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**Research Article**

# FASTING TEST DURING FLEXIBLE INSULIN THERAPY: ASSESSMENT AND CHANGE OF BASALDOSE (ABOUT 83 CASES)

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**ABSTRACT**

The Flexible Insulin Therapy (FIT) is a method of therapeutic education with the aim of improving the glycemic control and relieved the constraints related to diabetes in patients with type 1 (T1D) by adapting insulin therapy to their lifestyle. The purpose of this prospective study was to demonstrate the importance of the fasting test in adjusting the dose of basal insulin and to detect other causes of glycemic variability. The patients underwent a no-carbohydrate fasting test. We compared the dose of basal insulin before and after the fasting test. We checked for a dawn phenomenon, ahyperglycemia escape effect, insulin sensitivity and for the right dose of carbohydrates ingestion needed to correct the hypoglycemia. The study included 83 patients aged of 25.2 years on average. Most of these patients were imbalanced with an average HbA1c of 8.9%. The basal dose was on average lower after the FIT vs before. The fasting test showed a basal insulin overdose in 81% of patients. This test revealed a phenomenon of dawn in 53% of patients and a hyperglycemia escape effect in 22% of cases. Our results showed the main role of the fasting test in the determination of the appropriate basal insulin dose. Hyperglycemia escape effect or/and a dawn phenomenon may explain the glycemic imbalance in some patients. This test was very important for assessing insulin sensitivity, for adaptation the carbohydrate ingestions dose to correct hypoglycemia and consequently allowing the patients, a better management of theirs blood sugar levels in real life.

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## INTRODUCTION

The Flexible Insulin therapy (FIT) is an innovative therapeutic approach intended for type 1 diabetic patients with a desire for autonomy and life style flexibility. This method consists of mimicking the normal physiological secretion of insulin through a multiple daily injections regimen, divided into basal, prandial and corrective insulin[1]. Its main purpose is to improve the glycemic control and the quality of life for the diabetic patients without increasing the frequency of hypoglycemia and in particular, the severe form of it[2]. The determination of the basal insulin dose during the initiation of the FIT is a basic step, which could it be done either by calculating the theoretical dose based for the weight of the patient or after a total (or no-carbohydrate)fasting test [3].

The purpose of our study is to demonstrate the interest of the fasting test in the adjustment of the basal insulin and the detection of some glycemic variabilities including the down phenomenon and the hyperglycemia escape effect.The test would evaluate as well the insulin sensitivity and calculate the right carbohydrate dose needed for hypoglycemia corrections in fasting conditions.

## MATERIALS AND METHODS

This was a prospective longitudinal descriptive study. The cohort studied is mono-centric, formed within the Endocrinology and Diabetology Department of University Hospital Center Ibn Rochd in Casablanca and achieved between April 2013 and November 2018.

The target population consisted of 83 patients with type 1 diabetes insulin treated under multiple daily injections either an external insulin pump. This group of patients has benefited by a flexible insulin therapy animated by the care team of our department.

The preparation for the test started 15 days before hospitalization. The candidates perform a 3-day glycemic surveillance before hospitalization: before going to sleep,at 03h AM andat 06h AM in order to adjust the basic needs before andafter the fasting test.

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In the hospital, patients start the carbohydrate fasting test in the first day of hospitalization for a period of 36 hours and they received the following menu:

- ✓ Breakfast: tea, coffee or herbal tea without sugar
- ✓ Lunch and dinner: a green salad + a fillet of chicken or turkey of 100g grilled without fat, without bread or fruit.

Before breakfast, we provided patients with the right dose of rapid actinginsulin analogue for that meal and the specificcorrection dose of it if necessary: In general,we recommended one to two units of rapid acting insulinfor the proteins meal in ours protocols.

***Monitoring during the fasting test consisted in checking the capillary blood glucose level every 2 hours and then every 3 hours at night***

1. In case of hyperglycemia: correction by low bolus dose of rapid acting insulin analogue.
2. In case of hypoglycemia: liquid ingestion equivalent to 15 gcarbohydrate.

***The Parameters Studied were***

1. The basal insulin dose before and after the carbohydrate fasting test
2. The search for a phenomenon of dawn or/andhyperglycemia escape effect (inadequate basal insulin duration)
3. The insulin sensitivity
4. Hypoglycemia and the appropriate dose of carbohydrate ingestions for correcting it.

The data were collected from the medical files of the patients following the FIT training and the analytical study in our cohort was based on the of SPSS software, version 16

## RESULTS

We have enrolled 83 patients with type 1 diabetes mellitus in the FIT program. The epidemiological and clinical characteristics of the patients are summarized in Table 1. The basal insulin dose was between 0.12 and 0.85 IU / kg / day with an average of 0.33 IU / kg / day before the FIT. Frequent hypoglycemia was one of the most important indications for FIT. The frequency and severity of the hypoglycemia wasvariable. We noted that the majority of our patients (90.1%) had at least one episode of hypoglycemia per week. As regards the moderate form, the average hypoglycemia events found in our series wasthree episodes by patient per week. Of these patients, 21 had previously had severe hypoglycemia requiring a third person in the year preceding the FIT.

We stopped the fasting test in a patient because of diabetic ketosis and to another patient for the non-compliancetoprotocol.

This test allowed us to detect a basal insulin overdose in 81% of ours patients andunder dosing for basal insulin in 18% of cases. This test revealed a dawnphenomenon in 53%studied patients. We noticedthe hyperglycemic escape effect in 22% of ours patients. After fasting test, the average dose of basal insulin decreased to 0.27 IU / kg / day Vs 0.33 IU / kg / day initially (Figure 1). We were able to define the insulin sensitivity specific to each patient. This allowed us to calculate the insulin dose needed to correct the hyperglycemia before and after meals. We found that on average 1 IU of fast acting insulin analogueslowers blood glucose by an average of 0.37 g/l (0.2-0.8 g / l).We observed a moderate hypoglycemia in 52 patients with an average-correctingdose of carbohydrate needed ingestionevaluated during the fasting test at 20 g (5-30 g).

**Table 1** Epidemiological and Clinical Characteristics of the Patients

| **Age (years)** | **25,2 (13-49)** |
|---|---|
| Sexe : female | 48 (58%) |
| male | 35 (42%) |
| IMC (kg/m$^2$) | 22 (16-30) |
| Duration of the diabetes ( year) | 8.6 ( 5 months-25 years) |
| HbA1c (%) | 8,9 (5-13,8) |
| Regimen of insulin : Basal-bolus | 79 (95%) |
| Insulin pump | 4 (5%) |
| Type of basal insulin : Glargine | 76 (96%) |
| Detemir | 3 (4%) |

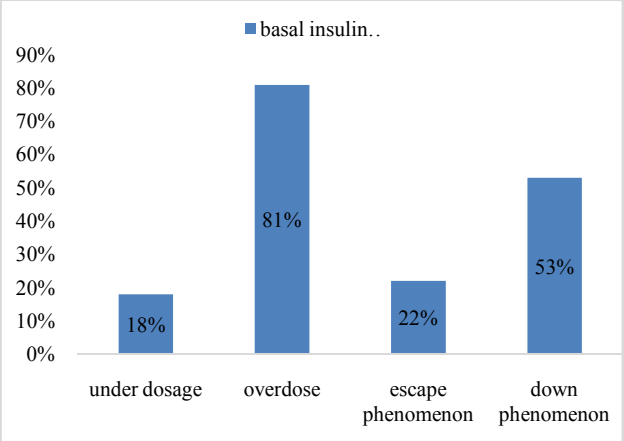


**Figure 1** Basal insulin analysis after fasting carbohydrate test

## DISCUSSION

Intensive insulin therapy[1] or flexible insulin therapy [2] is a pedagogical method that allows diabetic patients to acquire a personalized control of their treatment. It allows that insulin doses to be adjusted according to the insulin sensitivity, habits of eating and physical activity of the patient [3,4]. The principle of the FIT is to reproduce as faithfully as possible the physiological insulin secretion of normal β cells islets of Langerhans. To achieve this purpose, the FIT program can identify for each patient his own doses of insulin required for a good glycemic control:

- ✓ Basal insulin dose called "insulin for living"
- ✓ Prandial insulin doses called "insulin for eating"
- ✓ Fast insulin dose to correct blood glucose called "insulin to correct blood sugar"

The basal insulin has as main purpose the regulation of blood glucose at a distance or in the absence of a meal. The insulin administration in this case it is possible by two ways:

Subcutaneous injection of a slow insulin analogue. It may be a single injection of insulin Glargine, which it has a "flat" kinetics and prolonged duration of action or two injections of insulin Detemir.

Insulin pump that allows a continuous subcutaneous infusion of fast acting insulin analoguesand offers the advantage of programming different flow rates and boluses by day without increasing the number of injection.

The determination of the basal insulin dose required during the introduction of the FIT regime involves two complementary steps. In theory, the dose is initially estimated according to standard algorithms. According to Grimaldi's team, the basal dose is usually between 0.3 and 0.4 IU / kg / day and should not exceed 40-50% of the daily insulin dose. Waldhausl *et al* suggest the following equation [5]: Basal insulin dose per day = 0.35 IU x weight. After this theoretical determinationwe canbetter adjusted the insulin doseby monitoring the glycaemia during a period of 3 days: before going to sleep at 03h AM, at 06h AMand then validated it by the fasting test. The glycemic variation should not exceed 0.35g / l to consider that the basal dose was good from the beginning[6-8].

Fasting test is anecessary step in validating or correcting the theoretically determinedbasal insulin dose. The practice of fasting is not systematicand varies from one team to another. It usually lasts between 24 and 36 hours[9]. It may be a total fasting, where only unsweetened drinks (water, tea or coffee) are allowed or partial fasting which allows restricted protein intake (100 g of meat or fish), involving the pre-prandial injection of fast acting insulin analogues to avoid delayed hyperglycemia due to protein meals[10]. By Berger *et al* [11], each 20 g of protein requires 1 IU of rapid acting insulin.

The fasting test can take place in hospitalor in ambulatory. His practice in a hospital and in the presence of medical staffprovides the patient extra security in view of the risk of severe hypoglycaemia especially at night[12, 13]. For the ambulatory situation, the practice of fasting has an obvious economic advantage and greater flexibility especially for active patients who can thus choose the date that suits them, provided they commit to comply withprotocol of self-monitoring every two hours and remain under the cover of a specialized telephone support 24h/24h

***The fasting test has a fundamental role in the FIT and it allows to***

Demonstrate the importance of the basal dose of insulin to stabilized blood glucose levels at a distance from food intake. Thus finding the correct dose allowing the maintenance of a stable glycaemia, without glycemic variation (increase or decrease of 0.35g / l) and validated it [6-8-12].

Check the duration of action of the basal insulin. In case of hyperglycemia escape effect, it is possible to recommend the injection as late as possible in the evening or to divide it two injections and if not possible to cover this period of escape by an additional injection of rapid acting insulin analogs (Example: at the moment a snack).

Evaluate the effectiveness of the suggesteddose of carbohydrates for hypoglycemia events (10-30g of carbohydrates). Thus, the persistence of hypoglycemia after 15 min of ingestion of the theoretically carbohydrate dose should lead to an increase in the quantity of carbohydrate to correct hypoglycemia.

Looking for a dawn phenomenon, manifested by significant fluctuations in blood glucose in the early morning. This phenomenon generally tides to elevated plasma free fatty acids and insulin resistance induced by the nychthemeral cycle of counter-regulating hormones[15].

The fasting test has other pedagogical interests for patients to prove them the vital need of basal insulin. In addition, the possibility to vary the meal times or skip them if necessary even fasting without fear of severe hypoglycemia.

Following the fasting test, the basal insulin dose is usually reduced and remains relatively stable after FIT[12,16]. Our study in turn confirms the reduction of basal insulin doses that was 0.33U / kg / day initially vs. 0.27U / kg / day after FIT. In the study by Benhamou[12]the main objective wasto check the basal insulin dose in 40 T1D patients during a four-day hospitalization, where they underwent a carbohydrate fasting test. The study found a decrease in basal insulin dose between D0 and D4 of 0.31 ± 0.11 to 0.27 ± 0.09 IU/kg/day($p < 0.0001$) with a slight increase after one year (0.29 ± 0.09 IU/kg per day, $p = 0.004$) not exceeding 20% in the majority of cases. Thus, they made no major adjustment in the first year after FIT. This dose stability of basal insulin has also been reported by other studies[17-18].

## CONCLUSION

Well-coded standard algorithms can estimate theoretically the basal insulin requirements of a type 1 diabetic patient. However, by performing the fasting test we could validate or adjust these needs to the real life not only in theory. The test should not be restricted only in patients who are candidates for insulin pump therapy or who candidate for flexible insulin therapy because of its interest even for the other treatment options. Indeed, this fasting test showed in our series as in the literature its interest in the adjustment of the dose of basal insulin, the detection of a dawn phenomenon or ahyperglycemic escape effect. It has also allowed us to evaluate insulin sensitivity and adapted the right carbohydrate dose to correct the hypoglycemia episodes allowing our patients a better management of theirs hyperglycemia and hypoglycemia.

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