



**White Paper:
“Five Patients” and Their Experience
with The Vdex Protocol**

October 22, 2019

Introduction

Vdex has continued to refine its diabetes treatment protocols guided by a simple notion: care is not good enough. The current standards of care, even if achieved, and much less than 50% of patients actually reach the standards, still result in long term decline from the disease. Put more simply, we really don't control the disease of diabetes. We just try to slow the patient's decline from it. Consider that the current target HbA1c level recommended by the American Diabetes Association is below 7%. Yet, microvascular damage can occur as low as around 6%, a point very few patients reach. In effect, the diabetes-treating medical community has conceded as inevitable, long-term complications from the disease.

Vdex has developed a revolutionary treatment protocol that appears to result in dramatically superior care in most patients with diabetes. In the development of our protocol, we sought to understand the application of our protocol across the spectrum of diabetes patients. Were there patients who responded better to the protocols than others? Were there types of patients for whom the protocol failed? Did some patients have greater issues with hypoglycemia? Were there any persistent themes in patients that necessitated greater caution in the use of the protocol?

Vdex' goal for treatment is to render a patient physiologically non-diabetic. That is how we define actually "controlling the disease." To achieve that, patients' blood glucose levels must be maintained at far lower levels than is recommended by the ADA. Microvascular damage is de minimis at an HbA1c of 6.2 or lower. Of course, such low blood glucose levels must be safe. A significant incidence of hypoglycemia is unacceptable.

Objective

The objective of this White Paper is to present our findings on the application of the Vdex protocols to five different groups of patients, categorized by their level of blood glucose control at the beginning of treatment, and type of disease (see groupings below). While this categorization does not represent all types of diabetes patients, the five groupings cover the vast majority. With more than 400 patients treated in total, we at Vdex have treated many patients from each category. We present one case study for each category that we view as representative of the kinds of results other members of that category can expect following the Vdex protocol. We regard the conclusions from each case study to be generalizable to other patients who fall into the group.

The five categories are:

1. Severely Uncontrolled – defined as a Type 2 patient having an HbA1c above 10.
2. Moderately Uncontrolled – defined as a Type 2 having an HbA1c between 7 and 10.
3. Controlled – defined as a Type 2 with an HbA1c between 6.5 and 7.
4. Prediabetic – HbA1c of 6.5 or lower.
5. Type 1 – Uncontrolled, defined as HbA1c above 8.

Admittedly, these categories are somewhat arbitrary. Others might set the break points between groupings at slightly different points. But collectively they serve to capture most of the patients in the spectrum of diabetes. It is less important whether one defines “severely uncontrolled” as an HbA1c above 9 or 10.

1. Severely Uncontrolled, Type 2

Patient V.D., HbA1c: dropped from 13.2 at beginning of treatment, to 5.7 when fully titrated.

This patient saw his/her HbA1c drop from 13.2 to 8.5 in 6 weeks and then to 5.7 by week 10. The patient had no reported episodes of hypoglycemia despite a reduction in A1c of 7.5 points. Reductions of such magnitude are virtually unheard of with the conventional ADA protocols and would almost certainly be accompanied by frank episodes of hypoglycemia if one treated the patient according to the ADA recommendations. Further, few medical providers would even seek to “push” the blood glucose level so low. At this level, the Vdex provider was able render the patient physiologically non-diabetic while on therapy. The patient is unlikely to suffer long term complications from the disease so long as his/her control stays where it is.

2. Moderately Uncontrolled, Type 2

Patient R.W., HbA1c: dropped from 7.6 to 5.1.

This patient saw his/her HbA1c drop from 7.6 to 5.1 in 7 weeks with no reported hypoglycemia. The patient’s blood glucose control is at the mid-range of normal at this level. Here again, very few providers would even attempt to control a patient to this level with medication because of a concern with hypoglycemia.

3. Controlled, Type 2

Patient M.M., HbA1c: dropped from 6.9 to 6.1.

In five weeks, this patient brought his/her average blood sugar down to 6.1 again with no hypoglycemia. With a starting HbA1c of 6.9, this patient would be declined treatment by many physicians since that A1c meets the standard of control as recommended by the American Diabetes Association. Pursuant to the Vdex standard, however, an HbA1c of 6.9 is inadequate. Microvascular damage occurs well below this point.

4. Prediabetic

Patient L.B., HbA1c: dropped from 6.5 to 5.5.

In six weeks, the patient's HbA1c dropped from 6.5 to 5.5 with no hypoglycemia. As with the "controlled" category above, most physicians would not likely change anything about this patient's treatment based upon an initial HbA1c of 6.5. But, while an HbA1c of 6.5 is on the border between diabetic and prediabetic, it is undeniable that microvascular damage is occurring at such a blood glucose level. The mere label "prediabetic" should offer little comfort. Vdex' goal is to lower blood glucose levels below the point of microvascular damage.

5. Type 1 - Uncontrolled

Patient T. R., HbA1c: dropped from 9.2 to 5.2.

In five months, this Type 1 patient experienced a drop in A1c using the Vdex protocol from 9.2 to 5.2. This patient, while a diagnosed, Type 1 patient, actually has normal, ie. non-diabetic, blood sugar levels while following the Vdex protocol. This type of control is almost unheard of. Fear of hypoglycemia, and in particular, nocturnal hypoglycemia prevents providers from managing patients to such levels. This patient has had no hypoglycemic episodes since Vdex took over the care. S/he has no difficulty maintaining this level of control.

Conclusion

A few salient points about the results above deserve comment. First, it is clear that with the Vdex protocol that the vast majority of patients can be managed at much lower blood glucose levels. In fact, it appears many, and perhaps most, can be managed to a level at which they are physiologically non-diabetic while on therapy. This will almost certainly result in a dramatic reduction in long-term complications and the cost of care.

Second, we observed no severe hypoglycemia even when managing patients down to such low levels. Clearly, something is different about the therapeutic agents used. We believe the difference is Afrezza. There appears to be a protective effect with Afrezza that is absent from other insulins.

Third, we found we could achieve the treatment goals very quickly. We could literally achieve multi-point reductions in HbA1c in a matter of a few weeks. Part of this was due to the protocol and part seemed due to better patient compliance. It was not the point of this study to delve into patient compliance issues, but it seemed obvious that the Vdex protocol was easier/more satisfying than the ADA protocol patients had been following.

Fourth, we noted that “well-controlled” patients (as defined by the ADA) and even “prediabetic” patients achieved durable, non-diabetic blood glucose levels through our protocol. We have speculated that early intervention in accordance with the Vdex protocol will likely prevent many, if not most, patients from ever becoming diabetic.

At a time when the standards for blood glucose control for people with diabetes are being relaxed, this study stands in stark contrast. Many key opinion leaders now suggest maintaining an HbA1c between 7 and 8. This “moving of the goal posts” has been driven by the inability of the diabetes-treating community to successfully meet the ADA standard. But, microvascular damage has not suddenly begun to occur at much higher blood sugar levels. How does relaxing the standards benefit patients?

These study results suggest that it is not the position of the goal posts that need to be changed, but the people doing the kicking and the ball being kicked.