Clinical Challenges In the Treatment of Type 2 Diabetes: Endocrinologist’s Perspective

Carol H. Wysham, MD
Rockwood Clinic
Spokane, Washington
Premise

• Most diabetes consultations fit into three categories:
  – Worried well
  – Typical patient with progressive disease, ready for insulin
  – Patient with severe psychosocial issues

• By the time I see patients in the last two categories:
  – They have had diabetes for average of 10 years
  – Have been in suboptimal control for several years
  – Their beta cells are essentially gone
  – They have a poor knowledge base
  – Many have been “brow beaten” to believe that their lifestyle is the main reason for poor control
Diabetes: 24 Million and Climbing

- Estimated 19 million diagnosed + 5.0 million undiagnosed
- Each year over 1,000,000 new cases are diagnosed
- Since 1999:
  - 10% increase in the number of clinical endocrinologists
  - 4-fold increase in the number of antihyperglycemic medications

From Centers for Disease Control and Prevention, accessed 8/29/08.
Supply of Endocrinologists far Exceeds Demands

24,000,000 People with Diabetes

4000 clinical endocrinologists
We all hope that our patients can fulfill their dreams

Finished the Hawaii Ironman at age 80
To help our patients with diabetes get there:

- Early diagnosis
- Early and intensive treatment to target
- Aggressive management of cardiovascular risk factors
Why won’t our patients change their lifestyle?
Perceived Barriers To Diabetes Care Differ Between Patients and Healthcare Professionals

**Professionals**
- N = 436 Healthcare Professionals
  - Motivation
  - Systems barriers
  - Diabetes knowledge
- Influence of other health problems (10th or less important)

**Patients**
- N = 3,890 patients with diabetes
  - Strictness of regimen
  - Influence of other health problems
  - Systems barriers
- Knowledge (least important)

Current system of care creates major barriers to optimal care of people with diabetes

- Malaligned incentives
- Not enough time during patient visit
- Lack of planned, coordinated care
  - Poor utilization of diabetes educators
- Lack of adequate reimbursement for self-management support
- Poor coverage for mental health visits
- High copays (or lack of coverage) for newer therapies
- Lack of reimbursement for non face-to-face advice
- Insurance hassles
Systemic Factors Which Limit Our Ability to Provide Optimal Diabetes Care

Systems are perfectly designed to get the results they achieve.

Acute care model does not suit management of chronic disease.
Usual System of Medical Care

- Oriented to acute illness
- Focus on symptoms and lab results
- Focus on physician’s treatment, not patient’s role in management
- Interaction frustrating for both patient and doctor
- Care of the chronic illness often takes back seat to acute issues
- Incentives favor “expeditious resolution”
What Patients with Diabetes Need

Effective Treatment (clinical, behavioral, supportive)
Information and support for their self-management, and
Systematic follow-up and assessment tailored to clinical severity
Coordination of care across settings and providers
Endocrinologist ≠ Psychologist

Depression
Eating disorders
Other psychological/psychiatric issues
Endocrinologist ≠ Diabetologist

Team approach to management
Key function of the multidisciplinary team

To provide:
Continuous, accessible and consistent care focused on the needs of individuals with type 2 diabetes
Additional functions of a multidisciplinary team

• Provide input at diagnosis of condition and continually thereafter to:
  – agree standards of care
  – discuss rational therapeutic suggestions
  – monitor guideline adherence and short-term outcomes
  – avoid early complications or provide timely intervention to decrease diabetes-related complications

• Enable long-term patient self-management

The patient-centered multidisciplinary team: core members

Mental Health Professional

Diabetes specialist nurse

Patient

Physician

Dietician

Pharmacist

Lack of Reimbursement
Major paperwork
For medications
For self-management support
For technology
Revised ADA/EASD Algorithm

Tier 1: Well-Validated Core Therapies

At Diagnosis:
- Lifestyle + Metformin

Step 1
- Lifestyle + Metformin + Basal Insulin
- Lifestyle + Metformin + Sulfonylurea

Step 2
- Lifestyle + Metformin + Pioglitazone
- Lifestyle + Metformin + GLP-1 Agonist

Step 3
- Lifestyle + Metformin + Intensive Insulin
- Lifestyle + Metformin + Basal insulin
- Lifestyle + Metformin + Sulfonylurea

Tier 2: Less Well Validated Therapies

Lifestyle + Metformin + Pioglitazone
- No Hypoglycemia
- Oedema/CHF
- Bone Loss

Lifestyle + Metformin + GLP-1 Agonist
- No Hypoglycemia
- Weight Loss
- Nausea/Vomiting

a Sulfonylureas other than glyburide or chlorpropamide.
b Insufficient clinical use to be confident regarding safety.

Insulin Pump
Continuous Glucose Sensors
In My Practice

- 1000 patients with diabetes
  - 80% on insulin
  - 50% Type 1
  - 25% on insulin pump therapy
  - Visits comprise about 75% of my scheduled visits (average 22/day)

- On a typical day, I sign
  - 5 forms for glucose testing supplies
  - 2 LMN for new insulin pumps
  - 2 forms for renewal of insulin pump supplies
  - 10 prior authorization forms for medication
  - 3 letters of appeals for denial of coverage
  - countless medication refill requests

- In addition, I review and respond to
  - about 10 faxed/email glucose records
  - about 50 laboratory reports
With current system, I tend to see the patients too late
Clinical Inertia: “Failure to advance therapy when required”

Percentage of Subjects advancing when HbA$_{1c}$ > 8%

At Insulin Initiation, the average patient had:
- 5 years with HbA$_{1c}$ > 8%
- 10 years with HbA$_{1c}$ > 7%

Brown et al. The Burden of Treatment Failure in Type 2 Diabetes. Diabetes Care 27: 1535-1540, 2004
Glargine or Detemir
β-cell function declines, while... 

Progressive Impairment in β-Cell Function

β-Cell Function (%)

Diet/conv Rx (n=376)
Metformin (n=159)
SU/intensive (n=511)

β-cell function declines, while... 

...hyperglycemia increases

A1C

SU=sulfonylurea.

Continuous Glucose Monitoring in Type 2 DM

Monnier L et al. Diab Care 30:263, 2007
Variability is a Characteristic of Severe Insulin Deficiency

24-hour CGMS glucose sensor data
Type 1 diabetes (N=9)

Mean A1C = 6.7%

Glucose Concentration (mg/dL)

Data on file, Amylin Pharmaceuticals, Inc.
Variable Blood Glucose: Independent Risk Factor for Mortality

Variability of FPG and CV Mortality
10 year survival

Mean CV FPG

Survival Probability

Time (years)

Muggeo M et al. Diabetes Care 2000;23:45-50
Correlation Between Variability in Blood Glucose Response and Incidence of Hypoglycemia

BG = blood glucose; FBG = fasting blood glucose; CV = coefficient of variation

Effects of Lower Blood Glucose and Reduced Inter-Day Variability on Quality of Life in Type 2 Diabetes

- Blood glucose and day-to-day variability as represented by SD (BG) were both negatively correlated with M (QOL)
- Variability in daily QOL ratings was explained by absolute level and the day-to-day variation in BG
- Data provide additional evidence for benefits of maintaining a low and stable glucose profile and support conducting further studies of BG variability and QOL

Testa M, et al. 2003; ADA 63rd Scientific Sessions, New Orleans
In patients with Type 1 Diabetes, Residual β-cell function

- After long duration of diabetes is associated with less variability glucose levels and lower A1c (1)
- Is associated with lower A1c, lower risk for severe hypoglycemia and retinopathy (2)
- Is associated with slower rate of development of retinopathy (3)

Should We Worry About Preserving β-cells?

Yes!

Improved β-cell mass/function ⇒ less variability ⇒ less hypoglycemia ⇒ lower A1c values

Lifetime of lower glycemic exposure
UKPDS: 10 year follow-up study

Our patients are “in it for the long-haul”

Get to target A1c as fast as possible

How you get to target appears to affect outcome

An optimal system would have the patient in the center & the endocrinologist as a consultant.
We need systems that can address the common barriers to achieving good glycemic control.

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Adapted from Erhardt L et al. *Vascular Disease Prevention* 2004; 1:167-174