WHICH ARE THE INSULIN TREATMENT REGIMENS USED IN FRANCE?

The “Schema Survey”

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SUMMARY - Objective: To examine how insulin therapy is used in France under real life conditions for type 1 and insulin-treated type 2 patients.

Material and methods: The “Schema survey” was a cross-sectional survey carried out for all the insulin-treated patients seen by participating physicians on a given day. All registered diabetologists in France were invited to participate, 934 initially agreed, 450 returned at least one questionnaire. These 450 physicians appeared to be representative of the whole. The reasons for which 484 physicians who had initially agreed to participate did not were collected by telephone and do not seem to introduce a bias. 1,263 patients were included in the analysis, type 1: 57.6%, type 2: 36.8%.

Results: Over 54% of type 1 patients were treated with 3 or more insulin injections per day. Among type 1 patients treated with 2 injections per day, 30% were younger than 18. Over 82% type 2 patients were treated with 1 or 2 insulin injections per day. A regimen combining oral agents and bed time NPH was used in 18% of type 2 patients. Premixed insulins were used by 45.5% of type 2 and 39.5% of type 1 patients. For patients under 3 or more injections per day, over 30 different regimens were identified. About 40% of patients, either type 1 or 2, were poorly controlled (HbA1c > 8.5%). The frequency of blood glucose monitoring appears to comply with recommendations.

Conclusions: Under real life conditions, a majority of French type 1 patients are treated with intensified multiple injections but a lot are not, despite inadequate metabolic control. Only few type 2 patients are treated with intensified therapy.

Key-words: insulinotherapy, treatment, type 1 diabetes, type 2 diabetes mellitus.

RÉSUMÉ - Quels sont les schémas d’insulinothérapie utilisés en France : « l’enquête Schéma ». 

Objectif : Décrire les schémas d’insulinothérapie utilisés en France.

Matériel et méthodes : « l’enquête Schéma » a consisté à remplir un questionnaire anonyme pour les tous les diabétiques insulinotraités vus en consultation un jour donné : tous les diabétologues français ont été contactés, 934 ont accepté de participer au sondage, 450 ont répondu avec au moins un questionnaire. Ces 450 spécialistes sont représentatifs de l’ensemble. Les raisons pour lesquelles 484 médecins n’ont pas répondu ont été reconstituées par téléphone et n’affectent pas la représentativité de l’étude. 1 263 patients ont été inclus, dont 57,6 % de type 1 et 38,8 % de type 2.

Résultats : Plus de 54 % des diabétiques de type 1 étaient traités par des schémas à 3 injections d’insuline ou plus par jour. Plus de 82 % des type 2 étaient traités par des schémas à 1 ou 2 injections par jour. Un traitement combiné hypoglycémiants oraux et insuline NPH au coucher était utilisé chez 18 % des type 2. Les insulines prémélangées étaient utilisées par 45,5 % des type 2 et 39,5 % des type 1. Pour les patients sous 3 injections ou plus, plus de 30 schémas différents ont été identifiés. Environ 40 % des patients, qu’ils soient de type 1 ou type 2, étaient mal contrôlés (HbA1c > 8,5 %). La pratique de l’autosurveillance glycémique était correcte.

Conclusions : Une majorité des diabétiques de type 1 français mais une minorité des type 2 est traitée par une insulinothérapie intensifiée. Nombre des diabétiques insulinotraités sont mal contrôlés sous traitement non optimisé.

Mots-clés : insulinothérapie, traitement, diabète de type 1, diabète de type 2.
he good clinical practice guidelines for optimal management of type 1 and type 2 diabetic patients are periodically updated in France [1, 2] as well as in United States [3, 4] or other countries.

According to the French recommendations [2], type 1 diabetic patients should receive intensive insulin therapy by multiple injections or with an insulin pump. In type 2 insulin-treated diabetic patients, intensive insulin therapy with multiple injections should be attempted, at least for a few months, when adequate metabolic control is not achieved with one or two insulin injections daily.

However, there is no data on how French physicians and their patients actually apply these good clinical practice guidelines in daily practice. This survey was conducted among French diabetes specialists to determine how insulin therapy is used under real life conditions for type 1 and 2 diabetic patients.

**METHODS**

The “Schema survey” was a nationwide “one-day snap-shot” cross-sectional survey carried out among all the insulin treated patients seen by participating physicians on a given day. Between September 1 and October 16, 1998, all registered diabetologists-endocrinologists in France, a total of 1,300 physicians, were invited to participate in the survey, 934 initially agreed to participate.

The physicians were to fill out an anonymous questionnaire (the physician questionnaire) for every patient seen in their office on the chosen day (November 24, 25 or 26, 1998) and meeting the following inclusion criteria: type 1 or type 2 diabetic patients, treated with insulin, and agreeing to fill out a patient-questionnaire. At the end of the visit, the physician gave the patient an anonymous self-administered questionnaire (the patient questionnaire) that he or she was to fill out and return to statistical analysis center. In order to ensure optimal representativeness of the patient sample, the physicians were asked to include all patients they had seen on the day of the survey and who met the inclusion criteria.

The anonymous physician questionnaire collected information about the physician’s profile, the patient’s main relevant clinical characteristics, and a detailed description of the insulin regimen. Each question was answered by an open statement, made on the basis of the patient’s medical records. Complications were considered either present or absent. By convention, the injection devices were categorized as “syringes” if the patient used only syringes to the exclusion of any other device. The type of insulin was classified as insulin lente for patients who used long-acting insulin such as zinc crystallized.

The patient questionnaire collected data on diet, perception of the advantages and drawbacks of insulin regimens and home blood glucose monitoring. A total of 1,373 physician and/or patient questionnaires were returned. The physician and patient questionnaires both bore the same number, to allow for a consistency check between responses. Of the 1,373 subjects on whom data were collected, 1,263 patients were included in the analysis (87%). Among the 110 subjects excluded from the analysis, 5 were not on insulin therapy (violation of the primary inclusion criterion), 10 had major data inconsistencies between the physician and the patient questionnaires, and 95 had a missing physician questionnaire. Lastly, the sample size may differ for each question, because of missing data.

**Assays**

HbA1c was measured by the physician’s reference laboratory using the laboratory’s customary method. Laboratory assays were not centralized. Ninety-two percent of the clinical laboratories had an upper limit of normal below 7%.

**Statistical analysis**

The population (physicians and patients) and the therapy regimens were described using the following statistics:

- for quantitative data: mean, median, standard deviation;
- for quantitative or qualitative data grouped in classes: incidence, percentage.

Data were stratified by type of diabetes and daily number of insulin injections. Results were compared using Student’s test and the chi-square test.

**RESULTS**

**Physicians**

Of the 934 physicians who initially agreed to participate in this survey, 450 (42.8%) returned at least one questionnaire. The main characteristics of these 450 physicians are provided in Table I, comparatively with the characteristics of all diabetes specialists in France drawn from a national register. Each physician returned a mean of 2.9 ± 2 questionnaires. Eighty-nine percent of the physicians were qualified endocrinologists and 11% were qualified Internists. With the exception of minor differences in geographic distribution, these 450 physicians were representative of French diabetes specialists as a whole. In order to identify the reasons for nonparticipation in this anonymous trial, all 934 physicians who initially agreed to participate in the study were contacted by telephone in
January 1999, 763 (81.7%) were reached, and 129 could not be reached. Physicians who had initially agreed to participate gave the following reasons for failing to return any questionnaire on the appointed day:

- no patient seen on the day of the survey met the inclusion criteria (29%);
- the physician was absent on the day of the survey (27.2%);
- omission on the part of the physician (17.2%);
- medical questionnaires lost (4.1%);
- other (19.7%).

Patients

- The characteristics of the 1,263 patients included in the analysis were the following:
  - The majority of the patients were type 1 diabetics: n = 727, 57.6%. There were 465 type 2 diabetics (36.8%) and 71 not classified patients (5.6%).
  - The mean age was 37.3 ± 19.8 years for type 1 and 63.9 ± 11.3 years for type 2.
  - Mean time between diagnosis and beginning of insulin treatment was 1.3 ± 4.2 years for type 1 and 11.2 ± 8.2 years for type 2.
  - Sixty percent of the patients were followed in hospital out-patients clinics and 40% by a private physician.

- Two thirds of the type 2 diabetics and 36% of type 1 diabetics had at least one complication of diabetes mellitus.

Metabolic control assessed by measuring HbA1c is shown on Table II. On the day of the survey, an HbA1c value dating back less than three months was available for 82.2% of type 1 diabetics and for 76.6% of type 2 diabetics. HbA1c values did not differ between type 1 and 2. Approximately one third of the patients showed adequate metabolic control (HbA1c < 7.5%) and 40% were poorly controlled (HbA1c > 8.5%).

Insulin therapy regimens

Table III shows insulin therapy regimens defined by the number of insulin injections per day. The following figures are of particular interest:

- over 54% of type 1 diabetic patients were treated with three or more insulin injections per day,
- bearing in mind that 30% of type 1 diabetics who were treated with two injections per day are younger than 18,
- Most type 2 diabetics (82.6%) were treated with one or two insulin injections per day.

Table IV shows HbA1c values according to insulin therapy regimen. There was no correlation between HbA1c values and the number of insulin injections per day, for either type of diabetes.

Table V-1 shows the main characteristics of insulin therapy in patients treated with a single insulin injection per day. Nearly all these patients were type 2
diabetics, and 60% were on a combination regimen of oral hypoglycemic agents and an intermediate insulin injection at bedtime. The bedtime insulin was NPH insulin in 74% of the cases, given alone or with premixed short-acting insulin. Thirty-eight percent of these patients were adequately controlled (HbA1c < 7.5%) with this treatment.

Table V-2 shows the main characteristics of insulin therapy in patients treated with two daily insulin injections. NPH insulin was used by most patients. It was used in a premixed combination with short-acting insulin in more than 50% of cases in separate injections. 30% of type 1 diabetics were taking NPH along with additional injections of short-acting insulin. 30% of type 2 diabetics were using this type of insulin regimen in combination with oral agents.

Table V-3 shows the main characteristics of insulin therapy in patients treated with three or more injections per day. Patients on intensive conventional insulin therapy were younger than patients treated with 1 or 2 injections per day: type 1: 35 ± 17 years vs 39 ± 23 years, p = 0.004; type 2: 59 ± 12 years vs 65 ± 11 years, p < 0.001. These patients on intensive conventional insulin therapy had also been on insulin therapy for a longer time than those treated with one and/or two injections per day: type 1: 12.5 ± 11 years vs 10.8 ± 10 years, type 2: 4.8 ± 4.8 years vs 3.16 ± 3.7 years, p = 0.001. NPH insulin (alone or in a premixed combination with short-acting insulin) was the basal insulin therapy combined with separate injections of short-acting insulin in over 90% of the optimized regimens.

### Table IV. HbA1c values according to the insulin therapy regimens. Main characteristics of the insulin regimens according to the number of injections per day.

<table>
<thead>
<tr>
<th>TYPE 1</th>
<th>n = 136</th>
<th>type 1 (n = 18)</th>
<th>type 2 (n = 118)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular or Lispro</td>
<td>3 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPH</td>
<td>62 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lente</td>
<td>23 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premix</td>
<td>12 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>units (mean)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>combined with oral drugs</td>
<td>16</td>
<td>70 %</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
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<th>n = 548</th>
<th>type 1 (n = 287)</th>
<th>type 2 (n = 261)</th>
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</thead>
<tbody>
<tr>
<td>Insulins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>regular or Lispro</td>
<td>29 %</td>
<td>3 %</td>
<td></td>
</tr>
<tr>
<td>NPH</td>
<td>48 %</td>
<td>47 %</td>
<td></td>
</tr>
<tr>
<td>lente</td>
<td>8 %</td>
<td>2 %</td>
<td></td>
</tr>
<tr>
<td>premix</td>
<td>53 %</td>
<td>57 %</td>
<td></td>
</tr>
<tr>
<td>units (mean)</td>
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</tr>
<tr>
<td>combined with oral drugs</td>
<td>38</td>
<td>40</td>
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</table>

<table>
<thead>
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<th>type 1 (n = 365)</th>
<th>type 2 (n = 80)</th>
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</thead>
<tbody>
<tr>
<td>Insulins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>regular or Lispro</td>
<td>97 %</td>
<td>96 %</td>
<td></td>
</tr>
<tr>
<td>NPH</td>
<td>49 %</td>
<td>49 %</td>
<td></td>
</tr>
<tr>
<td>lente</td>
<td>27 %</td>
<td>8 %</td>
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<tr>
<td>premix</td>
<td>29 %</td>
<td>51 %</td>
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<td>units (mean)</td>
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<tr>
<td>combined with oral drugs</td>
<td>49</td>
<td>59</td>
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used by type 2 diabetics, whereas insulin lente was used by 29% of type 1 diabetics. More than 30 different insulin therapy regimens with multiple injections have been identified. Six regimens were used by 70% of the patients: NPH in the morning and in the evening and three short-acting insulins (17%), one lente and three short-acting insulins (14%), two short-acting insulins and one premixed (short-acting and NPH) (12%), three short-acting insulins and one NPH at bedtime (11%), one premixed insulin in the morning and in the evening and one short-acting insulin at lunch (9%), one insulin lente in the morning and in the evening and three short-acting insulins (6%).

Among the young patients below the age of 18 (n = 154), 56.3% used two injections daily, 42.4% used three or more injections daily and 1.3%, used one injection daily.

Miscellaneous data

- Injection devices: 17% of the patients used only a syringe and 83% used a pen, 55% of type 1 patients used a reusable pen and 45% of type 2 patients used a disposable pen.
- Self-monitoring of glucose: 75% of type 1 diabetics and 50% of type 2 diabetics carried out three or more capillary blood glucose determinations per day. Less than 3% of the patients never carried out self-monitoring of blood glucose.
- Hypoglycemia (clinical and/or capillary episode < 0.50 g/L) occurred more often in case of intensive therapy: the mean number of hypoglycaemic episodes over the previous two weeks was 4.52 ± 5.18 in patients using three injections or more vs 3.25 ± 6.03 in type 1 diabetics using less than 3 injections; p = 0.004. The mean number was somewhat lower among type 2 diabetics: 1.39 ± 2.31 in those who required three or more injections vs 0.74 ± 1.97 in those who required less than three injections; p = 0.01.
- Dietary prescriptions: 85% of type 1 diabetics and 72% of type 2 had three main meals per day. 70% of type 1 diabetics and 55% of type 2 diabetics reported snacking once or more per day.
- The main drawbacks of insulin therapy reported by patients were as follows, in decreasing order: capillary blood glucose determination (47.5%), hypoglycemia (46.4%), dietary prescriptions (44.8%), insulin injections (39.4%).

**DISCUSSION**

The “Schema survey” is the first of its kind in France. Data on file at the National French Health Insurance shows that approximately 300 000 diabetics are treated with insulin in France, of whom about 50% are type 1 diabetics and 50%, type 2. However, no data are available on how insulin therapy is administered under real life conditions. The “Schema survey” was conducted only among physicians specialized in Diabetes. Most diabetics on insulin therapy in France consult a specialist at least occasionally, but the exact proportion of patients who consult only a general practitioner and the frequency of specialist consultations are unknown.

The 450 specialists who took part in this survey account for one third of all diabetes specialists practicing in France, and appear to be representative of this overall population (*Table 1*), at least in terms of the main parameters of sex ratio and type of practice. The geographic distribution of specialists who participated in the survey shows only minor differences compared to what is known for the whole. The reasons for which 484 physicians who had initially agreed to participate did not fill out any questionnaire on the day of the survey were collected by telephone and do not seem to introduce a bias in the results. The two most frequently reported reasons were the lack of appropriate patients and/or the physician’s absence that day.

The quality of the questionnaires was satisfactory, as 87% of the report forms were included in the analysis after checking for consistency between the responses given on the anonymous physician questionnaire and those on the anonymous patient questionnaire. This was a one-day cross-sectional national survey in which physicians were asked to fill out one questionnaire for every patient on insulin therapy they saw that day. A total of 1,263 patients seen that day could be analysed. This figure limits potential recruitment bias.

In this population, 60% of the diabetics on insulin therapy were being followed by a hospital physician, whereas 40% were being followed by a private physician. By way of comparison, over 90% of type 2 diabetics who are not on insulin therapy are followed in France by a private general practitioner according to data on file at The National French Insurance). Fifty percent of the physicians in the survey had a hospital practice and 27% were only in private practice. Therefore, the physicians who had both a hospital and a private practice tended to include the patients they saw in their private practice.

The characteristics of the patients included in the survey confirm the description of the general traits of that population, especially as regards age, duration of diabetes, presence or absence of complications. Most patients were type 1 diabetics, accounting for 57% of the cases. This may reflect the fact that these patients more often consult a specialist. A high proportion of type 2 diabetics had complications: 63% as compared with 36% of type 1 diabetics, for a similar mean disease duration of 14 years. This figure is higher than that given by the UKPDS [5] and shows that type 2 diabetics treated with insulin in France are for the most part severely affected. The excess complications seen in type 2 diabetics primarily affected the cardio-
vascular and renal systems, a logical finding given the age of these patients.

Most French specialists regularly request an assay of HbA1c, in compliance with good clinical practice guidelines [1-4], as evidenced by available HbA1c values, dating back less than three months, for 82% of type 1 diabetics and for 76% of type 2 diabetics.

HbA1c values were disappointing because adequate control was shown in only one third of the patients (HbA1c < 7.5%), without any difference between type 1 and type 2 diabetics.

The primary objective of this survey was to describe insulin therapy regimens as they are used by specialists in France. Pump therapy is currently used in France by around 3500 patients, representing 2% of type 1 diabetics [6]. Over 54% of type 1 but only 17% of type 2 diabetics in this survey were treated with an optimized intensive conventional regimen consisting in three or more injections per day. HbA1c values did not differ according to insulin therapy regimen, whatever the type of diabetes. This kind of survey provides a description of the practice of insulin therapy as actually done in real life situation, but neither the study design nor the study objectives aimed at demonstrating the superiority of one regimen over another. Indeed, it appears that 40% of type 1 and type 2 diabetics are poorly controlled (HbA1c > 8.5%) even though their insulin therapy regimen of one or two injections daily (including premixed insulins), has not been optimised to a multi injections regimen, as recommended by good clinical practice guidelines, either because the patient was not given this option or because he refused it.

Available data on the practice of insulin therapy in different countries are scarce. In 1998, the Hvidore Study Group on Childhood Diabetes published the data collected in 1995 from 2,873 children in 18 countries in Europe, North America and Japan [7]. Sixty per-cent of the children used two daily insulin injections while 37% used three or more, a figure similar to that found in our surgery among the 154 patients under 18 years of age. The Wisconsin Epidemiology Study [8] showed that between 1980 and 1990, there was an increasing trend towards the use of three or more injections per day. The figure for 1990 as a whole remained below that found in our "survey" which primarily included adult patients for whom there are very few, if any, published data.

Recent data essentially come from market data on insulin consumption. Insulin manufactures follow up the data about the consumption of insulin at the market and collect informations though random screening programs of representative panel of patients. Due to non specific nature of these so-called IMS data [6, 9], they are seldom share with health providers. The estimated number of patients on insulin therapy is highest in Germany (over one million patients treated), followed by Spain (600,000 patients), the UK (435,000 patients), Italy (410,000) and France (310,000).

Figure 1 represents the split of insulin formulations (short-acting, intermediate acting and premixed combination of short and intermediate acting insulin) used in various European countries. One can see that short acting insulin is used substantially more in Italy than elsewhere in Europe and accounts for 46% of all insulins used in that country. This clearly suggests that intensive treatments with 3-4 daily injections are used more frequently in Italy than in other countries. An Italian multicentre epidemiological study similar to the "Schema survey" performed in 1997 (unpublished data) further confirms these data. The study demonstrated that 80% of type 1 patients and 38% of type 2 patients, who are below the age of 65 years, are treated with intensive insulin therapy. Greece, Portugal and Spain are the countries where short acting insulin is used the least, accounting for less than 10% of all insulins used. In major European countries, such as France, Germany and the UK, short acting insulin accounts for 20-30% of insulins used. The use of intermediate acting insulins used alone also varies substantially across Europe. In Spain, 61% of all insulins used is intermediate acting insulin. Similarly high proportions of intermediate insulins use are found in other southern European countries, such as Portugal and Greece. The smallest share of intermediate acting insulin used alone is found in Germany and in the Netherlands. Consequently, these countries also have the highest use of premixed formulations of short and intermediate acting insulin. In Germany, premixed insulins used in that country. This clearly suggests that intensive treatments with 3-4 daily injections are used more frequently in Italy than in other countries. An Italian multicentre epidemiological study similar to the "Schema survey" performed in 1997 (unpublished data) further confirms these data. 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formulations account for 56% of all insulins used. Fixed mixtures are typically used as two insulin injections daily, one in the morning and the other in the evening. Market research data from Germany demonstrate that 42% of diabetics use two insulin injections daily. These are mainly type 2 diabetics. France has a balanced split of insulin formulation with 20% of short-acting, 40% of intermediate acting and 40% of premixed insulin formulations.

Compared with these data collected from European market data bases [6, 9], our “survey” gives additional and more accurate information for France that can be summarized as follows:

- the regimen combining oral hypoglycemic agents and bed time NPH insulin is often used in type 2 patients (18% of cases);
- the conventional combination treatment with oral hypoglycemics and several insulin injections per day is used by approximately 30% of type 2 diabetics and only exceptionally by type 1 diabetics.
- Premixed insulins that combine short-acting and NPH insulins in one cartridge or syringe are widely used by 45.5% of type 2 diabetics and by 39.5% of type 1 diabetics, all regimens considered as a whole, especially those than call for two injections per day;
- Lente insulin is only used by type 1 diabetics treated with three or more injections per day, and only by 29% of these patients.
- A wide variety of basal/bolus combinations exist for diabetic patients who use three injections per day or more: over 30 have been listed, although six regimens account for 70% of the patients.
- Patient acceptability of insulin injections is not reported to be the major drawback of insulin therapy. Perhaps the widespread use of pens by 83% of the patients surveyed in this study, explains the relatively good acceptability of injections. The most commonly reported drawback of insulin treatment is the need for regular monitoring of glucose. Despite this reticence, self-monitoring of glucose frequency generally appears to comply with good practice guidelines.

- French good clinical practice guidelines [1, 2] for insulin therapy, as other guidelines, recommend insulin therapy with multiple injections in type 1 diabetes and at least an attempt at such an intensified insulin therapy for type 2 diabetics in case of failure of metabolic control with conventional simplified insulin therapy. The “Schema survey” showed at the same time that a majority of type 1 diabetics follow these recommendations but also that a lot of patients did not. Indeed, a certain number of patients have undoubtedly been offered, but have refused, intensive three-injection insulin therapy. In contrast, the survey shows inadequate compliance with the guidelines by type 2 diabetics.

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