Preservation of renal function by percutaneous transluminal angioplasty in ischaemic renal disease

Dag Paulsen1, Nils-Einar Kløw2, Bård Rogstad1, Torbjørn Levestad3, Bjørn Lien4, Karleif Vatne2 and Per Fauchald1

1Department of Medicine, 2Department of Radiology, 3Institute of Transplantation Immunology and 4Department of Surgery, Rikshospitalet, Oslo, Norway

Abstract

Background. The purpose of this study was to evaluate the effects of percutaneous transluminal renal angioplasty (PTRA) on preservation of renal function in patients with bilateral renal artery stenoses or stenosis of the artery of one functioning kidney.

Methods. A total of 227 PTRAs of 223 stenoses in 135 patients were performed from 1982 to 1993 in a single centre and retrospectively reviewed. The number of PTRAs per patient was 1.7, range 1–6. Angiographical follow-up was performed in 77%, 120±82 days after the first PTRA and 273±345 days after the last PTRA. Follow-up of serum creatinine and blood pressure was performed in 85% after 414±558 days. Long-term follow-up was performed for dialysis, surgical revascularization, renal transplantation and death, mean follow-up 8.8 years, range 5.5–14.8.

Results. The immediate technical success was 90%, and another 5% were improved. The primary patency rate per patient was 43% and the secondary patency rate 64%. Improved renal function was achieved in 23% of the patients, stabilized in 56% and failed in 21%. Stabilized or improved function was higher when baseline serum creatinine was ≤250 μmol/l (85%) than >250 μmol/l (60%). Three of 99 (3%) patients with creatinine ≤250 μmol/l started dialysis during follow-up (41 days, 7.4 and 8 years), as did 13 of 36 (36%) patients with creatinine >250 μmol/l. Blood pressure and the number of antihypertensive drugs decreased in patients with creatinine ≤250 μmol/l, but was unchanged in those with creatinine >250 μmol/l. The 5-year survival rates were 84, 66 and 17% for patients with creatinine <125 μmol/l, 125–250 μmol/l and >250 μmol/l, respectively. Twelve patients (9%) experienced complications, including two deaths.

Conclusions. Our study shows that PTRA improved or preserved the renal function in most patients with normal to moderately impaired renal function. Close follow-up and possibly re-intervention are necessary to obtain satisfactory clinical and angiographical result.

Key words: atherosclerosis; hypertension; ischaemic renal disease; PTRA; renal artery stenosis

Introduction

Atherosclerotic renal artery stenosis is a frequent finding in patients with coronary artery disease (30%) and peripheral vascular disease (49%) [1,2]. Severe renal artery stenosis may lead to ischaemic renal injury. Antihypertensive treatment may result in reduced renal blood flow and thereby a further decline of the renal function. Patients at particular risk are those with bilateral stenoses or those with renal artery stenosis in a single functioning kidney, treated by angiotensin-converting enzyme inhibitors [3]. Patients with progressive renal artery obstruction have a higher risk of renal atrophy and deterioration of the renal function than patients with stable disease [4,5]. Following the natural course, it has been shown that in patients with significant renal artery stenosis there is high risk of occlusion [4,6–8]. In recognition of renal artery stenosis as a frequent cause of end-stage renal disease (ESRD) with the need for renal replacement therapy, it is important to diagnose and treat these patients properly. Percutaneous transluminal renal angioplasty (PTRA) is the preferred method of revascularization, but surgery is also an option [9–13]. From 1982 to 1993, we performed 595 PTRAs of 419 patients [14]. In this single centre retrospective study, we present the results of 135 of these patients (32%) treated for bilateral stenoses or stenosis of the artery of one functioning kidney. We assessed to what extent the procedure was able to prevent occlusion and thereby loss of function.
Follow-up angiography was performed using intra-arterial angiography. Complete angiographical follow-up was performed after 7% of the angioplasties. The angiography was done after 120±82 days, range 1 month to 2 years. Final follow-up angiography was performed after 273±345 days, range 1 month to 6.3 years.

Clinical evaluation, analysis and follow-up

The duration of hypertension, co-morbidity, serum creatinine, blood pressure and antihypertensive drugs were recorded before the PTRA and at follow-up. Clinical data before the PTRA were obtained in all patients. Twenty one patients did not have complete follow-up data for creatinine and blood pressure because of death (n=9), uraemia (n=6) and data missing (n=6), giving a follow-up of 85%. The presented data are from before the first PTRA and after the last PTRA, mean follow-up after 414±558 days, range 40 days to 8.7 years. The patient survival data were obtained from the Norwegian National Registry, giving 100% follow-up. Renal replacement therapy data was obtained from the Norwegian Renal Replacement Registry, giving information about all the patients. The mean follow-up period from the initial PTRA regarding renal replacement therapy and survival was 8.8 years, range 5.5–14.8 years.

The effects on renal function were evaluated by measuring the serum creatinine. Improved renal function was defined as a decrease in creatinine of ≥20% when baseline was >100 μmol/l, and a decrease of ≥20 μmol/l when baseline was ≤100 μmol/l. Deteriorated renal function was defined as an increase in creatinine of ≥20% when baseline was >100 μmol/l, and an increase of ≥20 μmol/l when baseline was ≤100 μmol/l. The other patients were defined as having a stabilized renal function.

The effects of PTRA on blood pressure were evaluated using diastolic blood pressure and the defined daily doses (DDD) of antihypertensive drugs (World Health Organization Collaborating Center for Drug Statistics Methodology, January 1994). Blood pressure was measured in mmHg, using a mercury sphygmomanometer with the patient seated. Arterial hypertension was considered to be cured when blood pressure was ≤140/90 mmHg without antihypertensive medication, as improved when the diastolic blood pressure was reduced by ≥10 mmHg and the DDD was unchanged or decreased, and as a deterioration when the diastolic blood pressure increased by ≥10 mmHg and the DDD was unchanged or increased. The other patients were defined to have unchanged blood pressure.

Statistical methods

Mean±1 SD were used to express the data. Statistical computations were carried out using Biomedical Datapack (BMDP). A 2×2 table analysis with Yates correction was used for the categorical data, and paired t-test were used for the continuous data. Kaplan-Meier curves were used to study the survival of the patients and of the kidneys. The logrank test was used to compare the probability.

Results

Angiographical success

The immediate technical success was 90%, and another 5% were improved. There were six failures at the initial
PTRA: two were complications, with acute occlusion and successful surgery in one and an interrupted procedure because of acute heart failure in the other. Four failures were failed attempts to open the artery: two had successful surgery, one was treated successfully at a second attempt and the fourth was left with bilateral ostial lesions. The primary patency rate was 43%, and the secondary patency rate was 64%.

Evaluating each stenosis, the immediate success was 93%, the primary patency rate 55% and the secondary patency rate 72%. There was a significantly lower secondary patency rate for angioplasty of vessels <5 mm (43%, \( P = 0.001 \)). There was a tendency for a lower secondary patency rate in patients with abdominal aortic aneurysm (67%) than when the aorta was angiographically normal (86%). There was no significant difference between ostial lesions (71%) and lesions in the main renal artery (77%).

Twenty stents were placed at 18 procedures into 17 patients: at the initial procedure (\( n = 5 \)), at the second procedure (\( n = 6 \)), at the third (\( n = 2 \)), at the fourth (\( n = 1 \)), at the fifth (\( n = 3 \)) and at the sixth (\( n = 1 \)). The immediate technical result showed that the diameter of the stenosis was reduced from 75% (50–95%) to 10% (0–33%). At follow-up in 11 patients, the stenosis was 17%, range 0–50%. One of these had significant restenosis, she was re-angioplastied successfully, but the stent stenosis recurred and further treatment was abandoned. Another three patients were treated with surgical revascularization, of the same side in two (10 and 12 months) and the contralateral side in one.

Effects on blood pressure

The effects on blood pressure were correlated with baseline serum creatinine (Table 2). The systolic and diastolic blood pressures decreased significantly and the DDD was reduced when creatinine was \( \leq 250 \) \( \mu \)mol/l. When creatinine was \( > 250 \) \( \mu \)mol/l, there were no overall effects on the blood pressure or on the number of antihypertensive drugs. All patients with systolic blood pressure \( > 210 \) mmHg (\( n = 15 \)) and all patients with diastolic blood pressure \( > 115 \) mmHg (\( n = 13 \)) improved. When the systolic blood pressure was \( > 210 \) mmHg, the systolic blood pressure decreased from \( 232 \pm 22 \) to \( 162 \pm 27 \) mmHg and the diastolic blood pressure decreased from \( 114 \pm 16 \) to \( 90 \pm 11 \) mmHg. In patients with either recent onset of hypertension (\( < 12 \) months) or recent aggravation of hypertension (\( n = 21 \)), the blood pressure decreased from \( 181 \pm 24/106 \pm 12 \) to \( 159 \pm 29/92 \pm 14 \) (\( P < 0.001 \)) and the DDD decreased from \( 2.9 \pm 1.3 \) to \( 2.0 \pm 1.8 \) (\( P < 0.01 \)).

Seven patients (6%) were cured, 44 (36%) were improved, 56 (41%) were unchanged and eight (6%) had higher blood pressure at control. Patients with a successful blood pressure outcome were younger (61.2 years vs. 65.2 years, \( P = 0.05 \)) and had a higher diastolic blood pressure (105 mmHg vs. 93.7 mmHg, \( P < 0.0001 \)).

Table 2. Effects of renal artery angioplasty on serum creatinine, blood pressure and antihypertensive medication related to serum creatinine at initial treatment (mean ± SD)

<table>
<thead>
<tr>
<th>Serum creatinine level, ( \mu )mol/l</th>
<th>Baseline</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>(&lt; 125 ) (( n = 35 ))</td>
<td>125 ± 250</td>
<td>125 ± 250</td>
</tr>
<tr>
<td>( 125 – 250 ) (( n = 35 ))</td>
<td>250 ± 250</td>
<td>250 ± 250</td>
</tr>
<tr>
<td>( &gt; 250 ) (( n = 24 ))</td>
<td>250 ± 250</td>
<td>250 ± 250</td>
</tr>
</tbody>
</table>

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Twenty stents were placed at 18 procedures into 17 patients: at the initial procedure (\( n = 5 \)), at the second procedure (\( n = 6 \)), at the third (\( n = 2 \)), at the fourth (\( n = 1 \)), at the fifth (\( n = 3 \)) and at the sixth (\( n = 1 \)). The immediate technical result showed that the diameter of the stenosis was reduced from 75% (50–95%) to 10% (0–33%). At follow-up in 11 patients, the stenosis was 17%, range 0–50%. One of these had significant restenosis, she was re-angioplastied successfully, but the stent stenosis recurred and further treatment was abandoned. Another three patients were treated with surgical revascularization, of the same side in two (10 and 12 months) and the contralateral side in one.

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**Effects on renal function**

Table 2 shows the effects on serum creatinine related to the baseline serum creatinine. There were no significant effects on creatinine in any of the groups. However, patients with either recent onset of hypertension (<12 months) or recent aggravation of hypertension (n = 21) had a significant reduction, from 155 to 125 µmol/l (P < 0.006). Excluding 15 patients with an increase in creatinine of >50%, the creatinine decreased from 175 ± 86 to 159 ± 79 µmol/l (P = 0.005).

Table 3 summarizes the results of renal outcome related to baseline serum creatinine. In total, 23% were improved, 56% were stabilized and 21% were worse. When creatinine was <125 µmol/l, 85% of the patients were improved or stabilized. Over the following 6 months, one patient died, two underwent renovascular surgery and no patients underwent dialysis. When creatinine was between 125 and 250 µmol/l, 85% were improved or stabilized and 15% were worse. One of the patients with stabilized function had a serious non-renal complication, spinal anterior syndrome. Over the following 6 months, four died, two underwent renovascular surgery and one underwent dialysis but later died. When creatinine was >250 µmol/l, 60% were improved or stabilized and 39% were worse. Two of these patients died from complications before the follow-up creatinine was measured. Ten patients died and five underwent dialysis within 6 months. One of the patients underwent dialysis but died later.

There were significantly more patients with improved or stabilized function when creatinine was ≤250 µmol/l than when it was >250 µmol/l (P < 0.01). Of these 26 patients with renal parenchymal disease none had improved renal function; 13 (50%) were stabilized and 13 (50%) had deteriorated. Patients with known atherosclerotic disease of more than two organs (n = 57) had a higher risk of deterioration of renal function than those with less extensive disease (n = 78), 34% vs 19% (NS). For patients with aortic aneurysm, the numbers were 40% vs 25% (NS). There was no difference in renal outcome between patients with one functional kidney and those with bilateral stenosis, and there was no difference between the age of those with improved or stabilized renal function and those with deterioration.

Looking into those patients, 32 patients that had a poor outcome from the PTRA: because of death (including two complications) at <6 months (n = 16), renal replacement therapy at <6 months (n = 9), increased serum creatinine >50% (n = 5), serious complication in one, and lung cancer in one. The mean baseline serum creatinine was higher in this group than in the other patients, 380 µmol/l vs 172 µmol/l (P < 0.001). More of these patients had cardiovascular disease, 81% vs 23% (P < 0.001), more had cerebrovascular disease, 41% vs 18% (P = 0.08), and more had renal parenchymal disease, 47% vs 11% (P < 0.001). Mean age, gender, blood pressure, and number of patients with aortic aneurysm, diabetes and claudication were not statistically significantly different between the two groups.

**Long-term renal survival**

Figure 1 shows the percentage of patients that did not have dialysis, renal artery surgery or kidney transplantation after renal angioplasty, related to the baseline serum creatinine. Two patients having dialysis at the time of PTRA were excluded. In total, 16 patients started haemodialysis after the PTRA, two were allo-transplanted, and 14 were treated with surgical revascularization (three with aorto-renal bypass and 11 with auto-transplantation). Two of these underwent successful emergency surgery after angioplasty failure. None of the patients with baseline serum creatinine <125 µmol/l underwent dialysis during follow-up, but

**Table 3. Short-term renal and patient outcome after being treated with renal angioplasty, related to serum creatinine at initial treatment**

<table>
<thead>
<tr>
<th>Serum creatinine (µmol/l)</th>
<th>n</th>
<th>Improved n (%)</th>
<th>Stabilized n (%)</th>
<th>Deteriorated n (%)</th>
<th>Dialysis &lt;6 months</th>
<th>Death &lt;6 months</th>
<th>Vascular surgery &lt;6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;125</td>
<td>38</td>
<td>1 (3)</td>
<td>28 (82)</td>
<td>5 (15)</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>125–250</td>
<td>61</td>
<td>19 (32)</td>
<td>32 (53)</td>
<td>9 (15)</td>
<td>1</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>&gt;250</td>
<td>36</td>
<td>9 (27)</td>
<td>11 (33)</td>
<td>13 (39)</td>
<td>6</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>135</td>
<td>29 (23)</td>
<td>71 (56)</td>
<td>27 (21)</td>
<td>7</td>
<td>15</td>
<td>4</td>
</tr>
</tbody>
</table>
eight (21%) patients were treated by surgery. Three (5%) patients with creatinine 125–250 μmol/l underwent dialysis 41 days, 7.4 and 8 years after PTRA, one was allo-transplanted after 4 years 6 months, and five (8%) underwent surgical revascularization. Thirteen (38%) of the patients with creatinine >250 μmol/l underwent dialysis after a mean of 1.4 years, range 7 days–8 years, one was allo-transplanted after 7 months, and none underwent surgical revascularization.

Complications

Twelve patients (9%) experienced one or more complications, giving a complication rate per procedure of 5%. The complications included two deaths. One patient developed renal failure resulting in cardiac death after 18 days from pericardial effusion. The other patient died from a myocardial infarction after 33 days during surgical repair of a pseudoaneurysm at the puncture site. One patient developed paraplegia (th 12 with permanent damage. Two main renal artery occlusions were both auto-transplanted successfully, one at the first PTRA and one at the fourth. Other complications were retroperitoneal haematoma in one (no operation), pulmonary oedema in one, pseudoaneurysm in three, stent removed surgically at the puncture site in one, and segmental renal infarction in one. One of the patients who underwent emergency autotransplantation was transfused for puncture site haematoma at a previous angioplasty. Another patient was operated on for an arterio-venous fistula at the puncture site after follow-up angiography between the third and the fourth angioplasty, the only known complication from the pre- and post-procedural angiographies.

Ten patients (7%) had deterioration of the renal function that possibly could be related to the procedure. Five patients started renal replacement therapy within 1 year following a serum creatinine increase after the PTRA, and another five patients experienced a >50% increase in serum creatinine within 3 months. One of these patients underwent an emergency operation with auto-transplantation because of renal artery occlusion. The renal function of the other nine patients deteriorated after technically successful procedures.

Patient survival

Eighty (59%) of the patients died during follow-up. The mean observation time from first PTRA to death was 2.8 years (range 6 days–13.1 years) and the mean age at death was 70.3 years (range 41.4–82.6 years). For all patients, the actuarial 1-and 5-year patient survival rates were 82 and 58%, respectively. Two patients died within 30 days, another five between 30 and 60 days, and one between 60 and 90 days. All these eight patients suffered from advanced atherosclerotic disease.

Figure 2 shows the survival related to baseline serum creatinine; zero is the time of the first PTRA. The 5-year survival rates were 84, 66 and 17% for creatinine <125 μmol/l, 125–250 μmol/l, and >250 μmol/l, respectively. When creatinine was >250 μmol/l, the 5-year survival rate was significantly lower than that of the two other groups (P<0.001). For all the patients, the 5-year survival rate was lower when coronary heart disease, 43% vs. 75% (P<0.001), cerebrovascular disease, 44% vs. 62% (NS) or aortic abdominal aneurysm, 33% vs. 61% (P=0.08) were present. The 5-year survival rate was 31% when renal parenchymal disease, 50% claudication and 50% diabetes mellitus were present. In patients with both creatinine >250 μmol/l and coronary heart disease (n=29), the 5-year survival rate was 7% (two out of 29 patients).

Discussion

The overall results of PTRA of 419 consecutive patients at our hospital from 1982 to 1993 recently have been published, comprising 595 PTRA procedures [14]. This study presents the results of renal artery angioplasty of a subgroup of patients with high risk of renal artery occlusion and development of end-stage renal failure. A large series of atherosclerotic patients having undergone PTRA to prevent the need for renal replacement therapy has not been published to date. Consequently, this indication for PTRA so far has not been well supported by evidence-based data. The number of patients starting dialysis due to ESRD from ischaemic nephropathy has increased over the last few years. It has been estimated that ischaemic nephropathy is the cause of renal replacement therapy in 21% of patients aged over 65 years [17]. A recent study has shown an 11% risk of occlusion after 2 years when the renal artery stenoses were ≥60% [7]. Other studies are in agreement with this report [4,6–8]. PTRA may be performed prophylactically to prevent reduced renal function or prevent further deterioration of renal function, i.e. in patients with bilateral stenoses, or unilateral stenosis in patients with one functioning kidney. No prospective randomized study has been performed to compare revascularization of renal artery stenoses and
observation without intervention. Such a study is probably impossible to conduct. However, one retrospective study has indicated that mortality was higher in patients who were left untreated than in patients in whom revascularization had been performed [18].

Angiographical results

The immediate angiographical result after angioplasty of atherosclerotic renal artery stenoses, i.e. 90% successful treatment and 5% improvement, is quite satisfactory. In a recent review [13] of 19 studies with 1032 patients, range 8–165 patients, with atherosclerotic disease, technical success was 80%, range 46–100%. Our results showed low primary and secondary patency rates, 43 and 64%, respectively. The patency rates for the individual stenoses were higher, but low numbers were seen overall, since many patients had angioplasty of more than one artery. Therefore, the number of patients that obtained some benefit from the angioplasty was probably higher than the patency rates may indicate.

The main disadvantage of angioplasty of renal artery stenoses is the high restenosis rate. We have shown that re-angioplasty will result in an improved secondary patency rate. It is possible that restenosis can be reduced with placement of stents [19–21], but data so far are not consistent [13]. Surgical repair is known to be effective and should always be considered [12,22–24]. Although the complication rate is higher and the complications are more serious than with angioplasty, these risks have to be weighed against the need to undergo multiple angioplasty procedures.

From our data and from past publications, follow-up examination to detect recurrent stenosis is mandatory. Whether the follow-up should be intra-arterial angiography or a non-invasive test is moot. We have performed intra-arterial angiography for follow-up, but it is possible that non-invasive tests such as Doppler sonography [25–27], magnetic resonance angiography [28–30] or volumetric spiral computerized tomography [31,32] can replace the angiography in this situation. Although these methods are inferior to the intra-arterial angiography to the detection of renal artery stenoses, they are reliable for the detection of proximal stenoses and can, therefore, be used in most patients.

Renal function

Patients with long-standing hypertension and impaired renal function due to chronic ischaemic disease may already have irreversible nephron loss so that improvement after angioplasty cannot be expected. Few studies have actually shown improved renal function after revascularization. At best, angioplasty can prevent further deterioration. Stabilization or improvement of renal function in 76% is a favourable result compared with those of previous studies in small cohorts [21,33–36]. We found that patients who did better were characterized by normal or slightly impaired renal function, and by recent onset or recent (<12 months) aggravation of hypertension. That fewer patients with baseline serum creatinine > 250 μmol/l improved or stabilized their renal function may be explained by irreversible nephron loss. When treating this group of patients, one has to take into consideration that in some patients renal function may even deteriorate after the procedure. The same consideration applies to patients with extensive atherosclerotic disease or renal parenchymal disease.

During follow-up none of the 38 patients with normal serum creatinine and only three of 61 with creatinine 125–250 μmol/l required haemodialysis. The question is whether PTRA prevented deterioration of renal function. Data on the natural course of renal artery stenosis are scarce. One prospective study found an 11% risk of occlusion over 2 years when renal artery stenosis ≥ 60% was present, as evaluated by duplex ultrasonography [7]. Extrapolating this information to our patients, one would have expected renal failure in many of them. The small number of patients requiring dialysis or transplantation, at least when creatinine was normal or moderately elevated at the time of the procedure, is compatible with the notion that long-term preservation of renal function has been achieved. Obviously, we preserved renal function even in a certain proportion of patients with creatinine > 250 μmol/l, but overall in this group, survival was low, complications were frequent, and a large number of patients ultimately required dialysis. The two patients on haemodialysis before PTRA did not regain renal function. This observation supports the view that such patients are difficult to treat successfully with PTRA, despite some positive case reports [37,38].

Complications

The number of complications was higher than usually seen with angioplasty, but is comparable with that found in recent reports on PTRA in atherosclerotic patients [33,39,40]. The risk is particularly high in patients with advanced atherosclerosis and uraemia [41]. Although the two deaths which did occur did not happen immediately after the angioplasty, they were both clearly related to the procedure. Both patients had extensive atherosclerotic disease and severely reduced renal function. The patient that experienced paresis had severe changes of the abdominal aorta. When stents were first used, anticoagulation was more extensive in this initial period than at the present time. Some of the puncture site and bleeding complications were undoubtedly related to the more intensive anticoagulation regime. We are now giving the patients antiplatelet drugs after stent placement.

Many patients experienced deterioration of renal function after a technically successful procedure. It is difficult to decide if this was related to the procedure per se, or reflected progression as part of the natural history of this condition. It is also known that cholesterol emboli released during the balloon dilatation may reduce renal function. Furthermore, one has also to consider that the contrast medium used may induce
renal failure, particularly in patients with reduced renal function and diabetes. The risk is related to the volume that is given [42,43]. There may be a role for CO₂ contrast angiography in the future.

Survival
The 30 day mortality of 1.5% in our patients is comparable with other observations [34], and lower than the 29% mortality after 33 days reported in a selected group of patients with uraemia and extensive atherosclerosis [37], or the 30 day mortality of 5.6–15.5% in high risk patients treated by surgical renal vascular reconstruction [11,44–46]. Long-term patient survival in our series was dependent on the degree of atherosclerotic disease and the renal function at the time of PTRA. Our data do not permit any conclusions to be drawn about the effects of PTRA on survival [47]. One may argue that a preventive interventional procedure may not have been justified in some of our poor risk patients. Nevertheless, PTRA probably prevented dialysis dependence at least in some patients, albeit only for a short period of time before death.

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