ORIGINAL ARTICLE

Switching from MDI to CSII - Assessment of Qualitative and Quantitative Impact on Self-Management of T1DM Patients

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ABSTRACT

Introduction: Type 1 diabetes (T1DM) patients depend entirely on exogenous insulin. Most patients require multiple daily injections (MDI) for optimal control. Continuous Subcutaneous Insulin Infusion (CSII) is an effective alternative to MDI, usually affording better glycaemic control. Though many studies report these clinical benefits as well as the technical problems encountered with CSII, very few studies report patient / family perceptions about using CSII. Present study was undertaken to assess the impact of switching from MDI to CSII on self-management of T1DM patients. It focuses mainly on patient perceptions and concerns about shifting to CSII and the coping strategies they evolve to handle these concerns. Clinical outcome and problems encountered-the basis of these concerns - were also recorded. **Methodology:** Twenty Type 1 diabetes patients using insulin pump were interviewed in depth to understand their perceptions and concerns while shifting to CSII. A structured questionnaire was used to gather quantitative data regarding impact on clinical outcome and the problems encountered. **Results:** Our patients showed statistically significant improvement in HbA1c along with reduction in the total daily dose on shifting to CSII. Frequency of hypoglycaemia also reduced. However, 'silent blocks' experienced by 56% of patients were expressed as the most alarming technical problem with grave clinical and psychological implications. Convenience emerged as a major advantage of switching to CSII (80%) and prompted them to develop coping strategies to overcome the problems encountered.

Key words: Insulin pumps, patient perceptions, coping strategies, qualitative research, quality of life

Key Message: CSII significantly improves clinical outcome in T1DM. Patients perceive convenience and good clinical outcome as the most important advantages of CSII, while 'silent blocks' are perceived as the most dreaded of the possible technical problems. Patients develop effective coping strategies, but need ongoing technical and psychological support.

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INTRODUCTION

Type 1 diabetes (T1DM) patients depend entirely on exogenous insulin. Continuous Subcutaneous Insulin Infusion (CSII), is an effective alternative to multiple daily injections (MDI) required by most patients. Though many studies report clinical benefits and technical problems encountered with CSII,[1-5] there are very few studies reporting patient perceptions and concerns about using CSII.[6] Present study was undertaken to assess the impact of switching from MDI to CSII on self-management of T1DM patients, not only regarding clinical outcome and problems encountered, but importantly, patient concerns about shifting to CSII and the coping strategies they evolve to handle these concerns.

SUBJECTS AND METHODS

In this cross sectional observational study, 25 T1DM patients using insulin pumps were approached and explained about the study. Twenty patients willing to participate gave their informed written consent. After taking the basic demographic data, they were interviewed in depth to get an insight into their perceptions and concerns about shifting to CSII. A structured questionnaire was used to gather quantitative data regarding impact on clinical outcome and problems encountered. The four major aspects addressed were:

1. Clinical impact of switching from MDI to CSII

2. Technical problems encountered with the pump / infusion set

3. Patients' perceptions and concerns about shifting from MDI to CSII

4. Coping strategies evolved by the patients to tide over these problems and concerns.

Clinical impact of switching from MDI to CSII

a. Impact on glycaemic control was assessed primarily as altered HbA1c and change in total daily dose of insulin (TDD/kg). Other indicators of glycemic control like frequency of episodes of Hypoglycemia and/or Hyperglycemia and weight gain were also looked into.

b. Injection / Insertion site changes were assessed by observation of insertion sites and patient questioning.

Technical problems encountered

a. Pump problems like failure of delivery with or without alarm

b. Infusion set problems like kinking of the connecting tube, folding of cannula, dislodging of the cannula / patch or requirement of more frequent change of the infusion set than recommended were assessed.

Patients' concerns and effect on quality of life

Impact on quality of life was assessed by comparing practical aspects like frequency of Self-monitoring of Blood Glucose (SMBG) deemed necessary and practiced while on pump as against previously while using MDI, ease of taking/adjusting doses with MDI/pump, botheration of carrying injections (vials and syringes/pens) as against continuous wearing of pumps and carrying and changing the infusion sets and adjustments required for activities like sports, swimming or parties. Psychosocial consequences of changed reactions of people around were also assessed. Impact of technical problems experienced, if any, on their quality of life (like concern about wrong insertion of cannula, silent blocks) was also assessed through in-depth interviews.

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Coping strategies evolved by patients

Patients were asked how they adjusted to the altered routine and technical issues, how they managed in times of problems encountered and the coping strategies they adopted to avoid recurrence. Their comfort level in independently adjusting the bolus and basal doses with the pump was also assessed.

ANALYSIS OF DATA

The quantitative parameters while on MDI / CSII were compared by using Wilcoxon matched pairs signed rank test. The qualitative data gathered through in-depth interviews was analysed by identifying themes and categorizing the responses under these themes to assess the commonalities between responses as well as unique responses.

RESULTS

Demographic details

The 20 patients interviewed were between 10 to 58 years of age (Mean ± Std Dev: 24.8 yrs ± 15.95), nine (45%) being males. Duration of diabetes ranged from two years to 28 years (12.1 yrs ± 9.1), while duration of pump use ranged from three months to six years (31.4 months ± 26.3). All had been taking four to five injections per day (MDI) before switching to insulin pump. All were using Medtronic pumps, with Medtronic Quick-Set infusion sets. Most (75%) patients used nine mm cannula. Majority patients (70%) continued to use regular human insulin for the pump, while three patients (15%) used Lispro and three patients (15%) used Aspart.

Clinical impact of switching from MDI to CSII

a. Glycaemic control

As seen in Table 1, switching to CSII significantly improved glycaemic control indicated by reduced HbA1c (p=0.0025) along with reduced total daily dose requirement of Insulin (p=0.039). Thus switching to CSII appears to benefit the patients in terms of glycaemic control. Frequency of hypoglycaemia episodes per month was seen to reduce on switching to CSII, though the difference was not statistically significant (p=0.1). Patients overall reported better control of glycaemic variability in terms of reduced number of 'highs' as well as 'lows'. Switching to CSII proved to be particularly useful in two patients who, while on MDI, had severe glycaemic excursions on either side almost daily. Switching to CSII initially resulted in marked weight gain for six patients (30%) which were subsequently brought under control by adjustment of dose and diet, whereas five patients (25%) showed almost no change in weight.

b. Insertion site changes

The commonest complaint was appearance of dark spots at every site of insertion of the cannula (85%). The spots reportedly disappeared after variable time duration, from one week to more than a month, but five patients (25%) reported that the spots were almost permanent. One patient noted that the persistence of spots depended inversely on the frequency of change of insertion site; but more frequent change in insertion site meant more number of infusion sets, which increased the cost of treatment.

Next common problem was lipo-hypertrophy, which was seen in three patients (15%). Out of these, one patient had developed lipo-hypertrophy on the abdomen much before switching to CSII. Two patients (10%) had encountered repeated infection at insertion site at the start of CSII. The problem had subsequently been resolved with improved technique.

Technical problems encountered

a. Pump problems

As seen in Table 2, all patients had experienced a no delivery alarm at some time or the other. Greater concern was about 'Silent Blocks' experienced by 11 patients (55%). 'Silent block' was described as "interruption of insulin delivery without a warning alarm". Though all patients with silent block noted severe rise in blood sugar, none had needed hospitalization. All reported checking the BSL due to 'feeling different' and then taking corrective action by manual injection of regular insulin.

Table 1: Effect of switching to CSII on clinical parameters reflecting glycemic control

	Parameter	Before starting CSII	After 3-6 months on CSII	p value
1	TDD/Kg	1.08 ± 0.41	0.91 ± 0.31	0.039*
2	HbA1c	11.33 ± 2.7	8.81 ± 1.14	0.0025*
3.	Hypo glycaemia episodes/month	7.86 ± 8.06	4.04 ± 6.86	0.16
4.	Weight	49.31 ± 13.5	51.48 ± 11.93	0.001*

Table 2: Technical Problems encountered with the pump

I	Pump Problems	No of patients reporting the problem (% of total)	Probable causes
1	No delivery with alarm	20 (100%)	Kinking of infusion set tube, insufficient insulin, discharged battery
2	Silent No delivery, NO ALARM	11 (55%)	Unexplained - 5 (25%), Improper insertion of cannula, leakage at insertion, dislodged patch - 6 (30%)
3	Excess dose delivered	nil	

Table 3: Technical Problems encountered with the infusion set

II	Infusion Set Problems	No of patients reporting the problem (% of total)	Probable causes
1	Kinking of Infusion tube	11 (55%)	Wrong sleeping posture, apparel related,
2	Leakage from set	nil	
3	Leakage at site of insertion	11 (55%)	Folding of cannula
4	Wrong insertion of cannula	5 (25%)	Improper technique at the beginning (Bent cannula, intradermal insertion)
5	Dislodgement of cannula / patch	5 (25%)	Movement, apparel, sweating
6	Need for early change of infusion set	16 (80%)	Any of the above problems

b. Infusion set problems

Table 3 shows that kinking of infusion tube and leakage at the site of insertion were the most commonly reported problems (55%), next being wrong insertion or dislodgement of cannula due to various reasons like physical activity, posture, and sweat (25%). Sixteen patients (80%) were concerned about having to change the infusion set before time, and the increased cost involved. Improper Cannula Insertion technique was a problem repeatedly encountered by four patients initially. One patient could resolve the problem after switching from 6 mm to 9 mm cannula, highlighting the importance of right choice of the cannula for each patient.

No patient reported unexplained hypoglycaemia which could be attributed to unplanned excess dose of insulin delivered by the pump.

Patients' concerns and effect on quality of life

a. Comfort level using MDI / CSII:

Most patients (80%) reported great comfort on switching to CSII. Avoiding repeated pricks was a big plus point, particularly for the young patients and their parents (80%). Children did not mind even an extra dose to accommodate some unplanned snack/meal, which enabled better control on blood sugar levels with enhanced flexibility of routine (20%). Taking bolus doses unobtrusively before a meal was found to be a great comfort even by adults, particularly during social gatherings or at school/work (70%). Thus, convenience came out as a major plus point for switching to CSII (85%). Better control of BSL evidenced by better HbA1c values and lowered insulin doses, also made them feel more in control of their diabetes (60%). Most patients (85%) did not feel bothered about having to carry the pump all the while, but three patients (15%) thought it a big botheration, a constant reminder of their diabetes, felt uncomfortable about the curious looks while changing the set amidst people, were concerned about the extra cost involved and were overall not very comfortable with CSII. They were using it due to well-meaning family pressures (Parents/Children). Two patients (10%) appeared in full control of the situation, had mastered the dose adjustment technique, had good HbA1c and comfortably and safely enjoyed activities like swimming and even extensive trekking.

b. Coping with the technicalities

All but four patients easily learnt the technique of inserting the cannula. Attaching and detaching the cannula patch from the infusion set and pump for activities like bathing / swimming was also found easy. All patients found it easy to operate the pump for taking bolus doses. Calculating appropriate bolus doses also posed no problem for most (75%), as the skill required for calculating the bolus doses based on pre-meal BSL and carb counting was same as for MDI. However, only four patients (20%) had mastered the ability of adjusting the basal rates for optimal BSL control or to suite any sporadic changed requirements. Most (80%) had to completely rely for the basal dose adjustments on the clinician, diabetes educator or more commonly, the company representative who had initially trained them in the use of the pump. For 10 patients (50%), after shifting to CSII, follow up with the company representative had become more regular than visits to the diabetes clinic.

c. Concerns affecting quality of life

Eleven patients who had experienced silent blocks (55%) leading to very high BSL levels (>450 mg%) were always worried about the recurrence of such an event, particularly at night. Slightest of symptoms suggestive of hyperglycaemia prompted them to check the BSL and the infusion set. For these patients frequency of SMBG on CSII was almost same as that on MDI, while most others pricked less often for SMBG after switching to the pump. Eight patients (40%) were worried about having to change the infusion sets more frequently because of the technical problems, as it increased the financial burden.

Coping strategies developed by patients

1. Being very alert about symptoms of hypo or hyperglycaemia to catch pump malfunction before it assumes problematic proportions (80%).

2. Constant availability of glucometer with strips (60%)

3. SMBG before and 3 hours after insertion of new cannula to ensure proper insertion (30%).

4. Use of technological advances like Continuous Glucose Monitoring (CGM) to cover prolonged unaccustomed activities like trekking (10%)

5. Backup provision of insulin/syringe always at hand to manage pump malfunction (40%).

DISCUSSION

CSII is reported to improve glycaemia control in both T2DM[7] and T1DM[8,9] patients. Our patients also showed significant improvement in HbA1c along with reduction in the total daily dose requirement. Johnson *et al.* have observed a significant reduction in hypoglycaemia events.[10] Our patients reported reduced frequency of hypoglycaemia episodes on shifting to CSII, but the difference was not statistically significant. The benefit of reduced hypoglycaemia events was more marked in two patients who showed extreme variability in BSL levels on MDI, as has also been reported by Pickup.[1]

In different studies, 45 to 85% patients have been reported to have experienced adverse events related to technical problems in the pump and/or the infusion set.[11,12] Fifty six percent of our patients also reported technical problems, both with the pump as well as the infusion sets. Lip-hypertrophy at insertion site was reported in 26% patients by Pickup *et al.*[12] while it was seen in 15% of our patients. Pump malfunctions like 'no delivery alarms' were noted by them in about 43%, while this problem had been encountered by all our patients (100%) at some time or the other. All our patients were using a basic model of insulin pump, but the incidence of failure or malfunction of insulin pump requiring pump replacement is reported to be even higher for technologically advanced models.[3]

Hyperglycaemia and ketosis are reportedly the most common consequences of adverse events today, usually associated with infusion set failure, while infected infusion sites predominated with the older technology.[4] Many studies report emergency department visit or hospital admission as a consequence of pump related adverse events.[11,13] Though our patients reported hyperglycaemia to the extent of 450 mg% or more at the time of 'silent blocks', no one needed hospitalization.

Silent blocks were reported by 56% of our patients. In 50 percent of these, the cause could be attributed to dislodgement of the cannula due to physical activity, posture, and sweat, wrong insertion technique of the patient or some infusion set problems. In such situations, though there is no insulin delivered subcutaneously, pump has released insulin, hence does not give 'No Delivery' alarm. But 50% of 'silent block' incidents, could not be explained by any of the above causes, and could probably be due to some technical flaw in the pump itself.

One of the causes reported for dislodgement of the cannula/patch was sweat. Four of our patients reported that they almost had to switch to MDI in summer because of the problem of frequent dislodgement of the cannula patch due to excessive sweating. This highlights problems which could be climate/region specific. As mentioned earlier, one patient could resolve the problem after switching from 6 mm to 9 mm cannula, highlighting the importance of choosing the right length of

the cannula for each patient. This is also highlighted by the case of a slim and physically very active 10-year-old boy reported by Moser.[5] In this boy with very less subcutaneous fat tissue thickness, a 6 mm steel needle reportedly got dislodged from the set and lodged into the underlying muscle.

Liberman *et al*. while reviewing literature on 'Diabetes Technology and Human Factor', comment that they have come across only two studies examining the adverse events associated with CSII from the point of view of perceptions of the patient and his family.[6] Our study too, has focused more on assessing the patient perceptions about their experiences with CSII and importantly, strategies evolved by them to cope with these problems.

The study reviewed by Liberman *et al*. which assessed the psychosocial aspects of use of CSII, reports that 70% pump failures caused significant parent anxiety, while 52% failures significantly affected family schedules.[14] Our study has revealed that pump uncertainties did weigh heavily on the minds of the patients, especially for those who experienced silent blocks (55%). The anxiety was more profound when they could not identify any overt cause for the failure of the machine to give the warning alarm (25%). On the other hand, 45% who had always got an alarm whenever insulin delivery had been interrupted were more reassured and relaxed regarding use of the pump.

Our study also revealed the need for continuing patient support and education, especially when it comes to the use of technological advances in the day to day management of diabetes. This is especially true for T1DM patients, as knowledgeable involvement of the patient and his family is of utmost importance in optimal management of T1DM, The heavy reliance on the company representative for adjusting the bolus and basal insulin rates also underlines the importance proper training of these personnel, empowering them to give the crucial support required by the patients.

Thus, our study gives valuable observations about patient perceptions and concerns regarding the use of CSII and the coping strategies they evolve to handle these concerns, though it has a relatively small sample size to comment strongly on quantitative data about clinical improvement and technical problems faced with CSII,

To summarize, CSII significantly improves clinical outcome in T1DM patients. Convenience and good clinical outcome are the most important advantages of CSII, while 'silent blocks' are perceived as the most dreaded of the possible technical problems. Patients develop effective coping strategies, but need ongoing technical and psychological support. As mentioned in the joint statement released by the European (EASD) and American Diabetes Association (ADA),[15] evidence is still meagre on the safety and efficacy of CSII, and more rigorous studies need to be undertaken to understand both the technical issues as well as psychosocial aspects of use of CSII.

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