The Ontario Uterine Fibroid Embolization Trial. Part 1. Baseline patient characteristics, fibroid burden, and impact on life

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Objective: To determine baseline characteristics of women undergoing uterine artery embolization (UAE) for symptomatic fibroids.

Design: Multicenter, prospective, single-arm clinical treatment trial.

Setting: Eight Ontario university and community hospitals.

Patient(s): Five hundred fifty-five women undergoing UAE for fibroids.

Intervention(s): Baseline questionnaires completed before UAE.

Main Outcome Measure(s): Questionnaires were analyzed for demographic, medical, and gynecologic histories. Fibroid symptoms, impact of symptoms, previous consultations, and treatments were also analyzed.

Result(s): The Ontario cohort (66% white, 23% black, 11% other races) had an average age of 43. Thirty-one percent were under age 40. Most women were university educated (68%) and working outside the home (85%). Women reported heavy menstrual bleeding (80%), urinary urgency/frequency (73%), pain during intercourse (41%), and work absences (40%). They experienced fibroid-related symptoms for an average of 5 years and consulted with on average of three gynecologists before UAE. High fibroid life-impact scores were reported by 58%. Black women were significantly younger (40.7 vs. 44.0 years), more likely to experience symptoms longer (7 vs. 5 years), and more likely to undergo myomectomy before UAE (24% vs. 9%) than white women.

Conclusion(s): Our study illustrates that large numbers of women with highly symptomatic fibroid disease are averse to surgery despite their burden of suffering and are actively seeking alternatives to hysterectomy. (Fertil Steril[®] 2003;79:112–9. ©2003 by American Society for Reproductive Medicine.)

Key Words: Uterine artery embolization, leiomyoma, uterine fibroids, burden of disease, menorrhagia, clinical study

Uterine fibroids occur in 20%–50% of adult females, and when they are large enough they may produce disabling pelvic pain, menorrhagia, and urinary frequency (1, 2). These symptoms can have a tremendous impact on women's health and well-being. To date, most therapy for fibroids has been surgical, either myomectomy or hysterectomy. Of the over 50,000 hysterectomies performed annually in Canada and the over 600,000 hysterectomies performed annually in the United States, approximately 30% are performed for fibroids (3, 4). Surgical interventions require general anesthesia, lengthy hospital stays, and long recovery periods, presenting hardships for women working at home and in the workforce (5, 6). Furthermore, hysterectomy does not allow women to preserve their fertility.

In general, women would prefer to have a benign uterine disease such as fibroids treated as conservatively as possible. Uterine artery embolization (UAE) is a promising nonsurgical, minimally invasive therapy being offered to women for treatment of their fibroids. There have been a number of published clinical series involving the use of UAE therapy for fibroids

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0015-0282/03/\$30.00 PII S0015-0282(02)04539-9 (7–15). Most centers report significant decreases in fibroid size and improvements in symptoms after embolization therapy. The trials, however, have generally involved small series of patients. At the start of this study, there were no prospective reports describing the characteristics of large numbers of women undergoing embolization therapy or the burden of their fibroid disease.

The Ontario Uterine Fibroid Embolization (UFE) Trial is a prospective multicenter clinical study with objectives involving safety, technical success, efficacy, and durability of embolization therapy. The purpose of this report is to document the characteristics of women undergoing embolization therapy in the trial as well as their fibroid symptoms, burden, and impact on their lives. Fibroids occur much more commonly in black women (16-18), and as many as 75% of their hysterectomies have been reported to be for fibroids (19). Secondary objectives were therefore to determine if black women undergoing UAE differed from white women with respect to their demographics, fibroids, symptoms, and fibroid impacts. Although UAE was initially being evaluated as an alternative to hysterectomy, many women undergoing UAE were younger women interested in preserving fertility. Thus, another objective of this report was to determine if young women undergoing UAE differed from older women with respect to their fibroids, symptoms, and impacts on their lives. This report is based on the baseline questionnaires and ultrasound exams completed for the 555 women who underwent UAE at eight Ontario hospitals.

MATERIALS AND METHODS

Study Design and Participating Centers

The Ontario UFE Trial is a multicenter clinical trial involving the prospective follow-up of consecutive women undergoing embolization treatment for symptomatic uterine fibroids. Treatment was provided by 11 interventional radiologists practicing at eight Ontario hospitals. Institutional Review Board approval was obtained for the study at all institutes.

Patient Eligibility

Women were eligible for the study if they had symptomatic uterine fibroid(s) documented by pelvic ultrasound. Previous surgical or medical therapy for uterine fibroids were not prerequisites, but symptoms had to be severe enough to warrant consideration of hysterectomy. Eligibility was not restricted by age, fibroid size, or location. Although women desiring children were not excluded from the study, they were further informed of the uncertain effects of UAE on conception or carrying to full term. Patients were ineligible for the study if they had an active pelvic inflammatory disease, undiagnosed pelvic mass, endometrial carcinoma, pregnancy, or renal insufficiency.

Baseline Questionnaire

Before UAE, patients completed a six-page baseline questionnaire including information on demographics and medical and gynecologic history. Body mass index (wt kg/ ht² m) was grouped according to categories used by Statistics Canada in the National Population Health Survey (20): underweight (≤ 18.5); acceptable weight (18.6–24.9); overweight (25.0–29.9); obese (≥ 30.0).

The nature of fibroid symptoms, duration of symptoms, and previous fibroid treatment(s) were also determined. Symptom information included presence, extent, and impact and duration of pelvic pain, bleeding, and mass- or bulkrelated effects (such as urinary urgency/frequency). Specific questions about menstruation included average duration of menstruation and sanitary napkin use on heaviest menstrual day. Patient perception of excessive bleeding was determined by asking the patient whether she felt her menstrual bleeding was unusually heavy because of her fibroids. They were also asked if they were anemic or "low on blood" or used iron supplements or injections. Menorrhagia was defined as menstruation longer than 7 days or sanitary napkin use exceeding 12 for a 24-hour period. Postmenopausal status was defined as an absence of menstrual cycles for over a year.

Occurrence of pelvic pain was determined by asking women whether they ever had pain or pelvic cramping which they believed to be related to their fibroid. Questions on pelvic pain also included duration, timing, relief with medication, and interference in usual activities. Fibroid-related symptoms were grouped for statistical purposes according to symptom categories developed for hysterectomy professional practice guidelines (21). Symptom categories included group 1, pelvic pain only; group 2, pelvic pain with bleeding; group 3, bleeding only; group 4, bulk-related effects without pain or bleeding. Women were asked to rate the degree of overall impact or interference of fibroids on their lives using a 10-point visual numerical rating scale. A life-impact score of 1 represented little or minimal interference and 10 represented total or complete interference with their daily or usual activities.

Uterine and fibroid size was based on ultrasound measurements including maximum diameters in three planes (longitudinal [D1], anterior-posterior [D2], and transverse [D3]). Measurements were taken only of the dominant or largest fibroid. Uterine and fibroid volumes were calculated using the formula ($V = 0.5233 \times D1 \times D2 \times D3$) for an ellipsoid shape (22). The number (1–4, \geq 5) and location of fibroids were also recorded.

Analysis

Data forms were monitored for completeness and subsequently entered into a centralized database system. Overall trends in age and race (black vs. white) were examined. Differences between younger and older women were as-

TABLE 1

Patient demographics by race.

	All N (%)	Race		
		White N (%)	Black N (%)	Р
Education				
High school or less	171 (32)	113 (33)	42 (35)	
College/university	358 (68)	234 (67)	77 (65)	.59 ^a
Employment status				
Unemployed	64 (12)	39 (11)	17 (14)	
Employed	380 (72)	242 (70)	93 (76)	
Self-employed	81 (15)	60 (17)	12 (10)	
Retired	5 (1)	5 (1)	0 (0)	.11 ^a
Marital status				
Single	145 (27)	76 (22)	52 (42)	
Married/partner	303 (56)	220 (63)	46 (37)	
Divorced/separated	82 (15)	49 (14)	24 (20)	
Widowed	9 (2)	7 (2)	1 (1)	<.01 ^a
Family intentions				
No children	268 (50)	170 (49)	65 (53)	
Decided not to have	95 (18)	74 (21)	12 (10)	
Would like to have	127 (24)	69 (20)	42 (34)	
Unable to have	35 (7)	22 (6)	8 (7)	
Children	269 (50)	180 (51)	58 (47)	
Decided no more	196 (36)	138 (39)	33 (27)	
Would like more	37 (7)	19 (5)	15 (12)	
Unable to have more	30 (6)	21 (6)	6 (5)	.42ª
General health				
Excellent	89 (17)	59 (17)	21 (18)	
Very good	215 (40)	149 (42)	48 (40)	
Good	196 (37)	122 (35)	44 (37)	
Not very good	35 (7)	21 (6)	7 (6)	.88 ^b
Body mass index				
Underweight	6(1)	2(1)	2 (2)	
Acceptable weight	241 (47)	164 (49)	45 (39)	
Overweight	179 (35)	112 (33)	47 (41)	
Obese	87 (17)	59 (18)	20 (18)	.30 ^b
Menopausal status				
Premenopausal	431 (80)	271 (77)	103 (85)	
Perimenopausal	92 (17)	68 (19)	17 (14)	
Postmenopausal	14 (3)	13 (4)	1 (1)	.06 ^a

^a Pearson χ^2 .

^b Wilcoxon rank sum.

Pron. Women undergoing fibroid embolization. Fertil Steril 2003.

sessed comparing two age groups, those <40 years of age and those \geq 40 years of age. Mean differences between racial and age groups for uterine volume, fibroid volume, and length of time with symptoms were compared by the Student's *t*-test. The relationship of self-reported life-impact scores to symptom groups was determined by comparing differences in median life-impact scores. Differences in lifeimpact scores between two groups were tested by the Wilcoxon rank sum test and between more than two groups by the Kruskal-Wallis test. Differences in symptom grouping between racial groups and age groups were tested by Pearson's χ^2 test. P = .05 was considered statistically significant in two-sided tests. All analyses were performed with SPSS, version 10.1 (SPSS Inc., Chicago, IL).

RESULTS

Patient Characteristics

Baseline questionnaires were completed by 97% (539 of 555) of the participants (Table 1). The majority (66%) of women were white; 23% were black and 11% were of other races, mostly Asian. The women undergoing UAE were on average 43.0 years of age (SD = 6.04; range, 18-59 years). Thirty-one percent (167 of 539) were young women under

age 40. Black women were on average 3.3 years younger than white women (40.7 vs. 44.0 years; P < .01).

Most women (68%) were highly educated, either university graduates or postgraduates, and 79% of them had access to the Internet. Women undergoing UAE were mostly working outside the home (85%) and 15% were self-employed. Women were more likely to be married or with a regular partner (56%) than to be single, divorced, or separated (44%). Half (268 of 537) of women in this trial did not have any children. Fertility was still an issue for many; 31% (164 of 537) expressed a desire for children.

Only 17% of women described their general health, compared with other women of their age, as being excellent. Self-reported general health status varied by age group but not by race. Young women were more likely than older women (10% vs. 5%; P = .04) to self-report their health to be "not very good." Among women in the trial, 35% were overweight and 17% were obese. Nineteen percent (102 of 539) reported other major health problems such as hypertension, thyroid disease, asthma, diabetes, and arthritis. Five percent (28 of 539) also reported that they were considered at increased surgical risk because of a medical condition, such as anemia, high blood pressure, cardiomyopathy, or coagulopathy.

Most women were premenopausal (80%) (Table 1); 17% described themselves as perimenopausal and 3% as postmenopausal. Other gynecological problems were reported by 125 women (23%), and 101 of them had undergone previous treatment. Among their conditions were endometriosis, cervical dysplasia, and ovarian cysts.

Fibroid Uterine Characteristics

The majority of women (70%) had multiple fibroids (Table 2). Many of these fibroids were very large; pre-embolization average fibroid volume was 293 cm³ (95% confidence interval [CI], 259–327 cm³). Fibroid lengths were on average 8 cm (range 1–24 cm). Pre-embolization average uterine volume was 680 cm³ (95% CI, 626–734 cm³), and average uterine length was 14 cm (range, 5–30 cm). Black women were significantly (P<.01) more likely than white women to have multiple fibroids. Fibroid volume or uterine volume did not differ by race or age group (Tables 2 and 3).

Fibroid-Related Symptoms

Symptoms reported by the women tended to occur in combination (Table 2). Most (80%) women reported heavy menstrual bleeding, many of whom reported being anemic or taking iron supplements. Thirty-one percent (168 of 539) of the women reported lengthy, i.e., longer than 7 days, menstrual periods. Of the 405 women (75%) reporting pelvic pain, especially during menstruation, 195 (48%) of them reported that they had experienced the pain for over 2 years. Eighty-six of the women were not able to relieve their pain with medication.

Overall symptom groups differed by race (P = .02) and by age group (P < .01) (Tables 2 and 3). Black women were more likely (73% vs. 60%; P = .01) to report pain and bleeding than white women. The bleeding only symptom group was more common in older women (19% vs. 10%; P = .01).

Duration of Fibroid Symptoms

The mean duration of reported fibroid-related symptoms was 5 years; 42% reported longer than 5 years and 18% reported longer than 10 years (Table 2). Duration of symptoms varied by race, with black women reporting a significantly longer duration of symptoms than white women (7 vs. 5 years; P<.01).

During this period, women had extensive consultations with physicians, on average three gynecologists and as many as 10 physicians, about their uterine fibroids and treatment. Eighteen percent of the women had self-referred for UAE treatment. Forty percent of the women reported having undergone previous treatments for their fibroids. Included in self-help remedies were herbal treatment (8%), vitamin supplements (8%), and dietary changes (5%). They also reported undergoing traditional therapies such as hormonal therapies (12%), endometrial ablation (3%), dilation and curettage (10%), or myomectomy (14%). Prior myomectomy was found to vary significantly by race (Table 2). Black women were significantly more likely than white women (24% vs. 9%; P < .01) to undergo myomectomy before UAE.

Fibroid Symptom Impact on Life

For most women (88%), their fibroid size and/or location were bothersome. For women whose uterus was enlarged by fibroid(s), the appearance of being pregnant was embarrassing. Because of the large size and abdominal location of the fibroids, they often pressed on surrounding organs, causing increased urinary frequency or urgency (73%) and low back pain. For some women, they also caused pain during intercourse (41%) and limited their ability to exercise (45%). Many women (40%) also reported having to take time off work in the previous year for fibroid-related reasons-often several days a month, particularly around their menstruation. Excessive bleeding or menorrhagia interfered with their sleep, and many women reported being housebound or having to be close to a washroom during their menstruation. Almost all women reported that these symptoms had a heavy impact on their lives; over half (58%) reported life-impact scores of 7.0 or greater. Life-impact scores were strongly related to symptom group (P < .001; Fig. 1) and were highest for symptom groups of bleeding (median = 7.0) and bleeding with pain (median = 7.0).

DISCUSSION

The Ontario UFE Trial represents the largest reported patient group undergoing embolization therapy for fibroids

Fibroid uterine characteristics, symptoms, and impacts by race.

	All N (%)	Race		
		White N (%)	Black N (%)	P (t-test)
No. of fibroids				
1	150 (30)	110 (35)	13 (12)	
2–4	220 (44)	143 (45)	56 (50)	
≥ 5	125 (26)	62 (20)	43 (38)	<.01 ^a
Fibroid volume (cm ³)				
0-100	174 (35)	106 (32)	47 (41)	
101-200	114 (23)	69 (21)	32 (28)	
201-400	91 (18)	70 (21)	12 (11)	
≥401	121 (24)	83 (25)	23 (20)	
Mean (95% CI)	293 (259–327)	307 (264–349)	275 (200–350)	.46 ^b
Uterine volume (cm ³)		× ,		
0–250	106 (22)	71 (22)	24 (21)	
251-500	131 (27)	82 (26)	33 (29)	
501-1,000	149 (31)	101 (32)	28 (25)	
≥1,001	102 (21)	62 (20)	28 (25)	
Mean (95% CI)	680 (626–734)	656 (596–716)	765 (614–916)	.19 ^c
Symptom group				
Pelvic pain only	68 (13)	46 (13)	16 (13)	
Pain with bleeding	337 (63)	211 (60)	90 (73)	
Bleeding only	89 (17)	60 (17)	12 (10)	
Bulk/mass effects	45 (8)	35 (10)	5 (4)	.02 ^d
Symptom duration				
<1 year	20 (4)	14 (4)	2 (2)	
1–4 years	278 (54)	188 (56)	52 (43)	
5–9 years	122 (24)	83 (25)	29 (24)	
≥ 10 years	94 (18)	49 (15)	37 (31)	
Mean (95% CI)	5 (4.8–5.7)	5 (4.2–5.3)	7 (6.2–8.5)	<.01 ^c
Prior myomectomy	73 (14)	33 (9)	30 (24)	$< .01^{d}$
Fibroid impact score				
1–3	90 (17)	54 (16)	21 (18)	
4–6	135 (26)	91 (26)	30 (25)	
7–10	304 (58)	201 (58)	69 (58)	
Median score	7	7	7	.54 ^a

^a Equal variances assumed.

^b Equal variances not assumed.

^c Pearson χ^2 .

Pron. Women undergoing fibroid embolization. Fertil Steril 2003.

to date. Our study finds that, despite experiencing severe symptoms that have a heavy impact on their lives, women with uterine fibroids continued to seek alternatives to hysterectomy for their fibroids over extended periods of time. They had suffered with fibroid-related problems such as heavy menstrual bleeding and pain for many years, some for longer than 10 years. As a consequence, most women in our study also had large and multiple fibroids that often filled the entire uterus. Uterine gestational size, because of fibroids, was commonly estimated to be 4 months or greater. The women had multiple consultations with physicians, underwent extensive imaging follow-up, and had been repeatedly advised to have hysterectomy.

There may be several reasons for some women's reluctance to undergo hysterectomy. Many may have been largely delaying treatment decisions in the hopes of either a natural regression of their fibroids or the emergence of new nonsurgical treatment options like UAE. For some it may have been about treatment choice and being unwilling to undergo the risks of major surgery. As many women in the Ontario UAE Trial were young women under 40 years of age, fertility or at least uterine preservation was likely an important issue.

Women in this cohort were also highly educated: 68% of them had university or college education compared with approximately 38% of other Canadian women (23). Our findings are consistent with reports in the literature that suggest that women with less education are at greater risk of having a hysterectomy (24–26). In a study by Harlow and Barbieri (25), only one in five highly educated women com-

^d Wilcoxon rank sum.

TABLE 3

Fibroid uterine characteristics, symptoms, and impacts by patient age.

	Age group		D
	<40 N (%)	≥40 N (%)	P (t-test)
No. of fibroids			
1	56 (36)	92 (27)	
2–4	62 (40)	160 (47)	
≥ 5	38 (24)	87 (26)	.13ª
Fibroid volume (cm ³)			
0–100	54 (34)	120 (35)	
101-200	39 (24)	75 (22)	
201-400	26 (16)	65 (19)	
≥401	42 (26)	79 (23)	
Mean (95% CI)	325 (249-401)	278 (244-312)	.27 ^b
Uterine volume (cm ³)	. ,	× ,	
0-250	39 (26)	67 (20)	
251-500	39 (26)	92 (27)	
501-1,000	45 (30)	104 (31)	
≥1,001	29 (19)	73 (22)	
Mean (95% CI)	666 (559–772)	687 (624–749)	.73°
Symptom group	. ,		
Pelvic pain only	23 (14)	45 (12)	
Pain with bleeding	119 (71)	218 (59)	
Bleeding only	17 (10)	72 (19)	
Bulk/mass effects	8 (5)	37 (10)	<.01 ^a
Symptom duration			
<1 year	10 (6)	10 (3)	
1–4 years	88 (55)	190 (54)	
5–9 years	40 (25)	82 (23)	
≥ 10 years	23 (14)	71 (20)	
Mean (95% CI)	5 (4.0-5.3)	6 (5.0-6.1)	.04 ^b
Prior myomectomy	23 (14)	50 (13)	.92 ^a
Fibroid impact score	. ,		
1–3	26 (16)	64 (17)	
4–6	40 (25)	95 (26)	
7–10	97 (60)	207 (57)	
Median score	7	7	.20 ^d
2			

^a Pearson χ^2 .

^b Equal variances not assumed.

^c Equal variances assumed.

^d Wilcoxon rank sum.

Pron. Women undergoing fibroid embolization. Fertil Steril 2003.

pared with four out of five less educated women (high school or less) initially accepted hysterectomy as the treatment choice. However, not only were women in our study generally highly educated, most of them had access to the Internet. The use of additional sources of health information like the Internet may reflect the desire of these women to become more informed and participate more actively in decision making regarding their care. Their active participation is further evidenced by the high self-referral rate for UAE treatment.

We also noted that the Ontario cohort, in addition to experiencing long-term symptoms associated with their fibroids, was also relatively unhealthy. Unhealthy body weight categories were more common in this cohort than in other Ontario women: overweight (35% vs. 24%) and obese (17% vs. 11%) (20). The overall self-reported general health was also significantly lower compared with that of other Canadians: only 57% of UAE women reported their health to be "very good" or "excellent" compared with 67% of the Canadian population (27). The high rate of overweight and obese women undergoing UAE may also reflect referral patterns of gynecologists, who may be more likely to refer these patients because of potential increased risk of infection and postoperative complications. Heavy menstrual bleeding and pelvic pain were the most common symptoms reported by women undergoing UAE. Very few women reported only bulk-related affects. The high prevalence of bleeding is consistent with that reported in other clinical series involving UAE.

It has been reported that fibroids occur more commonly in black women and that they can occur earlier, are larger, and result in symptoms for a longer time before hysterectomy (28). We found similar results in our study. Black women undergoing UAE differed from white women in several respects. In general they were younger and had experienced symptoms longer. Black women were also more likely than white women to report pain and bleeding. They were also much more likely to have undergone surgery (myomectomy) for their symptoms. Although we did not find fibroid or uterine size to be larger in black women, they were more likely than white women to have multiple fibroids, suggesting a greater genetic predisposition for fibroids.

Younger women (both black and white) were also more likely to report pain and bleeding symptoms. Their reporting of more symptoms was consistent with their tendency to also report poorer general health than older women in the trial. Older women, in comparison, were more likely than younger women to report only bleeding symptoms. This is to some degree consistent with the general principle that menorrhagia itself increases with age (29).

At the time when this research was initiated, there was no disease-specific health-related quality-of-life assessment instrument for fibroids. Until recently, there were also no reports on the impact of fibroids and symptoms on the quality of life of women undergoing UFE. Spies et al. (30) recently developed a formal health-related quality-of-life questionnaire that included generic components from the Medical Outcomes Study (SF-36 scales) and additional questions on activity, sexual functioning, self-image, and health distress. The instrument, however, was developed on a small group of patients from one institution, and further testing on other patient groups has not been reported.

In our study, we developed a simple numerical rating scale to summarize the overall impact of fibroids and symptoms on women's lives. Most women in the Ontario cohort were highly symptomatic so the rating scale was not tested on a wider spectrum of less symptomatic women. Impact

FIGURE 1

Fibroid life-impact rating by symptom group.



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scores were not found to vary by race, patient age, or uterine size. They were, however, found to be strongly associated with symptoms, particularly heavy menstrual bleeding.

This result was consistent with quality-of-life scores reported for patients undergoing UFE in the study of Spies et al. (30), in which scores were higher for bleeding than for pain or bulk-related symptoms. Rowe et al. (31) have also shown that symptoms of bleeding and pain can have a significant functional impact on women and can even represent a greater health burden than other major chronic health conditions. In that study, women undergoing hysterectomy for benign uterine conditions and having symptoms of pain and/or bleeding scored significantly higher on SF-36 indices of emotional well-being than women with hypertension, diabetes, heart disease, chronic lung problems, and arthritis.

In conclusion, our study illustrates that women seeking minimally invasive treatment alternatives to hysterectomy have large fibroid uteri and experience long-term and severe symptoms of bleeding and pain. The women in the trial were highly educated, had access to the Internet, and had consulted with many physicians before UAE therapy. Black women in general were younger, experienced symptoms longer, were more likely to report pain and bleeding, and were more likely to have undergone myomectomy than white women. Almost all women rated these symptoms to have a heavy impact on their lives. Symptoms, particularly heavy menstrual bleeding, rather than fibroid or uterine size, were responsible for the high life-impact scores in this cohort. Our study illustrates that large numbers of women with highly symptomatic fibroid disease are averse to surgery despite their burden of suffering and are actively seeking alternatives to hysterectomy.

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