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ORIGINAL ARTICLE

Efficacy and Tolerance of the Tampsec Vaginal Tampon for Treating Stress Urinary Incontinence. A Randomized Controlled Trial

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Abstract

Introduction and Hypothesis Stress urinary incontinence (SUI) is a highly prevalent condition in women. We hypothesized that the Tampsec™ vaginal tampon will be efficacious and well tolerated in its treatment.

Methods This was a multicenter open-label parallel-group randomized control trial. All participants were recommended to make lifestyle modifications and perform pelvic floor muscle training for SUI treatment. Additionally, women in the tampon group were instructed to use a Tampsec™ throughout the day. The primary outcome measure was a ≥50% reduction in pad weight by the end of treatment. Secondary outcome measures were women's perception of improvement evaluated using the Patient Global Impression of Improvement (PGI-I) questionnaire, decrease in the mean number of SUI episodes/day, and improvement in the impact of urinary incontinence (UI) on everyday life. Tampon tolerance and usability were also evaluated.

Results Forty-six women with a positive urinary stress test were randomized 1:1 to tampon or control treatments. Regarding the primary outcome, a ≥50% reduction was achieved in 69.9% of patients in the tampon group and 26.1% in controls (RR 2.7; 95%CI 1.3-5.4). On the basis of PGI-I responses, the treatment was successful in 60.9% of women in the tampon group and 17.4% of controls ($p = 0.003$). The tampon group also reported greater decreases in SUI episodes/day (mean 2.0±2.2 vs 0.5±1.1; $p = 0.007$) and more improvement in the impact of UI on everyday life. Tolerance and usability were good in most women.

Conclusion The Tampsec™ tampon is efficacious and well tolerated in women with SUI. This treatment decreases the number of SUI episodes/day and improves UI-related quality of life.

Keywords Intravaginal mechanical devices · Stress urinary incontinence · Vaginal tampon · Women

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Introduction

Stress urinary incontinence (SUI) is a highly prevalent condition affecting up to 25% of female adults [1], greatly reducing their quality of life [2]. Women affected often limit their daily physical activities to reduce leakage episodes or avoid their favorite sports because of SUI [3]. The main treatments for SUI seek to correct excessive urethral mobility during effort. These treatments may be conservative, based on training the pelvic floor muscles (PFMs) to maintain the urethra in its usual position. Alternatively, they may involve surgery to provide permanent support for the urethra, the most frequent techniques being colposuspension and mid-urethral slings.

Another option for managing SUI is to use intravaginal devices to restore the position of the proximal urethra. Various types of devices have been described, including pessaries, tampons, and other mechanical devices specially designed for SUI treatment [4], but the latest Cochrane review on this matter concluded that the evidence available was insufficient to clarify the role of such intravaginal devices in the treatment of urinary incontinence (UI) in women [5]. The report of the most recent International Consultation on Incontinence (ICI) states that some intravaginal mechanical devices may be effective and relatively noninvasive, but there continues to be a lack of randomized controlled trials and long-term follow-up for most products [4].

The effects of pessaries and other intravaginal devices have been evaluated in some studies, indicating good outcomes [6–10]. Nonetheless, we have not found any randomized controlled trials evaluating vaginal tampons as a treatment for SUI. This study aimed to evaluate the Tampsec™ vaginal tampon in a randomized controlled trial. We hypothesized that this tampon will be efficacious and well tolerated in the treatment of SUI in women.

Material and Methods

This was a multicenter open-label parallel-group randomized control trial conducted in Spain (at six sites).

Women with symptoms of SUI attending the Pelvic Floor Unit at any of the six hospitals from October 2019 to October 2022 were invited to participate. The selection criteria are listed in Table 1 and the schedule of activities is reported in Table 2. A urinary stress test was conducted after filling the bladder with 300 mL sterile saline and it was considered positive if involuntary leakage from the urethra was synchronous with coughing, in accordance with the International Continence Society (ICS) definition of SUI sign [11]. The Incontinence Severity Index (ISI) score was used to evaluate the severity of UI [12]. Scoring is based on the frequency and amount of leakage reported by the woman and is categorized into slight, moderate, severe, and very severe. Postvoid residual volume was calculated using ultrasound according to the Haylen formula [13]. SUI and urgency urinary incontinence (UUI) episodes were recorded in a 7-day bladder diary. Women were asked to complete the diary differentiating between leaks associated with effort or physical exertion from those associated with urgency, following the ICS definitions [11]. All participants received oral and written information about the study and signed a consent form.

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Stress urinary incontinence confirmed by a positive stress test
Exclusion criteria
History of stress urinary incontinence or pelvic organ prolapse surgery
History of repeated urinary tract infections
Mixed urinary incontinence with predominant urgency incontinence
Pelvic organ prolapse in any compartment beyond the level of the hymen
Postvoid residual urine volume greater than 100 mL
Vaginitis
Undiagnosed vaginal bleeding
Hematuria
Acute urinary tract infection
Inability to fill the bladder with 300 mL of sterile saline
Inability to perform the exercises involved in the pad test

Randomization and Masking

Patients were randomized at a 1:1 ratio to the tampon (treatment) group or the control group using a computer-generated randomization sequence known only to the trial coordinators until the end of recruitment. The clinical trial was open in design because of the characteristics of the treatment under study and the lack of a placebo device made blinding impossible.

Intervention

Women in both groups were recommended to make lifestyle modifications and perform the PFM training usually indicated for SUI treatment. These recommendations were explained verbally, according to the conditions of each patient. They included weight loss, fluid intake reduction, changes in physical activity level, smoking cessation, and caffeine reduction. Regarding PFM exercises, we

Table 2 Schedule of activities

First visit: baseline
Medical record
Physical examination
Postvoid residual volume
Urine analysis
Severity of UI (Incontinence Severity Index)
Impact of UI on everyday life (ICIQ-UI SF)
Women were instructed to complete a 7-day bladder diary in the next week
Second visit (2 weeks)
Stress test
Randomization
First pad test
Women were instructed to complete a 7-day bladder diary the last week of treatment
Third visit (8 weeks)
Second pad test
Impact of UI on everyday life (ICIQ-UI SF)
Patient Global Impression of Improvement (PGI-I) questionnaire
Vaginal tampon tolerance
Tampon usability

recommended at least 10 consecutive contractions lasting 8–10 s performed 3 times per day.

In addition, women in the tampon group were instructed to use the Tampsec™ vaginal tampon throughout the day. The treatment lasted 6 weeks, and tampons were provided free of charge.

Tampsec™ tampons are made from polyvinyl alcohol and have been extensively tested for safety (Fig. 1). There are three sizes, ranging from 5.2 to 5.8 cm long and 2 cm to 3 cm wide, and to select the appropriate size, the tampons can be fitted by a healthcare provider or patients themselves. Each tampon can be used for a maximum of 12 continuous hours per day and re-used for up to a week. The main difference between the Tampsec™ and menstrual tampons is the material it is made of, which gives it enough flexibility to adapt to the vagina without discomfort. Before use, Tampsec™ should be briefly soaked in warm water (approximately 1 min), then it is inserted in the same way as a menstrual tampon. The removal method is also like a menstrual tampon. Despite the larger size, Tampsec™ flexibility facilitates both processes.

Fig. 1 Image of the Tampsec™ vaginal tampon

Outcome Measures

The primary outcome measure was a ≥50% reduction in pad weight from baseline to 6 weeks after starting the treatment. Two pad tests were performed in line with ICS

recommendations [14]. After filling the bladder with 300 mL of sterile saline, women were instructed to walk 250 m, climb one flight of stairs, and perform five repetitions of the following activities: coughing vigorously, standing up from sitting, and heel bounce. Women in the Tampsec™ group performed the second pad test with the tampon in place.

Secondary Outcome Measures:

- Women's perception of improvement with treatment was evaluated using the Patient Global Impression of Improvement (PGI-I) questionnaire [15]. Success was defined as a response of "very much better" or "much better."
- Decrease in the mean number of SUI episodes per day from 1 week before treatment to the last week of treatment, as measured by a 7-day bladder diary.
- Improvement in the impact of UI on everyday life from baseline to week 6 as measured by the Spanish version of the International Consultation on Incontinence Questionnaire Urinary Incontinence-Short Form (ICIQ-UI SF) [16]. We used the item: "Overall, how much does leaking urine interfere with your everyday life?" with 11 possible answers from 0 (not at all) to 10 (a great deal).
- Vaginal tampon tolerance. Women who were able to complete the 6-week treatment with the vaginal tampon without any incidents such as distress, discharge, bleeding, discomfort, or local irritation were considered tolerant.
- Tampon usability. Women were asked whether they considered the Tampsec™ tampon to be easy to use, practical, and comfortable, and whether they had any difficulties with its insertion or removal using specific questions with two possible answers (yes/no).

Statistical Analysis

The sample size calculation was based on the results of Lovatsis et al. [7]. It was hypothesized that a ≥ 50% reduction in pad weight would be achieved by 66% of the tampon group and only 22% of the controls. With this prediction, using a chi-square test, a two-tailed alpha of 0.05, and a power of 0.8, the required sample size was estimated to be 19 patients per group. Assuming a loss of 10%, the final sample size was 46 women.

The primary analysis was by intent-to-treat (ITT) and included all patients randomized. Secondary per protocol (PP) analysis was performed including only participants who completed the 6-week treatment period. Missing values were imputed using baseline observations carried forward. Between-group differences were analyzed using chi-square or Fisher's exact tests for categorical variables, and Student's *t*-test for continuous variables if they were normally distributed (and otherwise, the Mann–Whitney U test).

To assess the effect of the intervention on the primary outcome, the relative risk (RR) and number needed to treat (NNT) were calculated along with the corresponding 95% confidence intervals. A multiple logistic regression model was constructed to evaluate the effect of treatment on the primary outcome adjusted for BMI, as there were significant differences in baseline BMI between the groups. Differences were considered statistically significant at $p < 0.05$. For the statistical analysis, we use IBM SPSS, version 26.

Results

Between October 2019 and October 2022, 90 patients were assessed for eligibility at six hospitals. The second visit was canceled for 14 patients due to coronavirus disease 2019 restrictions, 10 women withdrew consent, and 20 did not meet the inclusion criteria. The remaining 46 patients were randomized at a 1:1 ratio to the tampon or control group. Four women did not attend the final visit: three in the control group and one in the tampon group. Two patients in the tampon group stopped using the tampons before the end of the study (Fig. 2).

The baseline characteristics of the groups are compared in Table 3. There were no significant differences, except in mean BMI, which was higher in the controls.

Regarding ITT analysis of the primary outcome, a ≥50% reduction in pad weight was achieved by 69.9% of patients in the tampon group and 26.1% of controls (RR 2.7; 95% CI 1.3–5.4) (Table 4). This result indicates that the probability of a favorable outcome was 2.7 times higher in the tampon group. The NNT calculation showed that two women would have to be treated for one to improve, with a 95% CI of 1–6. The binary logistic regression model adjusted for BMI continued to show significant differences in favor of the tampon group, women in this group having an odds ratio (OR) of achieving a ≥50% reduction in pad weight of 6.11 (95% CI 1.55–26.56), while there was no association between this level of improvement and BMI (OR 0.98; 95% CI 0.84–1.14). In the PP analysis, 80% of women in the tampon group and 30% of controls achieved a ≥50% reduction in pad weight.

The secondary outcomes are presented in Table 4. In the ITT analysis, 60.9% of women in the tampon group and 17.4% of controls ($p = 0.003$) reported their condition being "very much better" or "much better" and were considered to have successful outcomes. Results were also better in the tampon group in terms of reported decreases in the mean number of SUI episodes per day and perceived improvement in the impact of UI on everyday life.

Tampon use was tolerated by 86.9% of the women in the tampon group. Only three of the 23 patients in this group

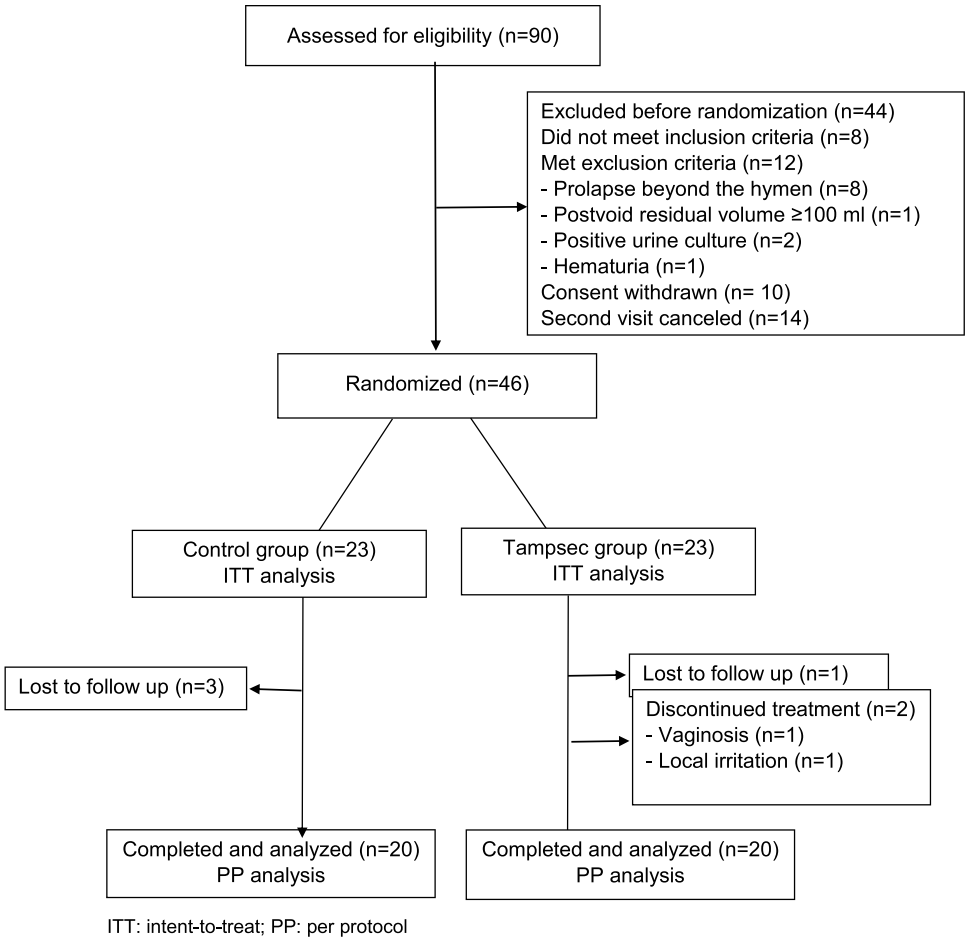

Fig. 2 Consort diagram of screening, randomization, and follow-up

Table 3 Patient characteristics and comparison between the groups

		Control group (n = 23)	Tampsec™ group (n = 23)	p value	Mean difference/OR
Age, years	mean ± SD	48.0 ± 8.0	46.7 ± 8.0	0.5	−1.3 (−6.1, 3.4) [a]
Body mass index, kg/m^2	mean ± SD	27.7 ±4.2	24.3 ±4.3	0.009	−1.3 (−5.9, −0.9)[a]
Pregnancies	mean ± SD	2.4 ± 1.0	2.3 ± 1.2	0.8	−0.1 (−0.8, 0.6)[a]
Vaginal deliveries	mean ± SD	1.9 ± 0.9	1.7 ± 0.8	0.3	−0.2 (−0.7, 0.3)[a]
Postmenopausal	n (%)	8 (34.8)	5 (21.7)	0.3	1.9 (0.5, 7.1) [b]
Smoker	n (%)	6 (26.1)	4 (17.4)	0.7	1.7 (0.4, 7.0)[b]
Pelvic floor muscle training	n (%)	12 (52.2)	14 (60.9)	0.5	0.7 (0.2, 2.3)[b]
Urinary incontinence severity				0.8	
Slight	n (%)	2 (8.7)	3 (13.0)		0.6 (0.09, 4.2)[b]
Moderate	n (%)	15 (65.2)	14 (60.9)		1.2 (0.4, 4.0)[b]
Severe	n (%)	6 (26.1)	6 (26.1)		1,0 (0.3, 3.7)[b]
Impact of UI on everyday life (ICQ-UI SF)	mean ± SD	7.0 ± 2.1	7.61 ± 1.1	0.3	0.6 (−0.4, 1.6)[a]
SUI episodes/day	mean ± SD	2.4 ± 1.9	3.0 ± 2.1	0.3	0.6 (−0.6, 1.8)[a]
UUI episodes/day	mean ± SD	0.5 ± 0.9	0.5 ± 1.4	0.8	0 (−0.7, 0.7)[a]
Pads/day	mean ± SD	1.4 ± 1.1	2.0 ±1.7	0.1	0.6 (−0.3, 1.5)[a]

ICQ-UI SF, International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form; *SUI*, stress urinary incontinence; *UUI* urgency urinary incontinence; *SD*, standard deviation

[a]Mean difference (95% CI). [b]Odds ratio (95% CI)

Table 4 Results of primary and secondary outcomes obtained from intent-to-treat and per-protocol analysis

		Intent-to-treat analysis			Per-protocol analysis		
		Control group (n = 23)	Tampsec™ group (n = 23)	p value	Control group (n = 20)	Tampsec™ group (n = 20)	p value
Reduction in pad weight ≥50%	n (%)	6 (26.1)	16 (69.9)	0.003	6 (30)	16 (80)	0.001
PGI-I: "much better" or "very much better"	n (%)	4 (17.4)	14 (60.9)	0.003	4 (20)	14 (70)	0.001
Decrease in mean number of SUI episodes/day	mean ± SD	0.5 ± 1.1	2.0 ± 2.2	0.007	0.6 ± 1.2	2.3 ± 2.2	0.005
Improvement in Impact of UI on everyday life (ICIQ-UI SF)	mean ± SD	0.7 ± 1.7	4.3 ± 3.0	0.000	0.8 ± 1.9	5.0 ± 2.7	0.000

PGI-I, Patient Global Impression of Improvement; *SUI*, stress urinary incontinence; *SD*, standard deviation

ICQ-UI SF, International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form

Table 5 Tampsec™ usability

		Tampsec™ group (n = 20)
Easy to use	n (%)	18 (90)
Practical	n (%)	17 (85)
No difficulty in insertion	n (%)	16 (80)
No difficulty in removal	n (%)	17 (85)
Comfortable	n (%)	17 (85)

did not complete the treatment. Of these, one patient did not attend the final visit and two discontinued the treatment for tampon incidents, one due to vaginosis and the other to local irritation. No serious adverse effects were reported, and no woman indicated that the tampon had fallen out of the vagina.

Table 5 summarizes participants' responses to the questions assessing various aspects of tampon usability. Most women found the tampon easy to use, practical, and comfortable and had no difficulty inserting or removing it.

Discussion

This randomized controlled trial demonstrates the efficacy of the Tampsec™ vaginal tampon for the treatment of SUI, using objective and subjective outcome measures. We have also shown good tolerance after 6 weeks of use. The likelihood of achieving a ≥50% reduction in pad weight was 2.7 times higher in the tampon group than in controls, and accordingly, it would be necessary to treat two women to achieve this extent of improvement in at least one case.

Women's perception of improvement after treatment was also significantly better in the tampon group. Success was achieved in 60.9% of the patients in the tampon group and only in 17.4% of controls. Most women in the tampon group (86.9%) used the tampons for 6 weeks without incident. These women showed a decrease of 2.0 in the mean number of episodes of SUI per day and an improvement in their UI-related quality of life.

A few randomized studies have evaluated the effect of pessaries and other intravaginal mechanical devices on SUI, generally indicating good outcomes. In many cases, however, their data are not comparable to ours because the outcome measures differ. Furthermore, several types of devices have been studied, and the results obtained for each device cannot generally be extrapolated to the others. Richter et al. [10] compared the effectiveness of a continence pessary to evidence-based behavioral therapy for SUI. They randomized 446 women with SUI symptoms into three groups: pessary, behavioral therapy, or combined treatment. In the pessary group, 39 of 149 (26%) dropped out of the study. The ITT analysis revealed that 40% of the pessary group reported that they were "much better" or "very much better" at 3 months. No objective outcome measures were included in this randomized study. The efficacy of the Uresta pessary was evaluated in a short-term randomized control trial including 36 women with urodynamic SUI. Following pessary placement, 66.7% of the patients in the treatment group achieved a ≥50% reduction in pad weight [7]. These results are similar to our ITT analysis; however, that study gathered no data on subjective outcomes or long-term efficacy. The 75NC007 is another intravaginal device designed for UI treatment. Its efficacy, tolerance, and acceptability were evaluated in a randomized controlled trial that included 68 patients with a positive urinary stress test and more than 8 incontinence episodes in a 2-week voiding diary [6]. The frequency of incontinence episodes fell by a mean of 31% in the vaginal device group after 2 weeks of treatment. The results with the 75NC007 device may be limited because 12 out of 29 patients (41%) in the treatment group dropped out.

Some other devices have also been evaluated in prospective studies without control groups. The results have been

promising in terms of efficacy and tolerability, but the evidence they provide is more limited [17–21].

Several factors influence SUI treatment decisions. First, we should consider a woman's desire to accept treatment, especially if it involves her active participation, as is the case with PFM training. Surgery has shown good results, although it is not usually the first recommended treatment option [22, 23]. Some women experience urine leakage associated with specific types of physical activity, and for them, surgery would be excessive. Other women, despite having severe SUI, do not wish to undergo surgery. Intravaginal devices may be a less invasive option for these groups.

Current recommendations on the use of intravaginal devices for SUI treatment differ between countries. The Canadian Urological Association guidelines recommend considering pessaries in the initial management of SUI. However, their recommendation is weak because of the moderate quality of the evidence [22]. Other guidelines, such as those of the National Institute for Health and Care Excellence (NICE), do not recommend intravaginal devices for the routine management of UI in women [23]. With this study, we provide more evidence in favor of the recommendation of using intravaginal devices for the treatment of SUI.

This study has some limitations that should be considered when interpreting the results. First, long-term efficacy and tolerance require confirmation since the treatment period studied was just 6 weeks. Another limitation was that the diagnosis of SUI was based on the sign and a urodynamic study was not performed to confirm it. It would also have been interesting to evaluate more objectively PFMT before inclusion, to assess whether there were differences between the groups. We have not recorded the duration of time women used the tampon each day, so the evaluation of the secondary outcome measures based on adherence was not possible. Further, the lack of blinding could have led to overestimation of the effect, especially in subjective measures such as satisfaction and impact on daily life. Nonetheless, the good results observed with the objective measures are consistent with the positive subjective assessments. Finally, although the ICS recommends a standardized 1-hour pad test, we followed a modified protocol. In particular, artificial bladder filling was used to improve the quantitative value of the test, and the activity program was adjusted to suit all patients. Nonetheless, both modifications were contemplated in their report.

Conclusions

The Tampsec™ vaginal tampon is efficacious for the management of SUI in women. We have also shown good tolerance after 6 weeks of use. This treatment decreases the number of SUI episodes per day and improves UI-related quality of life. Likewise, this tampon is easy to use, with most women reporting no difficulties with insertion or removal, comfortable, and practical.

Author Contributions I Diez-Itza: Project development, Data Collection, Data analysis, Manuscript writing.
J Cassadó: Project development, Data Collection.
A Martin: Project development, Data Collection.
E Muñoz: Project development, Data Collection.
E Lopez-Herrero: Project development, Data Collection.
C Bauset: Project development, Data Collection.
M Mancisidor: Project development, Coordinator of the randomization process.
C Sarasqueta: Project development, Data Collection, Data analysis, Manuscript writing.

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Declarations

Ethics Approval The protocol was approved by the Comité de Ética de la Investigación con medicamentos de Euskadi (04/2019) and institutional ethics committees at each site.

Conflict of Interest None.

Tapsec™ Tampon Additional Information The Tampsec™ tampons are marketed in Europe and have been approved by CE TUV Rheinland. These tampons are available over the counter.

Manufacturer: MED.SEE-SYSTEM GMBH
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Distribution company: ESPECIALIDADES MÉDICAS TONAL SL
Address: C/ MAESTRAT 41-43 1º 08225 TERRASA. SPAIN

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