Building the Evidence on Effective Insulin Injection for Patients at the High and Low Ends of the BMI Index: Testing a new framework for the Provision of Educational Services

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Introduction

The effective use of insulin to obtain the best metabolic control requires an understanding of many factors by the patient – but a basic need is the correct administration or injection of the insulin. There is a scarcity of published work that address problems linked to effective insulin injection for patients with high or low body fat. Obesity is a common risk factor in our patient base (=approximately 60%). Underweight status – although not as common – also contributes to control problems. Both factors complicate insulin injection. Our education team is seeking improved ways to instruct and assist these patients in better achieving self-management goals; thus, preventing complications and enhancing their quality of life. However, research to help guide or direct our efforts is lacking. The purpose of this study is to: 1) assess patients' difficulties with administration of insulin; and 2) investigate the use of two instructional strategies for insulin injection site rotation among patients at the high and low ends of the BMI index. The two strategies are a site selection paper guide (Becton, Dickinson and Company, Franklin Lakes, NJ) and an Injection Locator™(Three R's Product Development Corporation, British Columbia, Canada). Both tools address site selection and rotation, as well as visually show patients where all the sites are and how to access the sites.

Methods and Study Design

Phase I
A four-part survey was distributed to all clinic patients from April 2009 – April 2010. Survey sections included: 1) knowledge of injection techniques as well as general aspects of disease management and outcome; 2) attitudes concerning care, support, and autonomy; 3) an open-ended portion to provide an opportunity to share greater detail on the problems they encounter with their injections; and 4) a brief demographic section.

Phase II
A randomized crossover study design was employed to investigate two instructional approaches for organized site rotation injection techniques. One approach used a site selection paper guide (Becton, Dickinson and Company, Franklin Lakes, NJ). These are colorful paper pamphlets included in the starter kit provided to all patients instructed on insulin. The other approach used the Injection Locator™ (Three R's Product Development Corporation, British Columbia, Canada). This product is made from vinyl that contains holes approximately one inch apart. Patients use the vinyl guide to mark on their skin where to inject in order to keep track of injections for proper rotation.

Study subjects were recruited continuously over a nine-month period between September 2009 and May 2010 throughout Genesee County, Michigan (n = 67). The study protocol was reviewed and approved by the Institutional Review Board of Hurley Medical Center. Inclusion criteria included subjects with a BMI from either the low (18.5) or high (>35) ends of the index. Subjects were at least 18 years of age, had been diagnosed with Type 1 or Type 2 diabetes, had health insurance coverage, spoke English, and were enrolled or had completed a diabetes self-management education program. A $20 gift card was offered for each in-person visit, totaling $100.00 for the entire study.

Patients received both treatments but were randomly assigned to the treatment order. After six weeks of one rotation techniques, patients transferred to the alternative site rotation technique for six additional weeks. Patients in both groups received follow-up telephone support calls and participated in return demonstration and teach back activities. Primary outcome measures were knowledge, attitudes, and HbA1c. Knowledge and attitudes were measured by a paper survey given at three different times for each technique: 1) pre-test (pre-education); 2) post-test (immediately following education); and 3)follow-up (six weeks following the initial education session). HbA1c was measured at week 1 of the study, if not taken in the past three months, and at week 12.

Descriptive characteristics were calculated as means ± standard deviation for continuous variables and as percentages for categorical variables. Differences between pre-test, post-test, and follow-up measures were analyzed using Related Samples McNemar Test for binomial data and Related Samples Wilcoxon Signed Ranks Test for likert scale data. A paired t-test was performed to analyze change in HbA1c. All analyses were performed using PASW Statistics 18.

Results

Phase I
We received 106 responses (20% response rate). A majority profile for the survey respondents was an obese African-American female over 55 years of age with type 2 diabetes. Most patients were not very knowledgeable about managing their diabetes. Patients reported that they did not know the needle length they use (61%), or the needle angle (50%). Most preferred sitting (61%) and injecting in their abdomen (81%). Over 75% reported that they use different sites to rotate injections, and rotate injection sites with every injection (46%).

Patients reported that they regularly experience problems related to injection site (28%) and needle length (23%). Patients identified additional education or instruction as an area that could be helpful to them in better managing their disease. In assessing from whom they receive strong support – although family (88%) and friends (81%) ranked very high – the 'formal' sources of physician (88%) and Diabetes Center (95%) ranked highest. In gauging their perception of how well they manage their diabetes, a high percentage of patients expressed confidence in both their insulin injections (74%) and blood sugar monitoring (76%). The lowest rated area was stress management (52%), followed by meal plan (61%) and exercise plan (62%).

Phase I provides insight on the patients knowledge and attitudes of diabetes management. This will guide the Diabetes Center in its educational and support approach.

Phase II
We screened 231 persons for the study, with 67 enrolling in the study. A total of 54 completed the 12- week study.

A majority profile for the patients was an African-American female over 50 years of age with Type 2 diabetes. The BMI for all patients was over 35. The average number of years using insulin was 5.0 ± 5.5 years.

Site Selection Paper Guide
Overall, patients' knowledge of proper insulin injection techniques increased and some improvement in attitudes relating to injecting insulin were observed (Table 1). Statistically significant improvements were found in patients' knowledge of injection spacing and not injecting insulin near a stretch mark. Patients expressed more confidence in injecting insulin, as there was a decrease in the percentage of patients who felt fearful injecting insulin at the six-week follow-up.

Injection Locator
Knowledge and attitudes of injecting insulin using the Injection Locator™ parallel the results of the Site Selection Paper Guide. Overall, patients demonstrated increased knowledge of proper insulin injection techniques and showed some improvement in attitudes related to injecting insulin (Table 2). Statistically significant improvements in patients' knowledge of injection spacing and confidence in injecting insulin were observed at the six-week follow-up.

TABLE 1
Site Selection Paper Guide Summary

Area	Pre-Test: Agree	Post-Test: Agree	Follow-Up: Agree
Separation between injections 1"	67%	87%*	85%*
Cannot inject near mole	78%	89%	87%
Cannot inject near scar	79%	87%	87%
Cannot inject near stretch mark	70%	85%*	85%*
Should change injection site	98%	96%	100%
Important to take insulin	93%	92%	91%
Know how to inject using guide	59%	93%*	89%*
My diabetes is pretty bad	48%	57%	48%
Fearful about injecting insulin	17%	9%	11%
Insulin makes me feel better	91%	94%	94%

*Statistically significant from pre-test at the 0.05 level

TABLE 2
Injection Locator™ Summary

Area	Pre-Test: Agree	Post-Test: Agree	Follow-Up: Agree
Separation between injections 1"	67%	93%*	89%*
Cannot inject near mole	72%	89%*	83%
Cannot inject near scar	74%	85%	80%
Cannot inject near stretch mark	63%	87%*	80%
Should change injection site	98%	96%	94%
Important to take insulin	93%	87%	93%
Know how to inject using guide	52%	89%*	93%*
My diabetes is pretty bad	50%	50%	57%
Fearful about injecting insulin	17%	20%	9%*
Insulin makes me feel better	85%	93%	93%

*Statistically significant from pre-test at the 0.05 level

Comparison

Similar results of the 6-week follow-up measures were found using the site selection paper guide and the Injection Locator™. No statistical differences were found between the two tools (Figure 1). With both tools, patients: 1) increased knowledge related to injection technique; 2) were less fearful injecting insulin; 3) reported better site rotation; and 4) rated "ongoing" staff support as the most helpful in learning proper injection technique.

Figure 1
Comparison of Tools: Knowledge and Attitudes

HbA1c was also similar. Patients using the site selection guide first had a mean pre-study HbA1c of 8.5%±1.9% and mean 12-week follow-up HbA1c of 8.4%±1.9%. Patients using the Injection Locator™ first had a mean pre-study HbA1c of 9.2%±1.8% and a small decrease in mean 12-week follow-up HbA1c of 8.7%±1.9%. No significant differences were detected.

There were significant improvements in injection techniques. At the beginning of the study, there were no patients rotating injection site (i.e. right leg to left leg) every month, as recommended. By the first 6-week follow-up , 40% were rotating injection site every month. There were also improvements in injection spacing. At the beginning of the study, only 38% were injecting 1" apart as recommended, compared to 78% at the first 6-week follow-up.

At the last visit, after patients completed both instructional techniques, patients were asked, "What was the most helpful? Most patients found ongoing support most helpful, followed by the Injection Locator™ (Figure 2). Patients were also asked which technique they would continue to use. Over 65% reported that they would continue to use the Injection Locator™.
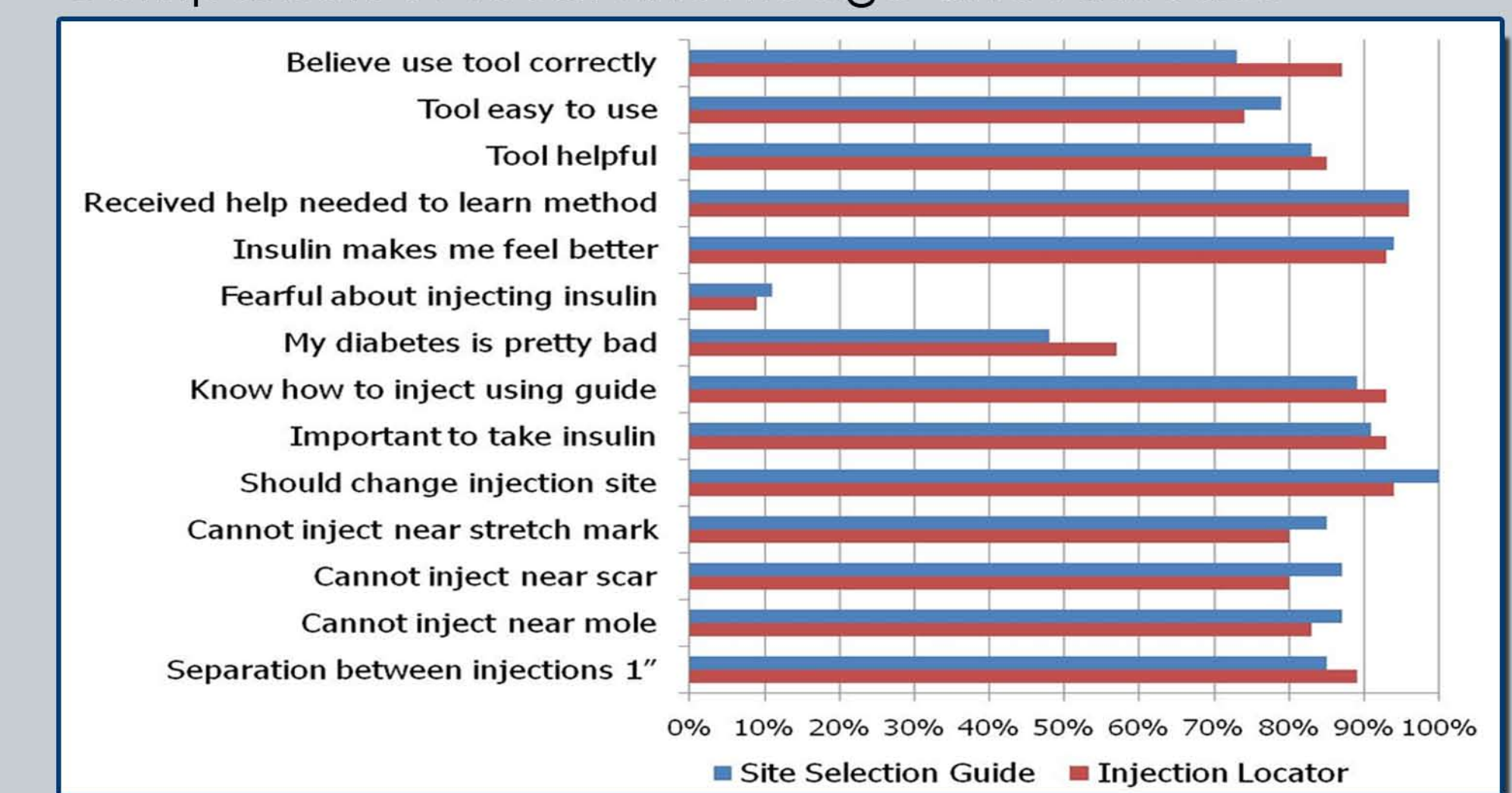

Figure 2
Most Helpful in Administering Insulin Injections

Discussion

Recruitment of patients at the low-end of the BMI index proved to be difficult, as no patients met the inclusion criteria. Future studies may need to include the pediatric population to study those at the low-end of the BMI Index. Retention of study participants was also challenging. Participants received a gift card during each in-person visit to increase compliance, but factors such as transportation, relocation, loss of interest in study, co-morbidities, and incarceration caused many to drop-out of the study.

In summary, subjects reported that they could inject their insulin properly regardless of the site rotation teaching aid used. Fear of injecting was decreased and appropriate site rotation was achieved with both teaching aides. Even though subjects had been injecting insulin for an average of 5 years, they ranked the ongoing support from the staff as the most helpful in injecting their insulin. This stresses to the importance that people who inject insulin should continuously work with their health care professional. This study can be used to strengthen current diabetes education and support services patients receive.