

RETHINK: An observational cross sectional study on the uptake of insulin therapy among type 2 diabetes patients with secondary drug failure treated in primary care

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Abstract

Aim: To determine the factors that deter the initiation of insulin therapy among type 2 diabetes patients with secondary drug failure.

Methods: An observational cross sectional study of 72 refusers (cases) and 72 acceptors (controls) of insulin therapy in primary care polyclinics in Singapore.

Results: Refusers have more concerns about insulin injections than acceptors (69.4 vs 22.2%, $p < 0.001$). Refusers cited 'fear of pain from the needle' as the main reason for refusing to start insulin therapy (45.8%), followed by 'financial constraint' (18.4%) and 'inconvenience' (12.5%). Refusers were less aware of the action of insulin (58.2 vs 34.6%, $p = 0.015$), perceived that insulin 'is unnecessary (because) other treatment is available' (70.8 vs 36.1%, $p = 0.001$) and regard regular injections as a hassle (50 vs 26.4%, $p = 0.001$). Acceptors were more likely to perceive insulin injection as 'effectively controls blood glucose levels' (84.7 vs 59.7%, $p = 0.002$), 'helps one feel better' (77.8 vs 40.3%, $p = 0.001$), 'helps one feel more energetic' (68.1 vs 31.9%, $p = 0.001$), and 'more effective than oral medication' (72.2 vs 43.1%, $p = 0.001$). Nonetheless, both groups were as likely to perceive that being put on insulin therapy is an indication of an 'advanced phase of illness' (65.3 vs 63.9%, NS), and a 'failure to care for oneself' (66.7 vs 55.6%, NS).

Conclusions: The two major barriers to insulin initiation among refusers are perception of pain and financial constraints. Refusers are more likely than acceptors to have concerns over insulin injection and regard insulin therapy as a last resort, although both groups possessed a number of negative perceptions regarding insulin therapy, which need to be addressed.

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Key words: diabetes mellitus, drug failure, insulin.

Introduction

Diabetes mellitus, a chronic progressive disease, has been the sixth leading cause of death in Singapore since 1997, affecting 9% of the population.¹

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Diabetic treatment generally begins with lifestyle modification, but if that fails to achieve satisfactory glycemic control, oral hypoglycemic agents (OHA), such as sulfonylureas and biguanides, are prescribed. Acarbose and the new thiazolidenediones are alternative medications. Failure to control diabetes with the different types of OHA makes initiation of insulin therapy necessary. Evidence from the United Kingdom Prospective Diabetes Survey (UKPDS) studies shows that many patients eventually require multiple drug regimens,^{2,3} as well as an escalation of dose over the years.⁴ Although insulin is not the panacea for every poorly controlled diabetic patient, combined treatment with several drugs including insulin has been

shown to be effective in achieving satisfactory glycaemic control over several years,^{5,6} and to retard microangiopathic complications.⁷

Despite the therapeutic effects and benefits of insulin, many patients in western countries are reported to be reluctant to initiate such therapy for reasons ranging from perception of pain and inconvenience to the social embarrassment of using syringes in public.⁸ Insulin administration is mostly via syringe and needle in the polyclinics in Singapore.

Methods

RETHINK (REconsider THERapy with INSulin Knowledge & attitude among type 2 diabetes patients) is a descriptive observational cross sectional study of type 2 diabetes patients in primary care in Singapore.

The main objective of the study was to explore the factors affecting insulin therapy initiation among type 2 diabetes patients with secondary drug failure. The secondary objective was to determine the demographic profile of 'acceptors' and 'refusors' of insulin therapy as there is paucity of such data in Singapore.

Recruitment was conducted from June to November 2001 at SingHealth Polyclinics (Institute of Health, Bedok, Bukit Merah, Geylang, Queenstown, Marine Parade and Tampines) and patients who satisfied the inclusion and exclusion criteria consented to the study. Patients were enrolled consecutively on a case encounter basis. Eight research nurses were trained to conduct personal interviews with patients using a standardized questionnaire comprising open and close ended questions and an attitude assessment based on the Likert scale. The interviews were tape recorded for cross examination and validated by a different research nurse from a separate polyclinic.

A 2-week pilot trial was conducted at one selected polyclinic, which led to further refinement of the questionnaire.

The questionnaire was translated into Mandarin and Malay. Back translation by different nurses was also carried out to check the accuracy of the translation. In most instances, the English version was used and the translated versions were used only if the patient could not understand English.

The SingHealth Polyclinics Ethics Committee approved the study in June 2001. Informed written consent was obtained from all the patients.

Study population

The required sample size was calculated using the EPISTAT program based on the following assumptions: (i) 20% secondary drug failure (excluding those on dietary control) among the diabetic population; (ii) maximum difference of 10% between the true diabetic

population with secondary drug failure rate and the sample rate; and (iii) a power of 90% and two sided test of 5%.

Assuming a non respondent rate of 10–15%, the minimum required sample size was 13. The non respondent rate is defined as the ratio of patients who qualify for the inclusion and exclusion criteria, but who refuse to participate in the study compared with the total number of patients in the study population.

Inclusion and exclusion criteria

All patients were Singaporeans or permanent residents who had resided in Singapore for at least 5 years. Patients were categorized as 'acceptors' or 'refusors'. 'Refusors' were defined as type 2 diabetics who refused insulin therapy, had been treated with a maximum total daily dose of two or more OHA (either a sulfonylurea and/or biguanide and/or glucosidase inhibitor) and had two consecutive HbA_{1c} readings of greater than 9% in the 6 months prior to the study. 'Acceptors' were type 2 diabetics who had accepted and were on insulin in combination with OHA for at least 6 months prior to recruitment.

Patients were excluded from the study if mentally ill or demented, prone to hypoglycemia, or unwilling to switch to insulin treatment because of short term life events (e.g. going overseas for holidays, elective surgery within the next month).

Refusors who did not wish to participate in the study were regarded as non respondents. They carried on with their existing management program and were referred to the nurse practitioners for reinforcement of diabetic therapy and counseling. Refusors who agreed to initiate insulin therapy after the interview were referred back to their doctors for further management.

Statistical analysis

All statistical analyses were performed using the Statistical Analysis Software (SAS version 6.12, SAS Institute, Cary, NC, USA). The χ^2 test was used to determine differences in categorical variables, and Fisher's exact test was used if the expected value was less than five in any of the cells. All statistical tests were two sided with a significance level of 5%.

Results

We screened 166 patients and 20 refused to participate in the study, giving a response rate of 88.0% ($n = 146$). Two of the 146 patients interviewed were later excluded from the analysis because they failed the inclusion criteria. Eventually, an equal number of acceptors and refusors ($n = 72$) were included in the statistical analysis.

Demographic profile of the subjects

Acceptors and refusers were comparable in their demographic profiles, except that refusers had a shorter duration of diabetes mellitus and were more likely to be widowed, divorced or separated and treated with multiple OHA such as glibenclamide and acarbose (Table 1).

Awareness, barriers, attitude and perceptions of insulin therapy

Most subjects knew about insulin, but were unaware of its mode of action (Table 2). The barriers towards insulin therapy included a perception of pain and inconvenience, financial constraint and incorrect perceptions of addiction and the availability of other modes of effective treatment. Acceptors were more likely to perceive insulin as effective in promoting their well being.

Role of health professional and family support

The majority of refusers were reluctant to initiate insulin therapy because of a perceived lack of family support to assist in insulin therapy and despite the accessibility of health professionals to educate on the mode of administration (Table 3). They preferred to speak to doctors and immediate family members, such as spouse and children, about insulin therapy.

Discussion

Demographic profile

The present study provides an insight of the demographic profile of type 2 diabetes patients with secondary drug failure in primary care in Singapore. Both acceptors and refusers were predominantly female, but the racial distribution appears to be comparable to the general population in Singapore, with the exception of a higher proportion of Indians among the refuser group (15.3 vs 5.6%). This correlates with the higher prevalence of diabetics among Indians in Singapore.¹

A smaller ratio of refusers-to-acceptors had had diabetes for a decade or longer (1 : 1.3), as compared with those that had had diabetes for 5–10 years (1 : 2.4). In the natural history of diabetes, endogenous production of insulin will decline over time and eventually exogenous insulin will be required for survival. Thus the longer the duration of diabetes, the more pressing is the need for insulin.

More refusers (63.9%) were on long-acting sulfonylurea than acceptors (33.3%). Similarly, more refusers (23.6%) than acceptors (4.2%) were on acarbose as an

add on medication to improve diabetic control. This is to be expected, as efforts to control diabetes without insulin need to be compensated with increased oral medication use. Consistent with these findings, a larger ratio of refusers-to-acceptors were taking three OHA (7.5 : 1) as compared with one or two OHA (1.2 : 1).

Administration of insulin

Among the insulin users, 23.6% could not recollect having heard of the word 'insulin'; among those who had heard of insulin, 41.8% admitted not knowing how it works in the body, and among those who claimed to know this, 46.9% actually misconceived its action and function. This could be related to the lack of reinforcement of the role of insulin in diabetic management. Health care professionals perhaps put more emphasis on the injecting mode of administration, resulting in adverse and skewed feedback on insulin therapy, but this needs to be substantiated with further studies.

Although a higher proportion of acceptors claimed they were aware of how insulin worked in the body (58.2 vs 34.6%, $p = 0.015$), the actual proportion of acceptors who had a correct understanding of the mode of action of insulin was not significantly different to that of the refusers. Deficiency in the knowledge of how insulin works did not appear to hinder the uptake of insulin, although 15.6% of the acceptors did not elaborate on the mode of action of insulin.

One third of acceptors and refusers were aware that errors in dosage and technique of insulin administration might result in side effects such as hypoglycemic symptoms.

Overcoming barriers to insulin initiation

The leading barrier to insulin initiation among refusers is the perception of pain from needle injection (Fig. 1). Needle phobia affects at least 10% of the population and researchers postulate that the etiology of needle phobia lies in an inherited vasovagal reflex of shock, triggered by needle puncture.⁹ Those who inherit this reflex often learn to fear needles through successive exposure, including blood sampling. In general practice, needle phobia can be managed by reassurance and education, postural and muscle tension techniques.⁹ Syringe alternatives, such as insulin pen devices, may also be helpful. Indeed, studies have shown that one reason patients favor pen devices over conventional syringes is decreased pain.¹⁰

Financial constraint is the next commonly cited reason for refusing to initiate insulin. However, there was no obvious difference in income and

Table 1 Demographic profile of the diabetic subjects, RETHINK Study

Variables	Acceptors n (%)	Refusors n (%)	p value
Age (years), mean	72 (61.3)	72 (61.0)	NS
Sex			NS
Male	19 (26.4)	24 (33.3)	
Female	53 (73.6)	48 (66.7)	
Race			NS
Chinese	46 (63.9)	38 (52.5)	
Malay	21 (29.2)	22 (30.6)	
Indian	4 (5.6)	11 (15.3)	
Other	1 (1.4)	1 (4.1)	
Education			NS
None	16 (22.2)	21 (29.2)	
Primary	42 (58.3)	30 (41.7)	
Secondary	13 (18.1)	19 (26.4)	
Pre-university/polytechnic	1 (1.4)	1 (1.4)	
Tertiary	0 (0.0)	1 (1.4)	
Marital status			0.042
Single	4 (5.6)	1 (1.4)	
Married	66 (91.7)	60 (83.3)	
Divorced/separated	1 (1.4)	5 (6.9)	
Widowed	1 (1.4)	6 (8.3)	
Combined household income per month			NS
<S\$500	5 (6.9)	6 (8.3)	
S\$500–2000	32 (44.4)	29 (40.3)	
S\$2000–4000	10 (13.9)	15 (20.8)	
S\$4000–6000	7 (9.7)	3 (4.2)	
S\$6000–8000	1 (1.4)	3 (4.2)	
>S\$8000	1 (1.4)	1 (1.4)	
Refused to divulge income	16 (22.2)	15 (20.8)	
Housing type			NS
Public housing flats	64 (88.9)	69 (95.8)	
Private apartments and condominiums	4 (5.6)	1 (1.4)	
Privately owned house	3 (4.2)	0 (0.0)	
Other	1 (1.4)	2 (2.8)	
Diabetic history			
Duration of diabetes mellitus			0.023
1–5 years	8 (11.1)	6 (8.3)	
5–10 years	10 (13.9)	24 (33.3)	
>10 years	54 (75.0)	42 (58.3)	
Type of medication (OHA)			
Glibenclamide	24 (33.3)	46 (63.9)	0.001
Tolbutamide	12 (16.7)	21 (29.2)	NS
Glipizide	1 (1.4)	3 (4.2)	NS
Metformin	69 (95.8)	71 (98.6)	NS
Metformin Retard (Glucophage R)	1 (1.4)	1 (1.4)	NS
Acarbose	3 (4.2)	17 (23.6)	0.001
No. of OHA per patient			0.001
1	36 (50.0)	0 (0.0)	
2	34 (47.2)	57 (79.2)	
3	2 (2.8)	15 (20.9)	

OHA, oral hypoglycemic agents; RETHINK Study, Reconsider therapy with insulin knowledge & attitude among type 2 diabetes patients.

Table 2 Awareness of, barriers to and perceptions of insulin therapy, RETHINK Study

Variables	Acceptors n (%)	Refusors n (%)	p value
Awareness of insulin	<i>n</i> = 72	<i>n</i> = 72	
You have been advised by your doctor to inject yourself with insulin. Have you heard of insulin?			NS
Yes	55 (76.4)	52 (72.2)	
No	17 (23.6)	20 (27.8)	
If yes, do you know how insulin works in your body?	<i>n</i> = 55	<i>n</i> = 52	0.015
Yes	32 (58.2)	18 (34.6)	
No	23 (41.8)	34 (65.4)	
If yes, how does it work?	<i>n</i> = 32	<i>n</i> = 18	NS
Correct response	12 (37.5)	5 (27.8)	
Incorrect response	15 (46.9)	11 (61.1)	
Did not comment	5 (15.6)	2 (11.1)	
Error in dosage can cause side effects	<i>n</i> = 72	<i>n</i> = 72	NS
Disagree	21 (29.2)	11 (15.3)	
Don't know	20 (27.8)	26 (36.1)	
Agree	31 (43.1)	35 (48.6)	
Error in technique can cause side effects	<i>n</i> = 72	<i>n</i> = 72	NS
Disagree	18 (25.0)	12 (16.7)	
Don't know	20 (27.8)	27 (37.5)	
Agree	34 (47.2)	33 (45.8)	
Barriers			
Which of these factors do you rate as the main and closest reason for your refusal to start insulin?			
Fear of pain from needle		33 (45.8)	
Physical difficulty in giving the injection		3 (4.2)	
Inconvenience of timing of the injection		9 (12.5)	
Poor vision and hence unable to see the syringe marking		3 (4.2)	
Financial constraint		14 (19.4)	
Other		10 (13.9)	
Concerns			
Insulin is given by injection using syringe and needle. Do you have any concerns with injection?			<0.001
Yes	16 (22.2)	50 (69.4)	
No	56 (77.8)	19 (26.4)	
Did not comment	0 (0.0)	3 (4.2)	
Do you feel that people will develop more complications in diabetes such as blindness and kidney failure?			NS
Yes	27 (37.5)	24 (33.3)	
No	32 (44.4)	31 (43.1)	
Uncertain	13 (18.1)	17 (23.6)	
Financial consideration			
Insulin therapy requires you to buy needles and syringes, thus incurring higher cost. Is financial consideration important to you?			0.001
Yes	30 (41.7)	53 (73.6)	
No	23 (31.9)	18 (25.0)	
Did not comment	19 (26.4)	1 (1.4)	
Negative perceptions			
Use of insulin involves painful injections			0.001
Disagree	37 (51.4)	20 (27.8)	
Don't know	1 (1.4)	16 (22.2)	
Agree	34 (47.2)	36 (50.0)	

Table 2 *Continued*

Variables	Acceptors <i>n</i> (%)	Refusors <i>n</i> (%)	<i>p</i> value
Insulin injection indicates an advanced phase of illness			NS
Disagree	17 (23.6)	16 (22.2)	
Don't know	8 (11.1)	10 (13.9)	
Agree	47 (65.3)	46 (63.9)	
Do you feel that people can become addicted to insulin injection?			0.001
Yes	6 (8.3)	33 (31.9)	
No	55 (76.4)	31 (43.1)	
Uncertain	11 (15.3)	18 (25.0)	
Use of insulin indicates past failure to care for one's self			NS
Disagree	17 (23.6)	22 (30.6)	
Don't know	7 (9.7)	10 (13.9)	
Agree	48 (66.7)	40 (55.6)	
Insulin injection is unnecessary, other treatment is available			0.001
Disagree	31 (43.1)	13 (18.1)	
Don't know	15 (20.8)	8 (11.1)	
Agree	26 (36.1)	51 (70.8)	
Insulin injections involve a lot of everyday hassle			0.001
Disagree	51 (70.8)	27 (37.5)	
Don't know	2 (2.8)	9 (12.5)	
Agree	19 (26.4)	36 (50.0)	
Insulin injection causes embarrassment			NS
Disagree	53 (73.6)	50 (69.4)	
Don't know	2 (2.8)	5 (6.9)	
Agree	17 (23.6)	17 (23.6)	
Positive perceptions			
Use of insulin helps one feel better			0.001
Disagree	11 (15.3)	12 (16.7)	
Don't know	5 (6.9)	31 (43.1)	
Agree	56 (77.8)	29 (40.3)	
Insulin injection effectively controls blood glucose levels			0.002
Disagree	2 (2.8)	12 (16.7)	
Don't know	9 (12.5)	17 (23.6)	
Agree	61 (84.7)	43 (59.7)	
Insulin is more effective than oral medication			0.001
Disagree	5 (6.9)	15 (20.8)	
Don't know	15 (20.8)	26 (36.1)	
Agree	52 (72.2)	31 (43.1)	
Insulin injections helps one feel more energetic			0.001
Disagree	13 (18.1)	15 (20.8)	
Don't know	10 (13.9)	34 (47.2)	
Agree	49 (68.1)	23 (31.9)	

RETHINK Study, Reconsider therapy with insulin knowledge & attitude among type 2 diabetes patients.

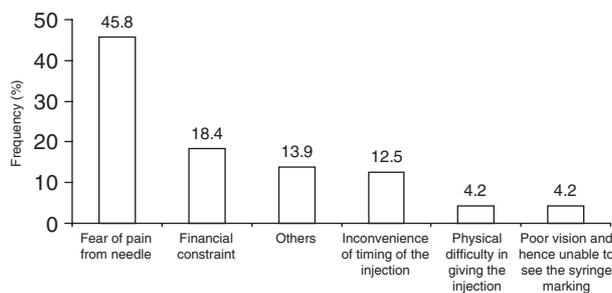
housing type between the acceptors and refusors. Almost half of the study population for both acceptors (51.3%) and refusors (48.6%) had a combined household income of less than S\$2000 (US\$1147) and most acceptors (88.9%) and refusors (95.8%) lived in public housing. Given this finding, the long term cost-effectiveness of injectable therapy may require further evaluation and

government intervention may be needed for the needy patients.

'Inconvenience' was the third reason for refusal. Indeed, more refusors (50 vs 26.4%) regarded insulin injection as a source of 'a lot of everyday hassle'. These findings are consistent with those of Fitzgerald *et al.* who demonstrated that patients consider injecting insulin to be inconvenient.¹¹

Table 3 Role of health professional and family support

Variables	Refusors n (%)
If the nurse teaches you how to use the syringe and needle for injection, are you keen to learn the technique?	
Yes	28 (38.9)
No	44 (61.1)
If you are not able to give injection yourself, is there anyone in the household who can be trained to give the injection?	
Yes	38 (38.4)
No	43 (59.7)
Able to self administer the injection	1 (1.4)
Who will you talk to before you start insulin treatment?	
Doctor	23 (31.9)
Nurse	6 (8.3)
Spouse	10 (13.9)
Children	17 (23.6)
Other family member	2 (2.8)
None	5 (6.9)
Other, please specify	8 (11.1)
Missing data	1 (1.4)

**Figure 1** Barriers to insulin initiation among refusors.

Unfounded concerns about complications

Both acceptors and refusors possessed unfounded concerns about 'complications', such as addiction, blindness and kidney failure. Miller showed that patients often avoid injection for fear of puncturing their stomach, liver, or other internal organ, and that family members often have the same concerns and fears as patients.⁸ Wallace and Matthews suggested that some patients regarded insulin therapy as a prelude to death, the medical equivalent of the last rites.⁴

Attitude and perceptions

The fact that most refusors (70.8 vs 36.1%) regarded 'insulin treatment to be unnecessary because other means are available' suggests that they perceived insulin therapy to be a last resort measure. Both refusors and acceptors viewed insulin injection to indicate an advanced phase of illness.

Acceptors' affirmation of the statements 'insulin effectively controls blood glucose levels' (84.7 vs 59.7%), 'insulin helps one feel better' (77.8 vs 40.3%), 'insulin helps one feel more energetic' (68.1 vs 31.9%), 'effectively controls blood glucose levels' (84.7 vs 59.7%) and 'insulin is more effective than oral medication' (72.2 vs 43.1%) suggests that they are more convinced of the therapeutic benefits of insulin therapy than refusors.

Nonetheless, 36.1% of acceptors indicated that 'insulin treatment is unnecessary, other means are available', suggesting their doubt on the reasons for insulin therapy. Acceptors should be encouraged to express their doubts about therapy and have them clarified by their healthcare professionals, so that their compliance with existing insulin treatment is not compromised.

Family support

Preliminary results from the landmark DAWN (Diabetes Attitudes, Wishes and Needs) study suggest that networks of supportive family, colleagues or friends are as important as medication, in relation to the patients' ability to manage their condition.¹² Indeed, the role of family networks in influencing patients' attitudes and acceptance of insulin therapy cannot be underestimated. In the present study, 31.9% of refusors revealed that they would talk to their doctors before starting insulin treatment, but 40.3% indicated that they would talk to a family member, be it a child, spouse or other family member, before doing so.

Behavioral change

The acceptors in the present study were once on multiple OHA therapy, akin to the 'refusors'. The significant difference between acceptors and refusors over concerns involving insulin therapy (22.2 vs 69.4%, $p = 0.001$) seems to suggest that once refusors are initiated onto insulin therapy, psychological barriers may diminish with time, and the patient gradually accepts the new treatment, as well as becoming more positive about the benefits of insulin therapy on lifestyle and general well being. Nonetheless, it is a challenge for family physicians and diabetic nurses to assist patients in overcoming this psychological hurdle.

Duration of diabetes mellitus

The present study was not designed to determine how diabetes duration affects patients' motivation to start insulin. It is nonetheless interesting to note that there was a significant difference between the acceptor and rejector populations in their diabetes duration profile ($p = 0.023$), with acceptors tending to have longer diabetes duration (75.0% of acceptors vs 58.3% of rejectors had diabetes >10 years), which in turn, suggests that patients with longer diabetes duration are less resistant to insulin initiation. Indeed, Evans *et al.* in examining the risk factors of insulin initiation, found that increasing diabetes duration is associated with increasing risk.¹³ This finding, together with the present data, seems to point to a dilemma between the necessity to start insulin therapy because of deteriorating glycemic control with time, on the one hand, and psychological barriers that prevent insulin initiation on the other.

Study limitations

Diabetic patients with secondary drug failure treated by private practitioners and tertiary hospitals were not involved in the study. Thus, caution should be exercised in any extrapolation of the results to the total diabetic population in Singapore. Visual acuity and refraction errors were not included in the assessment and this may be significant, as visual impairment can hamper administration of correct doses of insulin.

Lauritzen and Scott have argued that the main obstacle to improved patient acceptance of insulin therapy may originate from the attitudes and perceptions of general practitioners (and to a lesser extent some diabetologists) towards type 2 diabetes, who communicate to patients a lack of acceptance of insulin therapy, leading to patients' reluctance or anxiety

about accepting insulin.¹⁴ However, the influence of the health professionals was not determined in the present study.

Conclusions

Perception of pain and financial constraints were the two major barriers to insulin initiation. Both acceptors and refusors harbored negative perceptions of insulin therapy, which suggests a need for increased emphasis on patient education. Refusors tended to view insulin therapy as a last resort, and to correct this perception, healthcare providers should propose insulin therapy as a viable treatment option from the outset.

Implications for general practitioners and primary care nurses

A specific diabetic health education program, incorporating the various factors alluded to in the present study and neatly packaged for delivery in the primary care setting, will be a boon to this group of high risk diabetics.

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