Why pharmacovigilance of traditional medicines used as analgesics is important?

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Abbreviations
ADRs, adverse drug reactions; WHO, World Health Organisation; CAM, complementary and alternative medicine; EU, European Union; GMP, Good Manufacturing Practices.

Abstract
Traditional remedies have gained recognition for their effectiveness in treating various conditions such as diabetes, arthritic pain, liver disease, cough and cold, memory enhancement, and immunological stimulation. Their perceived safety has led to the increasing use of herbs by people without prescriptions. These therapies remain significant in areas with limited access to modern drugs or cultural preferences for traditional treatments. With a long history of use, traditional medicines have been the primary method of pain management. This review article explores natural and herb-based analgesics, their origins, and potential benefits, along with the growing scientific evidence supporting their effectiveness. Studies have examined their efficacy in treating musculoskeletal pain, neuropathic pain, and migraines. Rather than being seen as separate therapies, traditional medicines should be considered supplementary or alternative options that can be integrated into comprehensive pain management regimens. However, some studies have reported adverse drug reactions associated with herbal formulations and plants. Therefore, there is a need for pharmacovigilance in traditional medicine to ensure patient safety and promote evidence-based practices. Although pharmacovigilance in this field is still developing, it faces challenges due to the wide availability of herbal medicines without on-site medical supervision. This paper discusses the complex challenges of herbal pharmacovigilance, provides insights on recent advancements, and offers recommendations for improving the safety monitoring of traditional medications in the future.

Keywords: herbal medicine; pharmacovigilance; regulatory framework; traditional medicine
Traditional remedies have gained recognition for their effectiveness in treating various ailments. Traditional formulations used as analgesics are widely used especially for chronic pain. This has led to the increasing use of herbs/traditional formulations by people without prescriptions. This has necessitated reporting of Adverse Drug Reactions using pharmacovigilance as a tool. This article explores natural and herb-based analgesics, their origins, and potential benefits, Adverse Drug Reactions and need for pharmacovigilance for gathering scientific evidence supporting their effectiveness and patient safety.

**Medical history of objective**

Ayurveda, the science of life, is immortalized in the samhitas as graceful Sanskrit stanzas that detail how to diagnose and treat illnesses as well as maintain good health. Ayurvedic classic Charaka Samhita explains all of the negative effects of medications when they are produced or used improperly. Ayurvedic pharmacology (dravyaguna vigyan) and therapies (chikitsa) frequently discuss improving patient care and safety in connection to drug use and hence promoting rational drug use as its primary goals. In summary, Charaka asserts that with the right dosage, even a potent poison can function admirably as medicine. However, if used irresponsibly, even the most beneficial medication might behave poisonously.

**Background**

Traditional medicine has been practised by numerous cultures and civilizations worldwide since prehistoric times. Traditional medicines have seen an increase in non-prescription use during the past few decades [1]. Traditional formulations, such as anti-diabetics, aphrodisiacs, anti-arthritis, hepatoprotective, memory enhancers, cough cures and adaptogens, have gained universal acceptance as medicinal agents [2]. Since they come from natural sources, they are typically thought to be safe [3]. The majority of over-the-counter herbal medications, like ginseng, have attracted a lot of public interest despite the fact that there are several case reports of adverse effects of generally thought to be safe herbal medicines in the literature [4]. Though, risks associated with using traditional medicines as self-prescriptions and adverse drug reactions (ADRs) have been thoroughly documented [5]. Global harmonisation of herbal health claims requires an accurate scientific evaluation of conventional medicine. The World Health Organisation (WHO) has established particular recommendations for evaluating the quality, safety, and efficacy of conventional medications in this regard [6]. Pharmacovigilance, which comprises biologicals, blood products, vaccines, medical devices, and herbal, traditional, and complementary medicines in addition to chemical medications, aims to identify, evaluate, and comprehend harmful effects in addition to preventing them [7].

**History of use of traditional herbal medicines**

The useful plants have historically been referred to as “people’s medicine”. The WHO (1977) defines “a medicinal plant” as any plant that has one or more organs that contain compounds that can be utilized therapeutically, or that serve as building blocks for the production of effective pharmaceuticals [8]. This definition makes a distinction between plants that are thought to be medicinal but have not yet undergone extensive research and plants whose therapeutic properties and constituents have been proven via scientific study. They were frequently more affordable, more widely available, and safer than chemical medications. There are thought to be 21,000 medicinal plants in the world [9]. They are more prevalent in the hot spots’ of biodiversity found around the world, such as the Amazon rainforest in South America, the Western Ghats in South Asia, the Eastern Himalayas, and the Eastern Arc Mountains and Coastal Forests in East Africa. Both in the developed and developing worlds, medicinal herbs, shrubs, and trees are frequently utilized to prepare traditional treatments that are used in both home and commercial sectors [10]. More than 4,000 plant species are utilized as medicines throughout tropical Africa, and the area consumes 50,000 tonnes of herbal products each year. In South Asia, there are more than 8,000 plant species that have been used medicinally [11]. For more than 80% of Asia’s population, medicinal plants represent a readily available, reasonably priced, and culturally suitable source of primary healthcare (WHO). Indigenous, rural, and marginalized populations are particularly reliant on these technically straightforward, cost-efficient, culturally familiar, and typically effective traditional medicines because they cannot pay for or access formal healthcare systems [12]. According to WHO estimates, up to 80% of people in developing nations rely on traditional systems of care, mostly due to their wide availability, low cost, and cultural familiarity. In fact, traditional and folk medicine is the sole treatment available to the 40% of the world’s poor who do not have access to government health care [13].

As people look for all-encompassing methods of healthcare and well-being, complementary and alternative medicine (CAM) has significantly increased in popularity in the United States. A holistic approach, emphasizing the treatment of the full individual, embracing physical, mental, emotional, and spiritual components, is one of the guiding concepts of American CAM [14]. It recognizes the interdependence of these dimensions and seeks to correct imbalances by fostering all-around wellness. Additionally, CAM encourages integrative medicine and the coordination of conventional and complementary medical approaches. This method encourages comprehensive care while aiming for the best possible health results. It recognizes the benefits of combining evidence-based therapies with complementary modalities [15, 16].

The Committee on Herbal Medicinal Products provides information on suggested uses and safe situations for the European Medicines Agency, as well as scientific evaluations of traditional medications and preparations. The European Medicines Agency also manages the services and processes that enable pharmacovigilance in the European Union (EU) and coordinates the pharmacovigilance system for the EU10 in accordance with Directive 2010/84/EU [17]. This is because traditional medicinal products are regarded as medicinal formulations. This states that in order to market them based on the outcomes of research and experimentation on quality, safety, and efficacy, ad hoc authorization must be given. Similarly to that, all EU member states, including Committee on Herbal Medicinal Products, must comply with Regulation (EU) No. 1235/2010 and Commission Implementing Regulation No. 520/2012 on pharmacovigilance [18-21].

**Indian traditional medicines**

Ayurveda is a medical practise that has been practised largely in India for close to 5,000 years. It emphasises the body, mind, and spirit as well as disease prevention and treatment. It also involves food and herbal therapies [22]. The most essential element of our existence is herbal plants. Any part of the plant, including the root, stem, leaves, flowers, and fruits, can be used for its therapeutic, culinary, or aromatic characteristics. A plant is considered to be a herb if it has features that are appreciated, such as medical capabilities, flavour, fragrance, or extracts [23]. The principles of traditional medicine or folk medicine are founded on the utilisation of plants and plant products. Annual, biennial, and perennial herbal plants are all possible [24]. Annual herbaceous plants only live for half a year, dying entirely at the conclusion of the growing season or after they have flowered and produced fruit [25]. The lifespan of biennial herbal plants is one to two years. Herbal perennials have a long growth period. The plant’s stems die at the conclusion of each growing season, but its roots or
other portions live on from season to season [26]. Living tissues that are still present on or in the roots give rise to fresh plant development. By examining the annual growth rings in the secondary root xylem, it is possible to estimate the age of various herbal plants. Except for Allopathy, all of India’s officially recognised health systems—Ayurveda, Yoga, Siddha, Unani, Homoeopathy, and Naturopathy—include a significant portion of herbal medications. These non-allopathic medicinal systems are still used by the 1.1 billion people in India. There is currently no separate category for nutritional supplements or herbal remedies under the Indian Drugs Act. There is a significant body of empirical evidence supporting the use of several natural medicines. This provides tremendous prospects for reverse pharmacology and observational therapies [27]. A well-organized industry produces evidence-based herbalas in accordance with pharmacopoeial criteria and is widely employed in a variety of systems. Numerous Institutes/Universities have conducted extensive basic and clinical research using cutting-edge techniques on medicinal plants and their formulations. There are a few excellent examples. Antioxidants that are known to stop or postpone many disease states are also abundant in Indian medicinal herbs [28]. At various levels, the antioxidant protection is seen. The therapeutic plants also include other advantageous substances, such as components for functional foods. Therefore, knowledge of these plants’ scientific foundations should aid in improving global understanding of Ayurveda and Indian herbal medicines. This will yield substantial dividends in the ensuing years [29].

**Traditional medicines used as analgesics**

A growing number of pharmacological investigations demonstrate that natural products hold promise for the creation of novel compounds or treatments at the same time that traditional pain relief methods are losing their efficacy. The idea for this special issue was inspired by the growing demand for new therapeutic agents derived from plants currently being used in traditional medicine to treat and/or control pain. An in-depth study of the bioactivities of a variety of natural chemicals may lead to the development of brand-new medications and treatments that are highly efficient, affordable, safe, and readily available [30]. In light of this, researchers from many nations were asked to submit novel studies and critiques of fresh natural remedies having analgesic effects. Plant-based analogies have been used for pain relief in traditional medical systems for ages, including Ayurveda, traditional Chinese medicine, and indigenous healing techniques [31]. Strong pharmacovigilance systems are required to monitor and assess the safety profiles of conventional medicines in light of the growing interest in these treatments worldwide. Some common traditional medicines used in pain relief, along with their source, are mentioned below (Table 1) [32-52].

Considering the sumptuous use of herbal medicines worldwide, especially painkillers, there is a need to integrate a robust pharmacovigilance surveillance system into the health policy.

**Pharmacovigilance**

The use of CAM is expanding significantly in developed countries. The security, calibre, accessibility, preservation, standardization, and future growth of this healthcare system are issues that concern policymakers, healthcare professionals, and the general public worldwide [53]. Traditional remedies have a tremendous amount of potential, but many of them have not been adequately studied, and as a result, there is a lack of information concerning their potential negative effects. In the developed world, pharmacovigilance—a French term for the process of finding pharmacological adverse effects, treating them, documenting, reporting, and making regulatory decisions—is a well-established science [54]. The area of pharmacology known as pharmacovigilance is concerned with the identification, assessment, comprehension, and avoidance of any negative effects or other medication-related problems, particularly long-term and short-term pharmacological side effects [55]. Simply described, pharmacovigilance is the science of collecting, monitoring, looking into, assessing, and interpreting information from medical professionals and patients on the adverse effects of prescription medications, biological products, herbal medicines, and conventional therapies [56]. Any drug’s safety and effectiveness are its two main considerations. While a drug’s effectiveness can generally be predicted, this cannot be true for its safety as a drug’s side effects can occasionally be severe, and many individuals may be exposed to risk before the drug’s causality is shown [57]. As a result, pharmacovigilance, a new subfield of pharmacology, was created [58]. Herbal, conventional, and alternative medicines, blood products, biologicals, medical equipment, and vaccinations are now included in this list of recent concerns. It is quickly becoming a crucial method for the early diagnosis of pharmacological side effects and the implementation of the necessary regulatory measures to ensure safer drug use [59].

**Need of pharmacovigilance**

All nations’ laws compel pharmaceutical companies to conduct clinical trials—that is, test new medications on humans before making them widely available [60]. At most, a few thousand patients who fit the drug’s target demographic are typically chosen by the manufacturers or their representatives, along with a comparable control group. A placebo or another drug that has already been given approval to treat the ailment may be administered to the control group. Clinical studies are intended to establish effectiveness, any side effects, and the benefit-harm-risk analysis [61]. Clinical trials offer data that should be trustworthy for wider populations that share the trial group’s gender, age, health status, ethnic background, and other factors [62]. In a clinical study, the outcomes only apply to the population whose sample the trial group represents, and the factors are pre-set and controlled. Due to the following limitations, a clinical trial can never fully examine a drug’s effects in all circumstances where they are governed by laws and current opinions on the appropriate ratio of benefit to harm [63]. 1. Animal experiments have little predictive value for human safety. 2. The duration and number of subjects in clinical studies are constrained. 3. Patients are chosen based on a number of criteria, including their health (adults, no other medications, no other disorders). 4. Results do not accurately reflect use in actual life. 5. Rare or slowly occurring serious reactions are more likely to go unnoticed.

For detecting, evaluating, and responding to ADRs and drug safety concerns, pharmacovigilance is a useful post-marketing surveillance technique. In India, pharmacovigilance is a new and developing field; hence capacity and competency development are required [64]. Regulatory organizations are becoming more proactive in looking for potential safety issues with commercially available medications. Pressures from politics and society have grown, and communication methods are now more rapid. For all parties involved, litigation brought on by a lack of pharmacovigilance can be disastrous. A license may be revoked or suspended for failing to practice pharmacovigilance [65]. Pharmacovigilance in the context of American CAM is concerned with keeping an eye on the side effects and safety of CAM treatments, herbal medicines, and nutritional supplements. The Food and Drug Administration runs the MedWatch program, which encourages the reporting of adverse CAM-related occurrences to help uncover potential safety issues. Additionally, urged to voluntarily report adverse events through various avenues are CAM practitioners and manufacturers. While regulatory organizations, healthcare experts, CAM practitioners, and manufacturers work together to share information and implement regulations, and research institutes perform studies to evaluate safety and effectiveness. The Food and Drug Administration has the power to act against dangerous CAM products and regulates dietary supplements through good manufacturing practises to assure product quality. Initiatives for consumer awareness and public education need to educate the general public on CAM therapies, potential dangers, and the value of reporting adverse events in order to support a comprehensive pharmacovigilance system [16].
Pharmacovigilance is more important for traditional medicines in post-market control in the EU than food products [18]. However, when it comes to plants in Europe, European standards and laws offer substantial tools for consumer protection. In contrast to the second, which recommends a list of components that are prohibited, limited, or open to public discussion (EFSA, 2009; Regulation 20125/2006-2006), the first defines standards for safety assessments. France recently began exchanges with 13 EU member States in 2014. Traditional medications are subject to the same laws and regulations as conventional drugs in France, which introduced pharmacovigilance in 1985 [19]. The same Good Manufacturing Practices (GMP) guidelines that apply to the manufacture of conventional medications also apply to the manufacture of herbal drugs. To ensure that these requirements are being observed, inspections are utilized. The safety requirements are the same as for conventional pharmaceuticals, with the exception of the specific requirement of traditional usage without adverse effects that have been demonstrated. The Kingdom of Belgium approved the nation’s traditional medicine/CAM policy, legislation, and regulations in 1999. Prior to that, neither a national office nor a national program existed [20]. Traditional remedies are currently governed by laws roughly resembling those that apply to conventional pharmaceuticals. Similar rules that apply to conventional treatments also apply to dietary supplements, over-the-counter medications, and prescription medications. Legal statements about a product’s nutritional value and health benefits are permissible. One of the regulatory requirements for the production of herbal medicines is the adherence to GMP standards and information found in pharmacopoeias and monographs, according to the WHO (2005). The pharmacovigilance center and routine pharmacy inspections ensure that the same safety standards as for traditional medications are met [21].

**Pharmacovigilance in India**

India is a nation having a population of over one billion. India’s population uses a variety of modern medical systems, including Allopathy, Ayurveda, Homoeopathy, Siddha, etc. Without a monitoring and review process, drug interactions, bad effects, and misuse can wreak havoc on the nation’s healthcare system [66]. In India, ADR monitoring programs are not new. For the purpose of monitoring ADRs nationally, the Drug Controller General of India established five centers in 1982. Through its multi-institutional study, the Indian Council for Medical Research gathered over 58,000 ADR cases in 1987; however, in a short period of time, all of them ceased to exist for a variety of reasons, including a lack of funding and a lack of motivation [67]. Numerous medications have been taken off the market in the last 20 years as a result of major ADRs. The National Pharmacovigilance Programme (NPP) was introduced in November 2004 by the Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare, Government of India, in
recognition of the significance and advantages of pharmacovigilance. Most of its recommendations were based on the WHO document “Safety Monitoring of Medicinal Products-Guidelines for Setting Up and Operating a Pharmacovigilance Centre” [68]. Under this project, the entire country is split into zones and regions for operational efficiency. On Jan 1st, 2005, the WHO-sponsored and World Bank-funded National Pharmacovigilance Programme for India went into operation. The program seeks to promote a culture of reporting adverse drug events and as a result, aims to: create thorough ADR data for the Indian population and make it available to the world’s medical community through the WHO-Uppsala Monitoring Centre; ensure the highest level of drug product safety for the Indian market; the sharing of technical expertise for evaluating statutory adverse event data provided by sponsors of clinical trials being undertaken in India [69].

**Pharmacovigilance of traditional medicines used as analgesics**

Traditional remedies have been used as alternative pain management techniques for ages. They cover a broad spectrum of natural treatments and concoctions that have become more well-liked all around the world. The safety and effectiveness of conventional medications used as analgesics must be ensured, just like with any other pharmaceutical product, through strict pharmacovigilance procedures. It is essential for keeping track of the safety profiles of pharmaceuticals, including traditional remedies [70]. The pharmacovigilance of traditional medicines used as analgesics involves several key aspects:

- **Monitoring Adverse Effects:** Pharmacovigilance systems gather and analyze data on adverse effects associated with traditional analgesics. In order to identify any warning indications of danger or new dangers requires keeping track of adverse occurrences that have been recorded, both voluntarily and as part of clinical research.

- **Risk Assessment:** Experts in pharmacovigilance evaluate the documented side effects to establish their frequency, severity, and cause. This evaluation assists in locating probable safety issues and comprehending the risk-benefit ratio of conventional analgesics.

- **Detection of Herb-drug Interactions:** Multiple active substances included in traditional remedies frequently interact with modern pharmaceuticals. To ensure safe co-administration and avoid any negative interactions, pharmacovigilance initiatives concentrate on discovering and evaluating potential herb-drug interactions.

- **Quality Control and Standardization:** Traditional remedies might vary in composition and quality because they are made from natural sources. To assure consistency and lower the risk of negative effects brought on by contamination or adulteration, pharmacovigilance initiatives include monitoring the quality, purity, and standardization of conventional analgesics.

- **Education and Awareness:** Pharmacovigilance encourages education and awareness about the safe and responsible use of conventional analgesics among medical professionals, practitioners of traditional medicine, and members of the general public. This includes educating people on possible risks, appropriate dosage, and safety measures to reduce negative effects.

- **Collaboration and Regulatory Measures:** Collaboration between regulatory agencies, traditional medicine practitioners, manufacturers, and other stakeholders is necessary for the effective pharmacovigilance of traditional analgesics. The safety and quality of these medications are helped by regulatory measures such as product registration, licensing, and post-marketing surveillance.

By identifying and addressing safety problems, the pharmacovigilance of conventional medications used as analgesics plays a crucial role in protecting public health. It helps create suitable recommendations for their usage, promotes evidence-based decision-making, and guarantees the continuous availability of traditional analgesics that are both safe and efficient [71]. Healthcare professionals, practitioners of alternative medicine, and patients should actively report any side effects of conventional analgesics to pharmacovigilance systems. Such reporting aids in improving our comprehension of their safety profiles and supports the general advancement of pharmacovigilance procedures for conventional painkillers [72].

**Challenges in pharmacovigilance of traditional medicines used as analgesics**

The challenges associated with herbal and traditional medicine products are numerous. Firstly, there is a lack of clinical trial data, and instead, these treatments rely on historical medical use for licensing, making it difficult to gather safety and effectiveness data. Secondly, the complex chemical combinations with multiple ingredients make it challenging to determine the effects of individual constituents [73]. Moreover, there is variation in the chemical profiles of plants, leading to non-uniformity in batches and posing difficulties in assessing safety and toxicity. The use of plant-based ingredients from different sources and varying production methods and quality control measures further contribute to the unpredictability of these products. Moreover, there is a lack of technical knowledge and resources to properly assess the quality, adulteration, and contamination of traditional medicine products [74]. The potential interactions between different traditional medicine products and with food and allopathic drugs also complicate their usage and safety [75]. Furthermore, different regulations and categorizations of herbal products across nations create confusion and hinder accessibility to reliable information. The inconsistent nomenclature including contradictory names used for crude plants further impede the analysis and understanding of these products. Insufficient training in pharmacovigilance methods among medical professionals leads to underreporting of adverse effects [76]. Additionally, the lack of regulation and quality control gives rise to safety concerns associated with low-quality and harmful herbal medicines. Limited research exists on the quality of herbal medicine recommendations made by healthcare professionals, and patients often do not disclose their use of these products. Finally, the dearth of trustworthy information on the effectiveness and interactions of herbal medicines negatively impacts knowledge and reporting of adverse reactions [77].

**How can pharmacovigilance for traditional medicine be improved?**

Networking should involve manufacturers, drug stores (pharmacists), consumers, and health facilities (traditional medicine practitioners). Ensure that all member states have uniform regulations for herbal and traditional medicine goods [78]. The future of medication safety lies in proactive pharmacovigilance across the product life cycle. For instance, the regulatory system must provide a robust pharmacovigilance method for gathering safety information both before and after marketing authorization [79]. Practitioners of traditional medicines should be trained in causality assessment and should take part in the process. Pharmacovigilance ought to be included in the medical school curriculum. Pharmacovigilance ought to be incorporated into community pharmacies’ good pharmacy practices [80]. It is important to promote the use of contemporary technology and its advancement through information technology resources and mobile application tools. The ADR report for herbal medications should include the precise scientific name of the plant, the plant component utilized, and the name of the manufacturer [81]. Regular training courses should be supported in order to increase national capacity for assessing the security of traditional medicine items and for raising awareness. To foster a culture of reporting ADRs, it would be preferable to begin early with the professional training of healthcare students [82]. The use of herbal materials should be subject to national quality criteria and standards, including GMP, labeling, and licensing programs for production, importation, and marketing (including selection, sampling, testing of plant material, and stability studies) as mentioned in Figure 1 [83].

**Future strategies in regulatory framework**

Traditional herbal therapy is openly acknowledged and incorporated
into all facets of healthcare delivery in an integrative approach. This calls for the incorporation of traditional herbal medicine into the country’s national drug policy, registration and regulation of all herbal medicine suppliers and their products, accessibility of traditional herbal therapies in both public and private hospitals and clinics, and insurance coverage of the cost of traditional herbal medicine treatment. The traditional herbal registration holder must teach consumers how to use traditional herbal medicines safely and efficiently in order to develop a successful pharmacovigilance plan for herbal and traditional medicines, especially those used as analgesics. The regulatory agencies will be able to assess this data to identify the advantages and disadvantages of medications as well as what steps, if any, are required to improve their safe usage. Herbal analgesic medications must be classified and/or coded using accepted language and definitions. To fully comprehend the pharmacogenetics and pharmacoepidemiology of herbal medications, pertinent studies must be conducted. The study of conventional herbal medicine will be encouraged by financial incentives and research funding. By providing people with access to facilities for the analysis of goods suspected of creating adverse reactions, instructing people in crucial technical areas, and ensuring that people have access to trustworthy information, the capacity must be increased to monitor herbal medicines at national pharmacovigilance centers. In order to execute the necessary regulatory measures, a national safety monitoring plan for herbal pharmaceuticals needs to be put in place with the capacity and willingness to act on signals from reports of harmful effects.

**Conclusion**

Applying current pharmacovigilance approaches to monitor the safety of herbal analgesic medications raises additional issues beyond those covered for conventional drugs because the instruments associated with pharmacovigilance were created in relation to synthetic drugs. The terminology, perception, source, and use of herbal medicines are all associated with a number of issues. Since people usually do not seek expert advice before using herbal analgesic items or reporting if they have bad effects, it is projected that unreported ADRs for herbal medicines will be significant. It is challenging to get in touch with many clients through conventional healthcare professional channels (such as pharmacies), as they do not buy their items from registered/licensed pharmacy outlets. Therefore, adopting a range of extra techniques employed in the pharmacovigilance of conventional medications, such as prescription-event monitoring and the use of computerized health record databases, to assess the safety of herbal and other non-prescription medicines is worthless. If herbal analgesic medicines are to be marketed as a source of healthcare, responsible use of a pharmacovigilance network needs to be developed and holistically encouraged.

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