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Fasa Registry on Diabetes Mellitus (FaRD): Feasibility Study and Pilot Phase Results

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Abstract

Background: Diabetes mellitus (DM) is the most common chronic disease. This disease is the main risk factor for fatal diseases such as myocardial infarction and stroke. As there is no cure for DM, an effective strategy must control it. Every attempt to control DM and patients' outcomes require a surveillance system to consider the efficacy and safety measures. Fasa Registry on Diabetes mellitus (FaRD) is the first population-based registry for DM in Iran, which aims to provide an accurate description of social, mental health, clinical, and laboratory values of patients in order to consider the management patterns of these patients and discover the degree of adherence to the recommendations. **Materials and Methods**: The level of plasma glucose characterizes the diagnosis of diabetes (Type I and II). The pregnant women were excluded from this study. Three registrar nurses collected data from demographics, physical exams, past medical history, medication history, and laboratory findings. **Results:** The pilot phase included the first 381 patients, of which 257 (67.5%) were women, and 124 (32.5%) were men with a mean age of 57.54 ± 12.12 years among subjects, the 347 (94.5%) cases had DM type 2, and 20 (5.4%) ones had type 1. **Conclusion:** Based on our results, the characteristics of patients suffering from DM indicated that the jobless ones could not afford their medical expenditures; therefore, the majority of the patients were not adherent to the practice guidelines. The achievement of FaRD helps physicians and patients in improved management of the DM. The findings of this pilot study show the FaRD is feasible, and it will make a comprehensive population-based registry for DM in the region. **[GMJ.2021;10:e2137]** **DOI:10.31661/gmj.v10i0.2137**

Keywords: Diabetes Mellitus; Registry System; Feasibility Study; Fasa

Introduction

Diabetes mellitus (DM) can be considered as one of the most common chronic diseases globally, the prevalence of which has been rising dramatically each year. From 1985 to 2017, the number of patients with DM has increased from 35 to 415 million cases worldwide. Moreover, it is estimated that 642 million people will have DM by 2040 [1]. In Iran, the prevalence of patients with DM is similar to global trends, which is 11.3-14.6% [2, 3]. Moreover, due to the Pars Cohort Study in Southern Iran, 9.9% of individuals in this

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region have DM [4]. A study showed that in Fars province, 8.31% of the population have DM, if we consider the fasting plasma glucose (FPG) as a diagnostic test, while if we change it to hemoglobin A1c (HbA1c), 9.59% of people have DM [5]. In this disease, the treatment concept is different from other diseases, such as infections, because it cannot completely be eliminated as it is incurable. At the same time, it can only be managed or be prevented from progression and developing complications. Complications of DM include two main groups of microvascular and macrovascular complications. Nephropathy, neuropathy, retinopathy, and diabetic foot syndrome are microvascular complications, while coronary heart disease, cerebral artery disease, and peripheral artery disease are macrovascular complications [6]. The remarkable point regarding these complications is that no one can expect to have these complications quickly with the onset of DM, which can show the significance and benefit of prevention.

On the other hand, the effects of different management on the incidence and severity of these complications and the effects on various aspects of the patient's life are less focused and require long-term studies with the patient follow-up. The diabetes control and complications trial (DCCT) study in the USA showed that long-term treatment of type 2 DM has a better effect on preventing macrovascular complications [7]. Another large study in the UK, the UK prospective diabetes study (UKPDS) found that long-term treatment in patients with type 2 DM had similar effects [8]. Macrovascular complications in the DCCT and the epidemiology of diabetes interventions and complications (EDIC) studies have also proven that long-term treatment has a better outcome [6, 9]. Besides, due to the lack of studies on the costs of prevention, screening, and treatment, it is impossible to comment on the compliance and majority of international guidelines in our society. Witek *et al*. [6] in very different study designs with longer follow-ups, reported that the cut-off point of HbA1c for their population is not the same as the one for which American Diabetes Association (ADA) reports yearly [10]. The Polish Diabetes Association (PDA) demonstrated that the level of HbA1c in order to confirm DM diagnosis based on clinical evidence obtained in the year 2008, should be defined as ≥6.5, while in the year 2006, this cut-off point was ≥6.1 [6]. This discrepancy may be due to the subjects' cultural, social, and lifestyle differences [11].

Consequently, as an Iranian rural population, our region may also have many differences from other areas and countries. Although the progression and burden of DM in the Middle East have been predicted by the international health organizations due to the spread of the disease in our region and a need for national health organizations on a large scale, such as health ministries and governments, especially for treatment, complications and correlations between cognitive impairment, physical activity and sleep quality, a study should be conducted to prevent further complications; therefore, this study was designed to cover all diabetic patients in the region, and enable us to identify the DM prevalence, risk factors and complications by a population-based registry, and help us organize a better plan for health policies.

Materials and Methods

Objectives

Our objectives were i) to report a full-detailed description of the baseline characteristics of patients, referred to the Fasa Diabetes Clinic (FDC) associated with Fasa University of Medical Sciences (FUMS), ii) to explore our conventional management patterns of patients iii) to investigate if global treatment guidelines are practically helpful in an Iranian population, iv) to find out the prognostic factors for patients. In this population-based study, we have reported the prevalence and incidence rate of DM in the region. We defined our objectives as the determination of correlation between age, sex, education, job, living place, sleep pattern, anxiety, depression, physical activity, medication, and DM events with the outcomes (unpublished data). The administration of this study is performed by the endocrinology department. Also, Non- Communicable Diseases Research Center (NCDRC) is related to FUMS, which funds this study. NCDRC has previously run the Fasa Registry of Myocardial Infarction (FaRMI) [12] and Fasa

Registry For Systolic Heart Failure (FARSH) [13]. Relevant research projects are granted by NCDRC in a complementary manner. The team of FaRD includes one Endocrinologist, two internists, one psychiatrist, two general practitioners, and one pharmacologist. They have been asked not to change the conventional management patterns for the patients.

Patients

Every patient who has been referred to the FDC with the diagnosis of diabetes (Type I and II) characterized by the following criteria; Hemoglobin A1c ≥6.5%, or Fasting plasma glucose ≥126 mg/dL, or Glucose tolerance test ≥200 mg/dL during an oral glucose tolerance test, or Hyperglycemia symptoms, and random plasma glucose ≥200 mg/dL has been entered our study. Fasting condition has been considered as at least 8 hours, and oral glucose tolerance test should be measured plasma glucose two hour after intake 75gr of glucose dissolved in water. The glycemic goals were recommended by ADA are 80–130 mg/dL for pre-prandial capillary plasma glucose and less than 180 mg/dL for postprandial capillary plasma glucose and less than 7% for Hemoglobin A1C [11].

The classic symptoms of hyperglycemia have been defined as polyuria, polydipsia, weight loss, and also random definition at any time of the day without considering the previous meal. All of these tests should be performed in a certified and standardized laboratory. Patients with gestational DM and Diabetes Insipidus have been excluded.

Description of the Region

FUMS is the main responsible institution of the population in the Eastern part of Fars province in Iran. It is a referral center for a population more than 250,000 in one major city and several towns and villages around it.

The Family Physician program in urban and rural regions and healthcare workers called "Behvarz" from the primary health care system of the "health houses" in towns and villages have been previously implemented in the region for several years. This health network helped our study in the first step of screening prediabetic individuals and referring them to the FDC.

Recruitment of the Registry

Three dedicated nurses, who were in charge of the registration were trained by the head of the endocrinology department of FUMS, who was the main principal investigator (PI) for two months. The Endocrinologist was responsible for approving the final DM diagnosis of the patients. Two internists also helped the PI visit the patients. Patients were registered by nurses daily except for holidays and weekends in an online form by using a computer. The data were simultaneously recorded into a university-based server with a verified firewall. In case of a challenging situation in completion of online forms and missing data, the PI endocrinologist has been available for consultation.

Collecting the Data

For phase 1, the data have been collected in seven forms as follows; Demographics, lifestyle, occupation, physical exam, past medical history, medication history, and laboratory findings. The details of these forms are shown in supplement 1, and some of them have not been published till now.

The Patients' Follow-up

As we described earlier, each patient would be scheduled for a monthly visit at the beginning of the registry. In each visit, registrar nurses would record the data with a specific focus on the occurrence of hypo/ hyperglycemia and hospitalization for any reason. If the patients did not show up at the scheduled time, the registrar nurses would interview patients or their relatives via telephone, asking their reason for not coming at the scheduled time, and would re-schedule another visit for them. If the patients passed away, the regional and national death registers would search for the cause of death, and in the case of nonsense coding, a verbal autopsy would be done by trained staff.

The Quality of the Data

All data fields are sensitive to missing values, and the nurses would be notified if they want to save the forms with empty fields. A team of research assistants help to monitor the data monthly and check their quality. Every three months, the central database is analyzed by the steering committee placed in the NCDRC.

The Progress of the Study

The protocol of this study was registered in the NCDRC on the 1st of November 2019. The first patient was enrolled on the 1st of May 2020 and patient registration will continue until 1st of May 2026.

Ethics Approval and Consent to Participate

Our study protocol has been set out along with the relevant guidelines and regulations of the region and nation. Our study protocol was also approved by the regional and national research ethics committee (the equivalence of institutional review boards) of FUMS. (IR.FUMS.REC.1399.037). It must be mentioned that at the beginning of the study, registry personnel talked with patients and described this study aims and process. Each participant is informed comprehensively, and then is asked them to fill and sign a written consent willingly. Therefore, all participants write informed consent and compliance with enrollment in this study.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author upon a reasonable request.

Statistical Methods

Our continuous data have been reported as mean ± standard deviation (SD), minimums, maximums, frequencies, and percentages (%) have been used to report discrete variables.

Results

The pilot phase included 381 patients with a mean age of 57.54 ± 12.12 years and most of them were old adults. Moreover, 67.5% of patients were female, and 85.3% of subjects among the population were married. In total, 17 (4.5%) of subjects were cigarette and/or opium and/or water pipe users. The majority of patients did not have a regular job and an income. The details of baseline demographic variables of the patients are reported in Table-1. Table-2 shows that most of the patients had DM type 2 (94.5%) and more than half of them had hypertension.

Moreover, more than 70 % of patients had overweight or obesity. Sixty-three percent of

Table 1. The Demographic Variables of Patients with DM

Variables	Frequency (%)
Gender	
Man	124 (32.5)
Woman	257 (67.5)
Marital status	
Single	23 (6.0)
Married	325 (85.3)
Widow	30 (7.9)
Divorced	2 (0.5)
Age (Mean ± SD:57.54 ± 12.12)	
Below 40 years old	37 (9.7)
Between 40 to 59 years old	163 (42.8)
Above 60 years old	181 (47.5)
Number of children	
0	44 (11.5)
1	15 (3.9)
2	36 (9.4)
3	49 (12.9)
4 or more	237 (62.2)
Education	
Illiterate	104 (27.7)
Primary school	124 (33.0)
Secondary school	62 (16.5)
Diploma	53 (14.1)
Bachelor of Science	21(5.6)
Master of Science	11(2.9)
Regular consumption of tea	337 (92.3)
Regular consumption of coffee	3 (0.8)
Current addiction	
Cigarette	11(3.0)
Opium	5 (1.3)
Hookah	4 (1.0)
Job status	
Have a Job	151(39.6)
No job	230 (60.4)
Night shift status	
Without night shifts	298 (78.2)
With night shifts	83 (21.8)

Continue in the next page

Continue of Table 1. The Demographic Variables of Patients with DM

Work time per day	
Less than 1 hour	171(74.6)
Less than 6 hours	9 (3.9)
6 to 12 hours	44 (19.2)
12 to 24 hours	5 (2.1)
Workdays in week	
Less than 1 day	166 (72.1)
1 to 3 days	6 (2.6)
3 to 7 days	58 (25.2)
Income per month	
Do not have income*	62 (19.3)
Low income	185 (57.8)
Middle income	36 (11.2)
Upper middle income	34 (10.6)
High income	3 (0.9)

*support by charities

the patients had a positive family history of DM among their first relatives, and hypertension with 43.3% had the first rank among past medical histories. More than 90% of our patients did not have a history of admission to the hospital, but in those with a positive admission history, a range of some other background diseases were found. More details on the medical records of our patients are presented in Table-2.

In Table-3, the scales of adherence to self-care in patients are presented. More than 60% of subjects expected to do regular laboratory tests and the annual eye exam had the second rank self-care factor with 60% frequency, which was followed by daily foot exam (58.3%), self-capillary plasma glucose monitoring (56.0%) and regular physician visit (52.0%), respectively.

Table-4 presents the details of anthropometric values including blood pressure in sitting and supine positions, heart rate (HR), and raspatory rate (RR) ; the average of the BMI, systolic blood pressure, and diastolic blood pressure in sitting position was 28.17 ± 5.12 kg/m2, 127.31±16.52 mmHg, and 79.72±8.94 mmHg, respectively.

The primary symptoms and their duration that were guided to diagnose DM shows in Table-5. Polydipsia and polyuria were most

Table 2. The Medical Records of Patients with DM

Variables	Frequency (%)
Type of DM	
DM type 1	20 (5.4)
DM type 2	347 (94.5)
Blood Pressure	
Normal	66 (17.3)
Elevated	45 (11.8)
Hypertension stage 1	196 (51.4)
Hypertension stage 2	53 (13.9)
Weight Status	
Underweight (BMI< 18.5)	5 (1.6%)
Healthy Weight (BMI: 18.5 - 24.9)	82 (26.4%)
Overweight (BMI: 25 - 29.9	116 (37.3%)
Obese (BMI>30)	108 (34.7%)
Family history	
Do not have Family history	127 (33.3)
In first degree relatives	240 (63.0)
In second degree relatives	14 (3.7)
History of other diseases	
Hypertension	165 (43.3)
Hyperlipidemia	151(39.6)
Hypothyroidism	33 (8.7)
Myocardial infarction	5 (1.3)
Hyperthyroidism	4 (1.0)
Others	3 (0.8)
Records of hospital admission	
Do not have admission	347 (91.1)
Cause of hospital admission	
High blood sugar	14 (3.7)
Cardiovascular disease	10 (2.6)
Diabetic ulcer	1(0.3)
Others	9 (2.4)

frequent symptoms Moreover, 43.6% of the patients had two symptoms before being diagnosed with DM, and the majority of patients had symptoms of DM for less than six months. The baseline laboratory values, glucose statistics and HbA1c target of the patients are demonstrated in Table-6 and Table-7, respectively. The mean of pre and post prandial

Table 3. Scales of Adherence to Self-care in Registered Patients

	Always Frequency (%)	Most times Frequency (%)	Sometimes Frequency (%)	Never Frequency (%)
Regular physician visit	198 (52.0)	54 (14.2)	13 (3.4)	116 (30.4)
Daily foot exam	153 (58.3)	79 (30.1)	26 (9.9)	4 (1.5)
Self PG monitoring	148 (56.0)	72(27.2)	42(15.9)	2(0.7)
Annual eye exam	156 (60.0)	70 (26.9)	33(12.6)	1(0.3)
Regular laboratory test	232 (60.9)	27 (7.1)	7 (1.8)	115 (30.2)

PG: Plasma glucose

Table 4. The Details of Anthropometric Values, Blood Pressure in Sitting and Supine Position, Heart Rate, and Raspatory Rate in Patients with DM

Variables	Mean	SD	SE	Min-Max
Height (m)	161.08	9.44	0.52	128-192
Weight (Kg)	73.06	13.71	0.72	26-165
BMI (Kg/m^2)	28.17	5.12	0.28	13.27-67.80
Waist circumferences (cm)	91.52	16.06	1.041	42-130
Hip circumferences (cm)	95.53	16.15	1.047	44-140
Wrist circumferences (cm)	18.72	1.94	0.12	13-25
Blood Pressure				
SBP (mmHg) Sup	128.75	16.83	1.2	90-180
SBP (mmHg) Sit	127.31	16.52	0.87	90-180
DBP (mmHg) Sup	79.79	10.39	0.80	10-125
DBP (mmHg) Sit	79.72	8.94	0.47	50-125
Heart Rate (BPM)	81	6.07	0.58	58-90
Respiratory Rate (1/min)	19.88	0.174	1.81	16-26

BMI: Body Mass Index; **SBP:** Systolic Blood Pressure; **DBP:** Diastolic Blood Pressure; **Sup:** Supine position; **Sit:** Siting position.

plasma glucose higher than normal range and more than 60% of patients were higher than target range.

Moreover, HbA1C showed their PG were high in three months ago. The lipid profile also shows that among men the triglyceride concentrations were high. The renal function of patients was mildly disturbed. Table-8 presents the treatment regimen of our patients. In total, 145 (38.1% of the) subjects used insulin, and 312 (81.9% of the) patients used oral agents.

LANTUS® (Insulin glargine) was the most common, which was used by 74 (19.5%of) subjects. Then, came the following insulins, 67 (17.6%), 45 (11.8%), 15 (3.9%), 11 (2.9%), 9 (2.4%), and 1(0.3% of the) patients used NovoRapid® (insulin aspart), NovoMix® (biphasic insulin aspart 30/70), Toujeo® (insulin glargine injection), Apidra® (insulin glulisine), and LEVEMIR® (insulin detemir), respectively.

In oral medications, more than half of the patients used metformin as the most frequent oral agent. Two oral agents were the most popular regimen in our patients; however, one oral agent (32.3%) regimen was the second common strategy treatment.

Discussion

DM is a multifactorial and chronic disease that involves millions of people around the world every year. Apart from suffering from DM, patients endure the cost of treatment, which is an important matter for them and governments [1].

The mean of DM cost for patients with DM

Table 5. The Primary Symptoms of DM in Registered Patients

Variables	Frequency (%)
Symptoms	
Polydipsia	176 (46.2)
Polyuria	176 (46.2)
Weight loss	104 (27.3)
Weakness	96 (25.2)
Fatigue	56 (14.7)
Others	42 (5)
No symptoms	68 (17.8)
Symptom collection	
One symptom	36 (9.4)
Two symptoms	166 (43.6)
Three symptoms	63 (16.5)
Four or more symptoms	22 (5.8)
Duration of symptoms	
Less than six months	277 (72.7)
One year	16 (4.2)
One to two year(s)	17 (4.5)
More than two years	3 (0.8)

Table 6. Laboratory Values in Registered Patients.

Variables	Mean	SD	SE	Min-Max
Pre-prandial plasma glucose mg/dL	182.83	78.68	4.19	52-668
Postprandial plasma glucose mg/dL	267.10	103.60	6.00	95-783
Hemoglobin A1c %	8.73	2.42	0.15	4.5-24.6
white blood cell count$\times 10^3 \mu$/L	7.02	2.12	0.28	2.9-13.5
Red blood cell count$\times 10^{12}$/L	4.85	0.69	0.09	3.49-6.75
Hemoglobin g/L	12.66	1.54	0.21	8.8-16.3
Mean corpuscular Hemoglobin pg/cell	28.69	8.93	1.33	17.7-76.9
Mean cell volume fl	78.76	12.88	1.85	28.1-94.3
Red blood cell distribution width %	14.53	2.63	0.43	11.8-24
Platelet count$\times 10^9$/L	253.36	55.16	8.31	149-386
Cholesterol mg/dL	169.25	45.48	2.74	73-319
Low density lipoprotein mg/dL	94.88	48.2	3.25	27-505
Triglycerides mg/dL	172.20	102.89	6.19	38-887
High density lipoprotein mg/dL	46.34	16.86	1.13	24-178
Blood urea nitrogen mg/dL	16.44	6.81	0.56	7-61
Creatinine mg/dL	2.83	3.04	0.22	0.7-9.6
Glomerular filtration rate mL/min/m^2	58.36	37.99	2.90	5.01-194.2

Table 7. Glucose Statistics and Target in Patients with DM

Variables	Frequency (%)
Pre-prandial capillary plasma glucose N=352	
Hypoglycemia (level 1)	3 (0.9)
Under target range	5 (1.2)
Target range (80–130 mg/dL)	85 (22.3)
High plasma glucose	259 (68)
Postprandial capillary plasma glucose N=298	
Target range (<180 mg/dL)	64 (16.8)
High plasma glucose	234 (61.4)
Hemoglobin A1C N=220	
Target range <7%	39 (10.2)
Above 7%	181 (47.5)

Table 8. Medications were Recommended to Registered Patients.

Drug	Frequency (%)
Insulin	147 (38.6)
LANTUS®	74 (19.5)
NovoRapid®	67 (17.6)
NovoMix®	45 (11.8)
Toujeo®	15 (3.9)
Apidra®	11(2.9)
LEVEMIR®	9 (2.4)
Oral	312(81.9)
Metformin	208 (54.6)
Gliclazide	93 (24.6)
Zipmet® (Metformin +Sitagliptin)	73 (19.2)
Acarboz	66 (17.3)
GlibenClamide	35 (9.2)
GloRipa® (Empagliflozin)	31(8.1)
Ropixon® (Rosuvastatin)	11(2.9)
Others	51 (13,5)
Combination Therapy	
One oral agent	123 (32.3)
Two oral agents	127 (33.3)
Three oral agents	54 (14.2)
Four oral agents	8 (2.1)
One type insulin	72 (18.9)
Two type insulin	75 (19.7)
Basal Insulin + one oral agent	40 (55.6)
Basal Insulin + two oral agents	20 (27.8)
Basal Insulin + three oral agents	5 (6.9)
Basal Bolus Insulin + one oral agents	20 (26.7)
Basal Bolus Insulin + two oral agents	6 (8)
Basal Bolus Insulin + three oral agents	1 (1.3)

increases 70% annually.
Moreover, the cost of hospitalizations for each patient per year is more than 7,000 US dollars (USD) in China [14].
Other international registry programs as well as FaRD significantly decrease incidences of complications, mortality and cost of DM. For example, after five years, cost of DM was more than 7,200 (USD) less for each patient in the United States of America [15]. It has been estimated that the direct medical cost of diabetes in Iran is more than 4 billion (USD) per year [16]. The results of this study show that the patients who do have income, their plasma glucose is not under control. This is indicative that the patients cannot afford medical costs of their disease.
Therefore, real world insights about the specific characteristics of these patients is to manage the DM in order to decrease hospitalizations and complications of this disease. FaRD will provide the specific database to collect the details of demographic characteristics, clinical and laboratory findings of patients with DM to better controlling of their disease in order to reduce the rate of complications and mortality. FaRD provides a comprehensive range of characteristics related to DM. Hypertension and hyperlipidemia have been respectively the two medical conditions with the greatest positive correlation with DM found in this study. The well-being of the population is the main duty of the local medical university. Therefore, medical education and health improving indices must be provided by the FDC. The main strength of the FaRD is having a detailed data acquisition from multiple aspects. Unpredicted minimal missing data, selection bias due to lack of randomization, modest study population compared to the national population and current unstable conditions emanating from the coronavirus disease of the year 2019 (COVID-19) pandemic, though temporary, are limitations of this DM registry. Finally, the frequencies of chronic complications of DM in order to compare with the current status will be recorded during this study. It is recommended to register DM patients at the national level.

Conclusion

The base of the aforementioned framework of the population-based registration of DM cases in Fasa was feasible and the results of the pilot phase have been promising.

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All authors have read and approved the manuscript. This study has been extracted from the thesis of Dr. Aliasghar Karimi's residency course under advisor of Dr.Babak Pezeshki and was found to be in accordance to the ethical principles and the national norms and standards for conducting Medical Research in Iran.
The preprint of this paper is available here: https://www.researchsquare.com/article/rs-70131/v1

Conflict of Interest

The authors declare that they have no competing interests.

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