrent issues about the interchangeability of various LT4 brands. In the Netherlands, the LT4 brand Thyrax was often given for hypothyroidism; however, between February 2016 and April 2017, 350,000 people experienced a change in their recommended brands owing to a shortage. Patients whose brands were altered observed fluctuations in their serum TSH levels and were administered supplements to mitigate these variations(Gottwald-Hostalek et al., 2017).In France, 2.6 million individuals were administered Merck's levothyrox formulation and then transitioned to an alternative novel preparation by Merck; nevertheless, following this substitution, several side effects were identified. The GSK Eltroxin brand was utilized by 8,000 patients in Denmark. The Danish Medicines Agency of Denmark opted to replace the brand with an alternative formulation and subsequently modified the brand following reports of 900 people experiencing 5,000 potential side effects(Cerqueira et al., 2011).

In 2014, David Brancato investigated the innovative liquid formulation of thyroxine (LT4-OS) and assessed the efficacy of liquid and tablet versions of thyroxine in reducing increased TSH levels. This study revealed that LT4-OS exhibited superior absorption compared to the tablet dosage form, resulting in a more favorable impact on TSH levels(Brancato et al., 2014).In 2013, James Hennessy released a review study asserting the interchangeability of generic and brand-name thyroxine, adopting Synthroid as the benchmark for comparison. This research focused mainly on evaluating the purported therapeutic equivalency across various brands of thyroxin(Hennessey, 2013). Certain studies indicate that several brands of thyroxin may not be interchangeable, and it is recommended that patients adjust their dosage when switching brands(Brito et al., 2022). Pakistan has announced the amalgamation of a lethal concoction of inferior pharmaceuticals. A variety of brands and generics exist for hypothyroidism treatment. Data about the bioequivalence and interchangeability of LT4 and TSH is exceedingly scarce. In Pakistan, there is a lack of evidence on interchangeability and pharmacokinetic bioequivalence trends. The current study sought to ascertain the equivalency between the brands offered in Pakistan and their parent firm.

Materials and methods

Study Design

This randomized, cross-sectional observational study aimed to determine the equivalence between different LT4 manufacturers for the treatment of primary hypothyroidism. Participants were randomly assigned and randomized to different brands of LT4. This ensured that there was a systematic evaluation of the performance of several brands in managing patients with primary hypothyroidism.

Drug Purchasing

Four brands of LT4 were procured. We divided all the brands into four strata. One sample from each brand was drawn from licensed community pharmacies, inpatient pharmacies, outpatient pharmacies, and local unlicensed chemists. The parent medicine was bought from a registered community shop from anywhere in the world; the other brands were bought from one locally produced pharmaceutical company and two others from multinational local production sites in Karachi, Pakistan.

Sample size

This research was a cross-over observational cohort investigation carried out in Karachi, the biggest metropolitan area of Pakistan. The study included randomization of participants. Patients were randomly selected based on the methods of randomization. Calculations for the study's sample size were done using the open epi program,

especially the Cohort module found at https://www.openepi.com/SampleSize/SSCohort.htm. The statistical parameters used were a two-tailed significance level of 95% and a power of 80%. To balance, the uncovered-to-covered ratio was set at 1 with an odds ratio of 1.9. The probability of occurrence was assessed at 17%. For this, the sample size based on the inputs was computed at 168, which in turn was grouped into 84 patients in each brand and generic category.

Location and setting of the study

The research was conducted in Karachi, Pakistan. Karachi is Pakistan's biggest metropolis and an important urban center. It was executed in health care facilities and clinical settings in Karachi to evaluate the comparability of different brands of Levothyroxine (LT4) used to treat primary hypothyroidism among a heterogeneous group of volunteers in the urban setting. Karachi, being an important urban metropolis, was an ideal location for this study. Their general and wide-range characteristics enabled a global overview of several brands of LT4 available for the treatment of primary hypothyroidism.

Patient Screening

A total of 168 participants were selected who had a confirmed diagnosis of primary hypothyroidism. A total of 168 participants were further grouped into men and women: 69 were males (41.1%) and 99 were females (58.9%). Inclusion criteria included patients in the age range of 16 to 80 years with a confirmed diagnosis of primary hypothyroidism. The TSH levels of all the selected patients were followed up and were dependent on LT4 dosages between 50 to 200 mcg. The study excluded newborns, children, and females who were either pregnant or lactating. There was also exclusion of critically ill patients with variable TSH levels.

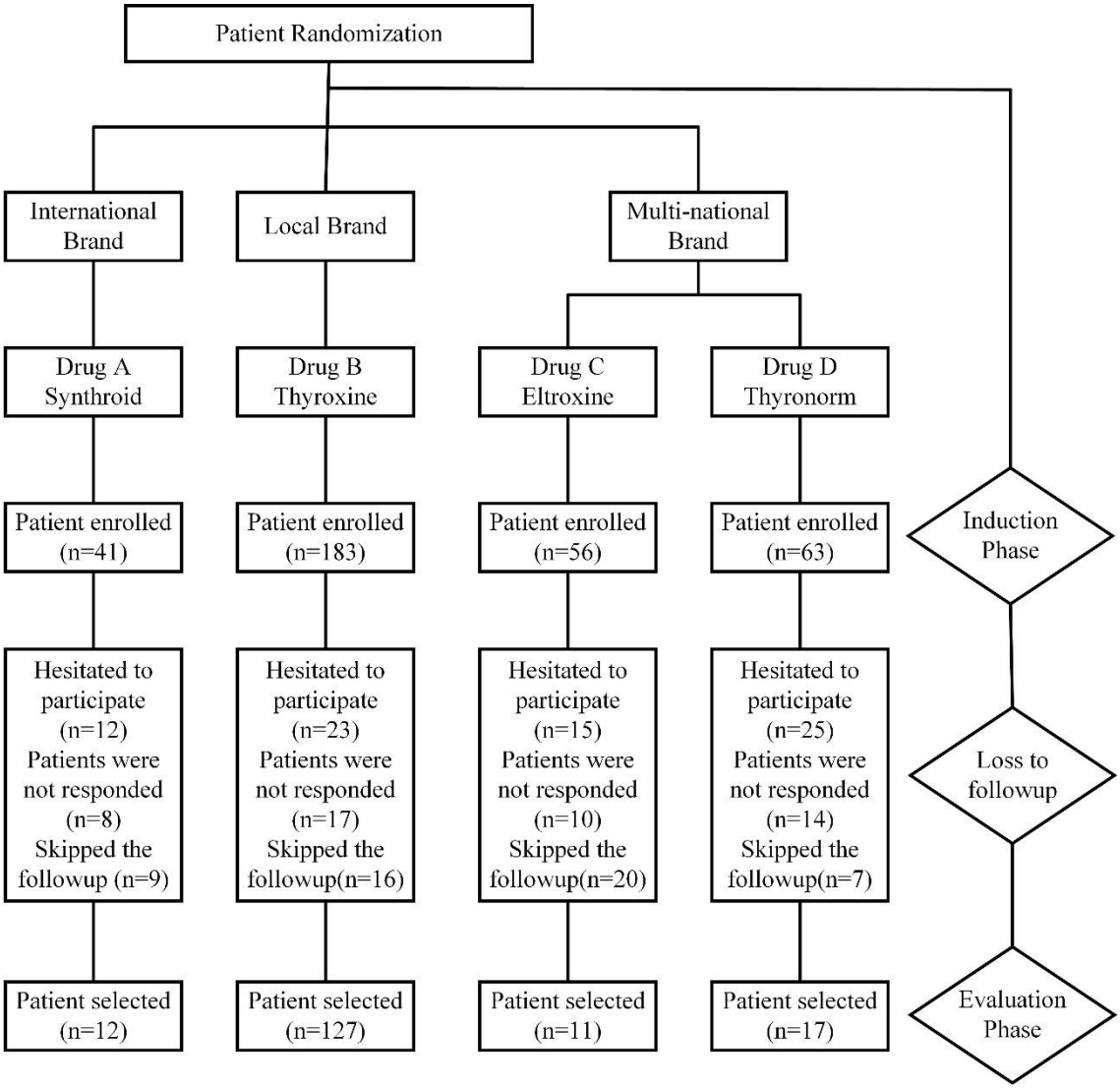

Figure 1. Randomization schedule and clinical evaluation of patients

Questionnaire for the data collection

A survey has been created for the Comparative Interchangeability Assessment of commercially available brands of Levothyroxine on the basis of serum Thyroid-Stimulating Hormone levels in Pakistan. Following demographics, various genders, and brands of levothyroxine, we set up a survey. To collect the data, we carried forward the survey questionnaire.

Questionnaire validation

To validate the questionnaires, we conducted a pilot study. The patients with primary thyroid dysfunction who received multiple brands of levothyroxine were at the center of this study. Pilot: In the various brands used and the adverse effects associated with different TSH levels, the consequences of TSH level fluctuations were assessed. The contributions from participants improved the accuracy and modified the questionnaire. The main aim of this pilot was to raise the validity and reliability of the study.

Data collection

This has been done by preparing a questionnaire in form of a structured survey. It was done to determine the interchangeability of various brands of Levothyroxine (LT4) in treating primary hypothyroidism. The instrument created was very comprehensive. It also added demographics of the respondents, drug use, health assessment, and brand specific questions. Data collection was achieved by selecting the respondents according to a certain set of rules according to which they were qualified, and their agreement was

taken in the form of signed forms before they took part in the research. Every gathering and transmission of the answers were done based on confidentiality and ethical standards. The data collected after collection of data was then subjected to statistical analysis to help estimate the efficacy and outcome of the different brands of LT4.

Diagnostic Parameters

The basic strategy of the diagnosis of primary hypothyroidism was to check the level of Thyroid-Stimulating Hormone (TSH). In this study, the TSH level of over 4.2 milli-International Units per liter (mIU/L) was set as criteria of diagnosing primary hypothyroidism.

Statistical Analysis

The data collected were coded and analyzed with the version of IBM SPSS 23. The t-test on independent samples was applied to analyze the data on some of the brands of experimental medication. The one-way ANOVA was used to assume the different effects on the relationships and outcomes in three different situations.

Ethical considerations

This was a study which was carried out in a careful manner in relation to ethical standards. To safeguard the rights and welfare of the participants and ensure adherence to the ethical standards and principles, the researchers received ethical permission of the institutional ethical review board of Jinnah University of Women, reference no JUW/IERB/PHARM-ARA-002/2023.

Consent form

Each patient or a subject has provided his/her consent after a thorough explanation of the objective and nature of all the strategies which are implemented.

Results

The data was collected on hypothyroid patients who are taking different brands of levothyroxine. The number of individuals that participated in our study was 168. The patients were picked through the randomization method as shown in Figure 1. The selection of the patient was divided into 4 groups (Drug A, Drug B, Drug C, and Drug D). The selection of the patients was divided into four categories including Drug A, Drug B, Drug C, and Drug D. In the former group, patients who were using Drug A, an international brand, were involved. First, 41 patients had been recruited, but the ultimate sample included 12 people of a global brand. The second category of patients used the local brand drug B, which was what group A used, but initially, the same number of patients were enrolled and at the end, 127 patients formed group B. In the third and fourth groups of patients, the local brand drugs C and D were utilized. Initially, patients selected for both groups were similar at 41; however, the final selection in the third group was 11, while the fourth group had 17. The patients were selected from various genders, age groups, and years of diagnosis. Among 168 patients, 69 were male (41.1%) and 99 were female (58.9%). The age group of 36-45 constituted the majority in the data collection, with 54 individuals (32.1%) of the total sample size, while the 26-35 age group was identified as the second most prevalent demographic with hypothyroidism. Thyroxine was the predominant brand among all others. Ede-ma (n=55) 32.7% and dry skin (n=77) 45.8% were the predominant adverse effects across all brands. Table 1.

Table 1. Baseline characteristics of the study population of hypothyroid patients

Gender n (%)

Male	69	41.1%
Female	99	58.9%
Age n (%)		
15-25	10	6%
26-35	44	26.2%
36-45	54	32.1%
46-55	34	20.2%
56-65	16	9.5%
66-75	10	6%
Years of diagnosis n (%)		
1-5 years	50	29.8%
6-10 years	89	53.03%
11-15 years	18	10.7%
16-20 years	11	6.5%
Total	168	100%
Drug used n (%)		
Drug A	12	7.14%
Drug B	127	75.59%
Drug C	11	6.5%
Drug D	17	10.1%
Side effects n (%)		
Weight gain	4	2.38%
Edema	55	32.7%
Hot flushes	21	12.5%
Cold intolerance	4	2.38%
Dry skin	77	45.8%
Libido	4	2.38%
PCOS	3	1.7%
Others	0	0

Various brands were selected for an evaluation of the interchangeability pattern of LT4. An independent sample t-test was used to compare the means of the four groups in the study: Drug A, Drug B, Drug C, and Drug D. All four groups exhibit no significant differences regarding the population association ($p>0.05$), as seen in Table 2. We utilized one-way ANOVA to assess the statistical differences in the means of the population to ascertain the interchangeability pattern of various accessible LT4 via serum TSH. No significant association was found between them ($p<0.05$), and all brands exhibited identical effects, as indicated in Table 3.

Table 2. Thyroid-stimulating hormones (TSH) test on hypothyroid patients with all 4 comparative brands

Drug name	Mean difference	Std. Error Difference	F	Sig
Drug A	0.21111	0.34698	4.363	0.556
Drug B	0.14672	0.15152	0.120	0 .335
Drug C	0.12857	0.27830	0.915	0.655
Drug D	0.26857	0.28390	0.018	0.359

Table 3. Interchangeability of different marketed brands of levothyroxine through serum thyroid-stimulating hormone (TSH)

Drug	TSH	Drug used	Mean Difference	Std. Error	Sig.
Drug A	Male	Drug B	-.00061	0.49921	1.000
		Drug C	-.03333	0.64308	1.000
		Drug D	-.06190	0.58103	1.000
	Female	Drug B	-.06499	0.26665	0.995
		Drug C	-.11587	0.38037	0.990
		Drug D	-.00444	1.39486	1.000
Drug B	Male	Drug A	.00061	00.4992	1.000
		Drug C	-.03273	0.43604	1.000
		Drug D	-.06130	0.33789	0.998
	Female	Drug A	.06499	0.26665	0.995
		Drug C	-.05088	0.29864	0.998
		Drug D	.06055	0.25450	0.995
Drug C	Male	Drug A	.03333	0.64308	1.000
		Drug B	.03273	0.43604	1.000
		Drug D	-.02857	0.52775	1.000
	Female	Drug A	0.11587	0.38037	0.990
		Drug B	0.05088	.29864	0.998
		Drug D	0.11143	0.37196	0.991
Drug D	Male	Drug A	0.06190	.58103	1.000
		Drug B	0.06130	.33789	0.998
		Drug C	0.02857	0.52775	1.000
	Female	Drug A	0.00444	0.34679	1.000
		Drug B	-.06055	0.25450	0.995
		Drug C	-.11143	0.37196	0.991

Discussion

The study's findings include significant therapeutic ramifications for the management of hypothyroidism in Pakistan. If the examined levothyroxine brands were deemed interchangeable, healthcare professionals would get supplementary prescription options, potentially resulting in cost savings for patients and the healthcare system. Moreover, it possesses the capability to eradicate supply chain challenges and enhance accessibility, ensuring the uninterrupted provision of pharmaceuticals. Furthermore, the findings of this research may serve as a basis for regulatory authorities in Pakistan to meticulously assess the interchangeability of marketed levothyroxine brands. Standardizing bioequivalence criteria and establishing brand-switching protocols may enhance patient safety and promote uniform treatment outcomes. Pakistan is regarded as one of the most populated nations in the eastern region(Organization, 2013). Pakistan's health budget is inadequate, resulting in minimal efficiency regarding regulations and a deficient healthcare system(Khan et al., 2024). Pakistan lags significantly in life expectancy and illness burden, as indicated by the Human Development Index (HDI) and Millennium Development Goals (MDGs)(Aziz et al., 2021; Mughal & Baig, 2024).

In micro budgeting, 77% of healthcare expenditures are allocated to inappropriate medicine purchases, such as hormones, anti-cancer drugs, and antipsychotic medications(Aslam et al., 2020; Babar & Jamshed, 2008).In underdeveloped nations, around 20 to 60% of expenditures are allocated to pharmaceuticals, with roughly 90%

of the population acquiring medications through out-of-pocket payments(Stevenson & Moran, 2014). Generic medications are seen not just as cost-reduction strategies, but also as essential for ensuring that patients can continue to access them at reasonable prices once the patent lapses(Mwenelupembe, 2024). The interchangeability between branded and generics has been contentious for many years(Patil et al., 2024). Our topic is not just contentious in underdeveloped countries but also raises concerns in rich nations. In Pakistan, the incidence of clinical and subclinical hypothyroidism was 4.1% in adults and 5.4% in children (Shah et al., 2021). The prevalence of hypothyroidism ranged from 2.3 percent to 5 percent, with a higher incidence observed in females as opposed to males, as in our results study(Narayana et al., 2011).

Similarly in 2004, it was conducted to investigate three different preparations of levothyroxine: test tablets, reference tablets and an oral solution. The findings showed that the test tablet is bio equivalent to the reference formulation both in the extent and rate of absorption(Koytchev & Lauschner, 2004) The study by Juan P. Brito involved a comparison of the effectiveness of generic and brand-name levothyroxine in achieving adequate thyrotropin levels as did ours. The results show that generic levothyroxine is as effective as branded levothyroxine during the first and initial treatment of moderate thyroid dysfunctions (Brito et al., 2020). Currently, there is little data about the comparative effects of generic and brand-name levothyroxine (LT4) pills on thyroid-stimulating hormone (TSH) levels. Research on babies with severe congenital hypothyroidism indicated significant disparities in the bioequivalence of generic and brand-name LT4 medicines. This study was limited in scope, done within an academic medical center, and comprised a rather small sample size. The existing literature reveals a deficiency of population-based studies investigating the effect of brand or formulation changes on blood TSH levels(Carswell et al., 2013).

In our study, comparable to that in the United States, four prominent brands and four distinct formulations of generic LT4 pills were accessible. A pharmacological monitoring study was conducted by leading American endocrine societies from 2005 to 2007 to evaluate the experiences of the populations they represent about LT4 replacement therapy. A total of 199 adverse events were noted in the intervention. The research identified correlations between changes in TSH levels. Of the total cases, 177 occurrences (88.9%) were recorded following the administration of LT4, as the tablets experienced a transition, as indicated by the reference (Hennessey et al., 2010). The switch was activated usually; the pharmaceutical product was manufactured by the pharmacy with a success rate of 99.4%. The majority of these instances, specifically 91.6%, were executed in the absence of the knowledge possessed by a physician. There was a transition from the process of transitioning from a brand-name LT4 preparation to a generic alternative. In 88.1% of the cases, there was evidence of preparation, as indicated by a total of 156 instances. The transfer of brands from one entity to another occurred in 12 instances, accounting for a proportion of 6.8%. Additionally, there were instances of brands being transferred from one entity to another. The transition from one generic entity to another was seen in 9 cases, accounting for 5.1% of the total sample (Hennessey et al., 2010).

LT4 is globally approved for the treatment of hypothyroidism. Patent and brand medicine rivalry has resulted in a restricted availability of medications for hypothyroidism in the market. We identified the optimal brands of LT4 and evaluated them against the parent corporation. In light of the dispute among brands over generics in hypothyroidism patients, we focused on serum TSH as a measure for assessing the medicine in serum. We selected three domestically produced brands of LT4 and put them against the parent firm. The difference between the two independent means was measured using independent t-test and came out to be the same that there is no difference between the brand and the generic products. Considering the four distinct populations for assessing serum TSH via both brand and generic formulations, Analysis of Variance (ANOVA) was utilized to ascertain the relationship between the means. No

significant difference was seen among the groups ($p>0.05$); all brands and generic molecules were equal, with no notable adverse effects reported. The serum TSH levels were consistent across all groups.

Strengths and Limitations

No studies exist in Pakistan on the interchangeability and equivalence of LT4, despite the therapeutic significance rendering the drug contentious in terms of clinical equivalency. This investigation was conducted in a singular, particular region. There is no analogous stratification for all groups because of randomization and convenience sampling.

Future recommendation

The investigation can be further broadened to assess biologic equivalents using a larger cohort of human participants and a greater variety of accessible levothyroxine brands. We can do the standardized fixed-dose protocol trial. Further investigation may be conducted on the pharmacogenomic factors influencing the way various sexes impact the bioavailability of brands.

Conclusion

The study determined that no substantial difference exists among different brands of Thyroxine (T4). This discovery may enhance the cost-effectiveness and accessibility of Thyroxine brands, providing a viable alternative for people requiring assistance. Switching from one brand to another, whether owing to storage issues or other factors, reveals no substantial difference between brand-name and generic products; both are statistically equivalent in developing countries. An exhaustive evaluation of patient reactions to different brands informed evidence-based decisions and enhanced the treatment standard for hypothyroidism patients nationwide.

Conflict of interest

The authors declared no conflict of interest for this study.

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Abbreviations

The following abbreviations are used in this manuscript:
TSH Thyroid Stimulating Hormone
LT4 Levothyroxine

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