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## Assessing Barriers to Insulin Therapy among Omani Diabetic Patients Attending Three Main Diabetes Clinics in Muscat, Oman

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### Abstract

**Objectives:** This study aimed to identify the main barriers which prevent patients with diabetes mellitus from accepting insulin therapy. **Methods:** This cross-sectional study was conducted from May to December, 2019. Convenience sampling was used to recruit participants from three Diabetes Clinics in Muscat. Eligible participants were interviewed in person based on a pre-prepared questionnaire. The questionnaire, which was administered in Arabic, includes demographic data, and 19 specific items on barriers to insulin therapy.

**Results:** A total of 201 participants (response rate 93 %) were enrolled in the study. The commonest barriers were as follows: concern of frequent blood glucose checking (36.3%), long- term injections (33.8%), side-effects of insulin (29.9%), and weight gain (29.4%). Needle phobia was considered as a barrier by only 9% of the participants. Overall, 125 (62.2%) of the participants were willing to initiate insulin therapy despite of the presence of

these barriers and only 20 (10%) of the participants were influenced by these barriers to the degree that they would reject insulin therapy. **Conclusion:** The majority of our participants had no identifiable reasons which would stop them from accepting insulin therapy. Effective strategies should be developed to address each of the main barriers to improve acceptance and adherence to insulin therapy.

**Keywords:** Diabetes; Insulin; Barrier; Needle phobia; Hypoglycemia; Weight gain.

### **Advances in Knowledge**

- *This study found that the main barriers to initiation of insulin therapy from the perspective of patients were concerns about the need for frequent blood glucose checking, long-term therapy, side-effects of insulin, and weight gain.*
- *Needle phobia was not found to be amongst the main barriers for initiation of insulin therapy.*
- *The identifiable barriers did not influence the decision of the participants whether to accept insulin therapy or not.*

### **Application to Patient Care**

- *It is important to address the main barriers for initiation of insulin therapy with the patient to ensure acceptance and adherence.*
- *Health education to diabetic patients must include clear messages about the common myths and misperceptions of insulin therapy.*
- *Community awareness campaigns are needed to improve awareness about the safety and value of insulin therapy for patients with diabetes mellitus.*

### **Introduction**

Diabetes mellitus (DM) is considered as one of the chronic diseases that threatens the world. In 2019, the International Diabetes Federation (IDF) has declared that 463 million people are having diabetes worldwide and its related deaths were estimated as 4.2 million. Unfortunately, 72% of the people who has diabetes are in the age range of 20 to 64 years which lead to a high economic burden on the majority of the countries.<sup>1</sup>

Type 1 diabetes (T1DM) is usually caused by absolute insulin deficiency that results from destruction of the beta cells of islet of pancreas.<sup>2</sup> Type 2 diabetes (T2DM) is the commonest type of diabetes and it results from a progressive insulin secretory defect in addition to insulin resistance.<sup>2</sup>

There are several pharmacological options which are widely available for the management of diabetes. These include the commonly used options such as metformin, sulphonylureas, meglitinides, thiazolidinediones, and DPP-4 inhibitors. Recently, other classes of drugs have been added and include GLP-1 receptor agonists, and SGLT2 inhibitors.<sup>2</sup> However, since diabetes is a progressive disease and oral hypoglycemic agents (OHA) eventually lose their effectiveness, a big proportion of diabetic patients will eventually need to be started on insulin therapy, either alone or in combination with OHA. Insulin therapy is still considered as the most effective pharmacological option for the treatment of diabetes.<sup>2</sup> Moreover, studies have shown that early initiation of insulin therapy resulted in lower rate of complications and a slower decline in the function of beta cells of the pancreas.<sup>3-5</sup>

Poor glycemic control is multifactorial and could be due to healthcare workers-related factors, patient-related factors like poor adherence, or factors related to the disease itself.<sup>6,7</sup> Poor control leads to multiple microvascular and macrovascular complications such as end-stage kidney disease and cardiovascular disease which would eventually cause early death.<sup>7,8</sup> Late initiation and refusal of insulin therapy have been identified to be among the main causes of poor glycemic control and the development of irreversible complications.<sup>9</sup>

Patients' beliefs and misconceptions have been implicated in being important barriers to insulin therapy.<sup>7</sup> Such barriers would either lead to poor adherence or refusal of insulin therapy. Needle phobia has been identified as one of the main barriers and has been reported to contribute significantly to the refusal of insulin therapy.<sup>10</sup> Generally, patients usually prefer oral medications over needles because of ease and convenience. Injection-based therapy is mostly feared because of poor knowledge on how to inject and the misconceptions that injections must always be given by doctors or experienced caregivers and that they are associated with complications.<sup>11</sup>

Several studies have been conducted to identify the most important barriers to initiation of insulin therapy.<sup>10-15</sup> These barriers include the following: 'insulin is for life-long', 'insulin could cause organ damage', and 'insulin is for more severe disease only'.<sup>12</sup> In addition, fear of stigma, lack of emotional support from people around them, and lack of support from their own physicians.<sup>13</sup> Moreover, studies have shown that these barriers are influenced by culture and by health care system-related factors which make them unique and different for each country in the world.<sup>8,13,14,16</sup> It has been also suggested that focused health education about insulin therapy and the appropriate self-care management could play a very important role to address these barriers.<sup>17</sup>

Hence, it is important to study the barriers to insulin therapy and to find appropriate strategies to address each barrier in order to optimize the management of diabetic patients. It is even of greater importance to conduct this study in Oman since there are no previous published studies addressing this important area.

Thus, the aim of this study is to identify the main barriers to the initiation of insulin therapy among patients with diabetes mellitus in Oman and to estimate the influence of these barriers on the decision of patients to accept or reject insulin therapy.

## **Methods**

This is a cross-sectional study, which was conducted in the following sites: the Diabetes Clinics at Sultan Qaboos University Hospital (SQUH), Bowsheer Polyclinic and A'seeb Polyclinic during the period from 1<sup>st</sup> of May to the end of December 2019. The total number of patients who visited these clinics during the study period was 2380. All diabetic patients who were 18 years of age and above and attended these clinics during the study period were invited to be enrolled in the study except those who were known to have severe mental disorders.

A minimum sample size of 195 patients was calculated based on anecdotal evidence of an estimated barrier prevalence rate of about 15% with a margin of error of 5% and 95% confidence intervals. The study eventually enrolled 201 subjects.

The patients, who agreed to participate, were interviewed in person by one of the main investigators to fill out a pre-prepared questionnaire. Convenience sampling method was used to recruit eligible participants from the three Diabetes Clinics. The questionnaire consisted of the following items: demographic data (age, gender, occupation, monthly income, and education), diabetes-related information (diabetes type, type of treatment, and number of injections per day, if on insulin therapy), and 19 specific items on barriers to insulin therapy. These items were adopted and modified from previous similar studies.<sup>18-20</sup> The constructed questionnaire was subsequently validated by three subject experts for content, appropriateness, and relevance. A four-point Likert Scale was used to classify the importance of each barrier as 'not at all important', 'sometimes important', 'frequently important', or 'very important'. A three-point scale was used to determine the impact of each barrier on accepting or rejecting insulin therapy as 'accept insulin therapy', 'borderline' or 'reject insulin therapy'. The questionnaire was translated from English to Arabic following the standard procedure of forward-and-backward translation. The questionnaire was administered in Arabic.

A pilot study was carried out for 20 participants to test the reliability of the questionnaire and achieved a Cronbach's alpha of 82.1%. The data were entered and analyzed in Epidata version 4.6 and analyzed using IBM SPSS Statistics 24.0 for windows (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.). Descriptive statistics that were used include percentages and frequencies. Continuous data were presented with mean with standard deviation. For the prevalence 95% confidence interval were reported.

Informed consent was taken from all the participants prior to enrollment in the study. The study was granted the ethical approval from the Medical Research Ethics Committee (MREC) of the College of Medicine and Health Sciences of Sultan Qaboos University.

## **Results**

The total number of patients who agreed to participate in the study was 218 out of 233 who were initially invited (response rate 93 %). None were excluded based on the exclusion

criteria of the study. A total of 17 questionnaires were excluded due to significant missing information. Thus, the remaining number of questionnaires which were eventually analyzed was 201.

### ***Demographic data (Table1)***

The average age of the participants was  $40.5 \pm 15.1$  years. The majority were males 122 (60.7%), 91 (45.3%) were working, and 110 (54.7%) were retired and had no job. Those who had diploma, bachelor and above level were 88 (43.8%), while, who had secondary, intermediate, or primary school or illiterate were 113 (56.2). Only 14 (6.9 %) had a poor income and the remaining had moderate to good income.

Most of our patients had T1DM 84 (41.8%), 63 (31.3%) had T2DM and 54 (26.9%) were not aware of the type of diabetes they had.

### ***Barriers to insulin therapy (Figure 1 and Tables 2,3)***

Analysis of our data revealed that the most common barriers were the following: frequent blood glucose checking in 73 (36.3%), long-term insulin injections in 68(33.8%), side-effects of insulin in 60 (29.9%), weight gain in 59 (29.4%), inconvenience of the insulin injections in 58 (28.9%), busy life schedule in 55 (27.6%), dependence on insulin in 55 (27.4%), hypoglycemia in 48 (24%), pain and discomfort of injections in 46 (22.9%), and lifestyle interference in 45 (22.5%). Needle phobia was considered as a barrier by only a minority of the participants [18 (9%) (95% C.I. 5-14%)].

Other barriers like those related to difficulty to learn, difficulty to inject due to physical disabilities, lack of support by family, fear of stigma or feeling of personal failure did not have a major impact and people did not consider them as barriers. All of these constituted less than 20%.

Overall, 125 (62.2%) of our patients were willing to initiate insulin therapy despite the presence of barriers to insulin therapy and only 20 (10%) of our patients were influenced by these barriers to the degree that they would reject insulin therapy. The remaining 56 (27.8%) patients were still hesitant about insulin initiation and requested more time to think about it.

## Discussion

This study identified the main barriers to initiation of insulin therapy as follows: concern of frequent blood glucose checking, long-term injections, side-effects of insulin, and weight gain. Needle phobia was not found to be a major concern by the participants of the study. Furthermore, these barriers did not seem to influence the decision of subjects whether to accept insulin therapy or not.

The concern of frequent blood glucose checking was one of the main barriers in this study. The two main factors that might have contributed to this finding in this study were the low level of education of the participants, and the fact that the majority were on insulin therapy which usually requires frequent blood glucose monitoring. Wallace *et al* attributed this barrier either to fear of hypoglycemia due to the patient's belief that insulin has an immediate action or to the patient's worry about hyperglycemia and their intention to seek rapid improvement.<sup>7</sup>

Other major barriers identified in this study included concern of long-term injections and its side-effects. Similar findings were demonstrated by a study which was conducted in USA. Insulin therapy was feared because subjects in the study mistakenly believed that taking insulin could lead to amputations (15%), renal failure (32%), strokes (19%), heart attacks, blindness (20%), and early death (19%).<sup>10</sup> The concern of hypoglycemia as a barrier to insulin initiation was also demonstrated in another study, especially in those who had increased their doses of insulin.<sup>11</sup>

People with T2DM are mostly overweight with an average body mass index of 27.5 kg/m<sup>2</sup> at the onset of diagnosis as shown in the United Kingdom Prospective Diabetes Study.<sup>22</sup> Due to the co-existence of the two medical problems of diabetes and obesity at an early stage, both patients and physicians will be reluctant to use any treatment which might induce weight gain. Indeed, studies have shown that fear of weight gain is a big concern in such patients especially if they have been treated with insulin.<sup>7,11</sup>

Usually, people prefer oral drugs over needles due to the pain and discomfort exerted by injection.<sup>9,14,15</sup> In this study, 46 (22.9 %) patients did not find insulin treatment convenient because of this reason.

Most people think that insulin will restrict their life schedule and restrict them from their work or doing sports.<sup>7,21</sup> Also, it might be associated with carrying the needles wherever the patients go unlike oral medications which are easier to carry specially with those people who travel a lot.<sup>9,15</sup> These findings are consistent with the results of this study which showed that insulin initiation was rejected because of lifestyle interference, inconvenience of the insulin needles treatment and busy life schedule (22.5 %, 28.9% and 27.6% respectively).

Insulin therapy might be initiated for a short period to combat severe hyperglycemia as in newly diagnosed T2DM patients. However, some of these patients might be reluctant to start insulin because of the fear of dependence to insulin and the concern that they will become dependent on it life-long.<sup>9,10,17</sup> This fact was also demonstrated in 55 (27.3 %) of the patients.

Difficult to learn is infrequent barrier to insulin initiation and was documented by 15 (7.5%) patients in this study. This can be probably seen more commonly among inhabitants of rural areas where people are expected to be less educated and do not have access to medical services. Thus, their knowledge about the disease and available therapies might be affected.<sup>21</sup> Moreover, a small number of patients have concern of stigma which is mostly related to the usage of insulin and administering insulin injection in public or being ashamed of telling people that they have a chronic disease, believing that it might affect their relationships or connections with others.<sup>12</sup>

In the current study, the prevalence of the needle phobia was only 9% in contrast to the findings of a qualitative study, which was conducted in five different countries (Germany, Sweden, The Netherlands, United Kingdom, and United States of America). The researchers reported a high prevalence (43.7%) of needle phobia among their subjects.<sup>17</sup> This phobia did not seem to be affected by variation in the person who gives the injection or the place where it is given.<sup>17</sup> A systematic review conducted by McLenon *et al* reported a higher prevalence of needle phobia in females, young adults, and in specific countries.<sup>23</sup> Thus, the low



prevalence in this study could be attributed to the predominant age and gender of the participants. In addition, to country-specific factors.

Interestingly, the majority of the participants in this study were willing to initiate insulin therapy despite confirming the presence of the barriers. This might be explained by the possibility that these barriers are not strong enough to influence their final decision about insulin therapy. Moreover, concerns about complications of poorly controlled diabetes and side-effects of other treatments could also lead to insulin acceptance.<sup>12</sup>

The findings of this study are important since it gives physicians an insight about the barriers to insulin initiation from the perspectives of the patients. This is the first critical step for the development of strategies to address these myths and misconceptions appropriately to aim for better care of diabetic patients in Oman.<sup>16, 24,25</sup>

There are several important limitations in this study. The design of the study being questionnaire-based is dependent on self-reported responses, which are usually influenced by social desirability. Since many of the responses obtained from the interviews particularly those related to the barriers among participants who were already on insulin therapy are dependent on their ability for recall, recall information bias can be considered as one of the limitations. The responses to questionnaires are usually influenced by the level of education and there was a big proportion of the subjects who had low level of education. This tool is also limited by its ability to capture attitudes and not real behaviors. The relationship between barriers and the decision to accept or reject insulin is also hypothetical and the responses might not reflect the real final decision. The study population since it is limited to attendants of outpatient clinics are not representative of the general population, which affect the generalizability of the findings.

## **Conclusion**

This study addressed the barriers which might influence the decision to accept insulin therapy or not amongst diabetic patients in Oman. The main barriers were as follows: the concern of frequent blood glucose checking, long-term therapy, and side-effects. The

majority of the study participants reported no impact for these barriers on their final decision whether to accept or reject insulin therapy. Contrary to the findings of other similar studies, needle phobia was not found to be a major barrier to insulin initiation in this study.

### **Authors' Contribution**

**AF** contributed with the research idea and study design. The literature review and creation of the questionnaire were done by **SG**. Data collection was done by **ASK** and **SQ**. Data analysis was done by **SP**. **AF**, **MA**, **SQ**, **SP** and **AM** were involved in writing the article. All authors approved the final version of this article.

### **Conflict of Interest**

The authors of this article declare that there is no conflict of interest.

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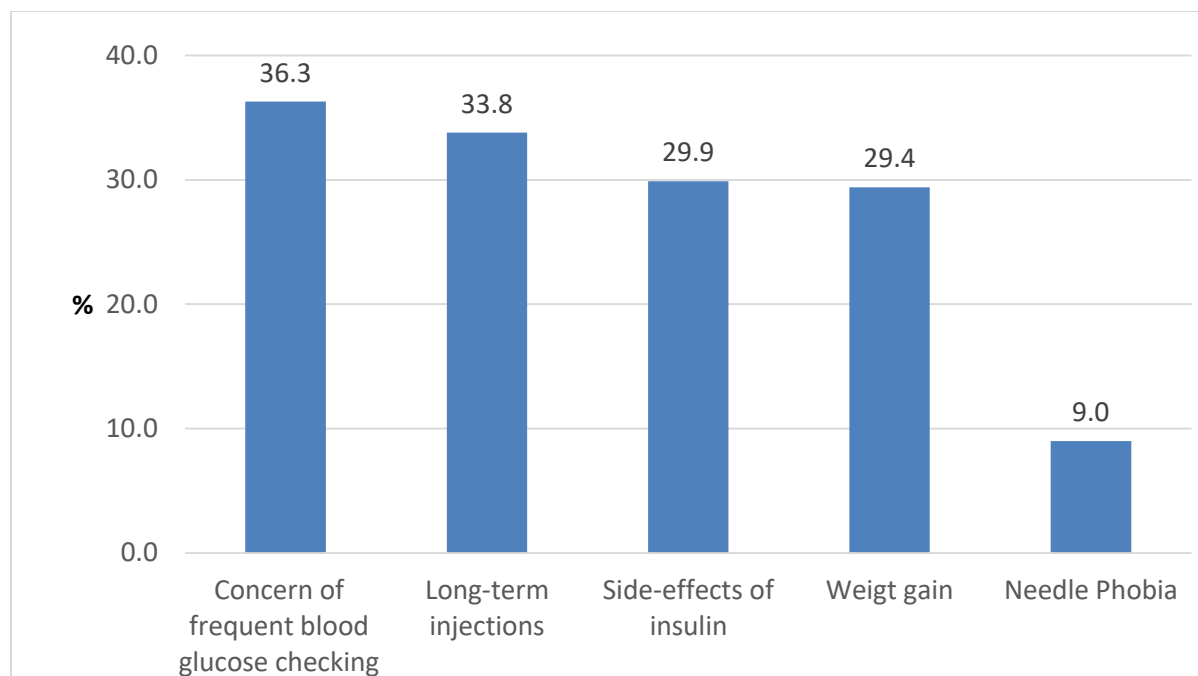
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**Table 1:** Socio-demographic and clinical characteristics of the study population (n=201).

<b>Variables</b>	<b>n (%)</b>
<b>Age (Mean <math>\pm</math> SD*)</b>	40.54 $\pm$ 15.17
<b>Gender</b>	
Male	122 (60.7)
Female	79 (39.3)
<b>Occupational status</b>	
Unemployed	73 (36.3)
Employed	83 (41.3)
Self-employed	8 (4.0)
Retired	37 (18.4)
<b>Monthly income in OMR<sup>#</sup></b>	
Low (< 300)	14 (7.0)
Moderate (300-1000)	108 (53.7)
High (> 1000)	79 (39.3)
<b>Education</b>	
Illiterate	14 (7.0)
Primary	13 (6.5)
Intermediate	28 (13.9)
Secondary school	58 (28.9)
Diploma	32 (15.9)
Bachelor and above	56 (27.9)
<b>Diabetes type</b>	
Type 1	84 (41.8)
Type 2	63 (31.3)
Don't know	54 (26.9)
<b>Type of Treatment</b>	
Not taking any medication	4 (2.0)
Tablets	46 (22.9)
Insulin injections	95 (47.3)
Tablets and insulin	50 (24.9)
Insulin Pump	6 (3.0)
<b>If injects, /day</b>	
1	15 (9.9)
2	25 (16.6)
3	42 (27.8)
4	64 (42.4)
>4	5 (3.3)

\*SD= Standard deviation, <sup>#</sup>OMR= Omani Rial.



**Figure 1:** The commonest barriers to initiation of insulin therapy amongst the participants of the study.

**Table 2:** The responses of the participants regarding the importance of each barrier to initiation of insulin therapy.

Items*	Not at all Important n (%)	Sometimes Important n (%)	Frequently Important n (%)	Very Important n (%)
Needle phobia (n = 201)	146 (72.6)	37 (18.4)	10 (5.0)	8 (4.0)
Feeling of personal failure (n = 200)	141 (70.5)	39 (19.5)	9 (4.5)	11 (5.5)
Pain, discomfort of injections (n = 201)	83 (41.3)	72 (35.8)	29 (14.4)	17 (8.5)
Lifestyle interference (n = 200)	100 (50.0)	55 (27.5)	27 (13.5)	18 (9.0)
Concern of hypoglycemia (n = 200)	81 (40.5)	71 (35.5)	30 (15.0)	18 (9.0)
Concern of insulin side-effects (n = 201)	90 (44.8)	51 (25.4)	32 (15.9)	28 (13.9)
Concern of insulin as a cause of long-term diabetes complications (n = 201)	95 (47.3)	38 (18.9)	29 (14.4)	39 (19.4)
Remarkably busy life schedule (n = 199)	92 (46.2)	52 (26.1)	25 (12.6)	30 (15.1)
Concern of weight gain (n = 201)	110 (54.7)	32 (15.9)	25 (12.4)	34 (16.9)
Concern of dependence on insulin	108 (53.7)	38 (18.9)	28 (13.9)	27 (13.4)

(n = 201)				
Concern of frequent blood glucose checking (n = 201)	96 (47.8)	32 (15.9)	38 (18.9)	35 (17.4)
Inconvenience (n = 201)	110 (54.7)	33 (16.4)	24 (11.9)	34 (16.9)
Concern of stigma (n = 200)	151 (75.5)	28 (14.0)	11 (5.5)	10 (5.0)
Difficult to learn (n = 201)	164 (81.6)	22 (10.9)	4 (2.0)	11 (5.5)
Difficult to inject due to physical disabilities (n = 201)	152 (75.6)	22 (10.9)	16 (8.0)	11 (5.5)
Cannot inject myself (n = 201)	171 (85.1)	11 (5.5)	4 (2.0)	15 (7.5)
No other person that can inject me (n = 201)	155 (77.1)	20 (10.0)	14 (7.0)	12 (6.0)
Lack of support from family for insulin treatment (n = 201)	164 (81.6)	15 (7.5)	15 (7.5)	7 (3.5)
Lack of general family support (n = 201)	172 (85.6)	15 (7.5)	10 (5.0)	4 (2.0)

\*The sum of the rows of responses for several items are < 201 due to missing responses.

**Table 3:** The responses of the participants regarding the impact of each barrier on whether to accept insulin therapy or not.

Items	Accept Insulin therapy n (%)	Borderline n (%)	Reject Insulin therapy n (%)
Needle phobia (n = 201)	146 (72.6)	47(23.4)	8 (4.0)
Feeling of personal failure (n = 200)	141 (70.5)	48(24)	11 (5.5)
Pain, discomfort of injections (n = 201)	83 (41.3)	101(50.2)	17 (8.5)
Lifestyle interference (n = 200)	100 (50.0)	82(41)	18 (9.0)
Concern of hypoglycemia (n = 200)	81 (40.5)	101(50.5)	18 (9.0)
Concern of insulin side-effects (n = 201)	90 (44.8)	83(41.3)	28 (13.9)
Concern of insulin as a cause of long-term diabetes complications (n = 201)	95 (47.3)	67(33.3)	39 (19.4)
Remarkably busy life schedule (n = 199)	92 (46.2)	77(38.7)	30 (15.1)
Concern of weight gain (n = 201)	110 (54.7)	57(28.3)	34 (16.9)
Concern of dependence on insulin (n = 201)	108 (53.7)	66(32.8)	27 (13.4)
Concern of frequent blood glucose checking (n = 201)	96 (47.8)	70(34.8)	35 (17.4)
Inconvenience (n = 201)	110 (54.7)	57(28.3)	34 (16.9)
Concern of stigma (n = 200)	151 (75.5)	39(19.5)	10 (5.0)
Difficult to learn (n = 201)	164 (81.6)	26(12.9)	11 (5.5)
Difficult to inject due to physical disabilities (n = 201)	152 (75.6)	38(18.9)	11 (5.5)

Cannot inject myself (n = 201)	171 (85.1)	15(7.5)	15 (7.5)
No other person that can inject me (n = 201)	155 (77.1)	34(17)	12 (6.0)
Lack of support from family for insulin treatment (n = 201)	164 (81.6)	30(15)	7 (3.5)
Lack of general family support (n = 201)	172 (85.6)	25(12.5)	4 (2.0)
Overall (n = 201)	125(62.2)	56(27.8)	20(10)

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