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Why do people with type 2 diabetes who are using insulin have poor glycemic control? A qualitative study.

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Abstract

Objective
This study aims to explore the factors influencing poor glycaemic control among people with type 2 diabetes using insulin.

Research design
This study used a qualitative methodology, comprising in-depth individual interviews. A semi-structured interview guide was used for the interviews, which were audio-recorded, transcribed verbatim and analyzed using a thematic approach.

Participants:
Seventeen people with type 2 diabetes using insulin with HbA1c ≥ 9% for > 1 year participated in this study.

Setting
This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC), Malaysia.

Results
Data analysis revealed participants faced difficulties in integrating diabetes self-care tasks into their daily work-life schedule. They could not resist food cravings and health-limiting conditions hampered their performing exercise, both of which contributed to poor glycaemic control. Psychosocial and emotional problems caused participants to neglect their diabetes self-care. Some gave up when there were no improvements in their glycaemic control. Side effects of insulin use, such as fear of hypoglycaemia, needles and pain, and increased hunger caused participants to overeat and omit insulin. Lack of awareness of glycaemic levels and targets rendered participants unsure to what extent they should control their diet. Some were not confident in adjusting their insulin dosage for fear of negative consequences.

Conclusion
This study identified factors, which explained the poor glycaemic control in people with type 2 diabetes using insulin. Healthcare providers may use these findings to address patients' concerns during consultations and help to improve glycaemic control.

Strengths and limitations of this study

- This is the first few studies provided insights into factors for poor glycaemic control despite insulin use.
- Healthcare providers could use the findings and help patients with type 2 diabetes using insulin to address their concerns during consultations and improve glycaemic control.
- The recruitment of participants was conducted in a single hospital, hence healthcare systems as a factor in poor glycaemic control cannot be further explored.
- The interviews conducted in the hospital environment may influence the participants to give a socially desirable response. However, they were informed that their responses will not affect their medical care and will be kept confidential.

Introduction

Insulin has been identified as the most effective glucose lowering agent, however, studies has showed that many people with diabetes who are using insulin still fail to achieve glycaemic control.[1, 2]

The challenges of achieving glycaemic control in people with diabetes using insulin were: the progression of the disease, the impact of hypoglycaemia and weight gain, the burden of poly-pharmacy, lack of resources in provision of diabetes self-care education and support of patients; and the inherent limitations of subcutaneous exogenous insulin administration.[3] Other predictors of poor glycaemic control include younger age, shorter duration of diagnosis of diabetes, the interaction of age and duration of diabetes, lower body mass index and poor physical functioning.[4]

To date, research on identifying factors for poor glycaemic control among people with type 2 diabetes was largely by quantitative studies involving patients on various treatment modalities; including lifestyle adapters, OHAs (oral hypoglycaemic agents), OHAs + insulin and insulin only,[5-7] while qualitative studies focused on barriers to diabetes self-care management in general.[8-11] Very few qualitative studies examined factors impacting poor glycaemic control from the patient's perspective, especially among people with type 2 diabetes using insulin with poor glycaemic control.

Since insulin is the most effective glucose-lowering agent, it is pertinent to understand from the patient's perspective why people with type 2 diabetes who are on insulin still fail to achieve glycaemic control. This study will help fill the gap in existing literature by exploring factors influencing poor glycaemic control in people with type 2

diabetes using insulin. An understanding of the barriers to achieving glycaemic control will help healthcare providers (HCPs) find ways to improve glycaemic control in this sub-population.

Research Design and Methods

This study used a qualitative methodology, comprising in-depth individual interviews to help understand patient experiences, as well as take into account the circumstances which led to poor glycaemic control among people with type 2 diabetes using insulin.

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC). We purposively sampled patients who were diagnosed with type 2 diabetes, have been using insulin, either alone or in combination with OHAs and with poor control of diabetes (HBA1c ≥ 9%) for at least one year. Participants were chosen from various socio-demographic backgrounds (age, ethnicity, education level) so that different perspectives on the reasons for poor glycaemic control can be explored.

We used a semi-structured interview guide (Table 1), which was developed based on the study's conceptual framework (Figure 1) drawn from literature review and experts' opinion. The interviews were carried out between January and August 2013 in consultation rooms in both clinics. Written informed consent and socio-demographic information was obtained from patients who agreed to participate. During the interviews, the participants were asked for the reasons why they think their blood sugar is not well controlled despite using insulin. When the participant could not give any more reasons that they could think of, the researcher would then probe

other areas contributing to poor glycaemic control, as developed in the interview guide. Data saturation was achieved upon the 17th interview, when no new factors influencing poor glycaemic control emerged from the interviews.

Audio-recordings of the interviews were transcribed verbatim and exported into NVivo qualitative software for data analysis using a thematic approach. Initially, the transcripts were read through for familiarization by the researchers and then codes were assigned to a particular phrase, sentence or paragraph that described the meaning of the text segment. Sentences that had a similar meaning were given the same code while texts with different meaning were given a new code. The whole transcript was analyzed until there were no new meanings from the texts to form new codes. Subsequently, all the codes were compared and related codes were clustered together under the same category. Irrelevant codes were omitted. The categories were later compared and further clustered under themes. The mapping of categories and themes resulted in the development of a coding frame. The coding frame was developed from the coding process on the first three transcripts by all the researchers (TWT, NCJ, SV). The coding frame was finalized when consensus was reached on the categories and themes. The finalized coding frame was used to code for the remaining transcripts by TWT. New emerging codes were added into the list of categories and themes that were created through constant discussion with other researchers to ensure the list of categories and themes produced the best representation of data that was obtained. Researchers constantly challenged one another's interpretation of the data to offset any potential biases when analyzing the data.

Results

Socio-demographic and diabetes profile of participants

There were 17 participants in this study. Their socio-demographic and diabetes profiles are listed in Table 2.

Emerging themes

Four themes, which corresponded to factors influencing poor glycaemic control despite insulin use, emerged from the data analysis (Table 3).

Lifestyle challenges in adhering to medical recommendations

Participants highlighted a range of lifestyle challenges in adhering to medical recommendations which contributed to their poor glycaemic control. These included difficulty in integrating diabetes medical recommendations into their work-life schedule, inability to control food cravings and eating habits, inappropriate diet recommendations by HCPs and health-limiting conditions affecting diabetes self-care.

Difficulty integrating diabetes medical recommendations into work-life schedule

Participants faced difficulties in integrating medical recommendations such as a medication regimen and meal times when they did not match with their daily activity schedule. When participants were too busy with their work-life, they tended to skip meals which caused them to become hungry and overeat later. Skipping meals also resulted in them missing or delaying their insulin injections.

> "The way I eat and take the medications is not consistent. Sometimes I forget. Maybe I am too busy. Every time my insulin use would be

delayed. For example, usually we inject at 12 right, sometimes I will inject at 2. Sometimes I did not inject at all" – *58 years old housewife*

Inability to control food cravings and eating habits

Participants also reported that the temptation of eating something delicious would lead them to lose control of their diet, causing them to overeat.

"My eating habit. Like I like to eat sweets, like kuihs [local dessert] and all that. But I have to control. I know I am not controlling. I must put a full stop to that." - *60 years old woman housewife*

It is also difficult to resist food when there is a variety of food available and coming from a lifestyle and culture where food and eating are a way of living.

"Basically it is also Malaysia lifestyle whereby people like to eat. You eat non-stop. Sugar is particularly everywhere in your diet so that's probably one of the main reasons why it is not controlled". - *22 years old student*

Inappropriate diet recommendations by healthcare providers

Participants felt that the diet recommended by HCPs provided insufficient energy for them to carry out their work. Some also expressed frustrations with regards to the monotony of eating the same type of food every day, such as bread and chapatti, which were recommended by the HCPs. Hence, they often neglected the dietary advice.

> "Every time they [HCPs] ask me to eat bread. Can you eat bread everyday? For sure you will hate it. They will ask to eat vegetables every day. Cannot like that " - *59 years old ex-lorry driver*

Health conditions affecting exercise

Not being able to exercise optimally due to health conditions was another reason cited by many for poor glycaemic control.

> *"*Another thing is exercise. Because of stroke, I have problem with walking. I have to exercise more". - *61 years old engineer*

Psychosocial issues and emotional hurdles

Psychosocial and emotional problems also affected the participants' diabetes self-care; some lost motivation while others perceived poor glycaemic control as part of ageing. These, they believed, had led to their poor glycaemic control.

Psychosocial problems affecting diabetes self-care

Participants felt that their poor glycaemic control was attributed to personal problems which caused them to feel anxious, stressed and sad, which resulted in some adopting unhealthy eating habits and not taking their diabetes medications, including insulin.

> "Actually when you have diabetes, you cannot be stressed. Previously when I was under stress [due to marital problems], my blood sugar level was very high because I did not eat and take my insulin. I was hoping to die." – *50 years old taxi driver*

Loss of motivation

Participants admitted that they were tired of adhering to diabetes medications after having taken them for such a long time that sometimes they would intentionally skip doses.

> "Sometimes I purposely miss them because I am just so tired of injecting". – *40 years old officer*

Additionally, an absence of significant improvements in glycaemic control despite efforts made to improve glycaemic control led participants to 'give up' in controlling their blood sugar.

> "There's one time actually I did go to the gym and the exercise was okay but it didn't really do anything to my weight. It does a little bit on my sugar but after a while I just give up. I think it would be as well [contributed to her poor glycaemic control] because the main thing is that, I think that if I actually lose weight, I would be able to control my sugar as well." – *40 year old officer*

Perceived poor glycaemic control as part of ageing

Many older participants of this study held the view that whatever their attempts to control blood glucose levels, their glycaemic control would still fall short due to their advanced age.

> "Maybe because I am getting old. As the days passed by, all my organs has deteriorated. Like engine, the more it is used, it will become spoilt." - *69 years old retiree*

Diabetes treatment-related factors

Diabetes treatment-related factors include side-effects of insulin and perception of appropriate dietary practices related to insulin.

Side-effects of insulin

Participants reported they would tend to overeat to prevent or counter the effects of insulin-induced hypoglycaemia. However, it is when participants overeat that their glycaemic control deteriorates.

> "I had fit once (due to hypoglycaemia), that fear is always there. On and off, I used to eat more to make sure I don't go into hypoglycaemia fit. It is extremely painful". - *47 years old doctor*

Participants also felt that insulin caused them to feel hungry, causing them to overeat, hence, raising their blood sugar levels.

> "But if use insulin, it makes me eat. I feel that after using insulin, the blood sugar goes even higher". – *37 years old clerk*

Fear of needles and pain also caused participants to delay insulin initiation as well as intentionally skipping injections, thus contributing to poor glycaemic control.

> "I don't quite like insulin actually. I'm very afraid of needles and the pain that follows. In a week I would say at least 3 times [skipping insulin injections]. Although my blood sugar was already up about 6 to 7 years ago, but I've only started insulin not far back from now. So that's the other reason [for poor glycaemic control]." – *40 years old officer*

Perception of appropriate dietary practices related to insulin

One participant felt that his poor glycaemic control was attributed to the diet recommendations given by the HCP. He voiced that the meal pattern recommended was not right and would instead reduce the efficacy of the insulin.

> "For example if you eat at 8pm, then you feel hungry and you eat again. So if I follow his [doctor] advice I will eat but this is wrong. The mistake is if lets say I eat at 7pm, then 8, 9, 10, 11, 12pm, for about 4 hours I will keep on eating. So the insulin cannot fight with my diabetes. Because I have experienced this so I know. The recommended cannot work. My diabetes reach 20, 30 something". – *50 years old taxi driver*

Lack of awareness and self-efficacy in diabetes self-care

Participants lacked awareness and self-efficacy in diabetes self-care. They did not know their glycaemic level and target and were not confident in adjusting the insulin dosage on their own.

Lack of awareness of glycaemic level and target

Lack of awareness of their glycaemic level and target was also cited as a reason for poor glycaemic control, as participants were not aware to what extent they should control their blood sugar. This lack of awareness was attributed to difficulties in performing SMBG due to financial reason, and some claimed that their HCPs did not inform them about their glycaemic levels and target.

> "I check less because sometimes when the needles are finished, I have to wait for my salary to buy. I check once a week but if I need to see the doctor then only I will check 4 times a day. Actually it is not enough. When I don't check, I cannot control my diet so that's why my blood sugar is not good". – *37 years old clerk*

> "I don't know why he [doctor] wants to lower (blood sugar level) some more. No, because I don't know what is the target. The doctor never mentioned. I am also not sure. So I also don't know whether I am okay or not. If I know, I will control no matter what". *-31 years old marketing coordinator*

Lack of self-efficacy in adjustment of insulin dosage

Despite receiving advice from the doctor that they could adjust their insulin dosage, some participants did not do so as they were afraid of making mistakes when

adjusting the insulin dose, which could lead to hypoglycaemia and other complications.

> "I'm just reluctant [to adjust insulin dosage] because they [doctor] won't be with me 24 hours. I didn't increase or decrease any of the medication. I just stick to it. So maybe that is the reason". - *36 years old personal bodyguard*

Discussions

Our study revealed that people with type 2 diabetes using insulin attributed their sustained hyperglycemia to lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of awareness of glycaemic levels and targets, as well as poor self-efficacy with regards to insulin dosage adjustment. Majority of the factors raised were not related to problems with insulin use per se, but were related to barriers in performing diabetes self-care tasks in general such as dietary control, adherence to exercise and medications including OHAs.

Our study participants faced difficulties in adhering to the recommended meal and insulin injection schedule due to work priorities and time constraints. In a multinational study involving 1530 people with type 1 diabetes (12.8%) and type 2 diabetes (88.2%) using insulin from eight countries, taking insulin at the prescribed time or with meals everyday was also reported to be difficult.[12] The lifestyle changes required for diabetes management in terms of diet and regular mealtimes were acknowledged to be hard to implement, even in people with type 2 diabetes using OHAs alone, who often report missed or delayed meals.[13] This showed that adherence to regular meal and medication times is a universal and major barrier to diabetes

management among people with diabetes. It is crucial to overcome that, especially among people with type 2 diabetes using insulin, as insulin administration has to be synchronized with meals. When regular meal times cannot be followed, it often results in delayed or skipped insulin intake, as reported in our study, which explains poor glycaemic control.

Our participants raised the issue of dietary recommendations by HCPs, which did not meet their dietary needs. Other people with type 2 diabetes using insulin also reported that clinicians would simply assume that patients would comply to the medical recommendations given; without considering their individual needs and preferences.[14] Additionally, it also appears that lack of understanding of the rationale behind dietary recommendations is common among type 2 diabetes patients. Our participants thought the meal pattern recommended by HCPs would thwart the efficacy of insulin, while type 2 diabetes patients on OHAs in another study perceived that frequent meals was a way to control their diabetes.[15] In fact, the main purpose of regular meals is actually to counter the effects of hypoglycaemia, due to insulin and long acting sulfonylureas. These findings highlight the importance of HCPs in individualizing treatment management plans according to the patient's needs. It is also pertinent that HCPs explain to patients the rationale behind the treatment recommendation so that misconceptions would not cause the patient to neglect the medical advice or to practice other treatment approaches.

The issue of psychosocial factors and lack of motivation is crucial, as it affects all aspects of diabetes self-care including adherence to insulin, as evidenced from our study. Diabetes self-care is a complex task that demands behavioral change in the

patient on a daily basis; the influences of social, cultural, familial and professional contexts further complicate management of the disease in diabetes patients as shown in other studies.[16-18] Furthermore, our participants also showed that when a patient's diabetes condition remains unimproved despite efforts to control it, this leads to 'diabetes burn-out' stemming from frustration and loss of motivation; eventually resulting in neglect of diabetes self-care. Perhaps explaining the disease progression in type 2 diabetes and that the progressive loss of β-cell function is common, will lift the feeling of frustration and loss of motivation in them.

Older participants of our study perceived that they would never be able to achieve glycaemic control due to their old age even with insulin use. Such misconceptions are alarming as they may decrease older people's perceived importance of glycaemic control. They may lower their expected treatment target in order to cope with the challenges in managing diabetes at such an age.[19] There is a need to inform elderly people with type 2 diabetes that insulin has no upper limit dosage and they will still be able to control their glycaemic levels even with increasing age.

It is not surprising that our participants reported fear of hypoglycaemia, needles and pain as reasons for poor glycaemic control. These factors have been well established as factors for intentional insulin omission[20] and overeating to prevent insulin-induced hypoglycaemia.[14,21] The UMMC has an established specialized diabetes clinic with trained diabetes nurses to provide education and skills training in diabetes self-care to patients. Therefore the patients would have been educated and trained on techniques of insulin administration and ways to prevent and manage hypoglycaemia. Furthermore, they have been using insulin for some time and were using insulin pens,

so the needle used is relatively thin which causes little or no injection pain. In addition to providing diabetes education and skills training to people with type 2 diabetes using insulin, provision of counselling to address these fears is warranted.

Lack of awareness of glycaemic level and targets was also a reason for poor glycaemic control in our participants. They were unsure to what extent they should control their glucose levels. The issue of lack of awareness of glycaemic levels and targets in our study stemmed from lack of SMBG and perceived minimal feedback from HCPs. Our participants reported financial constraints in carrying out effective SMBG, as costs for SMBG supplies are not subsidized by the Malaysian government. The impact of economic factors on SMBG adherence is well established[22] as an issue that limits glycaemic control.[23] Other diabetes patients reported that they were not informed by their doctor of their target blood glucose levels and perceived that as a barrier to diabetes self-management.[24] HCPs have a crucial role to play in discussing glycemia results with their patients and formulating mutually agreed glycaemic targets. Awareness of HbA1c had a positive impact on maintaining better glycaemic control.[25]

Self-adjustment of insulin dosage is a technically complex regimen[26] and people with diabetes spend most of their time managing their diabetes away from healthcare professionals. It is thus not surprising that our participants were still apprehensive about self-adjustment of their insulin dose; for fear of hypoglycaemia. Dependent and deferential attitudes towards health professionals were cited as the reasons why type 1 diabetes patients do not adjust their insulin dosage[26] and this may also be the reason for failure to adjust insulin dosing among our participants.

Some factors for poor glycaemic control as highlighted in the conceptual framework did not emerge in our study findings. The issue of social stigma was not raised by our participants as a reason for poor glycaemic control. We assumed that our participants had overcome this barrier upon initiation of insulin since they have been on insulin for at least one year; as they also reported of performing adaptive strategies such as injecting insulin in private in public places, for example in the toilet or in their car. Our participants did not blame their family, friends, employers, the healthcare system or HCPs for their poor glycaemic control. They however expressed dismay at the short consultation times and not being able to see the same doctor for their diabetes. Our participants expressed that diabetes control is a personal responsibility, therefore they tended to focus on their personal inadequacies when it came to poor glycaemic control. This may be due to diabetes self-care playing a huge role in disease control, hence people with type 2 diabetes may have felt greater responsibility for self-care. Thus, when glycaemic control cannot be achieved, this resulted in self-blame.[27]

Strengths and limitations of the study

The study provided insights into factors for poor glycaemic control despite insulin use, a topic that is surprisingly understudied. Furthermore, the reasons behind poor glycaemic control were uncovered from the perspectives of people with type 2 diabetes with sustained hyperglycaemia for more than one year despite insulin use. This provided reasons for poor glycaemic control from current real patient experiences. However, they were informed that their responses will not affect their medical care and will be kept confidential.

This study has a few limitations. The recruitment of participants in this study was only conducted in a single hospital, hence healthcare systems as a factor in poor glycaemic control cannot be further explored. The interviews were conducted in the hospital where the participants were recruited, hence the environment may influence them to give a socially desirable response.

Clinical and future research recommendations

HCPs should create individualized plans with people with type 2 diabetes using insulin, to ensure a routine that allows for proper meal times and exercise, which would enable them to take their diabetes medication, including insulin, in a timely manner. Patients reported they face problems with treatment recommendations, hence HCPs should continuously assess the efficacy and feasibility of treatment provided to their patients and clarify patient misconceptions. It is also pertinent for HCPs to recognise the psychological and emotional problems that impact on their patients' diabetes self-care and provide affective support to them. Lastly, HCPs should discuss glycaemic readings and adjustment of insulin dosage, as well as formulate a mutually agreed target with patients to facilitate improvement of glycaemic control.

More research is needed pertaining to this topic to uncover other factors that could influence poor glycaemic control despite insulin use. In addition, exploring views from HCPs and caretakers of the patients would provide a more holistic understanding of factors for poor glycaemic control despite insulin use. Accurate assessment of patient's knowledge, actual self-care practices, and, clinical characteristics could also be conducted. This would allow triangulation of multiple sources of data which would then provide more comprehensive understanding and

better identification of reasons for poor glycaemic control. Ultimately, the factors identified may help to develop a tool to be used by HCPs, as a checklist to address the barriers faced by people with type 2 diabetes using insulin in achieving glycaemic control.

Conclusions

Our findings revealed lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of awareness of glycaemic levels and targets, and poor self-efficacy with regards to insulin dosage adjustment as factors for poor glycaemic control despite insulin use. Healthcare providers could look into these factors and help patients with type 2 diabetes using insulin to address their concerns during consultations and thus improve glycaemic control.

Contributorship statement

All authors (WTT, SV, CJN) of this study conceived and designed the study, researched and analyzed the data, contributed to discussion, wrote, edited and reviewed the manuscript.

Competing interests

None.

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Ethics approval

This study received ethical approval from the University of Malaya Medical Centre Medical Ethics Committee (926.18).

Data sharing

No additional data are available.

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Table 1 Summary of interview guide topic on factors influencing poor glycaemic control despite using insulin

PREAMBLE: Actually you have had diabetes for a long time and are now using insulin to control your blood sugar. Since you are using insulin to control your blood sugar, but your blood sugar is still not well controlled.
• Can you share with me what do you think are the reasons why your blood sugar is still not well controlled?
Focussing on areas influencing poor glycaemic control
• Do you face any problems in adjusting lifestyle for your diabetes care? (Probe: diet, exercise, medications). How?
• What barriers do you face when using insulin? (Probe: injecting insulin in the public, negative beliefs about insulin, fear of needle, pain, blood, body injury, marks and scars, weight gain, hypoglycaemia, knowledge and skills in administrating insulin)
• Does your family, friends, or employer takes part in managing your diabetes? Do you think they affect you in your blood sugar control? How?
• Do you face any health problems that makes it difficult for you to manage your diabetes? (Probe: vision problems, dexterity, mobility, poly-pharmacy, exercise)
• There are some people with diabetes who are depressed and stressed and that affect their sugar control. Do you face this problem? How does it affect you in controlling your blood sugar?
• Do you perform self-blood glucose monitoring? If no, why not? Does it affect your blood sugar control? If yes, how?
• What barriers do you face when consulting the doctor/nurse for your diabetes? (Probe: language, communication, and interaction). Does it affect your blood sugar control?
• What do you think of the hospitals and clinics that you go for your diabetes? (Probe: resources, complexity of system, accessibility, long waiting time, short consultation time) Does it affect your blood sugar control?
• Do you face any financial difficulties to care for your diabetes? (Probe: Medication cost, transportation to hospitals, SMBG)

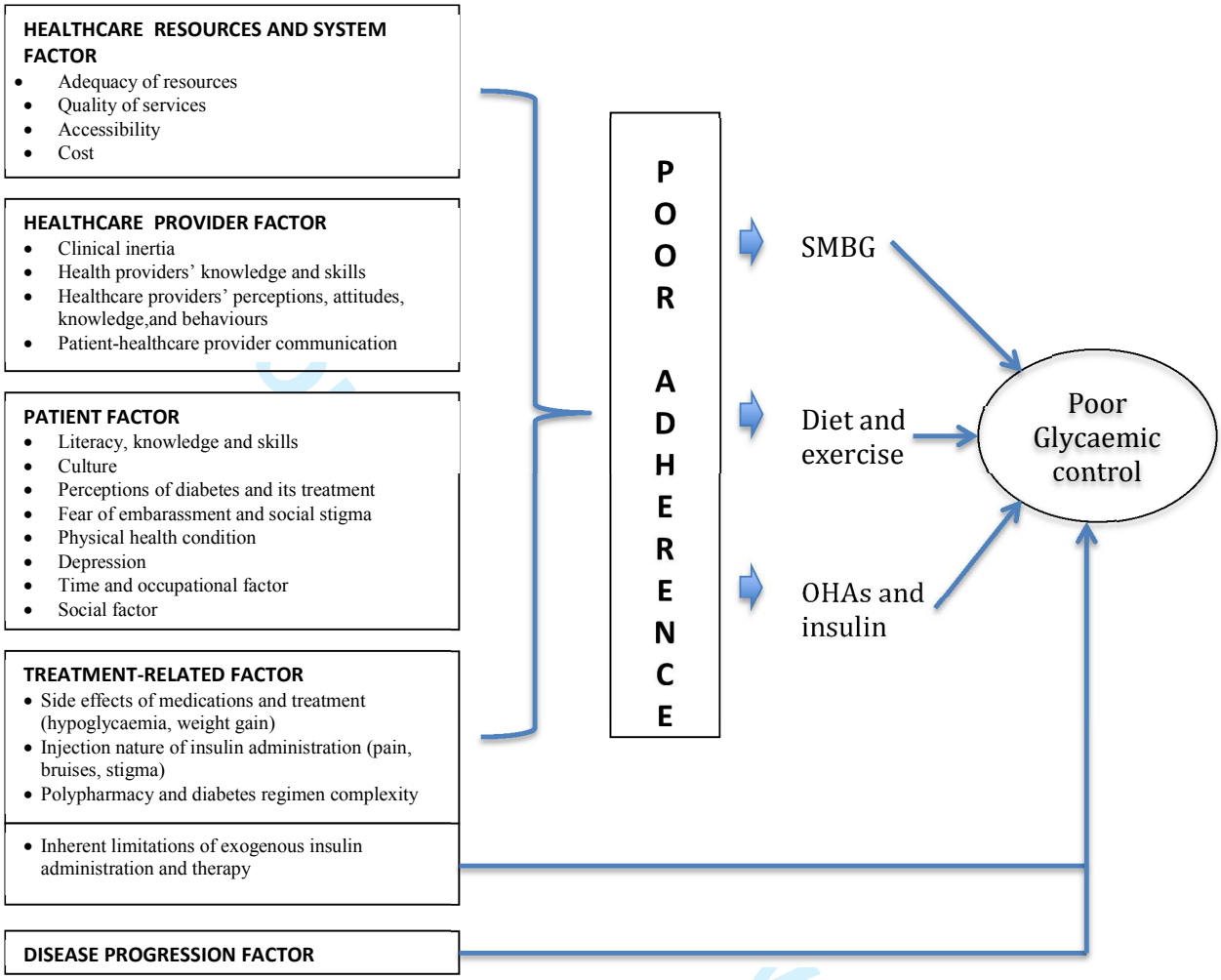
Table 2: Socio-demographic background and diabetes profile of participants

Characteristic	Participants (n=17)
Age (range)	22- 69 years
Sex	
Female	10
Male	7
Race	
Malays	8
Chinese	4
Indians	4
Nepalese	1
Education	
Secondary	9
Tertiary	5
Primary	2
No formal education	1
Years living with diabetes (range)	2-30
Years using insulin (range)	1-14

Table 3 Factors influencing poor glycaemic control in people with type 2 diabetes using insulin

	Theme	Category
1	Lifestyle challenges in adhering to medical recommendations	1. Difficulty integrating diabetes medical recommendations into work-life schedule 2. Inability to control food cravings and eating habits 3. Inappropriate diet recommendations by HCPs 4. Health-limiting conditions affecting exercise
2	Psychosocial issues and emotional hurdles	1. Psychosocial-problems affecting diabetes self-care management 2. Loss of motivation 3. Perceived poor glycaemic control as part of ageing
3	Diabetes treatment-related factors	1. Side-effects of insulin 2. Perception of appropriate dietary practices related to insulin
4	Lack of awareness and self-efficacy in diabetes self-care	1. Lack of awareness of glycaemic level and target 2. Lack of self-efficacy in adjustment of insulin dosage

Figure 1 Conceptual framework of study



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Why do people with type 2 diabetes who are using insulin have poor glycemic control? A qualitative study.

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Abstract

Objective

This study aims to explore the factors influencing poor glycemic control among people with type 2 diabetes using insulin.

Research design

This study used a qualitative methodology, comprising in-depth individual interviews. A semi-structured interview guide was used. The interviews were audio-recorded, transcribed verbatim and analysed using a thematic approach.

Participants:

Seventeen people with type 2 diabetes using insulin with HbA1c ≥ 9% for > 1 year participated in this study.

Setting

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC), Malaysia.

Results

Data analysis uncovered four themes. They were lifestyle challenges in adhering to medical recommendations, psychosocial and emotional hurdles, diabetes treatment related factors and, lack of knowledge and self-efficacy in diabetes self-care.

Conclusion

This study identified factors, which explained the poor glycaemic control in people with type 2 diabetes using insulin. Healthcare providers may use these findings to address patients' concerns during consultations and help to improve glycaemic control.

Word count: 163/250

Strengths and limitations of this study

- The major strength of this study lies in the fact that the reasons behind poor glycaemic control were uncovered from the perspectives of people with type 2 diabetes with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews.
- This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin.
- Issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system and HCPs did not emerge as reasons for poor glycaemic control despite insulin use.
- The recruitment of participants was conducted in a single hospital, hence healthcare systems as a factor in poor glycaemic control cannot be further explored.
- The interviews conducted in the hospital environment may influence the participants to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Introduction

Insulin has been identified as the most effective glucose lowering agent, however, studies has showed that many people with diabetes who are using insulin still fail to achieve glycemic control [1,2].

The challenges of achieving glycemic control in people with diabetes using insulin were: the progression of the disease, the impact of hypoglycemia and weight gain, the burden of poly-pharmacy, lack of resources in provision of diabetes self-care education and support of patients; and the inherent limitations of subcutaneous exogenous insulin administration [3]. Other predictors of poor glycemic control among people with type 2 diabetes using insulin include younger age, shorter duration of diagnosis of diabetes, lower body mass index and poor physical functioning [4]. Barriers to glycaemic control highlighted in a qualitative study among people with T2DM using insulin were fear about illness, guilt or self-blame, shame, ideas or beliefs about causation of diabetes, personal or cultural beliefs difficulty finding common grounds with clinicians on diabetes management [5].

To date, many studies have been conducted on barriers to insulin initiation [6-8], whereas, research on identifying factors for poor glycemic control among people with type 2 diabetes was largely by quantitative studies involving patients on various treatment modalities; including lifestyle adapters, OHAs (oral hypoglycemic agents), OHAs + insulin and insulin only [9-11], while qualitative studies focused on barriers to diabetes self-care management in general [12-15]. Very few qualitative studies examined factors impacting poor glycemic control from the patient's perspective,

especially among people with type 2 diabetes using insulin with poor glycemic control.

Since insulin is the most effective glucose-lowering agent, it is pertinent to understand from the patient's perspective why people with type 2 diabetes who are on insulin still fail to achieve glycemic control. This study will help fill the gap in existing literature by exploring factors influencing poor glycemic control in people with type 2 diabetes using insulin. An understanding of the barriers to achieving glycemic control will help healthcare providers (HCPs) find ways to improve glycemic control in this sub-population.

Research Design and Methods

This study used a qualitative methodology, comprising in-depth individual interviews to help understand patient experiences, as well as take into account the circumstances which led to poor glycemic control among people with type 2 diabetes using insulin.

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC). We purposively sampled patients who were diagnosed with type 2 diabetes, have been using insulin, either alone or in combination with OHAs and with poor control of diabetes (HBA1c $\geq$ 9%) for at least one year. Participants were chosen from various socio-demographic backgrounds (age, ethnicity, education level) so that different perspectives on the reasons for poor glycemic control can be explored.

We used a semi-structured interview guide (Table 1), which was developed based on the study's conceptual framework (Figure 1) drawn from literature review and experts' opinion. We reviewed the literature to identify possible factors, concepts and variables [16] that have been shown to influence glycaemic control among people with diabetes. A preliminary conceptual framework was developed based on these factors. Later, the conceptual framework was given to two researchers (NCJ and SRV) (one is a family medicine specialist and another is an endocrinologist) to provide feedback and strengthen the conceptual framework based on their clinical experience and expertise. Subsequently, the interview guide was constructed based on the revised conceptual framework.

The interviews were carried out between January and August 2013 in consultation rooms in both clinics. Written informed consent and socio-demographic information was obtained from patients who agreed to participate. During the interviews, the participants were asked for the reasons why they think their blood sugar is not well controlled despite using insulin. When the participant could not give any more reasons that they could think of, the researcher would then probe other areas contributing to poor glycemic control, as developed in the interview guide. Data saturation was achieved upon the 17th interview, when no new factors influencing poor glycemic control emerged from the interviews.

It is important to note that the participants of this study were recruited from the clinics where SRV and NCJ conduct their clinical practice. Thus, in order to offset the influence of power disparities between doctor and patient, all the interviews were conducted by WTT. WTT was competent in English, Malay and Cantonese, hence the

interviews were conducted in three languages. Out of the 17 interviews, there were two interviews that were conducted in Cantonese and seven in Malay. Given that the Cantonese language has many colloquialisms, the recordings were translated directly into English by WTT so the meaning would not be lost. Other interviews that were conducted in English and Malay were given to experienced transcribers for verbatim transcription. All the transcripts were checked for accuracy and quality by WTT by listening to the audio recording and checked against the transcript, before exported into NVivo qualitative software for data analysis using a thematic approach. Malay transcripts were analysed in the said language and the selected quotes were later translated to English. The translated quotes were checked with other researchers to ensure the meaning were not lost or distorted.

Initially, the transcripts were read through for familiarization by the researchers and then codes were assigned to a particular phrase, sentence or paragraph that described the meaning of the text segment. Sentences that had a similar meaning were given the same code while texts with different meaning were given a new code. The whole transcript was analyzed until there were no new meanings from the texts to form new codes. Subsequently, all the codes were compared and related codes were clustered together under the same category. Irrelevant codes were omitted. The categories were later compared and further clustered under themes. The mapping of categories and themes resulted in the development of a coding frame. The coding frame was developed from the coding process on the first three transcripts by all the researchers (WTT, NCJ, SRV). The coding frame was finalized when consensus was reached on the categories and themes. The finalized coding frame was used to code for the remaining transcripts by WTT. New emerging codes were added into the list of

categories and themes that were created through constant discussion with other researchers to ensure the list of categories and themes produced the best representation of data that was obtained. Researchers constantly challenged one another's interpretation of the data to offset any potential biases when analyzing the data.

Results

Socio-demographic and diabetes profile of participants

There were 17 participants in this study. Their socio-demographic and diabetes profiles are listed in Table 2.

Emerging themes

Four themes, which corresponded to factors influencing poor glycemic control despite insulin use, emerged from the data analysis (Table 3).

Lifestyle challenges in adhering to medical recommendations

Under this theme there are five subthemes identified.

Difficulty integrating diabetes medical recommendations into work-life schedule

Participants faced difficulties in integrating medical recommendations such as a medication regimen and meal times when they did not match with their daily activity schedule. When participants were too busy with their work-life, they tended to skip meals which caused them to become hungry and overeat later. Skipping meals also resulted in them missing or delaying their insulin injections.

"The way I eat and take the medications is not consistent. Sometimes I forget. Maybe I am too busy. Every time my insulin use would be delayed. For example, usually we inject at 12 right, sometimes I will inject at 2. Sometimes I did not inject at all" – 58 years old housewife

One participant described how the nature of his occupation made it difficult for him to adhere to healthy diet and insulin treatment.

"We are going around okay. So we can't just go and get what we want to eat. We can't go and pack something or bring the food from house. Furthermore, like now I'm taking the short-acting insulin, so every mealtime you have to inject. You just can't go and take insulin, you see. I'm working as a bodyguard you see, you have to follow the boss closely. I think so that is the reason [for poor blood sugar]". – Thomas 36 years old_personal bodyguard

Inability to control food cravings and eating habits

Participants also reported that the temptation of eating something delicious would lead them to lose control of their diet, causing them to overeat.

"My eating habit. Like I like to eat sweets, like kuihs [local dessert] and all that. But I have to control. I know I am not controlling. I must put a full stop to that." - 60 years old woman housewife

It is also difficult to resist food when there is a variety of food available and coming from a lifestyle and culture where food and eating are a way of living.

"Basically it is also Malaysia lifestyle whereby people like to eat. You eat non-stop. Sugar is particularly everywhere in your diet so that's probably one of the main reasons why it is not controlled". - 22 years old student

Inappropriate diet recommendations by healthcare providers

Participants felt that the diet recommended by HCPs provided insufficient energy for them to carry out their work. Some also expressed frustrations with regards to the monotony of eating the same type of food every day, such as bread and chapatti, which were recommended by the HCPs. Hence, they often neglected the dietary advice.

"Every time they [HCPs] ask me to eat bread. Can you eat bread everyday? For sure you will hate it. They will ask to eat vegetables every day. Cannot like that " - 59 years old ex-lorry driver

Health conditions affecting exercise

Not being able to exercise optimally due to health conditions was another reason cited by many for poor glycemic control.

"Another thing is exercise. Because of stroke, I have problem with walking. I have to exercise more". - 61 years old engineer

Psychosocial issues and emotional hurdles

Three subthemes emerged under this theme.

Psychosocial problems affecting diabetes self-care

Participants felt that their poor glycemic control was attributed to personal problems which caused them to feel anxious, stressed and sad, which resulted in some adopting unhealthy eating habits and not taking their diabetes medications, including insulin.

> *"Actually when you have diabetes, you cannot be stressed. Previously when I was under stress [due to marital problems], my blood sugar level was very high because I did not eat and take my insulin. I was hoping to die." – 50 years old taxi driver*

Loss of motivation

Participants admitted that they were tired of adhering to diabetes medications after having taken them for such a long time that sometimes they would intentionally skip doses.

> *"Sometimes I purposely miss them because I am just so tired of injecting". – 40 years old officer*

Additionally, an absence of significant improvements in glycemic control despite efforts made to improve glycemic control led participants to 'give up' in controlling their blood sugar.

"There's one time actually I did go to the gym and the exercise was okay but it didn't really do anything to my weight. It does a little bit on my sugar but after a while I just give up. I think it would be as well [contributed to her poor glycemic control] because the main thing is that, I think that if I actually lose weight, I would be able to control my sugar as well." – 40 year old officer

Perceived poor glycemic control as part of ageing

Many older participants of this study held the view that whatever their attempts to control blood glucose levels, their glycemic control would still fall short due to their advanced age.

"Maybe because I am getting old. As the days passed by, all my organs has deteriorated. Like engine, the more it is used, it will become spoilt." - 69 years old retiree

Diabetes treatment-related factors

There are two subthemes under this theme.

Side-effects of insulin

Participants reported they would tend to overeat to prevent or counter the effects of insulin-induced hypoglycaemia. However, it is when participants overeat that their glycemic control deteriorates.

> *"I had fit once (due to hypoglycaemia), that fear is always there. On and off, I used to eat more to make sure I don't go into hypoglycaemia fit. It is extremely painful". - 47 years old doctor*

Participants also felt that insulin caused them to feel hungry, causing them to overeat, hence, raising their blood sugar levels.

> *"But if use insulin, it makes me eat. I feel that after using insulin, the blood sugar goes even higher". – 37 years old clerk*

Fear of needles and pain also caused participants to delay insulin initiation as well as intentionally skipping injections, thus contributing to poor glycemic control.

> *"I don't quite like insulin actually. I'm very afraid of needles and the pain that follows. In a week I would say at least 3 times [skipping insulin injections]. Although my blood sugar was already up about 6 to 7 years ago, but I've only started insulin not far back from now. So that's the other reason [for poor glycemic control]." – 40 years old officer*

Perception of appropriate dietary practices related to insulin

One participant felt that his poor glycemic control was attributed to the diet recommendations given by the HCP. He voiced that the meal pattern recommended was not right and would instead reduce the efficacy of the insulin.

> *"For example if you eat at 8pm, then you feel hungry and you eat again. So if I follow his [doctor] advice I will eat but this is wrong. The mistake is if lets say I eat at 7pm, then 8, 9, 10, 11, 12pm, for about 4 hours I will keep on eating. So the insulin cannot fight with my diabetes. Because I have experienced this so I know. The recommended cannot work. My diabetes reach 20, 30 something". – 50 years old taxi driver*

Lack of knowledge and self-efficacy in diabetes self-care

Two subthemes were identified under this theme.

Lack of knowledge of glycemic level and target

Lack of knowledge of their glycemic level and target was also cited as a reason for poor glycemic control, as participants were not aware to what extent they should control their blood sugar. This lack of knowledge was attributed to difficulties in performing SMBG due to financial reason, and some claimed that their HCPs did not inform them about their glycemic levels and target.

> *"I check less because sometimes when the needles are finished, I have to wait for my salary to buy. I check once a week but if I need to see the doctor*

then only I will check 4 times a day. Actually it is not enough. When I don't check, I cannot control my diet so that's why my blood sugar is not good". – 37 years old clerk

"I don't know why he [doctor] wants to lower (blood sugar level) some more. No, because I don't know what is the target. The doctor never mentioned. I am also not sure. So I also don't know whether I am okay or not. If I know, I will control no matter what". -31 years old marketing coordinator

Lack of self-efficacy in adjustment of insulin dosage

Despite receiving advice from the doctor that they could adjust their insulin dosage, some participants did not do so as they were afraid of making mistakes when adjusting the insulin dose, which could lead to hypoglycaemia and other complications.

"I'm just reluctant [to adjust insulin dosage] because they [doctor] won't be with me 24 hours. I didn't increase or decrease any of the medication. I just stick to it. So maybe that is the reason". - 36 years old personal bodyguard

Discussions

Our study revealed that people with type 2 diabetes using insulin attributed their sustained hyperglycemia to lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of knowledge of glycemic levels and targets, as well as poor self-efficacy with regards to insulin dosage adjustment. Majority of the factors raised were not related to problems with insulin use per se, but were related to barriers in performing diabetes self-care tasks in general such as dietary control, adherence to exercise and medications including OHAs.

Our study participants faced difficulties in adhering to the recommended meal and insulin injection schedule due to work priorities and time constraints. In a multinational study involving 1530 people with type 1 diabetes (12.8%) and type 2 diabetes (88.2%) using insulin from eight countries, taking insulin at the prescribed time or with meals everyday was also reported to be difficult [17]. The lifestyle changes required for diabetes management in terms of diet and regular mealtimes were acknowledged to be hard to implement, even in people with type 2 diabetes using OHAs alone, who often report missed or delayed meals [18]. This showed that adherence to regular meal and medication times is a universal and major barrier to diabetes management among people with diabetes. It is crucial to overcome that, especially among people with type 2 diabetes using insulin, as insulin administration has to be synchronized with meals. When regular meal times cannot be followed, it often results in delayed or skipped insulin intake, as reported in our study, which explains poor glycemic control.

Our participants raised the issue of dietary recommendations by HCPs, which did not meet their dietary needs; the issues of the monotony of eating the same type of food every day and the recommended diet could not provide sufficient energy. Other people with type 2 diabetes using insulin have reported that clinicians would simply assume that patients would comply to the medical recommendations given; without considering their individual needs and preferences [5]. Additionally, it also appears that lack of understanding of the rationale behind dietary recommendations is common among type 2 diabetes patients. One participant of our study thought the meal pattern recommended by HCPs would thwart the efficacy of insulin, while type 2 diabetes patients on OHAs in another study perceived that frequent meals was a way to control their diabetes [19]. In fact, the main purpose of regular meals is actually to counter the effects of hypoglycemia, due to insulin and long acting sulfonylureas. HCPs may be a contributing factor to these barriers in adhering to dietary recommendations. In a collaborative study conducted in Austria, Canada, Germany and United Kingdom, it was found that general practitioners lack the knowledge and skills to educate, support and motivate patients on healthy lifestyle changes [20].

The issue of psychosocial factors and lack of motivation is crucial, as it affects all aspects of diabetes self-care including adherence to insulin, as evidenced from our study. Diabetes self-care is a complex task that demands behavioral change in the patient on a daily basis; the influences of social, cultural, familial and professional contexts further complicate management of the disease in diabetes patients as shown in other studies [21-23]. Furthermore, our participants also showed that when a patient's diabetes condition remains unimproved despite efforts to control it, this

leads to 'diabetes burn-out' stemming from frustration and loss of motivation; eventually resulting in neglect of diabetes self-care. Perhaps explaining the disease progression in type 2 diabetes and that the progressive loss of β-cell function is common, will lift the feeling of frustration and loss of motivation in them.

Older participants of our study perceived that they would never be able to achieve glycemic control due to their old age even with insulin use. Such misconceptions are alarming as they may decrease older people's perceived importance of glycemic control. They may lower their expected treatment target in order to cope with the challenges in managing diabetes at such an age [24]. There is a need to inform elderly people with type 2 diabetes that insulin has no upper limit dosage and they will still be able to control their glycemic levels even with increasing age.

Issues such as fear of hypoglycaemia and needles and pain have been well established as barriers to insulin initiation [6,7] and it is interesting to know that such problems still prevails even after participant initiate insulin use, as found in participants of our study. Moreover, these factors have been well established as factors for intentional insulin omission [25] and overeating to prevent insulin-induced hypoglycemia [5,26]. The UMMC has an established specialized diabetes clinic with trained diabetes nurses to provide education and skills training in diabetes self-care to patients. Therefore, our study participants would have been educated and trained on techniques of insulin administration and ways to prevent and manage hypoglycemia. In addition to providing diabetes education and skills training to people with type 2 diabetes using insulin, provision of counselling to address these fears is warranted.

Lack of knowledge of glycemic level and targets was also a reason for poor glycemic control in our participants. They were unsure to what extent they should control their glucose levels. The issue of lack of knowledge of glycemic levels and targets in our study stemmed from lack of SMBG and perceived minimal feedback from HCPs. Our participants reported financial constraints in carrying out effective SMBG, as costs for SMBG supplies are not subsidized by the Malaysian government. The impact of economic factors on SMBG adherence have been reported as an issue that limits glycemic control in other studies [27,28]. In a study by Onwudine et al., (2011), the study participants reported that they were not informed by their doctor of their target blood glucose levels and perceived that as a barrier to diabetes self-management [29]. HCPs have a crucial role to play in discussing glycemia results with their patients and formulating mutually agreed glycemic targets. A study has shown that knowledge of HbA1c and target goal had a positive impact on maintaining better glycemic control among people with type 2 diabetes [30].

Self-adjustment of insulin dosage have been shown to be a technically complex regimen for people with type 1 diabetes [31] and people with diabetes spend most of their time managing their diabetes away from healthcare professionals. It is thus not surprising that our participants were still apprehensive about self-adjustment of their insulin dose; for fear of hypoglycemia. Dependent and deferential attitudes towards health professionals were cited as the reasons why type 1 diabetes patients do not adjust their insulin dosage [31] and this may also be the reason for failure to adjust insulin dosing among our participants. Furthermore, the lack of skills to educate patients on how to monitor their glycaemic levels and adjustment of insulin has also been found to be a common challenge faced by general practitioners [20].

Some factors for poor glycemic control as highlighted in the conceptual framework did not emerge in our study findings even when the participants were probed. The issue of social stigma was not raised by our participants as a reason for poor glycemic control. We assumed that our participants had overcome this barrier upon initiation of insulin since they have been on insulin for at least one year; as they also reported of performing adaptive strategies such as injecting insulin in private in public places, for example in the toilet or in their car. Ethnicity was also not raised as a factor for poor glycaemic control in this study. Instead, the participants described eating culture as a way of living for Malaysians in general. Therefore, participants of this study might have adapted to the 'Malaysian' culture whereby they share and practise culture of others. Even if the recommended diet by HCPs may not be the types of food familiar with the specific ethnic group or culture, nevertheless, they could still follow the recommended diet. No specific ethnicity barrier was also reported for diabetes treatment aspects. Socio-economic was not a factor for participants in this study to seek healthcare treatment as the company where they or their spouses are working subsidized the medical costs. It should also be noted that the Malaysian government provides relatively cheap health care for the people and the cost for insulin is subsidized. However, this is not the case for SMBG where patients have to pay out-of-pocket for glucometer and test strips. This is the reason why the lack of knowledge of glycaemic status due to low performance of SMBG was raised as a reason for poor glycaemic control. Our participants did not blame their family, friends, healthcare system or HCPs for their poor glycemic control. They however expressed dismay at the short consultation times and not being able to see the same doctor for their diabetes. Our participants expressed that diabetes control is a personal responsibility, therefore they tended to focus on their personal inadequacies when it came to poor

glycemic control. This may be due to diabetes self-care playing a huge role in disease control, hence people with type 2 diabetes may have felt greater responsibility for self-care. Thus, when glycemic control cannot be achieved, this resulted in self-blame [32].

The strengths and limitations of the study

The major strength of this study lies in the fact that the reasons behind poor glycaemic control were gained from the insights of people with T2DM with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews to explain why their diabetes remains poorly controlled despite being on insulin. To researchers' knowledge, such findings has never been reported before. This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin, whereas, issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system factors and HCPs were found not to be reasons for poor glycaemic control despite insulin use.

This study has a few limitations. The recruitment of participants in this study was only conducted in a single hospital, hence healthcare systems as a factor in poor glycemic control cannot be further explored. The interviews were conducted in the hospital where the participants were recruited, hence the environment may influence them to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Clinical recommendations

HCPs should create individualized plans with people with type 2 diabetes using insulin, to ensure a routine that allows for proper meal times and exercise, which would enable them to take their diabetes medication, including insulin, in a timely manner. Patients reported they face problems with treatment recommendations, hence HCPs should continuously assess the efficacy and feasibility of treatment provided to their patients and clarify patient misconceptions. It is also pertinent for HCPs to recognise the psychological and emotional problems that impact on their patients' diabetes self-care and provide affective support to them. Lastly, HCPs should discuss glycemic readings and adjustment of insulin dosage, as well as formulate a mutually agreed target with patients to facilitate improvement of glycemic control.

Murray et al., (2011) has identified the common challenges faced by general practitioners when caring for people with type 2 diabetes across international and health system borders and they were related to knowledge, skills, attitudes, behaviours and context [20]. Some of the challenges faced by HCPs may explain the reasons for poor glycaemic control as faced by participants of this study such as the lack of knowledge and skills to: give clear explanations to the patients, actively engage their patients in their health management, educate patients on how to monitor their glycaemic levels, engage in shared decision making with patients and provide support and motivation to patients in their efforts towards lifestyle chnages for better glycaemic control. Therefore, it is pertinent that HCPs are equipped with accurate and latest knowledge and skills about diabetes and its treatment and be able to impart them to their patients to empower them to perform effective diabetes self-care tasks.

Future research recommendations

More research is needed pertaining to this topic to uncover other factors that could influence poor glycemic control despite insulin use. In addition, exploring views from HCPs and caretakers of the patients would provide a more holistic understanding of factors for poor glycemic control despite insulin use. Accurate assessment of patient's knowledge, actual self-care practices, and, clinical characteristics could also be conducted. This would allow triangulation of multiple sources of data which would then provide more comprehensive understanding and better identification of reasons for poor glycemic control. Ultimately, the factors identified may help to develop a tool to be used by HCPs, as a checklist to address the barriers faced by people with type 2 diabetes using insulin in achieving glycemic control. In addition, future study should look into the motivators of better glycaemic control among people with type 2 diabetes using insulin who is succesful in gaining glycaemic control. Understanding both the barriers and the motivators would help to improve glycaemic control among this subpopulation.

Conclusions

Our findings revealed lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of knowledge of glycemic levels and targets, and poor self-efficacy with regards to insulin dosage adjustment as factors for poor glycemic control despite insulin use. Healthcare providers could look into these factors and help patients with type 2 diabetes using insulin to address their concerns during consultations and thus improve glycemic control.

Contributorship statement

All authors (WTT, SRV, CJN) of this study conceived and designed the study, researched and analysed the data, contributed to discussion, wrote, edited, reviewed and approved the final version of the manuscript.

Competing interests

None.

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Ethics approval

This study received ethical approval from the University of Malaya Medical Centre Medical Ethics Committee (926.18).

Data sharing

No additional data are available.

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Title: Why do people with type 2 diabetes who are using insulin have poor glycemic control? A qualitative study.

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Keywords: Diabetes and endocrinology; qualitative research; social medicine

Abstract

Objective

This study aims to explore the factors influencing poor glycemic control among people with type 2 diabetes using insulin.

Research design

This study used a qualitative methodology, comprising in-depth individual interviews. A semi-structured interview guide was used. ~~for~~ T~~t~~he interviews ~~, which~~ were audio-recorded, transcribed verbatim and analys~~z~~ed using a thematic approach.

Participants:

Seventeen people with type 2 diabetes using insulin with HbA1c ≥ 9% for > 1 year participated in this study.

Setting

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC), Malaysia.

Results

Data analysis uncovered four themes. They were lifestyle challenges in adhering to medical recommendations, psychosocial and emotional hurdles, diabetes treatment related factors and, lack of knowledge and self-efficacy in diabetes self-care. ~~revealed participants faced difficulties in integrating diabetes self-care tasks into their daily work-life schedule. They could not resist food cravings and health-limiting conditions hampered their performing exercise, both of which contributed to poor glycaemic control. Psychosocial and emotional problems caused participants to neglect their diabetes self-care. Some gave up when there were no improvements in their glycaemic control. Side effects of insulin use, such as fear of hypoglycaemia, needles and pain, and increased hunger caused participants to overeat and omit insulin. Lack of awareness of glycaemic levels and targets rendered participants unsure to what extent they should control their diet. Some were not confident in adjusting their insulin dosage for fear of negative consequences.~~

Conclusion

This study identified factors, which explained the poor glycaemic control in people with type 2 diabetes using insulin. Healthcare providers may use these findings to address patients' concerns during consultations and help to improve glycaemic control.

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Strengths and limitations of this study

- The major strength of this study lies in the fact that the reasons behind poor glycaemic control were uncovered from the perspectives of people with type 2 diabetes with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews.
- This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin.
- Issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system and HCPs did not emerge as reasons for poor glycaemic control despite insulin use.
- ~~This is the first few studies provided insights into factors for poor glycaemic control despite insulin use.~~
- ~~Healthcare providers could use the findings and help patients with type 2 diabetes using insulin to address their concerns during consultations and improve glycaemic control.~~
- The recruitment of participants was conducted in a single hospital, hence healthcare systems as a factor in poor glycaemic control cannot be further explored.
- The interviews conducted in the hospital environment may influence the participants to give a socially desirable response. However, they were informed that their responses ~~will~~ would not affect their medical care and ~~will~~ would be kept confidential.

Introduction

Insulin has been identified as the most effective glucose lowering agent, however, studies has showed that many people with diabetes who are using insulin still fail to achieve glycemic control [1,2].

The challenges of achieving glycemic control in people with diabetes using insulin were: the progression of the disease, the impact of hypoglycemia and weight gain, the burden of poly-pharmacy, lack of resources in provision of diabetes self-care education and support of patients; and the inherent limitations of subcutaneous exogenous insulin administration [3]. Other predictors of poor glycemic control among people with type 2 diabetes using insulin include younger age, shorter duration of diagnosis of diabetes, ~~the interaction of age and duration of diabetes,~~ lower body mass index and poor physical functioning [4]. Barriers to glycaemic control highlighted in a qualitative study among people with T2DM using insulin were fear about illness, guilt or self-blame, shame, ideas or beliefs about causation of diabetes, personal or cultural beliefs difficulty finding common grounds with clinicians on diabetes management [5].

To date, many studies have been conducted on barriers to insulin initiation [6-8], whereas, research on identifying factors for poor glycemic control among people with type 2 diabetes was largely by quantitative studies involving patients on various treatment modalities; including lifestyle adapters, OHAs (oral hypoglycemic agents), OHAs + insulin and insulin only [9-11], while qualitative studies focused on barriers to diabetes self-care management in general [12-15]. Very few qualitative studies examined factors impacting poor glycemic control from the patient's perspective,

especially among people with type 2 diabetes using insulin with poor glycemic control.

Since insulin is the most effective glucose-lowering agent, it is pertinent to understand from the patient's perspective why people with type 2 diabetes who are on insulin still fail to achieve glycemic control. This study will help fill the gap in existing literature by exploring factors influencing poor glycemic control in people with type 2 diabetes using insulin. An understanding of the barriers to achieving glycemic control will help healthcare providers (HCPs) find ways to improve glycemic control in this sub-population.

Research Design and Methods

This study used a qualitative methodology, comprising in-depth individual interviews to help understand patient experiences, as well as take into account the circumstances which led to poor glycemic control among people with type 2 diabetes using insulin.

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC). We purposively sampled patients who were diagnosed with type 2 diabetes, have been using insulin, either alone or in combination with OHAs and with poor control of diabetes (HBA1c $\geq$ 9%) for at least one year. Participants were chosen from various socio-demographic backgrounds (age, ethnicity, education level) so that different perspectives on the reasons for poor glycemic control can be explored.

We used a semi-structured interview guide (Table 1), which was developed based on the study's conceptual framework (Figure 1) drawn from literature review and experts' opinion. We reviewed the literature to identify possible factors, concepts and variables [16] that have been shown to influence glycaemic control among people with diabetes. A preliminary conceptual framework was developed based on these factors. Later, the conceptual framework was given to two researchers (NCJ and SRV) (one is a family medicine specialist and another is an endocrinologist) to provide feedback and strengthen the conceptual framework based on their clinical experience and expertise. Subsequently, the interview guide was constructed based on the revised conceptual framework.

The interviews were carried out between January and August 2013 in consultation rooms in both clinics. Written informed consent and socio-demographic information was obtained from patients who agreed to participate. During the interviews, the participants were asked for the reasons why they think their blood sugar is not well controlled despite using insulin. When the participant could not give any more reasons that they could think of, the researcher would then probe other areas contributing to poor glycemic control, as developed in the interview guide. Data saturation was achieved upon the 17th interview, when no new factors influencing poor glycemic control emerged from the interviews.

It is important to note that the participants of this study were recruited from the clinics where SRV and NCJ conduct their clinical practice. Thus, in order to offset the influence of power disparities between doctor and patient, all the interviews were conducted by WTT. WTT was competent in English, Malay and Cantonese, hence the

interviews were conducted in three languages. Out of the 17 interviews, there were two interviews that were conducted in Cantonese and seven in Malay. Given that the Cantonese language has many colloquialisms, the recordings were translated directly into English by WTT so the meaning would not be lost. Other interviews that were conducted in English and Malay were given to experienced transcribers for verbatim transcription. All the transcripts were checked for accuracy and quality by WTT by listening to the audio recording and checked against the transcript, before exported into NVivo qualitative software for data analysis using a thematic approach. Malay transcripts were analysed in the said language and the selected quotes were later translated to English. The translated quotes were checked with other researchers to ensure the meaning were not lost or distorted.

Initially, the transcripts were read through for familiarization by the researchers and then codes were assigned to a particular phrase, sentence or paragraph that described the meaning of the text segment. Sentences that had a similar meaning were given the same code while texts with different meaning were given a new code. The whole transcript was analyzed until there were no new meanings from the texts to form new codes. Subsequently, all the codes were compared and related codes were clustered together under the same category. Irrelevant codes were omitted. The categories were later compared and further clustered under themes. The mapping of categories and themes resulted in the development of a coding frame. The coding frame was developed from the coding process on the first three transcripts by all the researchers (WTT, NCJ, SRV). The coding frame was finalized when consensus was reached on the categories and themes. The finalized coding frame was used to code for the remaining transcripts by ~~T~~WTT. New emerging codes were added into the list of

categories and themes that were created through constant discussion with other researchers to ensure the list of categories and themes produced the best representation of data that was obtained. Researchers constantly challenged one another's interpretation of the data to offset any potential biases when analyzing the data.

Results

Socio-demographic and diabetes profile of participants

There were 17 participants in this study. Their socio-demographic and diabetes profiles are listed in Table 2.

Emerging themes

Four themes, which corresponded to factors influencing poor glycemic control despite insulin use, emerged from the data analysis (Table 3).

Lifestyle challenges in adhering to medical recommendations

Under this theme there are five subthemes identified.

~~Participants highlighted a range of lifestyle challenges in adhering to medical recommendations which contributed to their poor glycemic control. These included difficulty in integrating diabetes medical recommendations into their work-life schedule, inability to control food cravings and eating habits, inappropriate diet recommendations by HCPs and health-limiting conditions affecting diabetes self-care.~~

Difficulty integrating diabetes medical recommendations into work-life schedule

Participants faced difficulties in integrating medical recommendations such as a medication regimen and meal times when they did not match with their daily activity schedule. When participants were too busy with their work-life, they tended to skip meals which caused them to become hungry and overeat later. Skipping meals also resulted in them missing or delaying their insulin injections.

> *"The way I eat and take the medications is not consistent. Sometimes I forget. Maybe I am too busy. Every time my insulin use would be delayed. For example, usually we inject at 12 right, sometimes I will inject at 2. Sometimes I did not inject at all" – 58 years old housewife*

One participant described how the nature of his occupation made it difficult for him to adhere to healthy diet and insulin treatment.

> *"We are going around okay. So we can't just go and get what we want to eat. We can't go and pack something or bring the food from house. Furthermore, like now I'm taking the short-acting insulin, so every mealtime you have to inject. You just can't go and take insulin, you see. I'm working as a bodyguard you see, you have to follow the boss closely. I think so that is the reason [for poor blood sugar]". – Thomas 36 years old personal bodyguard*

Inability to control food cravings and eating habits

Participants also reported that the temptation of eating something delicious would lead them to lose control of their diet, causing them to overeat.

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"My eating habit. Like I like to eat sweets, like kuihs [local dessert] and all that. But I have to control. I know I am not controlling. I must put a full stop to that." - 60 years old woman housewife

It is also difficult to resist food when there is a variety of food available and coming from a lifestyle and culture where food and eating are a way of living.

"Basically it is also Malaysia lifestyle whereby people like to eat. You eat non-stop. Sugar is particularly everywhere in your diet so that's probably one of the main reasons why it is not controlled". - 22 years old student

Inappropriate diet recommendations by healthcare providers

Participants felt that the diet recommended by HCPs provided insufficient energy for them to carry out their work. Some also expressed frustrations with regards to the monotony of eating the same type of food every day, such as bread and chapatti, which were recommended by the HCPs. Hence, they often neglected the dietary advice.

"Every time they [HCPs] ask me to eat bread. Can you eat bread everyday? For sure you will hate it. They will ask to eat vegetables every day. Cannot like that " - 59 years old ex-lorry driver

Health conditions affecting exercise

Not being able to exercise optimally due to health conditions was another reason cited by many for poor glycemic control.

"Another thing is exercise. Because of stroke, I have problem with walking. I have to exercise more". - 61 years old engineer

Psychosocial issues and emotional hurdles

~~Psychosocial and emotional problems also affected the participants' diabetes self-care; some lost motivation while others perceived poor glycemic control as part of ageing. These, they believed, had led to their poor glycemic control.~~ Three subthemes emerged under this theme.

Psychosocial problems affecting diabetes self-care

Participants felt that their poor glycemic control was attributed to personal problems which caused them to feel anxious, stressed and sad, which resulted in some adopting unhealthy eating habits and not taking their diabetes medications, including insulin.

"Actually when you have diabetes, you cannot be stressed. Previously when I was under stress [due to marital problems], my blood sugar level was very high because I did not eat and take my insulin. I was hoping to die." – 50 years old taxi driver

Loss of motivation

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Participants admitted that they were tired of adhering to diabetes medications after having taken them for such a long time that sometimes they would intentionally skip doses.

> *"Sometimes I purposely miss them because I am just so tired of injecting". – 40 years old officer*

Additionally, an absence of significant improvements in glycemic control despite efforts made to improve glycemic control led participants to 'give up' in controlling their blood sugar.

> *"There's one time actually I did go to the gym and the exercise was okay but it didn't really do anything to my weight. It does a little bit on my sugar but after a while I just give up. I think it would be as well [contributed to her poor glycemic control] because the main thing is that, I think that if I actually lose weight, I would be able to control my sugar as well." – 40 year old officer*

Perceived poor glycemic control as part of ageing

Many older participants of this study held the view that whatever their attempts to control blood glucose levels, their glycemic control would still fall short due to their advanced age.

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"Maybe because I am getting old. As the days passed by, all my organs has deteriorated. Like engine, the more it is used, it will become spoilt." - 69 years old retiree

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Diabetes treatment-related factors

~~Diabetes treatment-related factors include side-effects of insulin and perception of appropriate dietary practices related to insulin.~~There are two subthemes under this theme.

Side-effects of insulin

Participants reported they would tend to overeat to prevent or counter the effects of insulin-induced hypoglycaemia. However, it is when participants overeat that their glycemic control deteriorates.

> *"I had fit once (due to hypoglycaemia), that fear is always there. On and off, I used to eat more to make sure I don't go into hypoglycaemia fit. It is extremely painful". - 47 years old doctor*

Participants also felt that insulin caused them to feel hungry, causing them to overeat, hence, raising their blood sugar levels.

> *"But if use insulin, it makes me eat. I feel that after using insulin, the blood sugar goes even higher". – 37 years old clerk*

Fear of needles and pain also caused participants to delay insulin initiation as well as intentionally skipping injections, thus contributing to poor glycemic control.

> *"I don't quite like insulin actually. I'm very afraid of needles and the pain that follows. In a week I would say at least 3 times [skipping insulin injections]. Although my blood sugar was already up about 6 to 7 years ago,*

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but I've only started insulin not far back from now. So that's the other reason [for poor glycemic control]." – 40 years old officer

Perception of appropriate dietary practices related to insulin

One participant felt that his poor glycemic control was attributed to the diet recommendations given by the HCP. He voiced that the meal pattern recommended was not right and would instead reduce the efficacy of the insulin.

"For example if you eat at 8pm, then you feel hungry and you eat again. So if I follow his [doctor] advice I will eat but this is wrong. The mistake is if lets say I eat at 7pm, then 8, 9, 10, 11, 12pm, for about 4 hours I will keep on eating. So the insulin cannot fight with my diabetes. Because I have experienced this so I know. The recommended cannot work. My diabetes reach 20, 30 something". – 50 years old taxi driver

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Lack of ~~awareness~~ knowledge and self-efficacy in diabetes self-care

Two subthemes were identified under this theme.

~~Participants lacked awareness and self-efficacy in diabetes self-care. They did not know their glycemic level and target and were not confident in adjusting the insulin dosage on their own.~~

Lack of ~~awareness~~ knowledge of glycemic level and target

Lack of ~~awareness~~ knowledge of their glycemic level and target was also cited as a reason for poor glycemic control, as participants were not aware to what extent they should control their blood sugar. This lack of ~~awareness~~ knowledge was attributed to difficulties in performing SMBG due to financial reason, and some claimed that their HCPs did not inform them about their glycemic levels and target.

"I check less because sometimes when the needles are finished, I have to wait for my salary to buy. I check once a week but if I need to see the doctor then only I will check 4 times a day. Actually it is not enough. When I don't check, I cannot control my diet so that's why my blood sugar is not good". – 37 years old clerk

"I don't know why he [doctor] wants to lower (blood sugar level) some more. No, because I don't know what is the target. The doctor never mentioned. I am also not sure. So I also don't know whether I am okay or not. If I know, I will control no matter what". -31 years old marketing coordinator

Lack of self-efficacy in adjustment of insulin dosage

Despite receiving advice from the doctor that they could adjust their insulin dosage, some participants did not do so as they were afraid of making mistakes when adjusting the insulin dose, which could lead to hypoglycaemia and other complications.

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"I'm just reluctant [to adjust insulin dosage] because they [doctor] won't be with me 24 hours. I didn't increase or decrease any of the medication. I just stick to it. So maybe that is the reason". - 36 years old personal bodyguard

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Discussions

Our study revealed that people with type 2 diabetes using insulin attributed their sustained hyperglycemia to lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of ~~awareness~~ knowledge of glycemic levels and targets, as well as poor self-efficacy with regards to insulin dosage adjustment. Majority of the factors raised were not related to problems with insulin use per se, but were related to barriers in performing diabetes self-care tasks in general such as dietary control, adherence to exercise and medications including OHAs.

Our study participants faced difficulties in adhering to the recommended meal and insulin injection schedule due to work priorities and time constraints. In a multinational study involving 1530 people with type 1 diabetes (12.8%) and type 2 diabetes (88.2%) using insulin from eight countries, taking insulin at the prescribed time or with meals everyday was also reported to be difficult [17]. The lifestyle changes required for diabetes management in terms of diet and regular mealtimes were acknowledged to be hard to implement, even in people with type 2 diabetes using OHAs alone, who often report missed or delayed meals [18]. This showed that adherence to regular meal and medication times is a universal and major barrier to diabetes management among people with diabetes. It is crucial to overcome that, especially among people with type 2 diabetes using insulin, as insulin administration has to be synchronized with meals. When regular meal times cannot be followed, it often results in delayed or skipped insulin intake, as reported in our study, which explains poor glycemic control.

Our participants raised the issue of dietary recommendations by HCPs, which did not meet their dietary needs; the issues of the monotony of eating the same type of food every day and the recommended diet could not provide sufficient energy. Other people with type 2 diabetes using insulin ~~also~~ have reported that clinicians would simply assume that patients would comply to the medical recommendations given; without considering their individual needs and preferences [5]. Additionally, it also appears that lack of understanding of the rationale behind dietary recommendations is common among type 2 diabetes patients. One~~ur~~ participant of our study~~s~~ thought the meal pattern recommended by HCPs would thwart the efficacy of insulin, while type 2 diabetes patients on OHAs in another study perceived that frequent meals was a way to control their diabetes [19]. In fact, the main purpose of regular meals is actually to counter the effects of hypoglycemia, due to insulin and long acting sulfonylureas. HCPs may be a contributing factor to these barriers in adhering to dietary recommendations. In a collaborative study conducted in Austria, Canada, Germany and United Kingdom, it was found that general practitioners lack the knowledge and skills to educate, support and motivate patients on healthy lifestyle changes [20]. ~~These findings highlight the importance of HCPs in individualizing treatment management plans according to the patient's needs It is also pertinent that HCPs explain to patients the rationale behind the treatment recommendation so that misconceptions would not cause the patient to neglect the medical advice or to practice other treatment approaches.~~

The issue of psychosocial factors and lack of motivation is crucial, as it affects all aspects of diabetes self-care including adherence to insulin, as evidenced from our study. Diabetes self-care is a complex task that demands behavioral change in the

patient on a daily basis; the influences of social, cultural, familial and professional contexts further complicate management of the disease in diabetes patients as shown in other studies [21-23]. Furthermore, our participants also showed that when a patient's diabetes condition remains unimproved despite efforts to control it, this leads to 'diabetes burn-out' stemming from frustration and loss of motivation; eventually resulting in neglect of diabetes self-care. Perhaps explaining the disease progression in type 2 diabetes and that the progressive loss of β-cell function is common, will lift the feeling of frustration and loss of motivation in them.

Older participants of our study perceived that they would never be able to achieve glycemic control due to their old age even with insulin use. Such misconceptions are alarming as they may decrease older people's perceived importance of glycemic control. They may lower their expected treatment target in order to cope with the challenges in managing diabetes at such an age [24]. There is a need to inform elderly people with type 2 diabetes that insulin has no upper limit dosage and they will still be able to control their glycemic levels even with increasing age.

Issues such as fear of hypoglycaemia and needles and pain have been well established as barriers to insulin initiation [6,7] and it is interesting to know that such problems still prevails even after participant initiate insulin use, as found in participants of our study. Moreover,

~~It is not surprising that our participants reported fear of hypoglycemia, needles and pain as reasons for poor glycemic control.~~ t~~T~~hese factors have been well established as factors for intentional insulin omission [25] and overeating to prevent insulin-induced hypoglycemia [5,26]. [6]T~~T~~he UMMC has an established specialized

diabetes clinic with trained diabetes nurses to provide education and skills training in diabetes self-care to patients. Therefore, our study participants ~~the patients~~ would have been educated and trained on techniques of insulin administration and ways to prevent and manage hypoglycemia. ~~Furthermore, they have been using insulin for some time and were using insulin pens, so the needle used is relatively thin which causes little or no injection pain. In addition to~~ In addition to providing diabetes education and skills training to people with type 2 diabetes using insulin, provision of counselling to address these fears is warranted.

Lack of ~~awareness~~ knowledge of glycemic level and targets was also a reason for poor glycemic control in our participants. They were unsure to what extent they should control their glucose levels. The issue of lack of ~~awareness~~ knowledge of glycemic levels and targets in our study stemmed from lack of SMBG and perceived minimal feedback from HCPs. Our participants reported financial constraints in carrying out effective SMBG, as costs for SMBG supplies are not subsidized by the Malaysian government. The impact of economic factors on SMBG adherence have been reported ~~is well established~~ [27] as an issue that limits glycemic control in other studies [27,28]. In a study by Onwudine et al., (2011), the study participants ~~Other diabetes patients~~ reported that they were not informed by their doctor of their target blood glucose levels and perceived that as a barrier to diabetes self-management [29]. [20]HCPs have a crucial role to play in discussing glycemia results with their patients and formulating mutually agreed glycemic targets. A study has shown that ~~Awareness~~ knowledge of HbA1c and target goal had a positive impact on maintaining better glycemic control among people with type 2 diabetes [30].

Self-adjustment of insulin dosage ~~is a~~have been shown to be a technically complex regimen for people with type 1 diabetes [31] and people with diabetes spend most of their time managing their diabetes away from healthcare professionals. It is thus not surprising that our participants were still apprehensive about self-adjustment of their insulin dose; for fear of hypoglycemia. Dependent and deferential attitudes towards health professionals were cited as the reasons why type 1 diabetes patients do not adjust their insulin dosage [31] and this may also be the reason for failure to adjust insulin dosing among our participants. Furthermore, the lack of skills to educate patients on how to monitor their glycaemic levels and adjustment of insulin has also been found to be a common challenge faced by general practitioners [20].

Some factors for poor glycemic control as highlighted in the conceptual framework did not emerge in our study findings even when the participants were probed. The issue of social stigma was not raised by our participants as a reason for poor glycemic control. We assumed that our participants had overcome this barrier upon initiation of insulin since they have been on insulin for at least one year; as they also reported of performing adaptive strategies such as injecting insulin in private in public places, for example in the toilet or in their car. Ethnicity was also not raised as a factor for poor glycaemic control in this study. Instead, the participants described eating culture as a way of living for Malaysians in general. Therefore, participants of this study might have adapted to the 'Malaysian' culture whereby they share and practise culture of others. Even if the recommended diet by HCPs may not be the types of food familiar with the specific ethnic group or culture, nevertheless, they could still follow the recommended diet. No specific ethnicity barrier was also reported for diabetes treatment aspects. Socio-economic was not a factor for participants in this study to seek healthcare treatment as the company where they or their spouses are working

subsidized the medical costs. It should also be noted that the Malaysian government provides relatively cheap health care for the people and the cost for insulin is subsidized. However, this is not the case for SMBG where patients have to pay out-of-pocket for glucometer and test strips. This is the reason why the lack of knowledge of glycaemic status due to low performance of SMBG was raised as a reason for poor glycaemic control. Our participants did not blame their family, friends, healthcare system or HCPs for their poor glycemic control. They however expressed dismay at the short consultation times and not being able to see the same doctor for their diabetes. Our participants expressed that diabetes control is a personal responsibility, therefore they tended to focus on their personal inadequacies when it came to poor glycemic control. This may be due to diabetes self-care playing a huge role in disease control, hence people with type 2 diabetes may have felt greater responsibility for self-care. Thus, when glycemic control cannot be achieved, this resulted in self-blame [32].

The strengths and limitations of the study

The major strength of this study lies in the fact that the reasons behind poor glycaemic control were gained from the insights of people with T2DM with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews to explain why their diabetes remains poorly controlled despite being on insulin. To researchers' knowledge, such findings has never been reported before. This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin, whereas, issues such as social stigma, ethnicity, socio-

economic factors, family, friends, healthcare system factors and HCPs were found not to be reasons for poor glycaemic control despite insulin use.

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This study has a few limitations. The recruitment of participants in this study was only conducted in a single hospital, hence healthcare systems as a factor in poor glycemic control cannot be further explored. The interviews were conducted in the hospital where the participants were recruited, hence the environment may influence them to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Clinical recommendations

HCPs should create individualized plans with people with type 2 diabetes using insulin, to ensure a routine that allows for proper meal times and exercise, which would enable them to take their diabetes medication, including insulin, in a timely manner. Patients reported they face problems with treatment recommendations, hence HCPs should continuously assess the efficacy and feasibility of treatment provided to their patients and clarify patient misconceptions. It is also pertinent for HCPs to recognise the psychological and emotional problems that impact on their patients' diabetes self-care and provide affective support to them. Lastly, HCPs should discuss glycemic readings and adjustment of insulin dosage, as well as formulate a mutually agreed target with patients to facilitate improvement of glycemic control.

Murray et al., (2011) has identified the common challenges faced by general practitioners when caring for people with type 2 diabetes across international and health system borders and they were related to knowledge, skills, attitudes,

behaviours and context [20]. Some of the challenges faced by HCPs may explain the reasons for poor glycaemic control as faced by participants of this study such as the lack of knowledge and skills to: give clear explanations to the patients, actively engage their patients in their health management, educate patients on how to monitor their glycaemic levels, engage in shared decision making with patients and provide support and motivation to patients in their efforts towards lifestyle chnages for better glycaemic control. Therefore, it is pertinent that HCPs are equipped with accurate and latest knowledge and skills about diabetes and its treatment and be able to impart them to their patients to empower them to perform effective diabetes self-care tasks.

Future research recommendations

More research is needed pertaining to this topic to uncover other factors that could influence poor glycemic control despite insulin use. In addition, exploring views from HCPs and caretakers of the patients would provide a more holistic understanding of factors for poor glycemic control despite insulin use. Accurate assessment of patient's knowledge, actual self-care practices, and, clinical characteristics could also be conducted. This would allow triangulation of multiple sources of data which would then provide more comprehensive understanding and better identification of reasons for poor glycemic control. Ultimately, the factors identified may help to develop a tool to be used by HCPs, as a checklist to address the barriers faced by people with type 2 diabetes using insulin in achieving glycemic control. In addition, future study should look into the motivators of better glycaemic control among people with type 2 diabetes using insulin who is succesful in gaining glycaemic control. Understanding both the barriers and the motivators would help to improve glycaemic control among this subpopulation.

Conclusions

Our findings revealed lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of ~~awareness~~ knowledge of glycemic levels and targets, and poor self-efficacy with regards to insulin dosage adjustment as factors for poor glycemic control despite insulin use. Healthcare providers could look into these factors and help patients with type 2 diabetes using insulin to address their concerns during consultations and thus improve glycemic control.

Contributorship statement

All authors (WTT, SRV, CJN) of this study conceived and designed the study, researched and analysed the data, contributed to discussion, wrote, edited, reviewed and approved the final version of the manuscript.

Competing interests

None.

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Ethics approval

This study received ethical approval from the University of Malaya Medical Centre Medical Ethics Committee (926.18).

Data sharing

No additional data are available.

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Table 1 Summary of interview guide topic on factors influencing poor glycemic control despite using insulin

PREAMBLE: Actually you have had diabetes for a long time and are now using insulin to control your blood sugar. Since you are using insulin to control your blood sugar, but your blood sugar is still not well controlled.
• Can you share with me what do you think are the reasons why your blood sugar is still not well controlled?
Focussing on areas influencing poor glycemic control
• Do you face any problems in adjusting lifestyle for your diabetes care? (Probe: diet, exercise, medications). How?
• What barriers do you face when using insulin? (Probe: injecting insulin in the public, negative beliefs about insulin, fear of needle, pain, blood, body injury, marks and scars, weight gain, hypoglycaemia, knowledge and skills in administrating insulin)
• Does your family, friends, or employer takes part in managing your diabetes? Do you think they affect you in your blood sugar control? How?
• Do you face any health problems that makes it difficult for you to manage your diabetes? (Probe: vision problems, dexterity, mobility, poly-pharmacy, exercise)
• There are some people with diabetes who are depressed and stressed and that affect their sugar control. Do you face this problem? How does it affect you in controlling your blood sugar?
• Do you perform self-blood glucose monitoring? If no, why not? Does it affect your blood sugar control? If yes, how?
• What barriers do you face when consulting the doctor/nurse for your diabetes? (Probe: language, communication, and interaction). Does it affect your blood sugar control?
• What do you think of the hospitals and clinics that you go for your diabetes? (Probe: resources, complexity of system, accessibility, long waiting time, short consultation time) Does it affect your blood sugar control?
• Do you face any financial difficulties to care for your diabetes? (Probe: Medication cost, transportation to hospitals, SMBG)

Table 2: Socio-demographic background and diabetes profile of participants

Characteristic	Participants (n=17)
Age (range)	22- 69 years
Sex	
Female	10
Male	7
Race	
Malays	8
Chinese	4
Indians	4
Nepalese	1
Education	
Secondary	9
Tertiary	5
Primary	2
No formal education	1
Years living with diabetes (range)	2-30
Years using insulin (range)	1-14

744 **Table 3 Factors influencing poor glycemic control in people with type 2**
745 **diabetes using insulin**
746

	Theme	Category
1	Lifestyle challenges in adhering to medical recommendations	1. Difficulty integrating diabetes medical recommendations into work-life schedule 2. Inability to control food cravings and eating habits 3. Inappropriate diet recommendations by HCPs 4. Health-limiting conditions affecting exercise
2	Psychosocial issues and emotional hurdles	1. Psychosocial-problems affecting diabetes self-care management 2. Loss of motivation 3. Perceived poor glycemic control as part of ageing
3	Diabetes treatment-related factors	1. Side-effects of insulin 2. Perception of appropriate dietary practices related to insulin
4	Lack of ~~awareness~~ knowledge and self-efficacy in diabetes self-care	1. Lack of ~~awareness~~ knowledge of glycemic level and target 2. Lack of self-efficacy in adjustment of insulin dosage

747

748 **Figure 1 Conceptual framework of study**

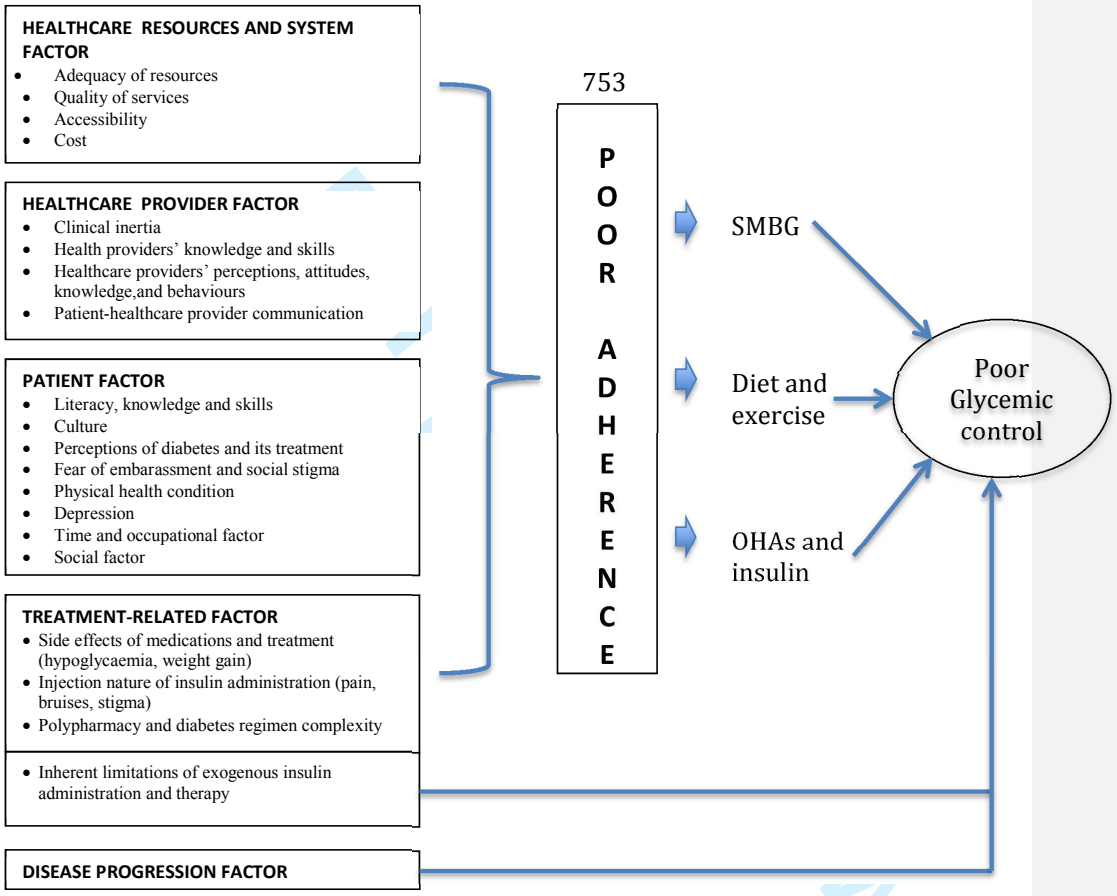

Table 1 Summary of interview guide topic on factors influencing poor glycemic control despite using insulin

PREAMBLE: Actually you have had diabetes for a long time and are now using insulin to control your blood sugar. Since you are using insulin to control your blood sugar, but your blood sugar is still not well controlled.
• Can you share with me what do you think are the reasons why your blood sugar is still not well controlled?
Focussing on areas influencing poor glycemic control
• Do you face any problems in adjusting lifestyle for your diabetes care? (Probe: diet, exercise, medications). How?
• What barriers do you face when using insulin? (Probe: injecting insulin in the public, negative beliefs about insulin, fear of needle, pain, blood, body injury, marks and scars, weight gain, hypoglycaemia, knowledge and skills in administrating insulin)
• Does your family, friends, or employer takes part in managing your diabetes? Do you think they affect you in your blood sugar control? How?
• Do you face any health problems that makes it difficult for you to manage your diabetes? (Probe: vision problems, dexterity, mobility, poly-pharmacy, exercise)
• There are some people with diabetes who are depressed and stressed and that affect their sugar control. Do you face this problem? How does it affect you in controlling your blood sugar?
• Do you perform self-blood glucose monitoring? If no, why not? Does it affect your blood sugar control? If yes, how?
• What barriers do you face when consulting the doctor/nurse for your diabetes? (Probe: language, communication, and interaction). Does it affect your blood sugar control?
• What do you think of the hospitals and clinics that you go for your diabetes? (Probe: resources, complexity of system, accessibility, long waiting time, short consultation time) Does it affect your blood sugar control?
• Do you face any financial difficulties to care for your diabetes? (Probe: Medication cost, transportation to hospitals, SMBG)

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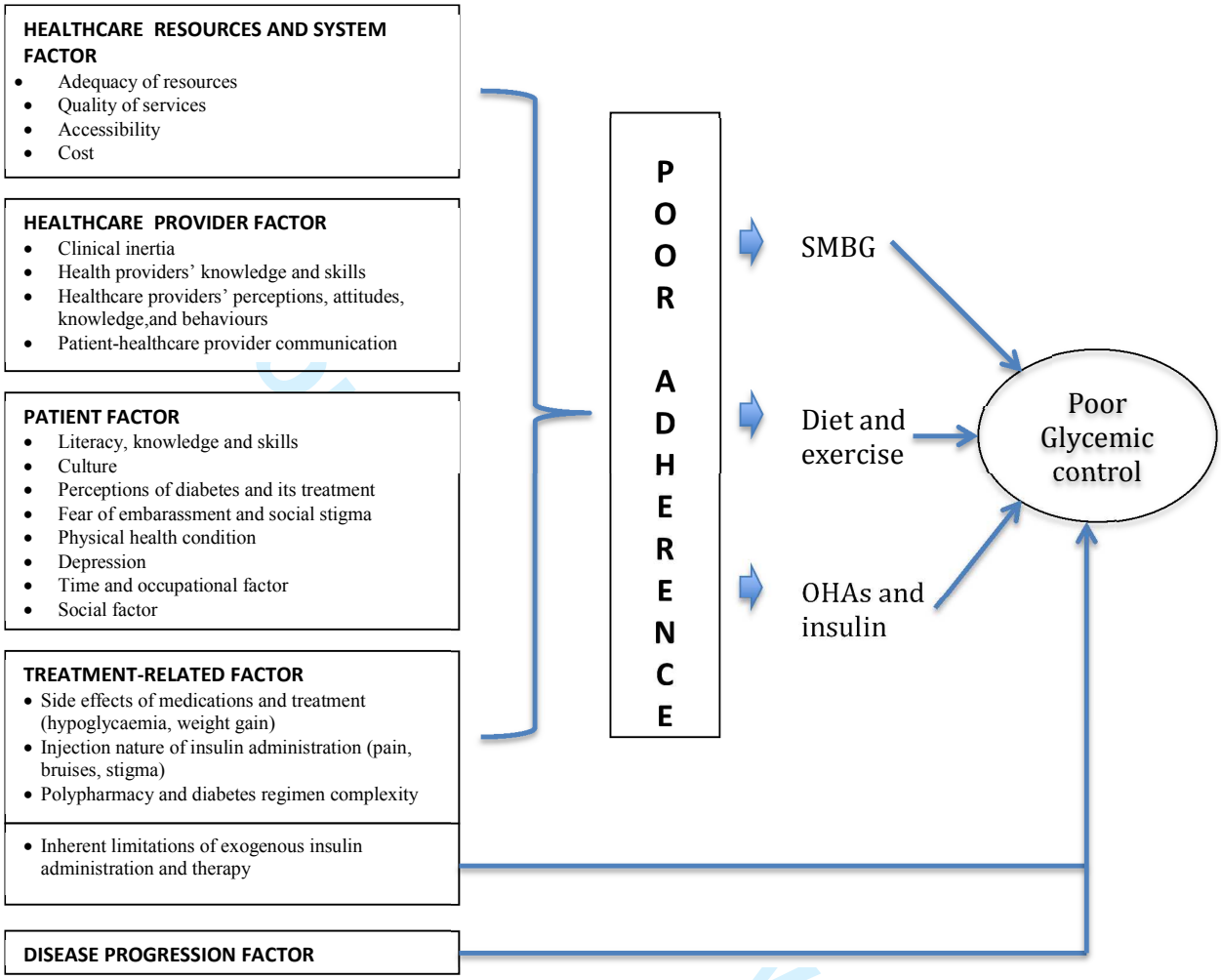
Tertiary	5
Primary	2
No formal education	1
Years living with diabetes (range)	2-30
Years using insulin (range)	1-14

Table 3 Factors influencing poor glycemic control in people with type 2 diabetes using insulin

	Theme	Category
1	Lifestyle challenges in adhering to medical recommendations	1. Difficulty integrating diabetes medical recommendations into work-life schedule 2. Inability to control food cravings and eating habits 3. Inappropriate diet recommendations by HCPs 4. Health-limiting conditions affecting exercise
2	Psychosocial issues and emotional hurdles	1. Psychosocial-problems affecting diabetes self-care management 2. Loss of motivation 3. Perceived poor glycemic control as part of ageing
3	Diabetes treatment-related factors	1. Side-effects of insulin 2. Perception of appropriate dietary practices related to insulin
4	Lack of knowledge and self-efficacy in diabetes self-care	1. Lack of knowledge of glycemic level and target 2. Lack of self-efficacy in adjustment of insulin dosage

Figure 1 Conceptual framework of study



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Why do people with type 2 diabetes who are using insulin have poor glycemic control? A qualitative study.

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Keywords: Diabetes and endocrinology; qualitative research; social medicine

Abstract

Objective

This study aims to explore the factors influencing poor glycemic control among people with type 2 diabetes using insulin.

Research design

This study used a qualitative methodology, comprising in-depth individual interviews. A semi-structured interview guide was used. The interviews were audio-recorded, transcribed verbatim and analysed using a thematic approach.

Participants:

Seventeen people with type 2 diabetes using insulin with HbA1c ≥ 9% for > 1 year participated in this study.

Setting

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC), Malaysia.

Results

Data analysis uncovered four themes. They were lifestyle challenges in adhering to medical recommendations, psychosocial and emotional hurdles, diabetes treatment related factors and, lack of knowledge and self-efficacy in diabetes self-care.

Conclusion

This study identified factors, which explained the poor glycaemic control in people with type 2 diabetes using insulin. Healthcare providers may use these findings to address patients' concerns during consultations and help to improve glycaemic control.

Word count: 163/250

Strengths and limitations of this study

- The major strength of this study lies in the fact that the reasons behind poor glycaemic control were uncovered from the perspectives of people with type 2 diabetes with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews.
- This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin.
- Issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system and HCPs did not emerge as reasons for poor glycaemic control despite insulin use.
- The recruitment of participants was conducted in a single hospital, hence healthcare systems as a factor in poor glycaemic control cannot be further explored.
- The interviews conducted in the hospital environment may influence the participants to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Introduction

Insulin has been identified as the most effective glucose lowering agent, however, studies has showed that many people with diabetes who are using insulin still fail to achieve glycemic control [1,2].

The challenges of achieving glycemic control in people with diabetes using insulin were: the progression of the disease, the impact of hypoglycemia and weight gain, the burden of poly-pharmacy, lack of resources in provision of diabetes self-care education and support of patients; and the inherent limitations of subcutaneous exogenous insulin administration [3]. Other predictors of poor glycemic control among people with type 2 diabetes using insulin include younger age, shorter duration of diagnosis of diabetes, lower body mass index and poor physical functioning [4]. Barriers to glycaemic control highlighted in a qualitative study among people with T2DM using insulin were fear about illness, guilt or self-blame, shame, ideas or beliefs about causation of diabetes, personal or cultural beliefs, and difficulty finding common grounds with clinicians on diabetes management [5].

To date, many studies have been conducted on barriers to insulin initiation [6-8]. Research on factors associated with poor glycemic control in people with type 2 diabetes was largely quantitative and tend to focus on specific treatment modalities such as lifestyle modifications, OHAs (oral hypoglycemic agents), OHAs + insulin and insulin only [9-11]. In terms of qualitative studies, many focused on barriers to diabetes self-care management in general [12-15] rather than reasons for poor glycaemic control. Very few qualitative studies examined factors impacting poor

glycemic control from the patient's perspective, especially among people with type 2 diabetes using insulin with poor glycemic control.

Since insulin is the most effective glucose-lowering agent, it is pertinent to understand from the patient's perspective why people with type 2 diabetes who are on insulin still fail to achieve glycemic control. This study will help fill the gap in existing literature by exploring factors influencing poor glycemic control in people with type 2 diabetes using insulin. An understanding of the barriers to achieving glycemic control will help healthcare providers (HCPs) find ways to improve glycemic control in this sub-population.

Research Design and Methods

This study used a qualitative methodology, comprising in-depth individual interviews to help understand patient experiences, as well as take into account the circumstances which led to poor glycemic control among people with type 2 diabetes using insulin.

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC). We purposively sampled patients who were diagnosed with type 2 diabetes, have been using insulin, either alone or in combination with OHAs and with poor control of diabetes (HBA1c $\geq$ 9%) for at least one year. Participants were chosen from various socio-demographic backgrounds (age, ethnicity, education level) so that different perspectives on the reasons for poor glycemic control can be explored.

We used a semi-structured interview guide (Table 1), which was developed based on the study's conceptual framework (Figure 1) drawn from literature review and experts' opinion. We reviewed the literature to identify possible factors, concepts and variables [16] that have been shown to influence glycaemic control among people with diabetes. A preliminary conceptual framework was developed based on these factors. Later, the conceptual framework was given to two researchers (NCJ and SRV) (one is a family medicine specialist and another is an endocrinologist) to provide feedback and strengthen the conceptual framework based on their clinical experience and expertise. Subsequently, the interview guide was constructed based on the revised conceptual framework.

The interviews were carried out between January and August 2013 in consultation rooms in both clinics. Written informed consent and socio-demographic information was obtained from patients who agreed to participate. During the interviews, the participants were asked for the reasons why they think their blood sugar is not well controlled despite using insulin. When the participant could not give any more reasons that they could think of, the researcher would then probe other areas contributing to poor glycemic control, as developed in the interview guide. Data saturation was achieved upon the 17th interview, when no new factors influencing poor glycemic control emerged from the interviews.

It is important to note that the participants of this study were recruited from the clinics where SRV and NCJ conduct their clinical practice. Thus, in order to offset the influence of power disparities between doctor and patient, all the interviews were conducted by WTT. WTT was competent in English, Malay and Cantonese, hence the

interviews were conducted in three languages. Out of the 17 interviews, there were two interviews that were conducted in Cantonese and seven in Malay. Given that the Cantonese language has many colloquialisms, the recordings were translated directly into English by WTT so the meaning would not be lost. Other interviews that were conducted in English and Malay were given to experienced transcribers for verbatim transcription. All the transcripts were checked for accuracy and quality by WTT by listening to the audio recording and checked against the transcript, before exported into NVivo qualitative software for data analysis using a thematic approach. Malay transcripts were analysed in the said language and the selected quotes were later translated to English. The translated quotes were checked with other researchers to ensure the meaning were not lost or distorted.

Initially, the transcripts were read through for familiarization by the researchers and then codes were assigned to a particular phrase, sentence or paragraph that described the meaning of the text segment. Sentences that had a similar meaning were given the same code while texts with different meaning were given a new code. The whole transcript was analyzed until there were no new meanings from the texts to form new codes. Subsequently, all the codes were compared and related codes were clustered together under the same category. Irrelevant codes were omitted. The categories were later compared and further clustered under themes. The mapping of categories and themes resulted in the development of a coding frame. The coding frame was developed from the coding process on the first three transcripts by all the researchers (WTT, NCJ, SRV). The coding frame was finalized when consensus was reached on the categories and themes. The finalized coding frame was used to code for the remaining transcripts by WTT. New emerging codes were added into the list of

categories and themes that were created through constant discussion with other researchers to ensure the list of categories and themes produced the best representation of data that was obtained. Researchers constantly challenged one another's interpretation of the data to offset any potential biases when analyzing the data.

Results

Socio-demographic and diabetes profile of participants

There were 17 participants in this study. Their socio-demographic and diabetes profiles are listed in Table 2.

Emerging themes

Four themes, which corresponded to factors influencing poor glycemic control despite insulin use, emerged from the data analysis (Table 3).

Lifestyle challenges in adhering to medical recommendations

Under this theme there are five subthemes identified.

Difficulty integrating diabetes medical recommendations into work-life schedule

Participants faced difficulties in integrating medical recommendations such as a medication regimen and meal times when they did not match with their daily activity schedule. When participants were too busy with their work-life, they tended to skip meals which caused them to become hungry and overeat later. Skipping meals also resulted in them missing or delaying their insulin injections.

"The way I eat and take the medications is not consistent. Sometimes I forget. Maybe I am too busy. Every time my insulin use would be delayed. For example, usually we inject at 12 right, sometimes I will inject at 2. Sometimes I did not inject at all" – 58 years old housewife

One participant described how the nature of his occupation made it difficult for him to adhere to healthy diet and insulin treatment.

"We are going around okay. So we can't just go and get what we want to eat. We can't go and pack something or bring the food from house. Furthermore, like now I'm taking the short-acting insulin, so every mealtime you have to inject. You just can't go and take insulin, you see. I'm working as a bodyguard you see, you have to follow the boss closely. I think so that is the reason [for poor blood sugar]". –36 years old personal bodyguard

Inability to control food cravings and eating habits

Participants also reported that the temptation of eating something delicious would lead them to lose control of their diet, causing them to overeat.

"My eating habit. Like I like to eat sweets, like kuihs [local dessert] and all that. But I have to control. I know I am not controlling. I must put a full stop to that." - 60 years old woman housewife

It is also difficult to resist food when there is a variety of food available and coming from a lifestyle and culture where food and eating are a way of living.

"Basically it is also Malaysia lifestyle whereby people like to eat. You eat non-stop. Sugar is particularly everywhere in your diet so that's probably one of the main reasons why it is not controlled". - 22 years old student

Inappropriate diet recommendations by healthcare providers

Participants felt that the diet recommended by HCPs provided insufficient energy for them to carry out their work. Some also expressed frustrations with regards to the monotony of eating the same type of food every day, such as bread and chapatti, which were recommended by the HCPs. Hence, they often neglected the dietary advice.

"Every time they [HCPs] ask me to eat bread. Can you eat bread everyday? For sure you will hate it. They will ask to eat vegetables every day. Cannot like that " - 59 years old ex-lorry driver

Health conditions affecting exercise

Not being able to exercise optimally due to health conditions was another reason cited by many for poor glycemic control.

"Another thing is exercise. Because of stroke, I have problem with walking. I have to exercise more". - 61 years old engineer

Psychosocial issues and emotional hurdles

Three subthemes emerged under this theme.

Psychosocial problems affecting diabetes self-care

Participants felt that their poor glycemic control was attributed to personal problems which caused them to feel anxious, stressed and sad, which resulted in some adopting unhealthy eating habits and not taking their diabetes medications, including insulin.

> *"Actually when you have diabetes, you cannot be stressed. Previously when I was under stress [due to marital problems], my blood sugar level was very high because I did not eat and take my insulin. I was hoping to die." – 50 years old taxi driver*

Loss of motivation

Participants admitted that they were tired of adhering to diabetes medications after having taken them for such a long time that sometimes they would intentionally skip doses.

> *"Sometimes I purposely miss them because I am just so tired of injecting". – 40 years old officer*

Additionally, an absence of significant improvements in glycemic control despite efforts made to improve glycemic control led participants to 'give up' in controlling their blood sugar.

"There's one time actually I did go to the gym and the exercise was okay but it didn't really do anything to my weight. It does a little bit on my sugar but after a while I just give up. I think it would be as well [contributed to her poor glycemic control] because the main thing is that, I think that if I actually lose weight, I would be able to control my sugar as well." – 40 year old officer

Perceived poor glycemic control as part of ageing

Many older participants of this study held the view that whatever their attempts to control blood glucose levels, their glycemic control would still fall short due to their advanced age.

"Maybe because I am getting old. As the days passed by, all my organs has deteriorated. Like engine, the more it is used, it will become spoilt." - 69 years old retiree

Diabetes treatment-related factors

There are two subthemes under this theme.

Side-effects of insulin

Participants reported they would tend to overeat to prevent or counter the effects of insulin-induced hypoglycaemia. However, it is when participants overeat that their glycemic control deteriorates.

> *"I had fit once (due to hypoglycaemia), that fear is always there. On and off, I used to eat more to make sure I don't go into hypoglycaemia fit. It is extremely painful". - 47 years old doctor*

Participants also felt that insulin caused them to feel hungry, causing them to overeat, hence, raising their blood sugar levels.

> *"But if use insulin, it makes me eat. I feel that after using insulin, the blood sugar goes even higher". – 37 years old clerk*

Fear of needles and pain also caused participants to delay insulin initiation as well as intentionally skipping injections, thus contributing to poor glycemic control.

> *"I don't quite like insulin actually. I'm very afraid of needles and the pain that follows. In a week I would say at least 3 times [skipping insulin injections]. Although my blood sugar was already up about 6 to 7 years ago, but I've only started insulin not far back from now. So that's the other reason [for poor glycemic control]." – 40 years old officer*

Perception of appropriate dietary practices related to insulin

One participant felt that his poor glycemic control was attributed to the diet recommendations given by the HCP. He voiced that the meal pattern recommended was not right and would instead reduce the efficacy of the insulin.

> *"For example if you eat at 8pm, then you feel hungry and you eat again. So if I follow his [doctor] advice I will eat but this is wrong. The mistake is if lets say I eat at 7pm, then 8, 9, 10, 11, 12pm, for about 4 hours I will keep on eating. So the insulin cannot fight with my diabetes. Because I have experienced this so I know. The recommended cannot work. My diabetes reach 20, 30 something". – 50 years old taxi driver*

Lack of knowledge and self-efficacy in diabetes self-care

Two subthemes were identified under this theme.

Lack of knowledge of glycemic level and target

Lack of knowledge of their glycemic level and target was also cited as a reason for poor glycemic control, as participants were not aware to what extent they should control their blood sugar. This lack of knowledge was attributed to difficulties in performing SMBG due to financial reason, and some claimed that their HCPs did not inform them about their glycemic levels and target.

> *"I check less because sometimes when the needles are finished, I have to wait for my salary to buy. I check once a week but if I need to see the doctor*

then only I will check 4 times a day. Actually it is not enough. When I don't check, I cannot control my diet so that's why my blood sugar is not good". – 37 years old clerk

"I don't know why he [doctor] wants to lower (blood sugar level) some more. No, because I don't know what is the target. The doctor never mentioned. I am also not sure. So I also don't know whether I am okay or not. If I know, I will control no matter what". -31 years old marketing coordinator

Lack of self-efficacy in adjustment of insulin dosage

Despite receiving advice from the doctor that they could adjust their insulin dosage, some participants did not do so as they were afraid of making mistakes when adjusting the insulin dose, which could lead to hypoglycaemia and other complications.

"I'm just reluctant [to adjust insulin dosage] because they [doctor] won't be with me 24 hours. I didn't increase or decrease any of the medication. I just stick to it. So maybe that is the reason". - 36 years old personal bodyguard

Discussions

Our study revealed that people with type 2 diabetes using insulin attributed their sustained hyperglycemia to lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of knowledge of glycemic levels and targets, as well as poor self-efficacy with regards to insulin dosage adjustment. Majority of the factors raised were not related to problems with insulin use per se, but were related to barriers in performing diabetes self-care tasks in general such as dietary control, adherence to exercise and medications including OHAs.

Our study participants faced difficulties in adhering to the recommended meal and insulin injection schedule due to work priorities and time constraints. In a multinational study involving 1530 people with type 1 diabetes (12.8%) and type 2 diabetes (88.2%) using insulin from eight countries, taking insulin at the prescribed time or with meals everyday was also reported to be difficult [17]. The lifestyle changes required for diabetes management in terms of diet and regular mealtimes were acknowledged to be hard to implement, even in people with type 2 diabetes using OHAs alone, who often report missed or delayed meals [18]. This showed that adherence to regular meal and medication times is a universal and major barrier to diabetes management among people with diabetes. It is crucial to overcome that, especially among people with type 2 diabetes using insulin, as insulin administration has to be synchronized with meals. When regular meal times cannot be followed, it often results in delayed or skipped insulin intake, as reported in our study, which explains poor glycemic control.

Our participants raised the issue of dietary recommendations by HCPs, which did not meet their dietary needs; the issues of the monotony of eating the same type of food every day and the recommended diet could not provide sufficient energy. Other people with type 2 diabetes using insulin have reported that clinicians would simply assume that patients would comply to the medical recommendations given; without considering their individual needs and preferences [5]. Additionally, it also appears that lack of understanding of the rationale behind dietary recommendations is common among type 2 diabetes patients. One participant of our study thought the meal pattern recommended by HCPs would thwart the efficacy of insulin, while type 2 diabetes patients on OHAs in another study perceived that frequent meals was a way to control their diabetes [19]. In fact, the main purpose of regular meals is actually to counter the effects of hypoglycemia, due to insulin and long acting sulfonylureas. HCPs may be a contributing factor to these barriers in adhering to dietary recommendations. In a collaborative study conducted in Austria, Canada, Germany and United Kingdom, it was found that general practitioners lack the knowledge and skills to educate, support and motivate patients on healthy lifestyle changes [20].

The issue of psychosocial factors and lack of motivation is crucial, as it affects all aspects of diabetes self-care including adherence to insulin, as evidenced from our study. Diabetes self-care is a complex task that demands behavioral change in the patient on a daily basis; the influences of social, cultural, familial and professional contexts further complicate management of the disease in diabetes patients as shown in other studies [21-23]. Furthermore, our participants also showed that when a patient's diabetes condition remains unimproved despite efforts to control it, this

leads to 'diabetes burn-out' stemming from frustration and loss of motivation; eventually resulting in neglect of diabetes self-care. Perhaps explaining the disease progression in type 2 diabetes and that the progressive loss of β-cell function is common, will lift the feeling of frustration and loss of motivation in them.

Older participants of our study perceived that they would never be able to achieve glycemic control due to their old age even with insulin use. Such misconceptions are alarming as they may decrease older people's perceived importance of glycemic control. They may lower their expected treatment target in order to cope with the challenges in managing diabetes at such an age [24]. There is a need to inform elderly people with type 2 diabetes that insulin has no upper limit dosage and they will still be able to control their glycemic levels even with increasing age.

Issues such as fear of hypoglycaemia and needles and pain have been well established as barriers to insulin initiation [6,7] and it is interesting to know that such problems still prevails even after participant initiate insulin use, as found in participants of our study. Moreover, these factors have been well established as factors for intentional insulin omission [25] and overeating to prevent insulin-induced hypoglycemia [5,26]. The UMMC has an established specialized diabetes clinic with trained diabetes nurses to provide education and skills training in diabetes self-care to patients. Therefore, our study participants would have been educated and trained on techniques of insulin administration and ways to prevent and manage hypoglycemia. In addition to providing diabetes education and skills training to people with type 2 diabetes using insulin, provision of counselling to address these fears is warranted.

Lack of knowledge of glycemic level and targets was also a reason for poor glycemic control in our participants. They were unsure to what extent they should control their glucose levels. The issue of lack of knowledge of glycemic levels and targets in our study stemmed from lack of SMBG and perceived minimal feedback from HCPs. Our participants reported financial constraints in carrying out effective SMBG, as costs for SMBG supplies are not subsidized by the Malaysian government. The impact of economic factors on SMBG adherence have been reported as an issue that limits glycemic control in other studies [27,28]. In a study by Onwudine et al., (2011), the study participants reported that they were not informed by their doctor of their target blood glucose levels and perceived that as a barrier to diabetes self-management [29]. HCPs have a crucial role to play in discussing glycemia results with their patients and formulating mutually agreed glycemic targets. A study has shown that knowledge of HbA1c and target goal had a positive impact on maintaining better glycemic control among people with type 2 diabetes [30].

Self-adjustment of insulin dosage have been shown to be a technically complex regimen for people with type 1 diabetes [31] and people with diabetes spend most of their time managing their diabetes away from healthcare professionals. It is thus not surprising that our participants were still apprehensive about self-adjustment of their insulin dose; for fear of hypoglycemia. Dependent and deferential attitudes towards health professionals were cited as the reasons why type 1 diabetes patients do not adjust their insulin dosage [31] and this may also be the reason for failure to adjust insulin dosing among our participants. Furthermore, the lack of skills to educate patients on how to monitor their glycaemic levels and adjustment of insulin has also been found to be a common challenge faced by general practitioners [20].

Some factors for poor glycemic control as highlighted in the conceptual framework did not emerge in our study findings even when the participants were probed. The issue of social stigma was not raised by our participants as a reason for poor glycemic control. We assumed that our participants had overcome this barrier upon initiation of insulin since they have been on insulin for at least one year; as they also reported of performing adaptive strategies such as injecting insulin in private in public places, for example in the toilet or in their car. Ethnicity was also not raised as a factor for poor glycaemic control in this study. Instead, the participants described eating culture as a way of living for Malaysians in general. Therefore, participants of this study might have adapted to the 'Malaysian' culture whereby they share and practise culture of others. Even if the recommended diet by HCPs may not be the types of food familiar with the specific ethnic group or culture, nevertheless, they could still follow the recommended diet. No specific ethnicity barrier was also reported for diabetes treatment aspects. Socio-economic was not a factor for participants in this study to seek healthcare treatment as the company where they or their spouses are working subsidized the medical costs. It should also be noted that the Malaysian government provides relatively cheap health care for the people and the cost for insulin is subsidized. However, this is not the case for SMBG where patients have to pay out-of-pocket for glucometer and test strips. This is the reason why the lack of knowledge of glycaemic status due to low performance of SMBG was raised as a reason for poor glycaemic control. Our participants did not blame their family, friends, healthcare system or HCPs for their poor glycemic control. They however expressed dismay at the short consultation times and not being able to see the same doctor for their diabetes. Our participants expressed that diabetes control is a personal responsibility, therefore they tended to focus on their personal inadequacies when it came to poor

glycemic control. This may be due to diabetes self-care playing a huge role in disease control, hence people with type 2 diabetes may have felt greater responsibility for self-care. Thus, when glycemic control cannot be achieved, this resulted in self-blame [32].

The strengths and limitations of the study

The major strength of this study lies in the fact that the reasons behind poor glycaemic control were gained from the insights of people with T2DM with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews to explain why their diabetes remains poorly controlled despite being on insulin. To researchers' knowledge, such findings has never been reported before. This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin, whereas, issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system factors and HCPs were found not to be reasons for poor glycaemic control despite insulin use.

This study has a few limitations. The recruitment of participants in this study was only conducted in a single hospital, hence healthcare systems as a factor in poor glycemic control cannot be further explored. The interviews were conducted in the hospital where the participants were recruited, hence the environment may influence them to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Clinical recommendations

HCPs should create individualized plans with people with type 2 diabetes using insulin, to ensure a routine that allows for proper meal times and exercise, which would enable them to take their diabetes medication, including insulin, in a timely manner. Patients reported they face problems with treatment recommendations, hence HCPs should continuously assess the efficacy and feasibility of treatment provided to their patients and clarify patient misconceptions. It is also pertinent for HCPs to recognise the psychological and emotional problems that impact on their patients' diabetes self-care and provide affective support to them. Lastly, HCPs should discuss glycemic readings and adjustment of insulin dosage, as well as formulate a mutually agreed target with patients to facilitate improvement of glycemic control.

Murray et al., (2011) has identified the common challenges faced by general practitioners when caring for people with type 2 diabetes across international and health system borders and they were related to knowledge, skills, attitudes, behaviours and context [20]. Some of the challenges faced by HCPs may explain the reasons for poor glycaemic control as faced by participants of this study such as the lack of knowledge and skills to: give clear explanations to the patients, actively engage their patients in their health management, educate patients on how to monitor their glycaemic levels, engage in shared decision making with patients and provide support and motivation to patients in their efforts towards lifestyle chnages for better glycaemic control. Therefore, it is pertinent that HCPs are equipped with accurate and latest knowledge and skills about diabetes and its treatment and be able to impart them to their patients to empower them to perform effective diabetes self-care tasks.

Future research recommendations

More research is needed pertaining to this topic to uncover other factors that could influence poor glycemic control despite insulin use. In addition, exploring views from HCPs and caretakers of the patients would provide a more holistic understanding of factors for poor glycemic control despite insulin use. Accurate assessment of patient's knowledge, actual self-care practices, and, clinical characteristics could also be conducted. This would allow triangulation of multiple sources of data which would then provide more comprehensive understanding and better identification of reasons for poor glycemic control. Ultimately, the factors identified may help to develop a tool to be used by HCPs, as a checklist to address the barriers faced by people with type 2 diabetes using insulin in achieving glycemic control. In addition, future study should look into the motivators of better glycaemic control among people with type 2 diabetes using insulin who is succesful in gaining glycaemic control. Understanding both the barriers and the motivators would help to improve glycaemic control among this subpopulation.

Conclusions

Our findings revealed lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of knowledge of glycemic levels and targets, and poor self-efficacy with regards to insulin dosage adjustment as factors for poor glycemic control despite insulin use. Healthcare providers could look into these factors and help patients with type 2 diabetes using insulin to address their concerns during consultations and thus improve glycemic control.

Contributorship statement

All authors (WTT, SRV, CJN) of this study conceived and designed the study, researched and analysed the data, contributed to discussion, wrote, edited, reviewed and approved the final version of the manuscript.

Competing interests

None declared.

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Ethics approval

This study received ethical approval from the University of Malaya Medical Centre Medical Ethics Committee (926.18).

Data sharing

No additional data are available.

Figure 1 Conceptual framework of study

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Table 1 Summary of interview guide topic on factors influencing poor glycemic control despite using insulin

PREAMBLE: Actually you have had diabetes for a long time and are now using insulin to control your blood sugar. Since you are using insulin to control your blood sugar, but your blood sugar is still not well controlled.
• Can you share with me what do you think are the reasons why your blood sugar is still not well controlled?
Focussing on areas influencing poor glycemic control
• Do you face any problems in adjusting lifestyle for your diabetes care? (Probe: diet, exercise, medications). How?
• What barriers do you face when using insulin? (Probe: injecting insulin in the public, negative beliefs about insulin, fear of needle, pain, blood, body injury, marks and scars, weight gain, hypoglycaemia, knowledge and skills in administrating insulin)
• Does your family, friends, or employer takes part in managing your diabetes? Do you think they affect you in your blood sugar control? How?
• Do you face any health problems that makes it difficult for you to manage your diabetes? (Probe: vision problems, dexterity, mobility, poly-pharmacy, exercise)
• There are some people with diabetes who are depressed and stressed and that affect their sugar control. Do you face this problem? How does it affect you in controlling your blood sugar?
• Do you perform self-blood glucose monitoring? If no, why not? Does it affect your blood sugar control? If yes, how?
• What barriers do you face when consulting the doctor/nurse for your diabetes? (Probe: language, communication, and interaction). Does it affect your blood sugar control?
• What do you think of the hospitals and clinics that you go for your diabetes? (Probe: resources, complexity of system, accessibility, long waiting time, short consultation time) Does it affect your blood sugar control?
• Do you face any financial difficulties to care for your diabetes? (Probe: Medication cost, transportation to hospitals, SMBG)

Table 2: Socio-demographic background and diabetes profile of participants

Characteristic	Participants (n=17)
Age (range)	22- 69 years
Sex	
Female	10
Male	7
Race	
Malays	8
Chinese	4
Indians	4
Nepalese	1
Education	
Secondary	9
Tertiary	5
Primary	2
No formal education	1
Years living with diabetes (range)	2-30
Years using insulin (range)	1-14

Table 3 Factors influencing poor glycemic control in people with type 2 diabetes using insulin

	Theme	Category
1	Lifestyle challenges in adhering to medical recommendations	1. Difficulty integrating diabetes medical recommendations into work-life schedule 2. Inability to control food cravings and eating habits 3. Inappropriate diet recommendations by HCPs 4. Health-limiting conditions affecting exercise
2	Psychosocial issues and emotional hurdles	1. Psychosocial-problems affecting diabetes self-care management 2. Loss of motivation 3. Perceived poor glycemic control as part of ageing
3	Diabetes treatment-related factors	1. Side-effects of insulin 2. Perception of appropriate dietary practices related to insulin
4	Lack of knowledge and self-efficacy in diabetes self-care	1. Lack of knowledge of glycemic level and target 2. Lack of self-efficacy in adjustment of insulin dosage

Title: Why do people with type 2 diabetes who are using insulin have poor glycemic control? A qualitative study.

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Keywords: Diabetes and endocrinology; qualitative research; social medicine

Abstract

Objective
This study aims to explore the factors influencing poor glycemic control among people with type 2 diabetes using insulin.

Research design
This study used a qualitative methodology, comprising in-depth individual interviews. A semi-structured interview guide was used. The interviews were audio-recorded, transcribed verbatim and analysed using a thematic approach.

Participants:
Seventeen people with type 2 diabetes using insulin with HbA1c ≥ 9% for > 1 year participated in this study.

Setting
This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC), Malaysia.

Results
Data analysis uncovered four themes. They were lifestyle challenges in adhering to medical recommendations, psychosocial and emotional hurdles, diabetes treatment related factors and, lack of knowledge and self-efficacy in diabetes self-care.

Conclusion
This study identified factors, which explained the poor glycaemic control in people with type 2 diabetes using insulin. Healthcare providers may use these findings to address patients' concerns during consultations and help to improve glycaemic control.

Word count: 163/250

Strengths and limitations of this study

- The major strength of this study lies in the fact that the reasons behind poor glycaemic control were uncovered from the perspectives of people with type 2 diabetes with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews.
- This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin.
- Issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system and HCPs did not emerge as reasons for poor glycaemic control despite insulin use.
- The recruitment of participants was conducted in a single hospital, hence healthcare systems as a factor in poor glycaemic control cannot be further explored.
- The interviews conducted in the hospital environment may influence the participants to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Introduction

Insulin has been identified as the most effective glucose lowering agent, however, studies has showed that many people with diabetes who are using insulin still fail to achieve glycemic control [1,2].

The challenges of achieving glycemic control in people with diabetes using insulin were: the progression of the disease, the impact of hypoglycemia and weight gain, the burden of poly-pharmacy, lack of resources in provision of diabetes self-care education and support of patients; and the inherent limitations of subcutaneous exogenous insulin administration [3]. Other predictors of poor glycemic control among people with type 2 diabetes using insulin include younger age, shorter duration of diagnosis of diabetes, lower body mass index and poor physical functioning [4]. Barriers to glycaemic control highlighted in a qualitative study among people with T2DM using insulin were fear about illness, guilt or self-blame, shame, ideas or beliefs about causation of diabetes, personal or cultural beliefs, and difficulty finding common grounds with clinicians on diabetes management [5].

To date, many studies have been conducted on barriers to insulin initiation [6-8] , ~~whereas,~~ Research on ~~identifying~~ factors ~~for~~ associated with poor glycemic control ~~among~~ in people with type 2 diabetes was largely ~~by~~ quantitative and tend to focus on specific treatment ~~studies involving patients on various treatment~~ modalities such as; ~~including~~ lifestyle ~~adapters~~modifications, OHAs (oral hypoglycemic agents), OHAs + insulin and insulin only [9-11]. In terms of ~~,~~ ~~while~~ qualitative studies, many focused on barriers to diabetes self-care management in general [12-15] rather than reasons for poor glycaemic control. Very few qualitative studies examined factors impacting

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poor glycemic control from the patient's perspective, especially among people with type 2 diabetes using insulin with poor glycemic control.

Since insulin is the most effective glucose-lowering agent, it is pertinent to understand from the patient's perspective why people with type 2 diabetes who are on insulin still fail to achieve glycemic control. This study will help fill the gap in existing literature by exploring factors influencing poor glycemic control in people with type 2 diabetes using insulin. An understanding of the barriers to achieving glycemic control will help healthcare providers (HCPs) find ways to improve glycemic control in this sub-population.

Research Design and Methods

This study used a qualitative methodology, comprising in-depth individual interviews to help understand patient experiences, as well as take into account the circumstances which led to poor glycemic control among people with type 2 diabetes using insulin.

This study was conducted at the Primary Care Clinic and the Diabetes Clinic in the University of Malaya Medical Centre (UMMC). We purposively sampled patients who were diagnosed with type 2 diabetes, have been using insulin, either alone or in combination with OHAs and with poor control of diabetes (HBA1c ≥ 9%) for at least one year. Participants were chosen from various socio-demographic backgrounds (age, ethnicity, education level) so that different perspectives on the reasons for poor glycemic control can be explored.

We used a semi-structured interview guide (Table 1), which was developed based on the study's conceptual framework (Figure 1) drawn from literature review and experts' opinion. We reviewed the literature to identify possible factors, concepts and variables [16] that have been shown to influence glycaemic control among people with diabetes. A preliminary conceptual framework was developed based on these factors. Later, the conceptual framework was given to two researchers (NCJ and SRV) (one is a family medicine specialist and another is an endocrinologist) to provide feedback and strengthen the conceptual framework based on their clinical experience and expertise. Subsequently, the interview guide was constructed based on the revised conceptual framework.

The interviews were carried out between January and August 2013 in consultation rooms in both clinics. Written informed consent and socio-demographic information was obtained from patients who agreed to participate. During the interviews, the participants were asked for the reasons why they think their blood sugar is not well controlled despite using insulin. When the participant could not give any more reasons that they could think of, the researcher would then probe other areas contributing to poor glycemic control, as developed in the interview guide. Data saturation was achieved upon the 17th interview, when no new factors influencing poor glycemic control emerged from the interviews.

It is important to note that the participants of this study were recruited from the clinics where SRV and NCJ conduct their clinical practice. Thus, in order to offset the influence of power disparities between doctor and patient, all the interviews were conducted by WTT. WTT was competent in English, Malay and Cantonese, hence the

interviews were conducted in three languages. Out of the 17 interviews, there were two interviews that were conducted in Cantonese and seven in Malay. Given that the Cantonese language has many colloquialisms, the recordings were translated directly into English by WTT so the meaning would not be lost. Other interviews that were conducted in English and Malay were given to experienced transcribers for verbatim transcription. All the transcripts were checked for accuracy and quality by WTT by listening to the audio recording and checked against the transcript, before exported into NVivo qualitative software for data analysis using a thematic approach. Malay transcripts were analysed in the said language and the selected quotes were later translated to English. The translated quotes were checked with other researchers to ensure the meaning were not lost or distorted.

Initially, the transcripts were read through for familiarization by the researchers and then codes were assigned to a particular phrase, sentence or paragraph that described the meaning of the text segment. Sentences that had a similar meaning were given the same code while texts with different meaning were given a new code. The whole transcript was analyzed until there were no new meanings from the texts to form new codes. Subsequently, all the codes were compared and related codes were clustered together under the same category. Irrelevant codes were omitted. The categories were later compared and further clustered under themes. The mapping of categories and themes resulted in the development of a coding frame. The coding frame was developed from the coding process on the first three transcripts by all the researchers (WTT, NCJ, SRV). The coding frame was finalized when consensus was reached on the categories and themes. The finalized coding frame was used to code for the remaining transcripts by WTT. New emerging codes were added into the list of

categories and themes that were created through constant discussion with other researchers to ensure the list of categories and themes produced the best representation of data that was obtained. Researchers constantly challenged one another's interpretation of the data to offset any potential biases when analyzing the data.

Results

Socio-demographic and diabetes profile of participants

There were 17 participants in this study. Their socio-demographic and diabetes profiles are listed in Table 2.

Emerging themes

Four themes, which corresponded to factors influencing poor glycemic control despite insulin use, emerged from the data analysis (Table 3).

Lifestyle challenges in adhering to medical recommendations

Under this theme there are five subthemes identified.

Difficulty integrating diabetes medical recommendations into work-life schedule

Participants faced difficulties in integrating medical recommendations such as a medication regimen and meal times when they did not match with their daily activity schedule. When participants were too busy with their work-life, they tended to skip meals which caused them to become hungry and overeat later. Skipping meals also resulted in them missing or delaying their insulin injections.

"The way I eat and take the medications is not consistent. Sometimes I forget. Maybe I am too busy. Every time my insulin use would be delayed. For example, usually we inject at 12 right, sometimes I will inject at 2. Sometimes I did not inject at all" – 58 years old housewife

One participant described how the nature of his occupation made it difficult for him to adhere to healthy diet and insulin treatment.

"We are going around okay. So we can't just go and get what we want to eat. We can't go and pack something or bring the food from house. Furthermore, like now I'm taking the short-acting insulin, so every mealtime you have to inject. You just can't go and take insulin, you see. I'm working as a bodyguard you see, you have to follow the boss closely. I think so that is the reason [for poor blood sugar]". – ~~Thomas~~ 36 years old_personal bodyguard

Inability to control food cravings and eating habits

Participants also reported that the temptation of eating something delicious would lead them to lose control of their diet, causing them to overeat.

"My eating habit. Like I like to eat sweets, like kuihs [local dessert] and all that. But I have to control. I know I am not controlling. I must put a full stop to that." - 60 years old woman housewife

It is also difficult to resist food when there is a variety of food available and coming from a lifestyle and culture where food and eating are a way of living.

"Basically it is also Malaysia lifestyle whereby people like to eat. You eat non-stop. Sugar is particularly everywhere in your diet so that's probably one of the main reasons why it is not controlled". - 22 years old student

Inappropriate diet recommendations by healthcare providers

Participants felt that the diet recommended by HCPs provided insufficient energy for them to carry out their work. Some also expressed frustrations with regards to the monotony of eating the same type of food every day, such as bread and chapatti, which were recommended by the HCPs. Hence, they often neglected the dietary advice.

"Every time they [HCPs] ask me to eat bread. Can you eat bread everyday? For sure you will hate it. They will ask to eat vegetables every day. Cannot like that " - 59 years old ex-lorry driver

Health conditions affecting exercise

Not being able to exercise optimally due to health conditions was another reason cited by many for poor glycemic control.

"Another thing is exercise. Because of stroke, I have problem with walking. I have to exercise more". - 61 years old engineer

Psychosocial issues and emotional hurdles

Three subthemes emerged under this theme.

Psychosocial problems affecting diabetes self-care

Participants felt that their poor glycemic control was attributed to personal problems which caused them to feel anxious, stressed and sad, which resulted in some adopting unhealthy eating habits and not taking their diabetes medications, including insulin.

> *"Actually when you have diabetes, you cannot be stressed. Previously when I was under stress [due to marital problems], my blood sugar level was very high because I did not eat and take my insulin. I was hoping to die." – 50 years old taxi driver*

Loss of motivation

Participants admitted that they were tired of adhering to diabetes medications after having taken them for such a long time that sometimes they would intentionally skip doses.

> *"Sometimes I purposely miss them because I am just so tired of injecting". – 40 years old officer*

Additionally, an absence of significant improvements in glycemic control despite efforts made to improve glycemic control led participants to 'give up' in controlling their blood sugar.

"There's one time actually I did go to the gym and the exercise was okay but it didn't really do anything to my weight. It does a little bit on my sugar but after a while I just give up. I think it would be as well [contributed to her poor glycemic control] because the main thing is that, I think that if I actually lose weight, I would be able to control my sugar as well." – 40 year old officer

Perceived poor glycemic control as part of ageing

Many older participants of this study held the view that whatever their attempts to control blood glucose levels, their glycemic control would still fall short due to their advanced age.

"Maybe because I am getting old. As the days passed by, all my organs has deteriorated. Like engine, the more it is used, it will become spoilt." - 69 years old retiree

Diabetes treatment-related factors

There are two subthemes under this theme.

Side-effects of insulin

Participants reported they would tend to overeat to prevent or counter the effects of insulin-induced hypoglycaemia. However, it is when participants overeat that their glycemic control deteriorates.

> *"I had fit once (due to hypoglycaemia), that fear is always there. On and off, I used to eat more to make sure I don't go into hypoglycaemia fit. It is extremely painful". - 47 years old doctor*

Participants also felt that insulin caused them to feel hungry, causing them to overeat, hence, raising their blood sugar levels.

> *"But if use insulin, it makes me eat. I feel that after using insulin, the blood sugar goes even higher". – 37 years old clerk*

Fear of needles and pain also caused participants to delay insulin initiation as well as intentionally skipping injections, thus contributing to poor glycemic control.

> *"I don't quite like insulin actually. I'm very afraid of needles and the pain that follows. In a week I would say at least 3 times [skipping insulin injections]. Although my blood sugar was already up about 6 to 7 years ago, but I've only started insulin not far back from now. So that's the other reason [for poor glycemic control]." – 40 years old officer*

Perception of appropriate dietary practices related to insulin

One participant felt that his poor glycemic control was attributed to the diet recommendations given by the HCP. He voiced that the meal pattern recommended was not right and would instead reduce the efficacy of the insulin.

> *"For example if you eat at 8pm, then you feel hungry and you eat again. So if I follow his [doctor] advice I will eat but this is wrong. The mistake is if lets say I eat at 7pm, then 8, 9, 10, 11, 12pm, for about 4 hours I will keep on eating. So the insulin cannot fight with my diabetes. Because I have experienced this so I know. The recommended cannot work. My diabetes reach 20, 30 something". – 50 years old taxi driver*

Lack of knowledge and self-efficacy in diabetes self-care

Two subthemes were identified under this theme.

Lack of knowledge of glycemic level and target

Lack of knowledge of their glycemic level and target was also cited as a reason for poor glycemic control, as participants were not aware to what extent they should control their blood sugar. This lack of knowledge was attributed to difficulties in performing SMBG due to financial reason, and some claimed that their HCPs did not inform them about their glycemic levels and target.

> *"I check less because sometimes when the needles are finished, I have to wait for my salary to buy. I check once a week but if I need to see the doctor*

then only I will check 4 times a day. Actually it is not enough. When I don't check, I cannot control my diet so that's why my blood sugar is not good". – 37 years old clerk

"I don't know why he [doctor] wants to lower (blood sugar level) some more. No, because I don't know what is the target. The doctor never mentioned. I am also not sure. So I also don't know whether I am okay or not. If I know, I will control no matter what". -31 years old marketing coordinator

Lack of self-efficacy in adjustment of insulin dosage

Despite receiving advice from the doctor that they could adjust their insulin dosage, some participants did not do so as they were afraid of making mistakes when adjusting the insulin dose, which could lead to hypoglycaemia and other complications.

"I'm just reluctant [to adjust insulin dosage] because they [doctor] won't be with me 24 hours. I didn't increase or decrease any of the medication. I just stick to it. So maybe that is the reason". - 36 years old personal bodyguard

Discussions

Our study revealed that people with type 2 diabetes using insulin attributed their sustained hyperglycemia to lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of knowledge of glycemic levels and targets, as well as poor self-efficacy with regards to insulin dosage adjustment. Majority of the factors raised were not related to problems with insulin use per se, but were related to barriers in performing diabetes self-care tasks in general such as dietary control, adherence to exercise and medications including OHAs.

Our study participants faced difficulties in adhering to the recommended meal and insulin injection schedule due to work priorities and time constraints. In a multinational study involving 1530 people with type 1 diabetes (12.8%) and type 2 diabetes (88.2%) using insulin from eight countries, taking insulin at the prescribed time or with meals everyday was also reported to be difficult [17]. The lifestyle changes required for diabetes management in terms of diet and regular mealtimes were acknowledged to be hard to implement, even in people with type 2 diabetes using OHAs alone, who often report missed or delayed meals [18]. This showed that adherence to regular meal and medication times is a universal and major barrier to diabetes management among people with diabetes. It is crucial to overcome that, especially among people with type 2 diabetes using insulin, as insulin administration has to be synchronized with meals. When regular meal times cannot be followed, it often results in delayed or skipped insulin intake, as reported in our study, which explains poor glycemic control.

Our participants raised the issue of dietary recommendations by HCPs, which did not meet their dietary needs; the issues of the monotony of eating the same type of food every day and the recommended diet could not provide sufficient energy. Other people with type 2 diabetes using insulin have reported that clinicians would simply assume that patients would comply to the medical recommendations given; without considering their individual needs and preferences [5]. Additionally, it also appears that lack of understanding of the rationale behind dietary recommendations is common among type 2 diabetes patients. One participant of our study thought the meal pattern recommended by HCPs would thwart the efficacy of insulin, while type 2 diabetes patients on OHAs in another study perceived that frequent meals was a way to control their diabetes [19]. In fact, the main purpose of regular meals is actually to counter the effects of hypoglycemia, due to insulin and long acting sulfonylureas. HCPs may be a contributing factor to these barriers in adhering to dietary recommendations. In a collaborative study conducted in Austria, Canada, Germany and United Kingdom, it was found that general practitioners lack the knowledge and skills to educate, support and motivate patients on healthy lifestyle changes [20].

The issue of psychosocial factors and lack of motivation is crucial, as it affects all aspects of diabetes self-care including adherence to insulin, as evidenced from our study. Diabetes self-care is a complex task that demands behavioral change in the patient on a daily basis; the influences of social, cultural, familial and professional contexts further complicate management of the disease in diabetes patients as shown in other studies [21-23]. Furthermore, our participants also showed that when a patient's diabetes condition remains unimproved despite efforts to control it, this

leads to 'diabetes burn-out' stemming from frustration and loss of motivation; eventually resulting in neglect of diabetes self-care. Perhaps explaining the disease progression in type 2 diabetes and that the progressive loss of β-cell function is common, will lift the feeling of frustration and loss of motivation in them.

Older participants of our study perceived that they would never be able to achieve glycemic control due to their old age even with insulin use. Such misconceptions are alarming as they may decrease older people's perceived importance of glycemic control. They may lower their expected treatment target in order to cope with the challenges in managing diabetes at such an age [24]. There is a need to inform elderly people with type 2 diabetes that insulin has no upper limit dosage and they will still be able to control their glycemic levels even with increasing age.

Issues such as fear of hypoglycaemia and needles and pain have been well established as barriers to insulin initiation [6,7] and it is interesting to know that such problems still prevails even after participant initiate insulin use, as found in participants of our study. Moreover, these factors have been well established as factors for intentional insulin omission [25] and overeating to prevent insulin-induced hypoglycemia [5,26]. The UMMC has an established specialized diabetes clinic with trained diabetes nurses to provide education and skills training in diabetes self-care to patients. Therefore, our study participants would have been educated and trained on techniques of insulin administration and ways to prevent and manage hypoglycemia. In addition to providing diabetes education and skills training to people with type 2 diabetes using insulin, provision of counselling to address these fears is warranted.

Lack of knowledge of glycemic level and targets was also a reason for poor glycemic control in our participants. They were unsure to what extent they should control their glucose levels. The issue of lack of knowledge of glycemic levels and targets in our study stemmed from lack of SMBG and perceived minimal feedback from HCPs. Our participants reported financial constraints in carrying out effective SMBG, as costs for SMBG supplies are not subsidized by the Malaysian government. The impact of economic factors on SMBG adherence have been reported as an issue that limits glycemic control in other studies [27,28]. In a study by Onwudine et al., (2011), the study participants reported that they were not informed by their doctor of their target blood glucose levels and perceived that as a barrier to diabetes self-management [29]. HCPs have a crucial role to play in discussing glycemia results with their patients and formulating mutually agreed glycemic targets. A study has shown that knowledge of HbA1c and target goal had a positive impact on maintaining better glycemic control among people with type 2 diabetes [30].

Self-adjustment of insulin dosage have been shown to be a technically complex regimen for people with type 1 diabetes [31] and people with diabetes spend most of their time managing their diabetes away from healthcare professionals. It is thus not surprising that our participants were still apprehensive about self-adjustment of their insulin dose; for fear of hypoglycemia. Dependent and deferential attitudes towards health professionals were cited as the reasons why type 1 diabetes patients do not adjust their insulin dosage [31] and this may also be the reason for failure to adjust insulin dosing among our participants. Furthermore, the lack of skills to educate patients on how to monitor their glycaemic levels and adjustment of insulin has also been found to be a common challenge faced by general practitioners [20].

Some factors for poor glycemic control as highlighted in the conceptual framework did not emerge in our study findings even when the participants were probed. The issue of social stigma was not raised by our participants as a reason for poor glycemic control. We assumed that our participants had overcome this barrier upon initiation of insulin since they have been on insulin for at least one year; as they also reported of performing adaptive strategies such as injecting insulin in private in public places, for example in the toilet or in their car. Ethnicity was also not raised as a factor for poor glycaemic control in this study. Instead, the participants described eating culture as a way of living for Malaysians in general. Therefore, participants of this study might have adapted to the 'Malaysian' culture whereby they share and practise culture of others. Even if the recommended diet by HCPs may not be the types of food familiar with the specific ethnic group or culture, nevertheless, they could still follow the recommended diet. No specific ethnicity barrier was also reported for diabetes treatment aspects. Socio-economic was not a factor for participants in this study to seek healthcare treatment as the company where they or their spouses are working subsidized the medical costs. It should also be noted that the Malaysian government provides relatively cheap health care for the people and the cost for insulin is subsidized. However, this is not the case for SMBG where patients have to pay out-of-pocket for glucometer and test strips. This is the reason why the lack of knowledge of glycaemic status due to low performance of SMBG was raised as a reason for poor glycaemic control. Our participants did not blame their family, friends, healthcare system or HCPs for their poor glycemic control. They however expressed dismay at the short consultation times and not being able to see the same doctor for their diabetes. Our participants expressed that diabetes control is a personal responsibility, therefore they tended to focus on their personal inadequacies when it came to poor

glycemic control. This may be due to diabetes self-care playing a huge role in disease control, hence people with type 2 diabetes may have felt greater responsibility for self-care. Thus, when glycemic control cannot be achieved, this resulted in self-blame [32].

The strengths and limitations of the study

The major strength of this study lies in the fact that the reasons behind poor glycaemic control were gained from the insights of people with T2DM with sustained hyperglycaemia for more than one year despite insulin use, through in-depth interviews to explain why their diabetes remains poorly controlled despite being on insulin. To researchers' knowledge, such findings has never been reported before. This study found that issues such as adherence to regular meal and medication times, fear of hypoglycaemia, needles and pain and lack of knowledge and self-efficacy in diabetes care remain as barriers for poor glycaemic control among people with type 2 diabetes using insulin, whereas, issues such as social stigma, ethnicity, socio-economic factors, family, friends, healthcare system factors and HCPs were found not to be reasons for poor glycaemic control despite insulin use.

This study has a few limitations. The recruitment of participants in this study was only conducted in a single hospital, hence healthcare systems as a factor in poor glycemic control cannot be further explored. The interviews were conducted in the hospital where the participants were recruited, hence the environment may influence them to give a socially desirable response. However, they were informed that their responses would not affect their medical care and would be kept confidential.

Clinical recommendations

HCPs should create individualized plans with people with type 2 diabetes using insulin, to ensure a routine that allows for proper meal times and exercise, which would enable them to take their diabetes medication, including insulin, in a timely manner. Patients reported they face problems with treatment recommendations, hence HCPs should continuously assess the efficacy and feasibility of treatment provided to their patients and clarify patient misconceptions. It is also pertinent for HCPs to recognise the psychological and emotional problems that impact on their patients' diabetes self-care and provide affective support to them. Lastly, HCPs should discuss glycemic readings and adjustment of insulin dosage, as well as formulate a mutually agreed target with patients to facilitate improvement of glycemic control.

Murray et al., (2011) has identified the common challenges faced by general practitioners when caring for people with type 2 diabetes across international and health system borders and they were related to knowledge, skills, attitudes, behaviours and context [20]. Some of the challenges faced by HCPs may explain the reasons for poor glycaemic control as faced by participants of this study such as the lack of knowledge and skills to: give clear explanations to the patients, actively engage their patients in their health management, educate patients on how to monitor their glycaemic levels, engage in shared decision making with patients and provide support and motivation to patients in their efforts towards lifestyle chnages for better glycaemic control. Therefore, it is pertinent that HCPs are equipped with accurate and latest knowledge and skills about diabetes and its treatment and be able to impart them to their patients to empower them to perform effective diabetes self-care tasks.

Future research recommendations

More research is needed pertaining to this topic to uncover other factors that could influence poor glycemic control despite insulin use. In addition, exploring views from HCPs and caretakers of the patients would provide a more holistic understanding of factors for poor glycemic control despite insulin use. Accurate assessment of patient's knowledge, actual self-care practices, and, clinical characteristics could also be conducted. This would allow triangulation of multiple sources of data which would then provide more comprehensive understanding and better identification of reasons for poor glycemic control. Ultimately, the factors identified may help to develop a tool to be used by HCPs, as a checklist to address the barriers faced by people with type 2 diabetes using insulin in achieving glycemic control. In addition, future study should look into the motivators of better glycaemic control among people with type 2 diabetes using insulin who is succesful in gaining glycaemic control. Understanding both the barriers and the motivators would help to improve glycaemic control among this subpopulation.

Conclusions

Our findings revealed lifestyle challenges, psychosocial and emotional problems, treatment-related factors and lack of knowledge of glycemic levels and targets, and poor self-efficacy with regards to insulin dosage adjustment as factors for poor glycemic control despite insulin use. Healthcare providers could look into these factors and help patients with type 2 diabetes using insulin to address their concerns during consultations and thus improve glycemic control.

Contributorship statement

All authors (WTT, SRV, CJN) of this study conceived and designed the study, researched and analysed the data, contributed to discussion, wrote, edited, reviewed and approved the final version of the manuscript.

Competing interests

None declared.

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Ethics approval

This study received ethical approval from the University of Malaya Medical Centre Medical Ethics Committee (926.18).

Data sharing

No additional data are available.

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Table 1 Summary of interview guide topic on factors influencing poor glycemic control despite using insulin

PREAMBLE: Actually you have had diabetes for a long time and are now using insulin to control your blood sugar. Since you are using insulin to control your blood sugar, but your blood sugar is still not well controlled.
• Can you share with me what do you think are the reasons why your blood sugar is still not well controlled?
Focussing on areas influencing poor glycemic control
• Do you face any problems in adjusting lifestyle for your diabetes care? (Probe: diet, exercise, medications). How?
• What barriers do you face when using insulin? (Probe: injecting insulin in the public, negative beliefs about insulin, fear of needle, pain, blood, body injury, marks and scars, weight gain, hypoglycaemia, knowledge and skills in administrating insulin)
• Does your family, friends, or employer takes part in managing your diabetes? Do you think they affect you in your blood sugar control? How?
• Do you face any health problems that makes it difficult for you to manage your diabetes? (Probe: vision problems, dexterity, mobility, poly-pharmacy, exercise)
• There are some people with diabetes who are depressed and stressed and that affect their sugar control. Do you face this problem? How does it affect you in controlling your blood sugar?
• Do you perform self-blood glucose monitoring? If no, why not? Does it affect your blood sugar control? If yes, how?
• What barriers do you face when consulting the doctor/nurse for your diabetes? (Probe: language, communication, and interaction). Does it affect your blood sugar control?
• What do you think of the hospitals and clinics that you go for your diabetes? (Probe: resources, complexity of system, accessibility, long waiting time, short consultation time) Does it affect your blood sugar control?
• Do you face any financial difficulties to care for your diabetes? (Probe: Medication cost, transportation to hospitals, SMBG)

Table 2: Socio-demographic background and diabetes profile of participants

Characteristic	Participants (n=17)
Age (range)	22- 69 years
Sex	
Female	10
Male	7
Race	
Malays	8
Chinese	4
Indians	4
Nepalese	1
Education	
Secondary	9
Tertiary	5
Primary	2
No formal education	1
Years living with diabetes (range)	2-30
Years using insulin (range)	1-14

Table 3 Factors influencing poor glycemic control in people with type 2 diabetes using insulin

	Theme	Category
1	Lifestyle challenges in adhering to medical recommendations	1. Difficulty integrating diabetes medical recommendations into work-life schedule 2. Inability to control food cravings and eating habits 3. Inappropriate diet recommendations by HCPs 4. Health-limiting conditions affecting exercise
2	Psychosocial issues and emotional hurdles	1. Psychosocial-problems affecting diabetes self-care management 2. Loss of motivation 3. Perceived poor glycemic control as part of ageing
3	Diabetes treatment-related factors	1. Side-effects of insulin 2. Perception of appropriate dietary practices related to insulin
4	Lack of knowledge and self-efficacy in diabetes self-care	1. Lack of knowledge of glycemic level and target 2. Lack of self-efficacy in adjustment of insulin dosage

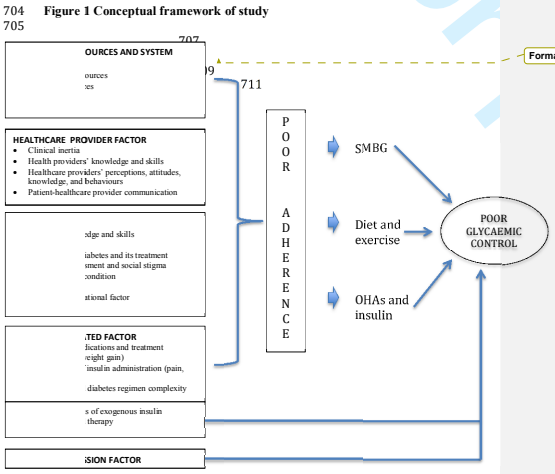
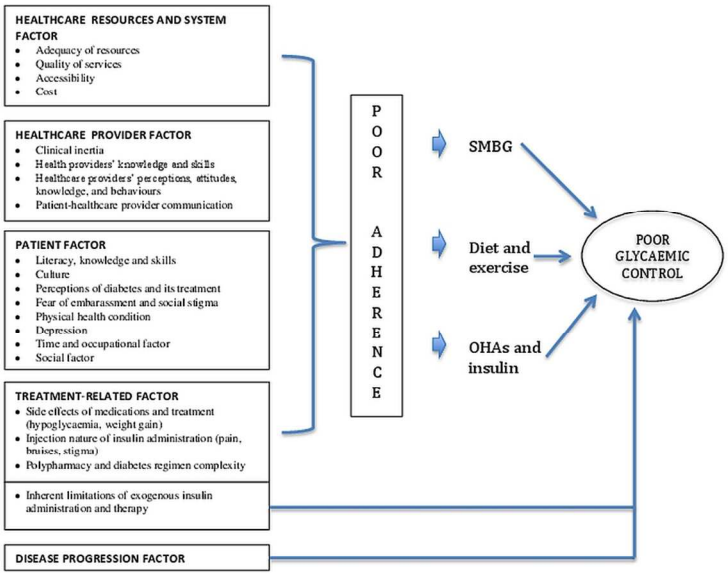


Figure 1 Conceptual framework of study

Figure 1 Conceptual framework of study



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