

Physicians' Perspectives of Barriers to Insulin Initiation for Adults with Type 2 Diabetes Mellitus in Primary Health Care Centers (PHCCs), Tabouk Province - Kingdom of Saudi Arabia (KSA)

Sameh F. Ahmed, MSc, MD(1), Ghurmallah A. Alghamdi, SBFM(2), Amerah A. Albalawi, SBFM(1), Majed S. Alqahtani SBFM(3), Ibrahim M. Ghonim, EBFM, MRCGP(1), Hoda M. Elhady, EBFM, MRCGP(1) Shima A. Abdelhamid, MRCGP, EBFM(1) Abderahman A. Eldesouky, M.B.Bch(1)

(1) Department of Public Health, MOH, Tabouk Health Region, KSA.

(2) General Health Affair, Tabouk Health Region, KSA.

(3) Diabetes Center, King Fahd Specialized Hospital, Tabouk, KSA.

Corresponding author:

Sameh Fawzi Ahmed, MBBS, MSc, MD,

Consultant Family Physician, Department of Family Medicine, MOH, Tabouk, Saudi Arabia

Department of Family Medicine, Suez Canal University, Egypt

Cell phone: +966-581803197

Email: sfmahdi3691@gmail.com

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Abstract

Aim: The goal of this study is to explore the family physicians' perspectives of the barriers in initiating insulin for adult patients with Type 2 diabetes mellitus (T2DM) in their primary health care settings.

Background: Insulin therapy often becomes necessary when oral anti-hyperglycemic agents are not enough, no longer effective or even as an initial choice. Timely insulin initiation was noticed to be a clinical problem among people with type 2 diabetes mellitus (T2DM) registered in primary health care centers (PHCCs) of Tabouk Province, KSA. Tackling this inertia or insulinophobia is a challenge in order to delay or prevent serious complications of uncontrolled diabetes. Our study and many other studies indicated that this therapeutic inertia is inappropriately due to many patient, system and physician-related factors. The present study aimed to investigate physicians' perspectives of barriers to insulin initiation for adults with T2DM registered in PHCCs, Tabouk Province - KSA and to identify opportunities for better outcomes.

Materials and Methods: This is a cross sectional study where 102 primary health care physicians (PHCPs) (58 females and 44 males) from multi PHCCs in Tabouk Health Province – Kingdom of Saudi Arabia (KSA), responded correctly to online reliable self-administered questionnaire (Cronbach alpha of 0.77344) to address their perspectives of barriers to insulin initiation for adult patients with T2DM. All participants were physicians attending PHCCs with well-equipped diabetes care clinics. Data were collected during a

period from 6th – 17th June 2021. Participants included 11 (10.8%) family medicine consultants, 14 (13.7%) family medicine specialists and 77 (75.5%) general physicians.

Results: 68.6 of the study participants had barriers in initiating insulin for their patients with T2DM. A significant statistical disproportional correlation was found between the level of specialty and the rate of reporting barriers to insulin initiation ($P < 0.001$). The top 10 listed barriers included the following: patients' refusal to initiate insulin (71.4%), physicians' fear of hypoglycemia (51.4%), inability of patients to perform home blood glucose monitoring (HMGM) (50%), physicians have no access to second opinion (44.3%), insufficient educational courses for physicians (37.1%), no family support for patients (34.3%), no clear MOH circular to support physicians' initiation of insulin at PHCCs (28.6%), insufficient hypoglycemic medications at PHCCs (25.7%), inability of patients to manage hypoglycemia (24.3%), and patients' noncompliance to insulin regimen (24.3%).

Conclusion: Despite the free of cost availability of all types of insulin, including the safest and peak less ultra-long (degludec) and long (Glargine), the availability of free of cost glucometers for all people with diabetes, the presence of a well-equipped diabetes clinic at every PHCC, the long list of guidelines and educational courses as well as an appointment system with electronic health information system (HIS), insulin inertia is a common problem among PHCPs working in Tabouk Health Region.

Key words: Barriers, insulin initiation, insulin, primary health care, type 2 diabetes mellitus.

Introduction

Globally, diabetes mellitus is a leading cause of mortality and reduced life expectancy with growing prevalence especially in the Middle East. In 2017, global incidence, prevalence, death, and disability-adjusted life-years (DALYs) associated with diabetes were 22.9 million, 476.0 million, 1.37 million, and 67.9 million, with a projection to 26.6 million, 570.9 million, 1.59 million, and 79.3 million in 2025, respectively. Estimated years of life lost (YLL) due to diabetes is 109,707 years, while estimated quality adjusted life years loss (QALY) is 133,054 years with overall economic burden that reaches 842 million \$ including direct and indirect costs (1).

The World Health Organization (WHO) has reported that Saudi Arabia ranks the second highest in the Middle East, and is seventh in the world for the prevalence of diabetes. It is estimated that around 7 million of the population are diabetic (13.4% of individuals aged 15 years and above) and almost around 3 million have pre-diabetes (2).

In 2014, the health care budget in KSA was 180 billion (Saudi Riyal) of which 25 billion was spent on the entire Saudi diabetic population. This implies that the direct expense of diabetes is costing Saudi Arabia around 13.9% of the total health expenditure (3).

The UKPDS Post Trial Monitoring Study, comprising 5102 patients, showed that intensive control of glycated hemoglobin (HbA1c) from the time of diagnosis can reduce the risk of myocardial infarction, and mortality in general (4). These data are also supported by the results of the ADVANCE and VADT studies in which patients on intensive treatment who reached lower HbA1c values had lower risk of developing both micro and macro vascular complications (5-7).

Despite increase in the availability and safety of insulin and evidence-based treatment guidelines, worldwide over the past decade, a significant proportion of people with type 2 diabetes (T2DM) fail to achieve glycemic goals. For example, in the USA, the proportion of patients who achieved the American Diabetes Association (ADA) recommended target of glycated hemoglobin A1c below 7.0% declined from 52.2% between 2007 and 2010 to 50.9% between 2011 and 2014 (8).

Similarly, a further study performed in 2018 in Spain showed that therapeutic inertia was seen in 26.2% of patients with HbA1c>7% and 18.1% of those with HbA1c>8%, with issues of non-intensification occurring after a median follow up of 4.2 years (9). In KSA only one third of patients with T2DM have optimum glycemic control (8).

Insulin treatment often becomes necessary due to the progressive nature of type 2 diabetes, when oral anti-hyperglycemic agents are not enough, or even as an initial choice. This problem of uncontrolled T2DM is partly due to inappropriate or delay in timely initiation of insulin. In our study and many other worldwide studies this therapeutic

inertia or insulinophobia is shown to be multifactorial and mainly due to patient, physician, and system-related factors (10).

This therapeutic inertia was noticed among many uncontrolled people with T2DM registered in PHCCs in Tabouk, KSA. Tackling this therapeutic inertia is a challenge in order to generate appropriate policy initiatives to improve the effectiveness of PHCPs in timely controlling diabetes and reducing the individual, social and economic burden of this serious disease.

Material and Methods

Type of study: qualitative cross sectional study

Study population: PHCPs working in MOH, Tabouk Province

Sample size and selection:

275 PHCPs are working in Tabouk Health Province. Using a confidence level of 95% and a marginal error of 5%, sample size was estimated by online sample size calculator to be 147 PHCPs(11). Questionnaires were distributed to all PHCPs working in PHCCs in Tabouk Province, Saudi Arabia to avoid any expected low response due to summer annual vacations. After 2 weeks 150 physicians returned their answers giving a response rate of 54.5%. Only 102 questionnaires were included in data analysis after exclusion of physicians with less than one year experience in PHCCs and physicians who filled in the questionnaire incorrectly. The questionnaire encompassed data as regards physicians' demographic details, years of experience, job classification according to Saudi Commission for Health Services (SCFHS), and types of barriers to the initiation of insulin (physicians', patients' and system's related barriers). The inclusion criteria were all physicians who are working in PHCC with diabetes clinics for at least one year.

Measurement tool:

A self-administered questionnaire was used among 102 PHCPs to explore physicians' perspectives of barriers in initiating insulin for adults with T2DM. The questionnaire was adapted from the PAINT questionnaire of the Japanese DAWN study (12) and was reviewed by 4 consultant family physicians and a clinical research expert working in Tabouk. A pilot study of 20 PHC physicians was done to assess the reliability of this questionnaire in our community. The internal consistency of the 20 responses collected was found to be good, with Cronbach alpha of (0.77344).

Sources of bias:

-Interpreter bias: To overcome this bias, an explanatory covering letter was attached to questionnaires and respondents were requested to call back the researchers if they have any ambiguities.

-Missing values: any missing value was excluded from data analysis.

Ethical issues considerations:

The cover letter of the questionnaire clarified the objectives of the study and the assurance of confidentiality. Study protocol was approved by the Institutional Review Board, Regional Directorate of Health Affairs, Tabouk Region, Saudi Arabia (Registration No. H-07-TU-077). Verbal informed consent was received from each participant before the study.

Statistical Analysis

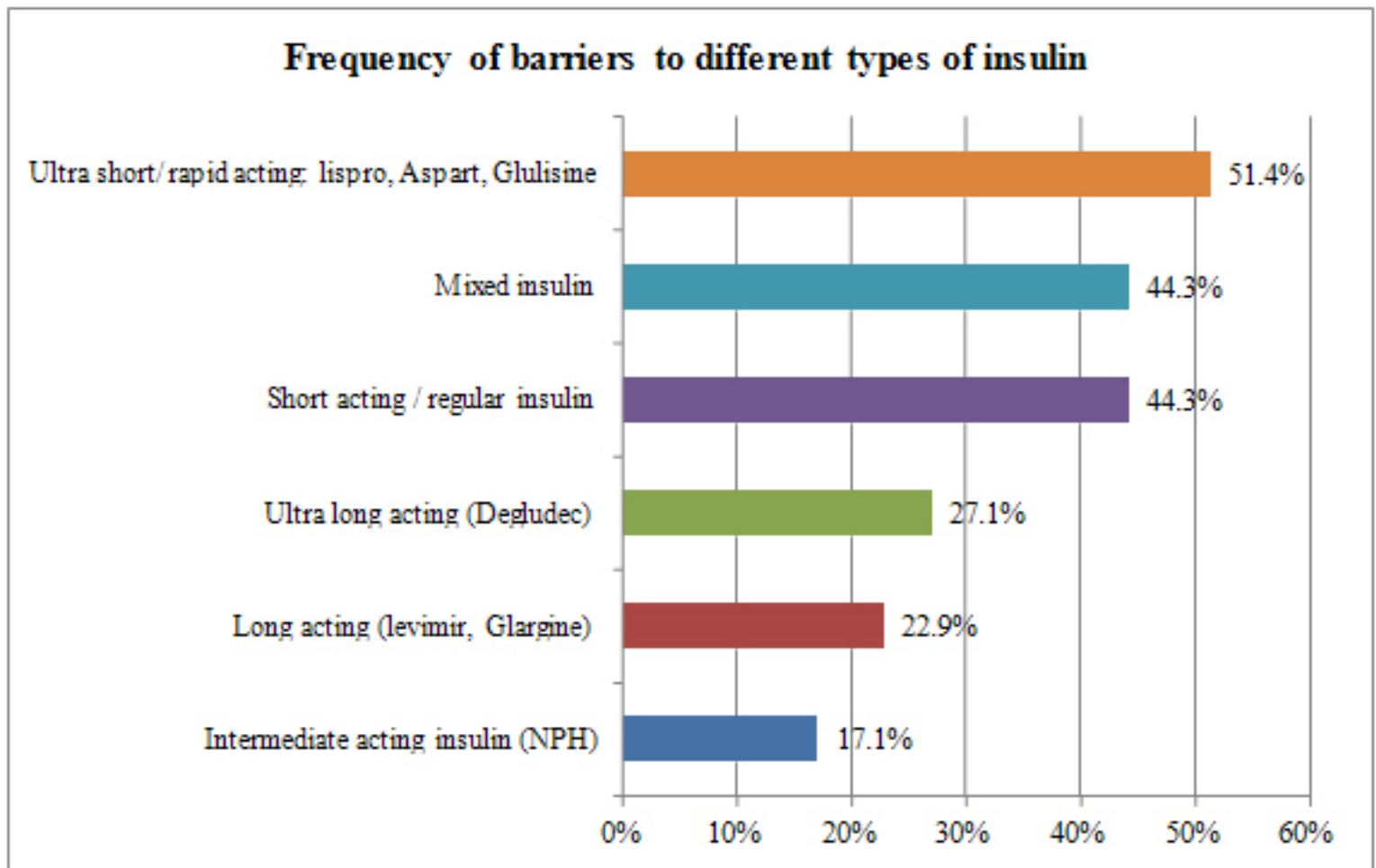
Recorded data were analyzed using the Statistical Package for Social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Appropriate statistical analytical techniques were performed. Frequency distribution tables were constructed with mean and standard deviation. Significant level was set at less than 0.05 throughout the study. Independent t-test, Pearson correlation coefficient and Chi-square were used to examine the association between each independent variable and each outcome measure.

Results**Table 1: Demographic and individual characteristics of participants**

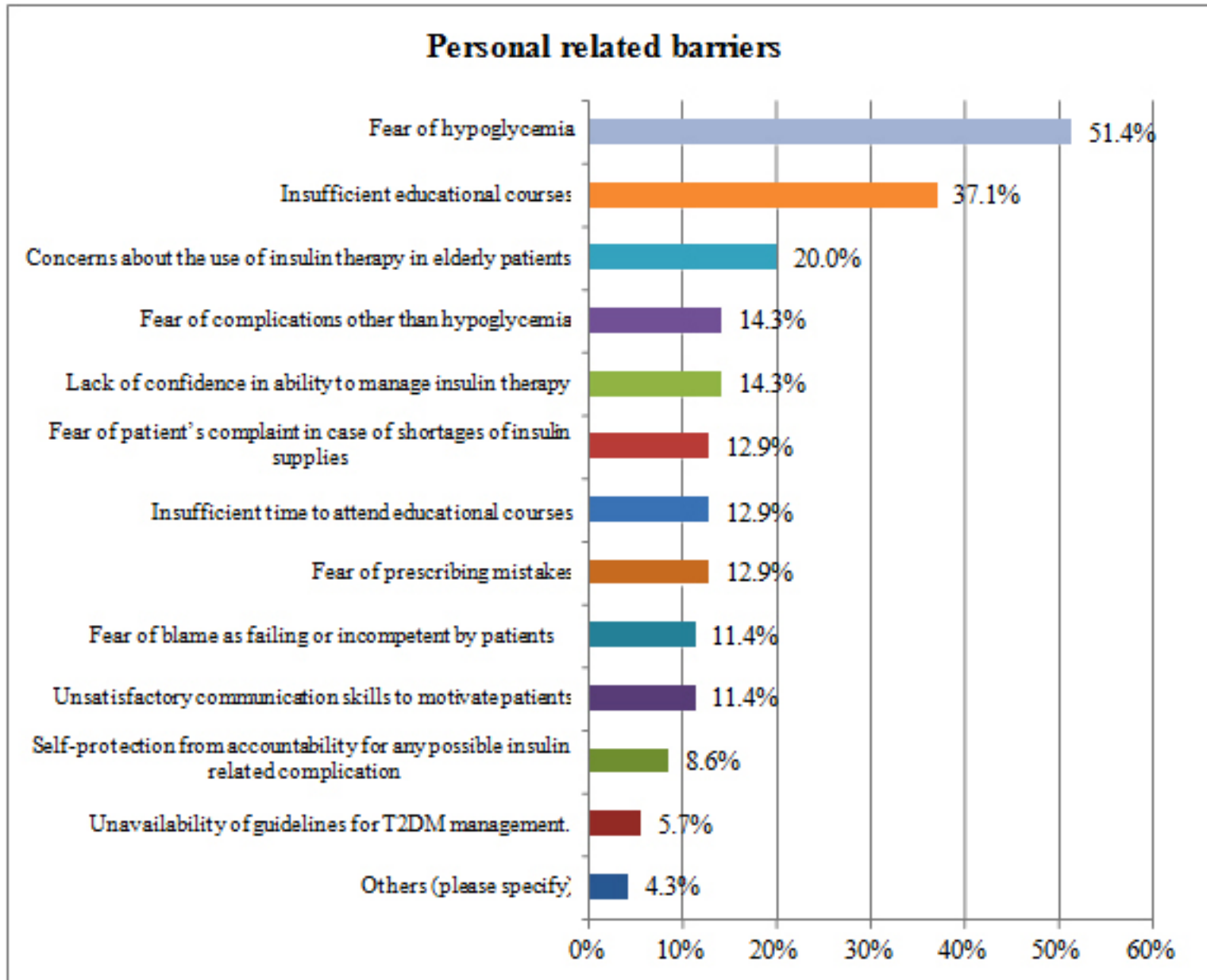
Demographic data	No.	%
Age (Group)		
<30 years	8	7.8%
30-<40 years	63	61.8%
40-<50 years	24	23.5%
50-60 years	7	6.9%
Sex		
Male	44	43.1%
Female	58	56.9%
Job title		
General physician	77	75.5%
Specialist	14	13.7%
Consultant	11	10.8%
Years of experience in PHC of MOH (KSA)		
<2 years	30	29.4%
2-5 years	18	17.6%
5-10 years	37	36.3%
≥10 years	17	16.7%
Nationality		
Saudi	5	4.9%
Non- Saudi	97	95.1%
Name of the PHC center/health sector		
Urban	79	77.5%
Rural	23	22.5%

The present study included 102 participants (43.1 % male and 56.9% female).

4.9% of physicians were Saudi and 95.1% non-Saudi. The majority of participants were general physicians (75.5 %), while specialists and consultants were 13.7 % and 10.8 % respectively. 70.6% of these participants have a cumulative experience of more than 2 years in providing family health care in KSA.

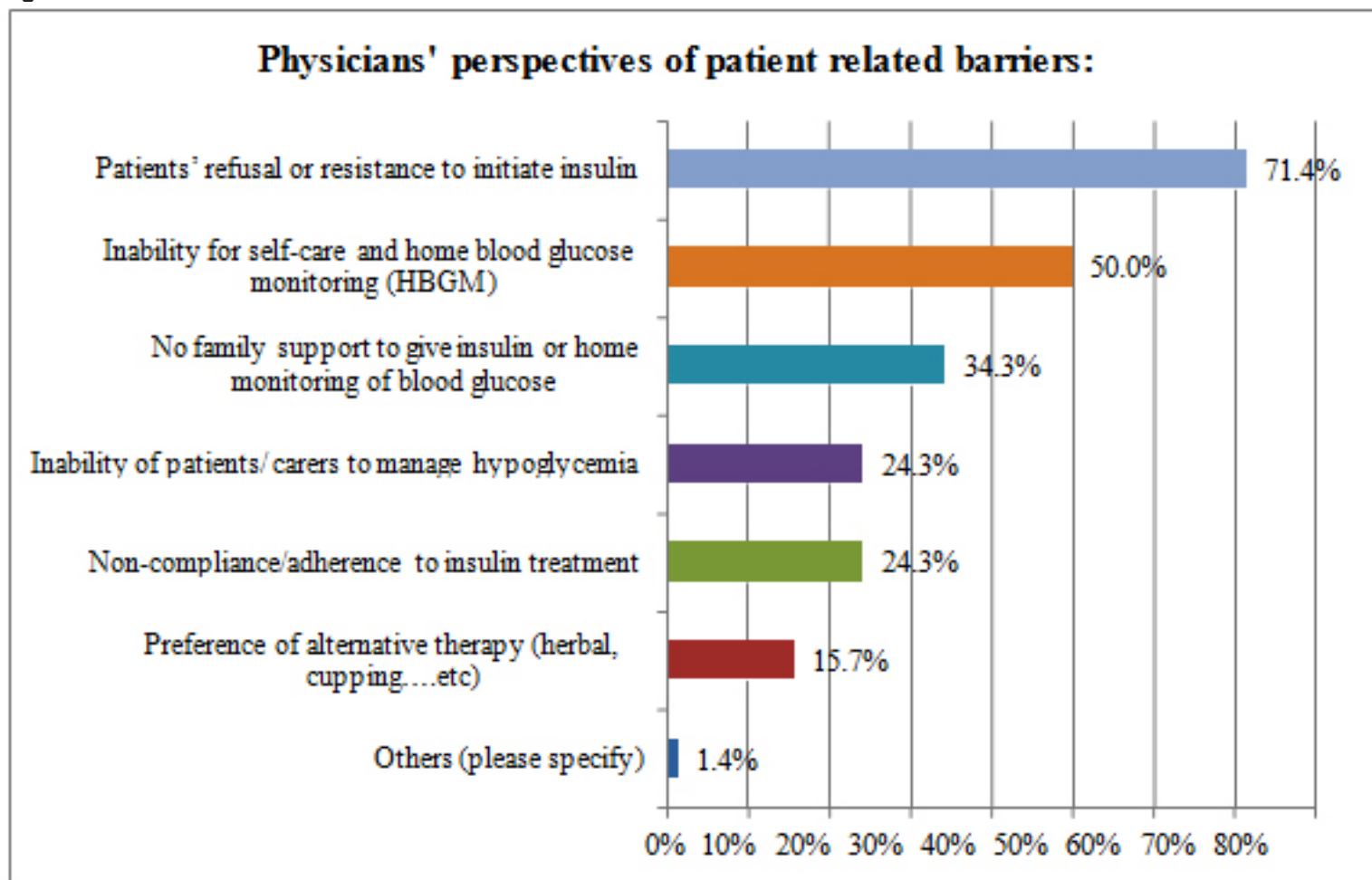
Figure 1: Barriers to specific types of insulin

51.4 % and 44.3% of participants expressed barriers to initiate ultra-short and rapidly acting insulin respectively, followed by mixed insulin (44%), ultra-long (27%), long acting (22%) and 17% for NPH insulin.

Figure 2: Physician related barriers to the initiation of insulin

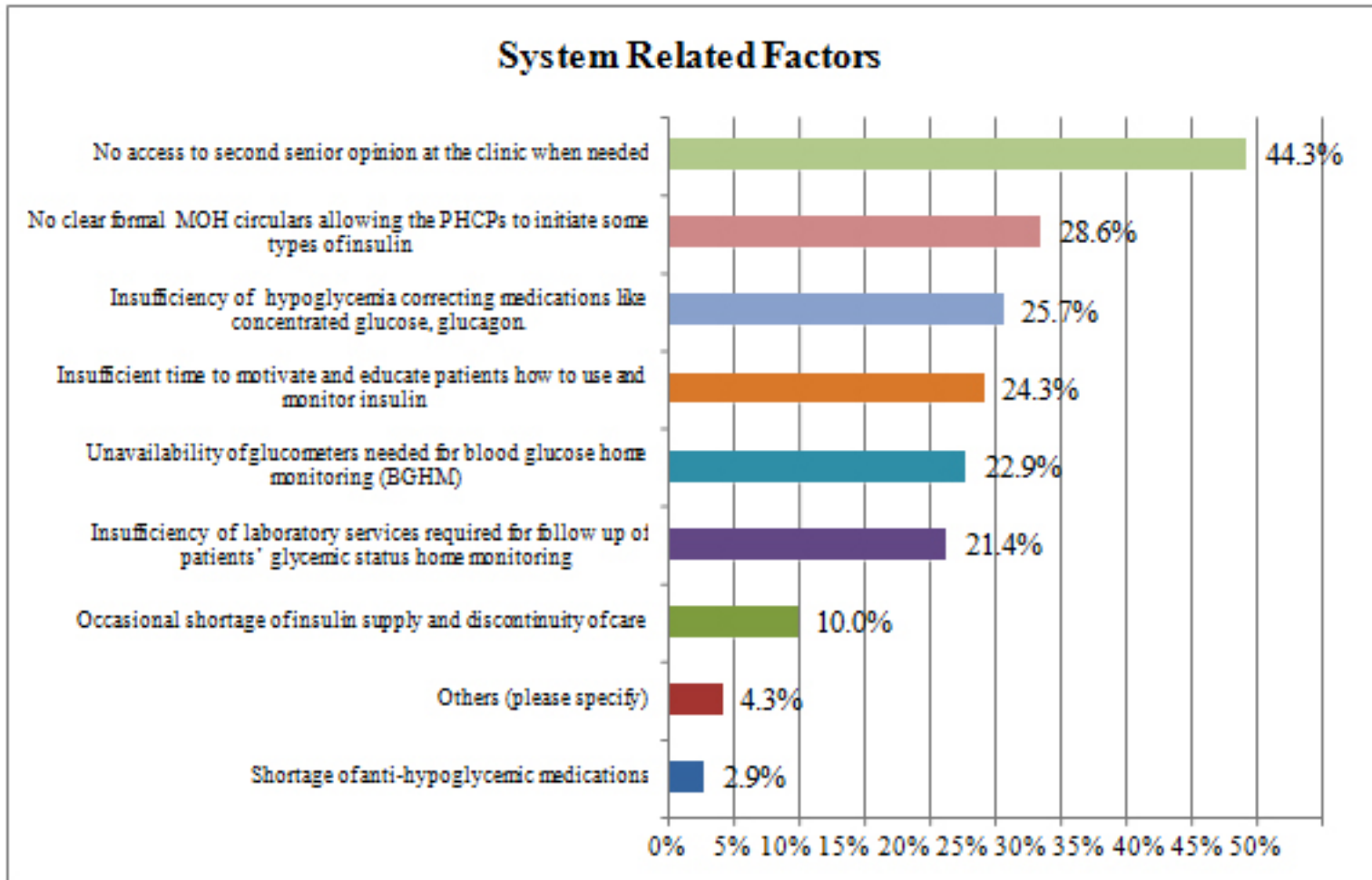
68.6% of participants reported barriers in initiating insulin. The most frequently reported personal barriers were fear of hypoglycemia (51.4 %) followed by insufficient educational courses (37.1 %), and use of insulin in elderly people (20 %). The list of personal barriers also included fear of complications other than hypoglycemia (14.3%), insufficient confidence in initiating insulin (14.3%), fear of patients' complaints in case of insulin supply shortage (12.9%), insufficient time to attend educational courses (12.9%), fear of prescribing mistakes (12.9%), fear of patients blaming them in case of failure (11.4%), unsatisfactory communication skills to motivate patients (11.4%) and only 5% expressed concerns regarding diabetes management guidelines.

Figure 3: Patient related barriers



The most frequently reported patient related barrier was patients' refusal or resistance to initiate insulin (71.4 %) followed by inability of self-care and home blood glucose monitoring (50%) and no family support in giving insulin or monitoring of home blood glucose (34.4 %). Other patient related barriers included fear from inability of the patient or family to manage hypoglycemia (24.3%), noncompliance to insulin regimen (24.3%) and preference of alternative medicines and procedures like herbal and cupping (15.7%).

Figure 4: Health system related barriers



The most frequently reported system barrier was no access to second senior opinion at the health center (44.3 %) followed by no clear MOH circular to allow physicians to initiate some types of insulin (28.6%) and insufficiency of anti-hypoglycemic medications (25.7%). Other system related barriers included insufficient time to motivate patients (24.3%), unavailable glucometers for HBGM ((22.9%), insufficient laboratory services required for follow up of patients (21.4%) and discontinuity of care due to occasional interruptions of insulin supply (12.9%).

Table 2: Correlation between barriers to initiate insulin and some personal characteristics

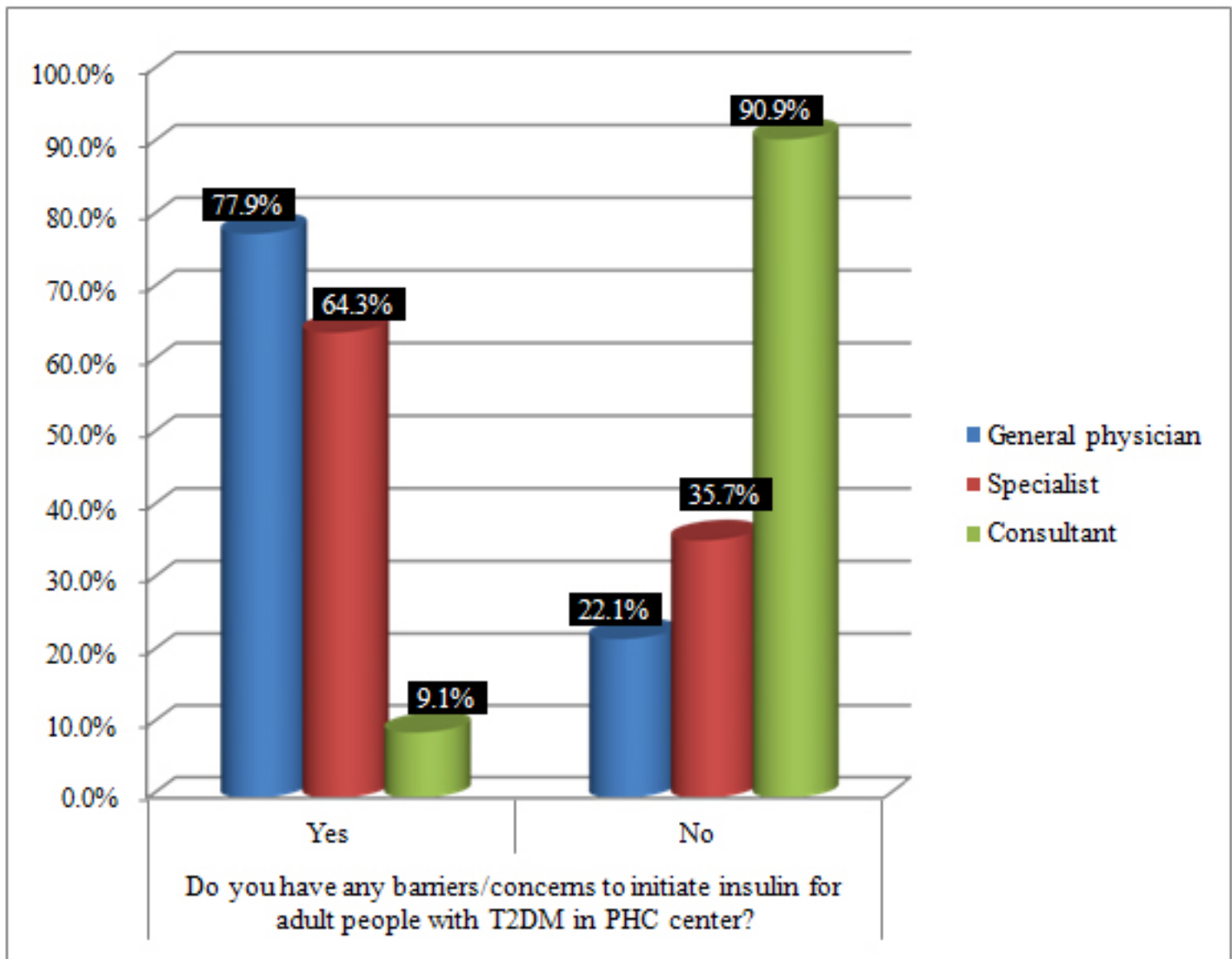
Demographic data	Do you have any barriers/concerns to initiate insulin for adult people with T2DM in PHC center?				Total	Chi-square test	
	Yes (n=70)		No (n=32)			No.	x2
	No.	%	No.	%			
Age (Group)							
<30 years	6	75.0%	2	25.0%	8	FE	0.165
30-<40 years	47	74.6%	16	25.4%	63		
40-<50 years	12	50.0%	12	50.0%	24		
50-60 years	5	71.4%	2	28.6%	7		
Sex						1.459	0.227
Male	33	75.0%	11	25.0%	44		
Female	37	63.8%	21	36.2%	58		
Job title						FE	<0.001**
General physician	60	77.9%	17	22.1%	77		
Specialist	9	64.3%	5	35.7%	14		
Consultant	1	9.1%	10	90.9%	11		
Years of experience in PHC of MOH (KSA)						5.163	0.16
<2 years	24	34.3%	6	18.75%	30		
2-<5 years	14	20%	4	12.5%	18		
5-10 years	23	32.9%	14	43.75%	37		
≥10 years	9	12.9.9%	8	25%	17		
Nationality						FE	0.574
Saudi	4	80.0%	1	20.0%	5		
Non- Saudi	66	68.0%	31	32.0%	97		
Type of the PHC center						0.385	0.535
Urban	53	67.1%	26	32.9%	79		
Rural	17	73.9%	6	26.1%	23		

Using: Chi-square test & Fisher's Exact test

Table (1) presented that, there were only significant disproportional relations between barriers to initiate insulin and the job title at (p-value <0.001).

There was no significant statistical correlation between having barriers to initiate insulin and years of experience in providing family health care in KSA, sex, age or whether the participant works in rural or urban family health center. Only 9.1% of consultants expressed barriers to insulin initiation, which was statistically significant (P<0.001) lower than both specialist and general physicians (64.3% and 77.9 % respectively).

Figure. 5: Relation between barriers to initiate insulin to job title



Discussion

Diabetes mellitus is a common chronic disease characterized by high incidence of micro and macro vascular complications with social, economic and health burden. Numerous studies have shown that optimizing metabolic control may reduce these risks, but unfortunately glycemic control in diabetic patients is often inadequate mainly due to the phenomenon of insulin inertia or insulinophobia which has been studied for almost 20 years (10).

Insulin inertia was noticed among patients with T2DM registered in PHCCs of Tabouk Province, KSA. Overcoming this problem is a key step in improving long-term care for people with T2DM. This requires an understanding of provider, patient, and healthcare system barriers that need to be addressed together, rather than as separate entities (10,13).

To the best of our knowledge, the present study is the first cross section study that has addressed insulin inertia among PHC physicians in KSA with its unique feature of involving more FM specialists and consultants (24.5% of total participants) in addition to general physicians (75.4%)

who work in PHCCs with diabetes clinics. Also most of the participants in the present study were non Saudi (95%) which reflects the reality of manpower of physicians working in PHCCs in Tabouk Province. This is in contrast to a similar Saudi study where Saudi physicians were (88,2%) and most of them were general practitioners (86.3%), specialists were (10 %) and consultants were only (3,8%).

(14). Another similar Saudi study involved mainly Saudi citizens and only 19.1% of them had postgraduate qualifications (15). We claim that these differences gave our study more reliability in exploring PHC physicians' perspectives of barriers to insulin initiation for patients with T2DM.

In our study 150 PHCPs timely answered and returned the questionnaires with 54.5% response rate. This is in contrast with another two similar Saudi studies (14,15) , where the overall response rate was 100% and 84% respectively. The low response rate in our study might be due to the time of distribution of questionnaires coincides with summer annual vacation of many physicians. In spite of this low response rate we reached the estimated sample size.

In our study 70.6% of physicians have cumulative experience of more than 2 years in PHCCs. This finding is consistent with two other similar studies: the Japanese study (DAWN) where most physicians had experience with insulin therapy and a similar Saudi study where 59.7% of physicians had experience from 0-5 years (14). But counter to these findings, in another Saudi study, half of the physicians reported that they have no experience with the initiation of insulin (15).

In the present study and as reported by many other studies, clinical inertia is multifactorial, with a range of contributing factors from patients, clinicians, and the healthcare delivery system (14-17). Almost all authors agree on the clinician's greater responsibility as a cause of inertia (18).

68.6% of physicians in our study addressed barriers to insulin initiation. This finding is higher than the global figure of insulin inertia that affects approximately one-third of patients with T2DM, but consistent with what has been stated by Lakkis et al where 73.6% of family physicians had insulin therapeutic inertia (16). In another study 29.6% of general physicians reported that insulin may not be needed for patients with T2DM initially irrespective of their blood glucose level (17). In a similar Saudi study, about 63.5% of physicians were neutral to barriers related to physicians, while 14,2% agreed and 22,3,% disagreed to presence of barriers (14).

Furthermore, 95.7 % and 44% of participants in our study addressed insulin inertia for short or rapidly acting insulin and premixed insulin respectively, but unexpectedly 27% and 22% of physicians expressed barriers to initiate the safest and peakless types of insulin, namely, ultra- long (like Deglutec) and long (like Glargine) respectively. We claim that this inertia might be partially improved if second specialist opinion is accessible especially for the initiation of short and rapid acting types of insulin. This claim is based on the findings that 44.3% of physicians in our study addressed the inaccessibility of a second specialist opinion as a barrier for insulin initiation. This explanation is supported by another study where 37% of general physicians expressed their need for a second opinion to initiate insulin for patients with T2DM (17).

The present study also revealed a highly significant disproportional correlation between the qualification level and the presence of insulin therapeutic inertia ($P < 0.001$). This is in concordance with the findings of the Japanese study (DAWN) where initiation of insulin was higher among PHC physicians with family medicine postgraduate qualifications (JDS-certified specialists and non JDS-affiliated physicians) (12). Another study in France found that early (versus late) initiation of insulin therapy was 9.9 times more likely to be prescribed by specialists than by a primary care physician ($P < 0.0001$) (19). Other Saudi studies reported similar findings (14,15). Accordingly health care policy makers in Tabouk, KSA need to recruit more family medicine specialists and consultants where they do not exceed 8% of the current PHC physician's work force. On the other hand our study did not state

any correlation between insulin inertia and factors like physician's age, sex, nationality, years of experience or whether the place of work is urban or rural. Counter to these findings, a similar study conducted in Jeddah, KSA by Randa et al. reported significant correlation between physician barriers and their age and years of experience (14). Absence of these logic correlations in our study needs further analysis.

In our study, in spite of the availability of safe and peakless types of insulin, the most frequently reported physician barriers to insulin initiation was fear of hypoglycemia (51.4 %) or fear of inability of the patient or family to manage hypoglycemia at home (24.3%). These findings are consistent with another Saudi study where 71.2% of physicians were worried about hypoglycemia when they initiate insulin (15). Moreover, the most commonly cited barriers to insulin initiation for physicians included hypoglycemia (20).

In our study insufficient home blood glucose monitoring (HBGM) due to lack of family support (34.4%) or unavailable glucometers (22.9%) were reported by 50% of physicians as a barrier to insulin initiation. In a similar Saudi study 45.0 % of physicians agreed that Lack of family support is a barrier to start insulin (14). We claim that unavailability of home glucometers were recently fixed with free access for all patients with diabetes in Tabouk Province. We believe some other reasons behind our physicians' concerns with the barrier of insufficient HBGM might include time constraints for health education and motivation of patients a barrier that has been reported 24.3% of physicians. Time constraints were commonly cited as a source of clinical inertia (14),

It is necessary for physicians to recognize that time spent to educate patients to avoid clinical inertia will ultimately save time, costs, and resources by reducing complications (18,21,22).

In this context we also believe that the National Health System should promote and facilitate chronicity management methods in line with technological advances, making use of telemedicine systems capable of guaranteeing the exchange of data and information between the healthcare facility and the patient (23).

In our study insufficient educational courses of diabetes was reported by 37.1 % of participants, but only 5% expressed concerns regarding updated diabetes management guidelines as barriers for insulin initiation. Although evidence-based target guidelines are generally seen as "enablers" for primary care practitioners, their potential for improving clinical inertia is limited (24,25). Similar findings have been reported in another study where physicians expressed lack of knowledge, lack of experience with and use of guidelines related to insulin therapy as a barrier to the initiation of insulin (14,26,27,28). Several studies refer the condition of "non-adherence" of the clinicians to the guidelines as a behavioral problem, because making therapeutic decisions is a complex task that involves a variety of cognitive processes (29).

Andreozzi addressed that with adequate training, clinicians can evaluate their own performances, identify critical areas and adopt suitable strategies to overcome their barriers (10). An effective approach would be to provide HCPs with a concise and readily accessible central resource, e.g., the “Wise List” in Sweden, which summarizes the recommended core medicines that should be used in the treatment of common diseases such as diabetes (30). Several studies have documented that monitoring of physician’s prescribing behavior with active feedback is very effective in improving insulin inertia (31).

37.2% of physician related insulin inertia to barriers like blaming of insulin shortage, prescribing mistakes and failure to control diabetes. We claim that this behavior is a defense of some physicians who try to avoid any intervention that may threaten their existence in a job especially as most participants are non-Saudi. This assumption needs further analytical research.

Both lack of communication skills and non-confidence were reported by 14.3% and 11.4% of our participants respectively as barriers to initiate insulin for patients with T2DM. These levels are much lower than what has been reported in another Saudi study where they were barriers for about a third of physicians(14).

20% of physicians in our study expressed barriers to initiate insulin for senior people. This is in contrast to the findings of a Canadian study which reported old age (60-69 years) as a factor strongly associated with early initiation of insulin (32).

In our study, the most frequent patient related barrier stated by physicians was refusal or resistance to initiate insulin (71.4 %). In contrast with another Saudi study where one quarter (24.4%) of the diabetic patients refused insulin. This study also showed different causes for their refusal including: fear of injection, pain, insulin injection needs help from others, fear of hypoglycaemia and embarrassment(33).

A literature review done by Jennifer et al. revealed that physicians often overestimate patient resistance to insulin initiation (33). We agree with the conclusion of this review and claim that our participants overestimated the barrier of patient resistance.

In Arab countries, 73% of PCPs prefer to delay insulin therapy until it is “absolutely essential (34). The reasons behind these assumptions were not analyzed in our study but we claim that patients’ preference of alternative medicines like herbal and cupping (15.7%) failure of HBGM (50%) insufficient family support (34.3%) and fear of non-compliance of patients to insulin regimens (24.3%) may partially explain this assumption among our participants. Patients’ preference of herbal medicine is reported by another Saudi study (15). Many other studies stated that expecting a new method of diabetes treatment (54.7%), fear of needles and requiring someone else to administer the injection (19.2%) are the main reasons behind patient refusal or resistance to start insulin therapy (14,18,34).

In our study, the most frequently reported system related barriers were: no access to second senior opinion at the

health center when needed (44.3 %) followed by no clear MOH circular to allow physicians to initiate insulin (28.6%), insufficiency of anti-hypoglycemic medications at family health centers (25.7%), insufficiency of laboratory services required for follow up of DM (21.4%) and discontinuity of care due to occasional interruptions of insulin supply (12.9%). In Tabouk, we claim that this situation appears to have changed and many of these barriers are already fixed. Saudi MOH Wasfaty initiative now allows all patients to collect their medication from private pharmacies, all health centers have been equipped with HbA1C measuring devices, glucometers are available free of cost for all people with DM, a system of referral to both hospital laboratory and central PHC laboratory services are now available. All these system related facilities make most of these barriers illogical, but we agree with their barriers related to clear MOH circular that supports insulin initiation by PHCPs and quick access to a second specialist opinion. System related barriers reported in another similar Saudi study included: excessive workload, lack of insulin, few number of diabetes educators and lack of continuity of care (14). The most cited system related barriers include: no clinical guidelines, no disease register, bureaucratic difficulties with new drugs, resource constraints, no decision support, no team approach to care, poor communication between physicians and staff and no structured education activity (10).

Limitations

- This study addresses barriers to insulin initiation from only PHC physicians’ perspectives and did not include patient’s perspectives.
- Time of the study coincides with summer annual vacation of many physicians, with low response rate.

Recommendations

It is important that provider, patient, and healthcare system level barriers are considered together rather than as separate entities. Overall, the lesson from this study is to focus on the methods of education for both patients and physicians to approximate the gap between the existing ways of ineffective teaching to another evidence based learning method that improves clinical performance including insulin inertia. Clinical trials reinforce the need for a combination of good education and support, clear concise treatment strategies, involvement of all diabetes team especially nurses and pharmacists in patient education, recruit more family medicine specialists and consultants to PHC centers to reduce insulin inertia.

Conclusions

Despite the availability of all types of insulin, including the safest and peakless ultra-long (degludec) and long (Glargine) and their availability along with glucometers free of cost for all people with diabetes, the presence of well-equipped diabetes clinics in every PHCC and a long list of guidelines and educational courses, insulin inertia is a common problem among PHCPs working in Tabouk Health Region. PHCPs related their barriers to personal, patient and system factors. Recruitment of more family

medicine specialists and consultants along with shift from the traditional methods of teaching to more practice performance monitoring, review of physician's insulin prescribing behavior and on practice dual feedback with physicians and other health team members are assumed by the researchers and supported by evidence, may help to overcome this insulin inertia.

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