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High prevalence with no gender difference of likely eating disorders in type 1 mellitus diabetes on insulin pump

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<u>Abstract</u>

Aim: The aim of this study was to determine the prevalence of likely eating disorders and insulin misuse in a prospective cohort of adults with type 1 diabetes mellitus (T1DM) treated with insulin pump therapy.

Methods: This prospective study was held at the participants' home. The participants completed the SCOFF questionnaire as well as a question related to insulin misuse.

Information about lifestyle, medical history, insulin pump and Continuous Glucose

Monitoring (CGM) data were collected.

Results: The analysis covered 198 participants with a median age of 51 [95% CI 38; 62] years. The prevalence of likely eating disorders was 21.7% (95% CI 16.3; 28.2) in the study population and 20.6% (95% CI 14.3; 28.6) and 24.2% (95% CI 14.6; 37.0) in males and females respectively. The prevalence of insulin misuse was 39.0% (95% CI 30.8; 47.7). There was no significant difference in prevalence between males and females for likely eating disorders and insulin misuse. The analysis of CGM data revealed no factors related to glycaemic control associated with likely eating disorders.

Conclusion: The results of this study indicate that the prevalence of likely eating disorders is high even in a middle-aged population with a T1DM and satisfactory glucose control.

Keywords

Diabetes Mellitus, Type 1; Diabulimia; Feeding and Eating Disorders; Insulin Infusion Systems; Blood Glucose Self-Monitoring; Middle Aged

Introduction

Type 1 diabetes mellitus (T1DM) increases the risk of developing an eating disorder for a variety of reasons including initial weight loss or focus on food [1]. Eating disorders in T1DM are most often atypical [2]. The neologism diabulimia has emerged to describe the restriction or omission of insulin self-administration in order to lose or stabilise weight. It has been qualified as "the world's most dangerous eating disorder" [3]. Indeed, diabulimia is associated with ketoacidosis and diabetes complications. It is generally accepted that eating disorders in T1DM increases the risk of diabetes complications since eating disorders are associated with poor glycaemic control; furthermore, eating disorders in T1DM remain underdiagnosed [4].

One of the difficulties for screening eating disorders in T1DM is the lack of consensus on the tools to be used to diagnose such disorders. Two questionnaires, namely the revised 16-item Diabetes Eating Problem Survey (DEPS-R) and the modified SCOFF (mSCOFF) have been validated in the paediatric population with T1DM but not in the adult population and in the French language [5,6]. In contrast, the original SCOFF, which is a five-question screening questionnaire for eating disorders, has been well validated in France in primary care for the general population but not specifically for patients with T1DM [7,8]. It has already been used in T1DM in Germany [9].

In T1DM, the prevalence of eating disorders and/or insulin restriction has been mainly studied in adolescent or young adult women. The prevalence ranges from a few percent to several tens of percent depending on the study population and the method used for the diagnosis [10]. To our knowledge, only two studies have described the prevalence of eating disorders in a general population of adults with T1DM. Both studies used DEPS-R questionnaire and found a prevalence of disordered eating around 30% [11,12].

Insulin pump therapy is currently the treatment of choice in T1DM due to its higher metabolic efficiency in comparison to multi-injection insulin therapy [13]. While it is well established that an insulin pump has higher metabolic efficiency, there has been little discussion on the association of technology use and eating disorders in T1DM [14]. The main objective of this study was to assess the prevalence of likely eating disorders in adult males and females with T1DM treated by insulin pump therapy. The secondary objectives were to determine the following: 1) prevalence of likely eating disorders in the cohort regardless of gender, 2) prevalence of insulin misuse, 3) factors associated with likely eating disorders and insulin misuse

Materials and methods

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Ethics statement

All subjects gave written informed consent. The protocol was registered under ID/RCB: 2020-A00147-32 and approved by the Human Protection Committee of Ile de France. This study was registered on ClinicalTrials.gov (NCT04506216 – Diaboulimia).

Study design and population

The "Diaboulimia" study was a prospective home study. Participants were included between September 1, 2020 and December 23, 2021. Subjects 1) aged 18 and older 2) with T1DM on insulin pump 3) followed by the home health care provider (AGIR à Dom) in the South-East of France were eligible for inclusion. Subjects 1) with a pacemaker, which is a contraindication to the bioelectrical impedance analysis 2) pregnant or breast-feeding 3) under legal protection were excluded.

Study protocol and collection of data

A single home follow-up visit was planned. The study visit was combined with the visit as part of the standard of care, unless the participant preferred two different visits. In France, at least a visit each 6 months is planned with a nurse for patients with T1DM on insulin pump. The day of the visit, after signing the consent form, the participants completed the SCOFF questionnaire, the fifth question of the m-SCOFF, the international physical activity questionnaire (IPAQ) and the questions related to eating habits and diabetes. The

investigators collected information about lifestyle, medical history, insulin pump and Continuous Glucose Monitoring (CGM) data. They also measured anthropometric data.

SCOFF questionnaire. The (Sick, Control, One stone, Fat, Food) SCOFF questionnaire is a 5-item screening tool used to identify risk of eating disorders. The questionnaire has been translated into French and validated [7,8]. It is scored from 0 to 5, according to the number of positive answers. Two or more positive responses indicate a likely eating disorder.

Insulin misuse. The m-SCOFF was developed to screen eating disorders in subjects with T1DM. The first four questions of the SCOFF and the mSCOFF are the same. The fifth question, related to voluntary insulin restriction "Do you ever take less insulin than you should?" is different. This question was translated into French by our research team but was not validated.

CGM data collection

We analysed CGM data over the last 14 days to define time wearing of the sensor, self-monitoring of blood glucose for participants under Freestyle Libre device, time in range (TIR), mean amplitude glycaemic excursion (MAGE) as previously described [15].

Physical activity data collection

The IPAQ is a validated questionnaire for people over the age of 15, which assesses physical activity and sedentary time during the past seven days across a comprehensive set of domains daily, leisure and working as well as transportation [16]. Nevertheless, to our knowledge, the French translation of the short version of the questionnaire has not been validated.

Anthropometric data

Weight was measured by standardised methods and with homogeneous material. Height was not measured but collected by the investigator. A bioelectrical impedance (Bioimpendancemètre Bodystat 1500®, CronkBourne, Isle of Man, UK) was used to measure phase angle at 50 Hz. The method was performed in a standardised way: patient lying down for 10 minutes, after emptying the bladder and after a breakfast without too much water intake (1 bowl maximum). Measurements were done on the right side, with the insulin pump positioned on the left to avoid interference.

Statistical analysis

A sample size of 200 participants (62 female and 138 male) was calculated based on the estimation of prevalence of SCOFF positive of 20% in females (error of more or less than 10 points) and 10% in males (error of more or less than 5 points) with 95% confidence interval (CI) [9,17]. Categorical variables are reported as count and percentage. Continuous variables are presented as the median value and interquartile range [25th and 75th percentile]. For the description of the population, the analysis of the results is performed on the modified intention-to-treat (mITT) population, i.e. all patients included, with no missing data for the SCOFF questionnaire score and no major deviations. The prevalence of participants with SCOFF positive, mSCOFF positive or with insulin misuse is reported independently in males and females, and in the total population. Calculation of 95% CI was performed using Wilson's method with continuity correction [18]. In order to determine the parameters associated with the risk of likely eating disorders or insulin misuse, univariate logistic regressions were performed. When log-linearity was not respected, continuous parameters have been recoded. The Akaike Information Criteria (AIC) was used to optimise the subthreshold (median, quartile 1 or 3). A significant interaction with gender was assessed for each of the parameters. When it was the case, the Odds Ratios (OR) associated with the univariate logistic regressions were reported separately for males and females. Statistical analysis was performed using SAS software version (9.4 (SAS Institute Inc). P-values <0.05 were considered significant.

Results

Patient inclusion and characteristics

A total of 201 patients were included. For the 27 subjects, who did not wish to participate in the study, 19 agreed that their data be collected. The flow chart of the patient selection is Figure 1. Of the included participants, 187 wore CGM.

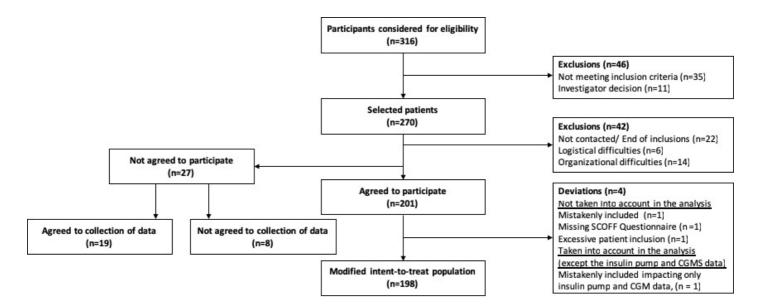


Figure 1. Flow chart

SCOFF: Sick, Control, One stone, Fat, Food; CGM: Continuous glucose monitoring

Patients' clinical and demographic baseline characteristics as well as their medical history and complications of diabetes are shown in **Table 1**.

Total population, n= 198				
	Median [IQR] or n (%)			
Age (years)	51 [38; 62]			
Body mass index (kg/m²)	25.8 [22.6; 29.1]			
# Sex, Males	136 (68.7)			
Females	62 (31.3)			
HbA1c (%)	7 [7; 8]			
Age at diagnosis of diabetes (years)	20 [11; 33]			
Age at onset of insulin pump (years)	41 [26; 51]			
Diabetes duration (years)	25 [16; 37]			
# Total number of admissions for diabetic ketoacidosis or	13 (6.6)			
glycaemic imbalance in previous 12 months				
# Diabetic retinopathy, yes	49 (25.0)			
# Diabetic nephropathy, yes	9 (4.6)			
# Diabetic foot ulcer, yes	11 (5.6)			
# Cardiac complications including high blood pressure	51 (26.1)			
# Mental disorders, yes	42 (21.3)			
# Sleep disorders, yes	63 (32.0)			
# Eating disorders, yes	9 (4.6)			
# Cancer, yes	18 (9.1)			

 Table 1. Descriptive characteristics and self-reported comorbidities.

IQR: interquartile range

The symbol # indicates that the variables are reported as count and %, the other variables are presented as the median value and IQR.

Prevalence of likely eating disorder and insulin misuse

The prevalence of SCOFF positive was 21.7% (95% CI 16.3; 28.2) in the study population and 20.6% (95% CI 14.3; 28.6) and 24.2% (95% CI 14.6; 37.0) in males and females respectively (Figure 2A). The percentage of positive response for each of the five questions of the SCOFF is shown in Figure 2B. The prevalence of insulin misuse according to the fifth question of the m-SCOFF was 39.0% (95% CI 30.8; 47.7) and 37.7% (95% CI 25.9; 51.1) in males and females respectively. Using the m-SCOFF the prevalence of likely eating disorders was 21.3% (95% CI 15.9; 27.8) in the study population and 21.3% (95% CI 14.9; 29.3) and 21.3% (95% CI 12.3; 34.0) in males and females respectively.

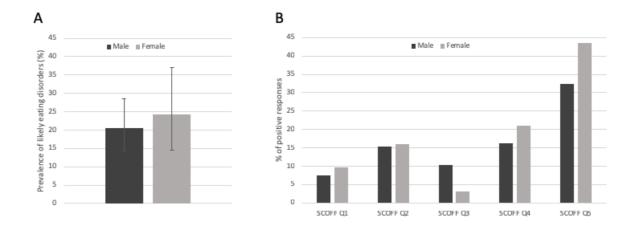


Figure 2. Response to SCOFF questionnaire (Sick, Control, One stone, Fat, Food) in the participants with type 1 diabetes mellitus for males (n=136) and females (n=62)

(A) Prevalence (median (95% CI)) of likely eating disorders according to SCOFF questionnaire

(B) Positive answers to each SCOFF question (Q)

Factors associated with likely eating disorders (i.e., SCOFF ≥ 2)

The factors associated with the risk of likely eating disorders are summarised in Table 2. Three factors (BMI greater than 29.1 kg/m², age under 62 years and a history of eating disorders) were significantly associated with an increased risk of likely eating disorders. The other factors, including factors related to CGM and insulin pump were not statistically significantly associated with a positive SCOFF.

1		_		
	SCOFF<2 (n= 155)	SCOFF≥2 (n= 43)		
	Median [IQR] or n (%)	Median [IQR] or n (%)	OR, 95% CI	P-Valu
# Sex, Female	47 (30.3)	15 (34.9)	1.23 [0.60; 2.52]	0.57
BMI > 29.1 kg/m²	25.7 [22.4; 28.2]	28.4 [23.8; 31.6]	2.68 [1.29; 5.56]	0.008
Age > 62 years	52 [38; 63]	49 [34; 52]	0.32 [0.12; 0.87]	0.025
HbA1c > 7 %	7 [7; 8]	7 [7; 8]	0.92 [0.46; 1.86]	0.82
Basal/bolus ratio per day > 0.94	0.86 [0.57; 1.36]	1.00 [0.73; 1.46]	1.52 [0.77; 3.02]	0.23
Bolus insulin per day > 3.8	3.9 [3.2; 4.9]	3.7 [3.3; 4.9]	0.85 [0.43; 1.67]	0.63
Phase angle at 50 Hz > 6.6°C	6.5 [5.5; 7.4]	6.7 [5.9; 7.3]	1.17 [0.58; 2.37]	0.66
# Diabetic retinopathy, yes	41 (26.8)	8 (18.6)	0.62 [0.27; 1.46]	0.28
# Diabetic foot ulcer, yes	9 (5.8)	2 (4.7)	0.79 [0.17; 3.81]	0.77

	1	1	1	-
# Mental disorders, yes	30 (19.4)	12 (28.6)	1.67 [0.77; 3.63]	0.20
# Sleep disorders, yes	45 (29.0)	18 (42.9)	1.83 [0.91; 3.70]	0.09
# History of Eating disorders (self-reported), yes	3 (2.0)	6 (14.0)	8.16 [1.95; 34.17]	0.004
# Cancer, yes	16 (10.3)	2 (4.7)	0.42 [0.09; 1.92]	0.27
# Diabetic nephropathy, yes	8 (5.3)	1 (2.3)	0.43 [0.05; 3.53]	0.43
# Cardiac complications, yes	44 (28.6)	7 (17.1)	0.52 [0.21; 1.25]	0.14
Sedentary time h/day > 5	5 [3; 7]	5 [4; 8]	0.82 [0.39; 1.73]	0.61
Physical activity level/week				
# High (vs low)	39 (51.3)	14 (56.0)	0.77 [0.26; 2.28]	0.40
# Moderate (vs low)	22 (29.0)	4 (16.0)	0.39 [0.10; 1.57]	
Time in range (70-180mg/dL) > 52%	53 [44; 67]	51 [45; 59]	0.77 [0.38; 1.55]	0.47
Time wearing CGM > 98 % (on 24h)	95 [89; 100]	93 [83; 98]	0.61 [0.28; 1.32]	0.21
Self-monitoring of blood glucose >7 (sample/day)	8 [5; 12]	7 [5; 10]	0.59 [0.28; 1.24]	0.16
MAGE > 138 (mg/dL)	138 [113; 163]	141 [120; 168]	1.10 [0.51; 2.37]	0.81

Table 2. Odds Ratio (OR) comparisons of descriptive characteristics, self-reported comorbidities, physical activity level (n = 198), and data related to Continuous glucose monitoring (CGM) in the sub-population of patients wearing one (n = 187) according to the SCOFF questionnaire.

BMI: Body Mass Index; HbA1c: Glycated Haemoglobin; MAGE: Mean Amplitude Glycaemic Excursion

The Akaike Information Criteria (AIC) was used to optimise the subthreshold (median, quartile 1 or 3)

The symbol # indicates that the variables are reported as count and %, the other variables are presented as the median value and IQR.

Factors associated with insulin misuse

The factors associated with the risk of insulin misuse (positive response to the fifth question of the m-SCOFF questionnaire) are summarised in **Table 3**. Only one factor (Age greater than 51 years) was significantly associated with a decreased risk of insulin misuse. In the subpopulation of participants with a CGM, higher CGM wearing time was significantly associated with a decreased risk of insulin misuse in females.

	Insulin misuse	No insulin misuse		
	(n= 155)	(n= 43)		
	Median [IQR] or n (%)	Median [IQR] or n (%)	OR, 95% CI	P-Value
# Sex, Female	38 (31.4)	23 (30.3)	0.95 [0.51; 1.77]	0.87
BMI > 25.8 kg/m ²	26.2 [22.8; 29.3]	25.8 [22.2; 28.3]	0.74 [0.41; 1.32]	0.30
Age > 51 years	52 [39; 63]	45 [34; 58]	0.49 [0.27; 0.88]	0.017
HbA1c > 7 %	7 [7; 8]	7 [7; 8]	0.95 [0.53; 1.72]	0.87
Basal/bolus ratio per day > 0.94	0.85 [0.57; 1.26]	1.00 [0.73; 1.61]	1.70 [0.94; 3.04]	0.08

Bolus insulin per day > 3.8	3.9 [3.3; 5.1]	3.7 [3.2; 4.5]	0.65 [0.36; 1.17]	0.15
Phase angle at 50 Hz > 6.6	6.5 [5.7; 7.4]	6.6 [5.7; 7.3]	1.06 [0.59; 1.91]	0.84
# Diabetic retinopathy, yes	29 (24.4)	20 (26.3)	1.11 [0.57; 2.15]	0.76
# Diabetic foot ulcer, yes	7 (5.8)	4 (5.3)	0.91 [0.26; 3.20]	0.88
# Mental disorders, yes	24 (20.0)	18 (23.7)	1.24 [0.62; 2.48]	0.54
# Sleep disorders, yes	39 (32.2)	24 (32.0)	0.99 [0.53; 1.83]	0.97
# Eating disorders, yes	6 (5.0)	3 (4.0)	0.78 [0.19; 3.22]	0.73
# Cancer, yes	15 (12.4)	3 (4.0)	0.29 [0.08; 1.04]	0.06
# Diabetic nephropathy, yes	7 (5.9)	2 (2.7)	0.44 [0.09; 2.17]	0.31
# Cardiac complications, yes	33 (27.7)	18 (24.0)	0.82 [0.42; 1.60]	0.57
Sedentary time h/day > 7	5 [3; 8]	5 [3; 7]	0.65 [0.32; 1.26]	0.25
# Physical activity level/week High (vs low)	34 (54.0) 14 (22.2)	19 (51.4) 12 (32.4)	1.40 [0.47; 4.20] 2.14 [0.63; 7.27]	0.45
Moderate (vs low) Time in range (70-				
180mg/dL) > 52 %	52 [45; 68]	52 [43; 62]	0.94 [0.52; 1.69]	0.83

Time wearing CGM > 98 %				
(Out of 24H)	Interaction with gender significant, p = 0.010			
Female (n = 57)	98 [89; 100]	94 [86; 97]	0.17 [0.04; 0.67]	0.012
Male (n = 130)	94 [85; 98]	95 [83; 100]	1.39 [0.61; 3.15]	0.43
Self-monitoring of blood glucose > 7 (sample/day)	7 [5; 12]	7 [5; 11]	0.98 [0.52; 1.88]	0.97
MAGE > 117 (mg/dL	137 [106; 155]	141 [120; 173]	1.78 [0.76; 4.19]	0.19

Table 3. Odds Ratio (OR) comparisons of descriptive characteristics, self-reported comorbidities, physical activity level (n=198) and data related to continuous glucose monitoring system (CGM) in the sub-population of patients wearing one (n= 187) according to the insulin restriction.

BMI: Body Mass Index; HbA1c: Glycated Haemoglobin; MAGE: Mean Amplitude Glycaemic Excursion

The Akaike Information Criteria (AIC) was used to optimise the subthreshold (median, quartile 1 or 3)

The symbol # indicates that the variables are reported as count and %, the other variables are presented as the median value and IQR.

Discussion

It is well known that T1DM increases the risk of eating disorders. Nevertheless, in clinical practice, this risk is underdiagnosed. The majority of prevalence studies have been done in adolescents and young adults. Thus, a neglected area in this field is the prevalence of eating disorders in the general population with satisfactory glycaemic control. The main

objective of our study was to assess the prevalence of likely eating disorders using the SCOFF in a cohort of T1DM on insulin pump with regular follow-up.

The most striking result to emerge from the data is that the prevalence of likely eating disorders is high in our cohort of patients on insulin pumps with satisfactory glycaemic control. In the French general population-based NutriNet-Santé e-cohort, the prevalence of likely eating disorders estimated with SCOFF was 15.8% in women and 8.0% in men, which is lower than in our cohort. The population of this e-cohort was comparable in terms of age (50.4 ±14.6 years) and BMI (24.0 ±4.5 kg/m2) [19]. Our experiments are in line with previous results showing that the prevalence of eating disorders is higher in T1DM [20]. Few studies used SCOFF to identify likely eating disorders in T1DM population, studies were performed by the same team in youths in Germany [9,21,22]. It was demonstrated that in a cohort of 819 participants with T1DM, 28.2% of the female and 9.2% of the male patients were SCOFF positive [9]. In adults, the available studies in the literature are few and based on DEPS-R, which is a 16-item diabetes-specific self-report measure of disordered eating not validated in French [6]. The prevalence of likely eating disorders was 31% and 30% in an Australian cohort of 199 people and a Greek cohort of 103 people respectively [11,12]. It is in the same order of magnitude even if it is a bit lower in our cohort (21.7%). One of the likely causes of this discrepancy could be related to an older study population in our cohort of 51 [38; 62] years vs 32 ±13 years and 37 ±22 years respectively for the two studies mentioned above. Indeed, prevalence of eating disorders decreases with age in adulthood with a peak at approximately age 21 years [23]. We also confirmed in our study that age decreased the risk of likely eating disorders.

Contrary to expectations, the prevalence of likely eating disorders was not significantly different between male and female. Even though these results differ from earlier studies in

prevalence of eating disorders in the general population [24] or in T1DM [11], they are consistent with a study in T1DM [12]. There are at least two possible explanations for this result: 1) While the lifetime prevalence of all eating disorders is higher in women than in men in the general population, for eating disorders not otherwise specified (EDNOS), it is quite similar [24]. And, it was previously demonstrated that the most common eating disorder in T1DM is EDNOS [2]. 2) The female to male ratio for eating disorder symptoms decreases with age, and our study population is middle aged and older than in previous studies in T1DM [25].

We are aware that our research may have two main limitations. First, we assessed eating disorders with the SCOFF questionnaire, which is a screening questionnaire. The diagnosis has not been confirmed by a medical interview. For this reason, we used in this article the terminology of likely eating disorders. We chose to use the SCOFF and not the mSCOFF since the mSCOFF has been validated only in English and in the paediatric population [5]. Nevertheless, in this study, the use of the mSCOFF and SCOFF gave a similar prevalence of likely eating disorders. And, the results on insulin misuse and likely eating disorders give similar results in terms of risk factors. The DEPS-R is also a screening questionnaire, which is widely used in the literature but not validated in French. Furthermore, the DEPS-R has been mainly validated in the paediatric population with only one study validating this questionnaire in the adult population [6,26]. In contrast, the SCOFF has been widely validated in the adult population and in two cohorts of French adults [8,27,28]. It is important to notice that the SCOFF questionnaire has excellent psychometric properties with a very high specificity of 0.93 in a meta-analysis of 882 cases and 4,350 controls [27].

We think that the originality of our study was to assess eating disorders in a population with a satisfactory glycaemic control. In contrast to earlier findings, the parameters associated with glycaemic control were not worsened in the SCOFF positive group [11,12]. To the best of

our knowledge, this study is one of the first to assess prevalence of eating disorders and insulin restriction in a population with such good glycaemic control. It can thus be conceivably hypothesised that even in a favourable metabolic situation, patients with T1DM are struggling with eating behaviour. We agree with Wisting & Snoek, who suggest that diabulimia is insufficient to describe the range of eating disorders in T1DM [4]. Our study illustrates that even in case of good glycaemic control, eating disorders are frequent.

This study is a first step towards enhancing our knowledge of eating disorders in a population of patients with T1DM with satisfactory glycaemic control. We believe that the SCOFF could probably be used in such a population in clinical routine. Even if in the study population, a SCOFF positive questionnaire has no negative consequences on glycaemic control, it could induce poor quality of life [29,30]. Future work will focus on how to manage people at risk of eating disorders in T1DM. Currently diabetes technology and flexible insulin therapy are two treatments for glycaemic optimisation. Since diabetes technology may decrease the risk of subsequent eating disorders [14,31], we planned to assess if the use of a pump at the beginning of diabetes may reduce the risk of disturbed eating disorder. In our study, the median diabetes duration was 25 years and thus, few patients were on insulin pump at the beginning of diabetes. It seems also important to assess the impact of flexible insulin therapy. On the one hand, the use of flexible insulin therapy improves the quality of life in the short term [32], on the other hand, it can increase the risk of eating disorders since it induces focus on food [1].

In conclusion, the results of this study indicate that the prevalence of likely eating disorders is high even in a middle-aged population with T1DM and satisfactory glucose control. More than one in five participants was SCOFF positive. In contrast to most of the literature, there was no gender difference in prevalence of likely eating disorders in T1DM. In

this study, increasing age was associated with a decreased risk of likely eating disorders and insulin misuse, while increasing BMI was associated with an increased risk of likely eating disorders. We hope that this study will encourage the diabetologist practitioner to be more attentive to the risk of eating disorders even in case of satisfactory glucose control. Future studies should focus on the impact of diabetes technology and flexible insulin therapy on eating disorders.

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Declaration of competing interest

Pauline Périnet-Marquet, Nathalie Arnol, Sophie Logerot and Jean-Christian Borel were employed by AGIR à Dom at the time the study was conducted. Cécile Bétry has received fees for presenting from AGIR à Dom. Sylvain Iceta has received research grants from Takeda and Diabetes Canada; has been a consultant or member on advisory panels for Takeda and Bausch Health.

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Supplementary table 1

The supplementary table 1 compares the characteristics of included and not included participants, who gave their consent for collection data. Mann-Whitney test was used for comparisons of continuous variables, while Chi2 test was used for comparisons of proportions.

	Included participants	Included participants Not included participants	
	(n =198)	(n = 19)	
	Median [IQR] or n (%)	Median [IQR] or n (%)	P-Value
Sex, Male	136 (68.7)	16 (84.2)	0.16
Age (years)	51 [38; 62]	51 [33; 58]	0.48
HbA1c (%)	7 [7; 8]	7 [7; 8]	0.15

Supplementary table 1. Comparison of included versus non-included participants

HbA1c: Glycated Haemoglobin