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**In patients with type 1 diabetes mellitus, does insulin pump therapy provide greater patient satisfaction than use of multiple daily injections?**

Jacob Miller, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## ABSTRACT

**OBJECTIVE:** The objective of this selective EBM review is to determine whether or not “In patients with type 1 diabetes mellitus, does insulin pump therapy provide greater patient satisfaction than use of multiple daily injections?”

**STUDY DESIGN:** Review of two randomized controlled trials (RCT’s) and one cross-sectional study. All studies were published in English.

**DATA SOURCES:** The two randomized controlled trials and one cross-sectional study were found via Cochrane Collaboration and PubMed. All sources were published in peer-reviewed journals and were chosen based on their relevance to the clinical question.

**OUTCOMES MEASURED:** The primary outcome measured in the selective EBM review was treatment satisfaction. Treatment satisfaction was measured using an Insulin Treatment Satisfaction Questionnaire (ITSQ)- based on six items of insulin device delivery satisfaction, an eight-item treatment satisfaction questionnaire (scored on a 1-5 scale), and a treatment satisfaction questionnaire (scored on a 7-point Likert scale).

**RESULTS:** In a cross-sectional study conducted by Hussain et al., insulin pump users showed a statistically significant increase in treatment satisfaction than those on multiple daily injections. Overall mean of scale for treatment satisfaction questions was 25.3 and 29.7 for the MDI and pump treatment groups, respectively. In an RCT by Speight et al., ITSQ scores were analyzed at the 6-month RCT interval, in which insulin pump participants reported a statistically significant increase in satisfaction with their insulin “device delivery” than those allocated to MDI (94.4 and 75.0), respectively. Lastly, in an RCT by Thraikill et al., patients using insulin pump therapy reported a statistically significant increase in satisfaction with form of treatment compared to those allocated to MDI. At 12 months, 2.7 times the odds were reported in favor of the insulin pump treatment group (OR = 2.74, 95% confidence interval 1.41, 5.29, P = 0.001).

**CONCLUSIONS:** All three studies in this evidence-based review confirmed that in patients with type 1 diabetes, insulin pump therapy provides greater treatment satisfaction than use of multiple daily injections. Future trials emphasizing increased sampling sizes and expanded follow-up intervals may be found beneficial in supporting this data.

**KEYWORDS:** type 1 diabetes, treatment satisfaction, insulin delivery

## INTRODUCTION

Type 1 diabetes mellitus, also known as insulin-dependent diabetes, is a chronic disease of insulin deficiency, resulting from an autoimmune-mediated progressive destruction of pancreatic  $\beta$ -cells. Insulin, produced by these pancreatic  $\beta$ -cells, is an essential hormone that facilitates the final digestion of glucose into energy. As glucose is the main source of energy used by cells of the human body, insulin deficiency prevents these cells from using glucose as fuel needed to function. As seen in type 1 diabetes, lack of this hormone causes glucose (blood sugar) levels to rise, leading to a myriad of health ramifications. While the pathology of the disease is not fully understood, research has shown that certain genetic factors, such as HLA-DR3 and HLA-DR4, may increase the likelihood of developing the disease. Other data suggests a possible environmental component, such as a virus, to play a role in the development of type 1 diabetes.<sup>1-2</sup>

Approximately 1.6 million Americans are affected by type 1 diabetes, averaging 64,000 new cases per year. An estimated 5 million Americans are expected to have type 1 diabetes by the year 2050. With the disease on the rise, healthcare costs for type 1 diabetes have increased as well. In the US, \$16 billion are associated with type 1 diabetes-associated health care expenditures annually.<sup>3</sup> There are no data currently available estimating type 1 diabetes office visits per year, although the CDC estimates 11.5% of visits indicate diabetes (both type 1 and type 2) on the medical record.<sup>1</sup>

Despite promising research of the disease in the last few decades, there is currently no cure for type 1 diabetes. Mainstay of treatment includes the use of exogenous insulin to supplement the lack of the hormone produced by the body. Insulin is indigestible; therefore, it cannot be taken orally but rather administered subcutaneously via injections.<sup>1-2</sup> While all type 1

diabetics must take insulin, the route of insulin administration may vary based on patient preference. Insulin delivery methods include multiple daily injections via insulin vials and syringes, pre-filled insulin pens, and insulin pumps. Treatment also includes carbohydrate counting, frequent blood sugar monitoring via finger sticks or continuous glucose devices, maintaining a healthy diet, exercising regularly, and maintaining a healthy weight.<sup>1-2</sup>

The treatment options mentioned above all play a role in decreasing mortality rates and long-term complications of the disease. Insulin, being the mainstay of treatment, was first invented by Sir Frederick G Banting, Charles H Best, and JJR Macleod at the University of Toronto in 1921. An illness once known for its high fatality, often within 2 years of onset, had suddenly transformed into a manageable disease. The discovery has ultimately saved millions of lives throughout the years, revolutionizing the disease forever.<sup>4</sup> Since then, insulin is known to be the only effective treatment for the disease. While treatment of type 1 diabetes has not changed over the last several decades, the route of insulin administration has evolved. With enhancing technology, insulin delivery methods have advanced from multiple daily injections via vials/syringes and pre-filled insulin pens, to now continuous subcutaneous insulin therapy via insulin pumps. While several studies have proven the efficacy of these advancing technologies, limited studies have attempted to evaluate treatment satisfaction between these insulin delivery methods. This paper evaluates two randomized control trials and one cross-sectional study comparing patient satisfaction among type 1 diabetic patients using insulin pump therapy vs. multiple daily injections.

## **OBJECTIVE**

The objective of this selective EBM review is to determine whether or not “In patients

with type 1 diabetes mellitus, does insulin pump therapy provide greater patient satisfaction than use of multiple daily injections?”

## **METHODS**

The studies used in this review were found by searching Cochrane Collaboration and PubMed databases with the key words “type 1 diabetes”, “treatment satisfaction”, and “insulin delivery”. Studies were chosen for this review if they proved relevance to the clinical topic, results were measured by Patient-Oriented Evidence that Matters (POEMs) and fit the inclusion and exclusion criteria for this study. Inclusion criteria consisted of studies published after 2010. Exclusion criteria consisted of studies published earlier than 2010 and studies evaluating type 2 diabetes. The statistics analyzed in this review included OR, mean treatment satisfaction, and p-value. All of the studies selected were written in English and published in peer-review journals.

Two randomized controlled trials and one cross-sectional study were utilized in this review. The focused population for the studies of this review included patients with type 1 diabetes mellitus. The intervention applied in all three studies was insulin pump therapy, compared to the use of multiple daily injections (MDI). Demographics and characteristics of the studies can be found below in Table 1.

## **OUTCOMES MEASURED**

The primary outcome measured in this selective EBM review was treatment satisfaction. Treatment satisfaction was measured using an Insulin Treatment Satisfaction Questionnaire (ITSQ)- based on six items of insulin device delivery satisfaction, an eight-item treatment satisfaction questionnaire (scored on a 1-5 scale), and a treatment satisfaction questionnaire (scored on a 7-point Likert scale).<sup>5-7</sup>

**Table 1. Demographics & Characteristics of Included Studies<sup>5-7</sup>**

Study	Type	# Pts	Age (years)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Hussain <sup>5</sup> (2017)	Cross-sectional	72	11.4 ± 4.4	Children and adolescents with type 1 diabetes mellitus	Adults and patients with type 2 diabetes mellitus	0	Insulin pump therapy VS. multiple daily injections
Speight <sup>6</sup> (2019)	RCT	96	18-74	Adults with longstanding type 1 diabetes mellitus and problematic hypoglycemia	Children/adolescents and adults with previous experience with RT-CGM	20	Insulin pump therapy VS. multiple daily injections
Thraillkill <sup>7</sup> (2011)	RCT	24	8-18	Children and adolescents with newly diagnosed type 1 diabetes mellitus	Moderate/severe DKA at time of diagnosis, type 2 diabetes mellitus, history of chronic systemic inflammatory disease, pregnancy, or use of another investigational treatment agent for T1D	2	Insulin pump therapy VS. multiple daily injections

## RESULTS

Hussain et. al conducted a cross-sectional study comparing treatment satisfaction and health perception in children and adolescents with type 1 diabetes on multiple daily injections, insulin pump, and sensor-augmented pump therapy. A total of 72 patients were selected for this study based on the inclusion/exclusion criteria found in Table 1.<sup>5</sup> Patients were divided into three groups based on treatment used: multiple daily injections (30), insulin pump (23), and sensor-augmented pump therapy (19). Data were collected using a customized questionnaire

during patient follow-up visits at the Mafraq Hospital diabetes clinic in Abu Dhabi. Answers were obtained via 30-40-minute interviews in a private room at the clinic department.<sup>5</sup>

The questionnaire consisted of two parts, treatment satisfaction and health perception. The treatment satisfaction portion included an eight-item questionnaire (scored on a 1-5 scale). The questionnaire analyzed four subscales: perceived general management (Q1-3), feeling toward hypo/hyperglycemia (Q4-5), perceived frequency of use of treatment method to correct high blood glucose or give extra insulin for snacks (Q6-7), and perceived compatibility of the treatment methods with the lifestyle related to dietary habits (Q8).<sup>5</sup> The higher the score, the higher the satisfaction. Overall mean of scale for treatment satisfaction questions was 25.3 and 29.7 for the MDI and pump treatment groups, respectively. The difference was significantly different between the groups with a p value of 0.00.<sup>5</sup>

**Table 2. Treatment Satisfaction Analysis<sup>5</sup>**

	MDI (23)	Pump (23)	P-value
Treatment Satisfaction Total Mean	25.3	29.7	0.00

Speight et al. conducted a randomized controlled trial assessing treatment satisfaction with the use of different technologies for insulin delivery and glucose monitoring among adults with longstanding type 1 diabetes and problematic hypoglycemia. This study is a follow-up from the HypoCOMPaSS randomized clinical trial performed by Speight et al. in 2014. In brief, the study was a multicenter trial (including five UK tertiary referral diabetes centers). A total of 96 patients were selected for this study based on the inclusion/exclusion criteria found in Table 1.<sup>6</sup> Participants were randomized into two groups, MDI (50) and insulin pump therapy (46). Half of this sample (n=48) was randomized to either self-monitoring of blood glucose (SMBG) or real-time continuous glucose monitoring (RT-CGM). Data was collected using two subscales



of an Insulin Treatment Satisfaction Questionnaire (ITSQ): “hypoglycemic control” (five items) and “device delivery” (six items).<sup>6</sup> Participants responded to questions about their insulin treatment based on six items of insulin device delivery satisfaction, higher scores indicating greater satisfaction. Patient-reported outcome measures were completed at baseline, 6-months (RCT endpoint), and 2 years (study endpoint). At the conclusion of the 6-month RCT, participants had the option of switching their insulin delivery modality. At 2 years, 20 (21%) of participants were lost to follow-up.<sup>6</sup> Due to this limitation, only data from the 6-month interval was used in this review.

ITSQ scores were analyzed at the 6-month RCT interval, in which insulin pump participants reported greater satisfaction with their insulin “device delivery” than those allocated to MDI (94.4 and 75.0), respectively. The difference between the groups were significantly different with a p-value of <0.001. Furthermore, the insulin pump group reported greater satisfaction with “hypoglycemic control” compared to the MDI group (76.7 and 63.3), respectively. This disparity was also found to be significantly different with a p-value of 0.048.<sup>6</sup>

**Table 3. Insulin Treatment Satisfaction Questionnaire (ITSQ)<sup>6</sup>**

	Endpoint	MDI	Insulin Pump	P-value
Delivery	RCT 6 months	75.0 (61.1-94.4) (n=45)	94.4 (83.3-100) (n=38)	<0.001
Hypoglycemic Control	RCT 6 months	63.3 (63.3-80.0) (n=45)	76.7 (63.3-88.3) (n=37)	0.043

Thraikill et al. is a randomized controlled trial comparing MDI therapy with insulin pump therapy in newly diagnosed type 1 diabetics. A total of 24 patients (8-18 years old) were selected for the study, recruited from clinics at Arkansas Children’s Hospital, Little Rock. Further inclusion/exclusion criteria can be found in Table 1.<sup>7</sup> Patients were randomly assigned into two treatment groups, MDI (12) or insulin pump treatment (12), with the use of Breeze/STAT software. As a secondary outcome measure, treatment satisfaction was assessed in

this study via a self-report questionnaire. Questions were scored on a 7-point Likert scale at the 6-month and 12-month follow up visits. Differences between groups on the satisfaction responses were examined using Fisher's Exact P-value test.<sup>7</sup>

Participant satisfaction was significantly different between treatment groups for various aspects of the assigned treatment. While overall patient satisfaction with treatment efficacy did not differ between groups, the route of treatment administration did significantly differ. As seen in Table 4, participants assigned to insulin pump treatment reported increased satisfaction with form of treatment at both time intervals. At 12 months, 2.7 times the odds were reported in favor of the insulin pump treatment group (OR = 2.74, 95% confidence interval 1.41, 5.29, P = 0.001).<sup>7</sup>

**Table 4. Participant Self-Report of Satisfaction, MDI vs. Insulin Pump<sup>7</sup>**

	6 months		12 months	
	OR (95% CI)	Fisher's Exact P	OR (95% CI)	Fisher's Exact P
(Q8) Satisfied with form of treatment	1.70 (1.01, 2.58)	0.033	2.74 (1.41, 5.29)	0.001

## DISCUSSION

Type 1 diabetes mellitus is a chronic medical condition that comes with many unique challenges. While advancing technologies have shown improvement in treatment and regulation of glucose levels, adjusting to these insulin delivery methods can be a difficult process. Many studies have examined the efficacy of these modalities, although few studies have addressed treatment satisfaction among the type 1 diabetic population. This systematic review assesses the treatment satisfaction of the two most common methods of insulin delivery, multiple daily injections and insulin pump therapy. All three studies evaluated treatment satisfaction among these two treatment groups via treatment satisfaction questionnaires. Hussain et. al demonstrated an increased overall mean scale of treatment satisfaction among insulin pump users.<sup>5</sup> Speight et

al. confirmed participants were more satisfied with insulin pump therapy in terms of insulin delivery device.<sup>6</sup> Thraill et al. reported greater satisfaction with route of treatment administration of the insulin pump group as well.<sup>7</sup> While further studies including larger treatment trials may help support this claim, it is clear in patients with type 1 diabetes, insulin pump therapy provides greater treatment satisfaction than use of multiple daily injections.

Superiority of treatment satisfaction of pump therapy over MDI can be attributed to several different factors. First, the added flexibility of pump function is an important added benefit. With the insulin pump, patients have the flexibility to make various adjustments to their insulin levels to suit exercise, sleep, and various types and timing of food.<sup>8</sup> Another reason for this disparity is the decreased sense of physical and dietary restrictions. Hussain et al. found a significant difference among study groups in relation to dietary restriction and insulin method used, with insulin pump users scoring higher.<sup>3</sup> These results may be attributed to the user-friendliness and accessibility of the insulin pump, rather than those who rely on multiple daily insulin injections. Hussain et al. also reported that insulin pump users found greater ease with meal coverage and hyperglycemia correction compared to the MDI group.<sup>5</sup>

Although the trials mentioned revealed promising data in regard to insulin treatment satisfaction, various limitations were noted among the studies in this review. Hussain et al. mentions the relatively low number of patients involved in the study. Similarly, Thraill et al. emphasizes the trial's intention as a pilot study. Consequently, the study cohort was small. In both cases, larger trials involving more patient subjects may further support their findings.<sup>5,7</sup> Speight et al. highlights various limitations as well, including the impossibility of concealing insulin delivery device allocations from clinicians/study participants when their features and capabilities are so different. The study also discusses the possibility of bias involved in the

study, as treatment satisfaction is necessarily a subjective, patient-reported outcome. While many biomedical outcomes are objective markers (e.g. HbA1C), the concept of satisfaction can be subjected to ideas like “gratitude bias” (i.e. participants feel indebted for the opportunity to access the latest treatments).<sup>6,9</sup>

Limitations were also noted in the research of this evidence-based review. While many studies exist that focus on the treatment efficacy of type 1 diabetics, few studies concentrate on patient treatment satisfaction. Research validity was also a limitation to this review, considering the majority of studies available were not randomized controlled trials. Furthermore, of those that were found to be RCT’s, several studies were found to be outdated and lacked significance to this review.

The use of insulin pump therapy was noted in the 1970’s as an alternative to multiple daily injections. Since then, the insulin pump is a common insulin delivery modality used among type 1 diabetics. An estimated 400,000 people in the U.S use insulin pumps today.<sup>10-11</sup> Currently, there are multiple variations of insulin pumps available on the market. Medtronic Minimed, T-slim, and the Omnipod are some of the more popular pump brands that exist today that offer touchscreen, tubeless, and user-friendly options. In addition to improved treatment satisfaction, increasing evidence indicates insulin pump therapy to be associated with improved glycemic control and lower levels of HbA1C. However, similar to MDI therapy, side effects such as erythema and scar tissue formation at administration sites may be seen in patients. Additional side effects of the insulin pump include increased risk of infection due to cannula insertion and possible psychological problems on account of 24/7 device attachment.<sup>10</sup> Another issue with insulin pump therapy is that many insurance plans require patients to meet certain criteria to earn coverage eligibility. This criteria includes prior authorization from a healthcare

provider and evidence of medical necessity. As the average cost of an insulin pump can range from \$3,000-\$6,000 annually, insurance coverage is a substantial factor when considering insulin pump therapy.

## **CONCLUSION**

All three studies in this evidence-based review demonstrated that in patients with type 1 diabetes, insulin pump therapy provides greater treatment satisfaction than use of multiple daily injections. With the use of insulin treatment satisfaction questionnaires, all studies found a significant difference among the two groups, favoring insulin pump therapy.<sup>5-7</sup> As treatment satisfaction is a subjective patient-reported outcome, an insulin treatment satisfaction is a practicable method of assessment. Future trials emphasizing increased sampling sizes and expanded follow-up intervals may be found beneficial in supporting this data. It is also important to monitor safety, adverse side effects, and satisfaction of treatment of both treatment modalities long-term. Type 1 diabetes is a chronic auto-immune disease that has surged to historic high levels of incidence across the globe.<sup>11-12</sup> Although research today is focused much on finding a cure for the disease, insulin therapy has been the only known effective treatment for the past 98 years. Additional research trials are imperative at this time to further provide care and treatment satisfaction to those afflicted by type 1 diabetes.

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