



RESEARCH ARTICLE

INTEGRATED CARE MODEL FOR TYPE 2 DIABETES PATIENTS DURING RAMADAN: CONTRIBUTION OF NEW GUIDELINES

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Abstract

Fasting during Ramadan is a major challenge for diabetics because of its various risks. A therapeutic management plan can ensure fasting while minimizing the associated risks. Our aim was to implement a pre-Ramadan management program and to define patient profiles that are more adapted to fast.

Methods: 262 type 2 diabetic patients were recruited from both 2019 and 2021 Ramadan campaigns organized at the endocrinology department of the Mohammed VI University Hospital of Marrakech, excluding pregnant women and patients with chronic end-stage kidney disease.

Results: Predominantly female and aged between 50 and 70 years, with a high BMI. Glycemic control was close to target for fasters. The most common comorbidities in our series were hypertension and dyslipidemia. 19.8% of our patients had an associated cardiovascular complication and 10.5% had kidney disease. After stratification, the "non fasting" decision concerned most of our diabetics in 2021 compared to 2019.

Conclusion: A therapeutic management plan help to fit guidelines. Compared to 2017, the updated 2021 stratification guidelines are more comprehensive and have defined more non fasters patients.

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Introduction:-

Ramadan is the ninth month of the Islamic calendar, this holy month can occur either during hot or cold weather, as well as varies the duration of fasting according to geographical location and season (1).

During this period, dietary, fitness and sleeping rhythms are considerably changed. Such a month of conviviality and sharing can generate deep frustration for "non fasters". On the other hand, fasters find themselves obliged through major adjustments of their therapeutic patterns.

Even though Islam permits such an exemption, diabetics express an oppressive impulse for fasting (1,2). Facing this annual request, physicians need to make a delicate and multidisciplinary based decision (1).

This requires a redefinition of glycemic, degenerative and therapeutic profiles in order to deal with the risks of fasting in terms of glycemic excursions (3,4), dehydration and exacerbation of chronic complications.

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First guidelines relating to fasting risks were developed in Morocco around 1995(5). Extensively reviewed by scientific societies, these guidelines are constantly updated and adapted to suit patients' lifestyles. The ADA published a consensual statement on managing diabetes during Ramadan, which was updated in 2010, followed by the IDF-DAR collaboration revised in 2017 and refreshed in 2021. This latest update brought major changes in stratification for more flexible handling, using a calculated score, considering new parameters: fasting duration, previous fasting experience and detailing old parameters (6-9).

Our work first establishes the glycemic, degenerative and therapeutic profiles of diabetics to stratify the risk of fasting and then compares these profiles in fasters and non-fasters to assess the different approaches between 2019 and 2021 guidelines.

Material And Methods:-

Study description:

As part of supporting our diabetics, within the weeks before the blessed month, each year, the "Ramadan days" are held in the endocrinology department of Mohamed 6 University Hospital of Marrakech.

This unique campaign aims to stratify the risk of fasting in diabetics. To do so, a clinical and biological evaluation, specialized cardiovascular and ophthalmological exploration and therapeutic educational sessions are performed. It ends at a stratification station. Here, a detailed questionnaire according to the 2017 guidelines (Table I) for Chaaban 1413/2019 and those of 2021 for Chaaban 1415/2021 is used to classify patients as "fasters" and "non-fasters" according to their risk:

-Low to moderate risk: the decision of fasting should be shared between the physician and the patient.

-High risk: the patient should not fast

-Very high risk: the patient should not fast under any circumstances.

Low to moderate risk	Well-controlled type 2 diabetes treated with : Hygienic and dietetic measures (HDM) Metformin Acarbose Thiazolidinediones 2nd generation sulphonylureas Incretins SGLT2 inhibitors Basal Insulin
High risk	Well controlled type 1 diabetes Uncontrolled type 2 diabetes Type 2 diabetes on mixed insulin or multiple doses of insulin Pregnant woman with type 2 diabetes or gestational diabetes on metformin or HDM Stage 3 renal failure Stable macrovascular complications Comorbidity leading to additional risk strenuous physical activity Concomitant treatment that impairs cognition
Very High risk	Uncontrolled type 1 diabetes Severe unexplained hypoglycaemia, Acidotic decompensation or hyperosmolar coma < 3 months before fasting Previous history of recurrent or asymptomatic hypoglycaemia Acute additional disease. Pregnant woman with known diabetes or gestational diabetes on insulin or sulfonylurea Stage 4-5 renal failure Advanced macrovascular complications Fragile older patient

Table I:- Risk stratification according to the IDF-DAR 2017.

Unfortunately, due to the COVID-19 pandemic, this activity was cancelled in 2020, as well as reduced staff in 2021 to deal with safety measures.

We realized a retrospective descriptive study over a period of two and a half years from Chaâbane 1413 to Chaâbane 1415 including 262 beneficiaries of both Ramadan campaigns 2019-2021.

Target population:

Inclusion criteria:

Confirmed type 2 diabetics managed at the Endocrinology Department of Mohammed VI University Hospital or referred from general consultations.

Exclusion criteria:

1. Type 1 diabetics.
2. Patients with end-stage kidney disease.
3. Pregnant and breast-feeding diabetics.

Data Collection:

Data were collected by a questionnaire filled within the process, using closed questions for patients, and a report of the cardiological and ophthalmological consultations for physicians.

Data collection used Excel software (version 2016) then analysed with SPSS software (version 26.0).

Results:-

Population general characteristics:

Our population consisted of 262 type 2 diabetics, with a mean age of 58.32 $\pm$ 10.89 years (extremes: 25-83 years), the modal class is between 60 and 69 years. There was a predominance of females: 194 or 74% females, versus 68 or 26% males, with a sex ratio of 0.35.

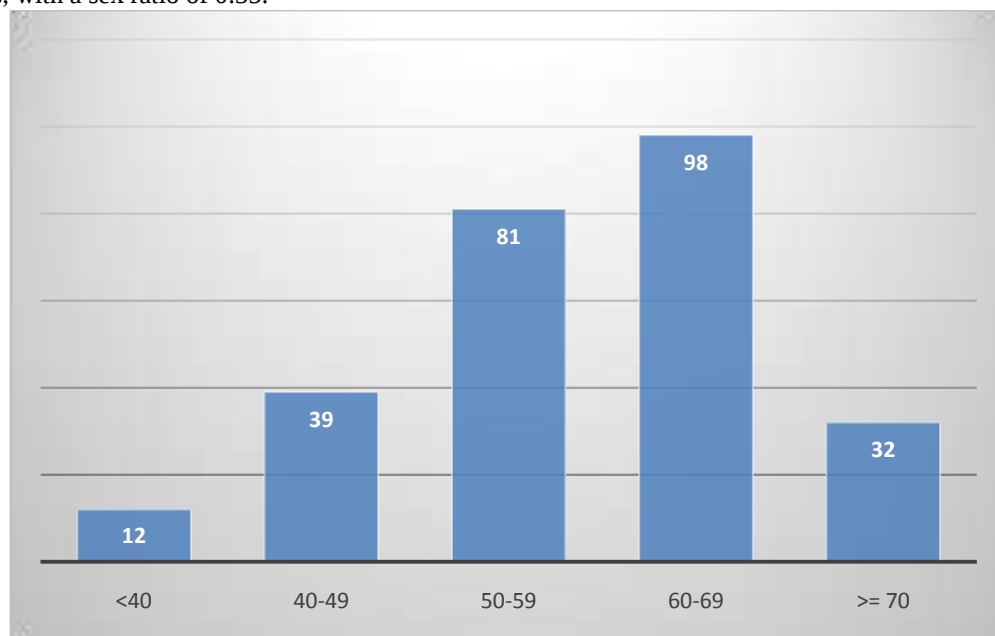


Figure 1:- Age distribution.

Most patients in our study lacked any formal education (61.5%). 19.5% had primary school education, 14.1% had high school level and 4.9% had university degree.

Anthropometric parameters

The majority of our diabetic patients were overweight and/or obese. The mean body mass index (BMI) was 31.58 $\pm$ 7.07 kg/m², with extremes ranging from 21 kg/m² to 52 kg/m². The mean waist circumference was 104.34 $\pm$ 13.57 cm, with extremes ranging from 73 cm to 133 cm.

Diabetes

Therapy consisted of hygienic dietary measures in 15 patients (5.7%), oral mono- or bi-therapy in 126 patients (48.1%), 69 patients (26.3%) were on insulin and 46 patients (17.6%) on insulin combined with an oral anti-diabetic agent; 6 patients (2.3%) were on another treatment, including 2 patients on GLP-1 analogue.

156 patients (59.5%) were diagnosed less than 10 years ago and 106 (40.5%) more than 10 years ago.

The mean HbA1c was 8.94 +/- 1.86% and the mean glycemic value was 1.67 +/- 0.69 mg/L.

Comorbidities and Complications

Hypertension was found in 99 patients (37.8%) and dyslipidemia in 50 patients (19.1%).

17 patients (19.8%) had established cardiac disease, predominantly ischemic heart disease, and 9 patients (10.5%) had pre-existing nephropathy under treatment.

Diabetic retinopathy was found in 29% of patients.

Risk stratification

Over the two editions organized in 2019 and 2021, of all the 262 patients in, 116 (44.3%) were allowed to fast while 146 patients (55.7%) were not authorized due to a higher risk of complications.

During 2019, out of 176 patients received, 95 (54%) were advised not to fast because of their high or very high risk.

While during 2021, there were 86 patients in care, a reduced number due to the sanitary protocols of Covid-19 period. 59% of those presented were advised not to fast, 22% had to make a coordinated decision and 19% were at lower risk as shown in figure 2:

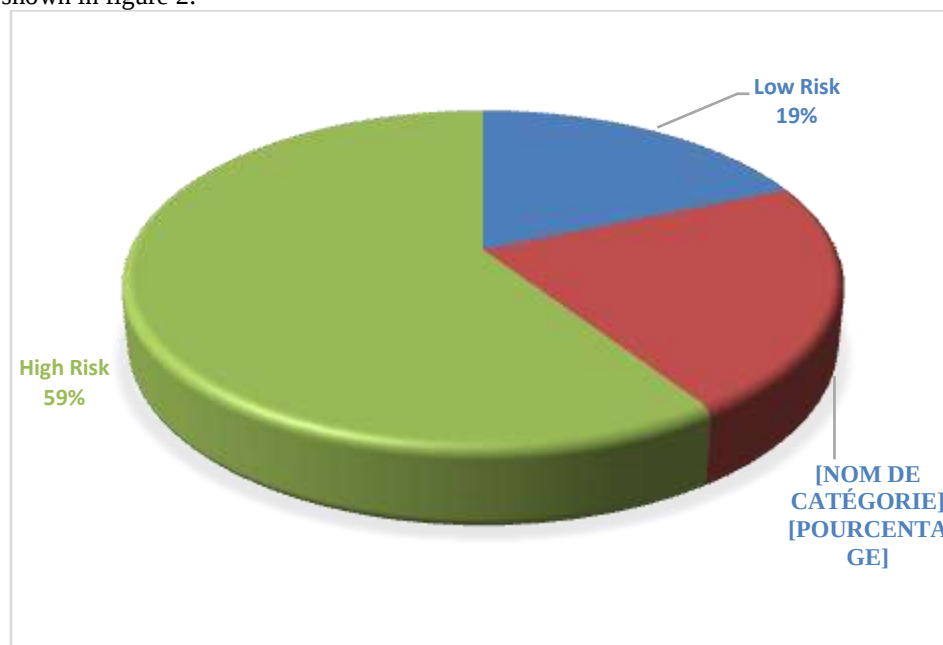


Figure 2:- Distribution according to the level of fasting risk.

This repartition allowed us to divide our population according to the profiles listed in Table II:

Parameters	Fasters	Non-Fasters
Effective number	35 (40,7%)	51 (59,3%)
Age	59,5 ± 10,21 years	57,5 ± 10,04 years
Sex M/F	8/27	12/39
Hypertension	18 (51,4%)	21 (41,17%)
Cardiac diseases	4 (11,4%)	13 (25,5%)

Kidney diseases	1 (2,9%)	8 (15,7%)
Diabetesduration	<10 years ; 24 (68,6%)	>10 years ; 33 (64,7%)
Mean HbA1c	7,9 $\pm$ 1,5%	9,1 $\pm$ 1,9%
Average blood glucose	1,4 $\pm$ 0,44 mg/L	1,86 $\pm$ 0,86
Treatment		
Diet alone	4 (11,4%)	2 (3,9%)
OAD alone	24 (68,6%)	6 (11,8%)
Insulin	3 (8,6%)	26 (51%)
Insulin+OAD	4 (11,4%)	16 (31,4%)
GLP-1	0	1 (1,9%)
Diabetic retinopathy	8 (22,9%)	17 (33,3%)
creatinine	6,2 $\pm$ 2,08 mg/l 125,4 $\pm$ 41,27 ml/mn	7,81 $\pm$ 7,8 mg/l 120,7 $\pm$ 45,5 ml/mn
Previous fasters	32 (91,4%)	29 (56,9%)

TableII:- Patient characteristics according to the IDF-DAR 2021 stratification.

Although mean glomerular filtration rate (GFR) does not seem to discriminate between fasting and non-fasting patients, a GFR < 60ml/min was not noted in low-risk patients. (Figure 3)

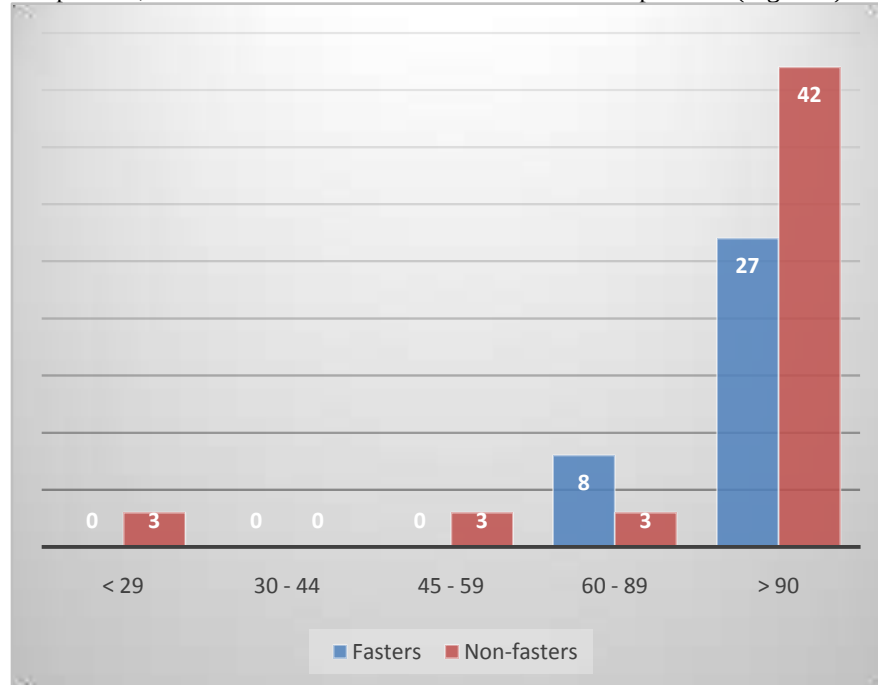


Figure 3:- Disposition according to glomerular filtration rate.

Discussion:-

Despite being a common practice situation, few studies focused on fasting risk stratification during the pre-Ramadan period.

This stratification allows us to guide the patient's choice of fasting, so the assessment must be rigorous and ultimately group patient profiles to base the decision. The IDF-DAR offers all physicians a detailed questionnaire summarizing the patient's current status.

Age:

The increasing ageing trend of our population as well as that of the Fasting-Non-Fasting sub-populations, agrees with the literature data, since age is an undeniable factor in type 2 diabetes pathophysiology (10-12)

Gender:

Like most studies, we noted a female predominance overall and in subgroups (10,11,13).

BMI:

The BMI of our fasting and non-fasting patients remains high due to its implication in the genesis of type 2 diabetes (10,13,14)

Progression of diabetes:

The evolution of diabetes beyond 10 years is closely related to severe and chronic complications which contraindicate fasting. Patients with less than 10 years of diabetes are therefore the ones can be approved after risk stratification (13,14).

HbA1c control:

Glycemic control in fasters is generally closer to target as glycated hemoglobin is central in fasting risk stratification (15,16), compared to the general population and non-fasters (10,17).

Antidiabetic therapy:

Since very complicated insulin regimens are not compatible with fasting, oral antidiabetic drugs and mono-injection insulin feature more on the charts of fasting patients (10,11,15), compared to total population (10,11,17)

Therapeutic adjustment:

Always concerned with ensuring an incident-free fasting experience especially without hypoglycemia, clinicians mostly go for therapeutic adjustment as the holy month approaches (2,18,19).

Similarly, due to the disruption of the dietary rules in non-fasting patients, therapeutic adjustment is also advised.

Comorbidities:

Type 2 diabetes is often associated with hypertension and dyslipidemia (14).

In addition, the literature has recently demonstrated the benefits of fasting on lipid profile and hypertension (13,20,21).

Cardiovascular complications:

Regarding the degenerative profile of our patients, cardiovascular disease comes first before kidney complications, which highlights the particularity of type 2 diabetes.

Cardiac pathology, once considered a major obstacle to fasting, makes now the headlines of studies, which currently approve fasting in coronary syndrome and stable heart failure. Indeed, the literature even goes so far towards attesting the benefits of fasting in reducing blood pressure and dyspnea, as well as improving volumetric expansion (20-23).

However, it is necessary to consult a cardiology team for more delicate cases (8).

Kidney disease:

Since the risk of hypoglycemia related to kidney damage can be increased by fasting, studies are focusing on this critical aspect of degenerative disease in diabetics, especially fasters (24).

Some studies support fasting for glomerular filtration rates (GFRs) > 60 ml/min, while others have explored its safety in terms of worsening long-term injury (25).

Stratification:

The current trend of stratification seems lighter and takes into consideration fasting hours, macro and microangiopathic injuries by specifying stability, detailing impairments and type of treatment.

The 2021 stratification guidelines use a cumulative score that refers to risk, this allows flexibility and customization to ensure it fits patient's condition (8,12,13).

Based on our study, there was an increased percentage of non-fasting patients who were estimated to be at higher risk in 2021 using the new guidelines compared to those in 2019. Patients with a lower risk of fasting were those with newly discovered diabetes, on oral therapy with good glycemic control and no major complications, especially renal.

Conclusion:-

New guidelines on fasting risk stratification seem to be more global and take into account several clinics, biological and environmental aspects of patients' lives. No criterion alone can formally contraindicate fasting; it is combined effects of many factors, each rated differently, that contribute to the decision of fasting. A therapeutic implementation program and an adapted healthcare are required. This new stratification method seems more flexible, nevertheless, it allowed to defer fasting in most of our type 2 diabetics with high risk.

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