Breaking the Cycle: Using Incretin-Based Therapies to Overcome Clinical Inertia in Type 2 Diabetes

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6:00 AM - 8:00 AM
Philadelphia Marriott Downtown

Clinical Inertia: Challenges in Managing Type 2 Diabetes in a Primary Care Setting

Scott V. Joy, MD, FACP
Associate Professor of Medicine
Medical Director, Duke Primary Care at Pickett Road
Duke University Health System
Durham, North Carolina

Case Study: Surita Patel

• 48-year-old female of Indian descent
• Type 2 diabetes diagnosed 7 years ago
• Obese
  – Weight = 176 lbs
  – BMI = 31.2 kg/m²
• A1C
  – Current = 8.0%
  – Previous (18 months ago) = 7.9%

Surita’s Medication List

• Medications reconciled and entered into electronic prescribing system:
  – Metformin: 1000 mg, by mouth, twice daily
  – Glipizide: 5 mg, by mouth, once daily
  – Lisinopril: 20 mg, by mouth, once daily
  – Aspirin: 81 mg, by mouth, once daily
  – Simvastatin: 40 mg, by mouth, once daily
• Metformin and glipizide doses have not been changed since previous visit (18 months ago)

Additional Issues for Surita

• Not at goal with:
  – Weight (176 lbs, 31.2 kg/m²)
  – Blood pressure (144/92 mm Hg)
  – Lipids (LDL = 132 mg/dL)
• Missing appointments (≈ 12-18 months between appointments)
• Does not have SMBG results
• Feels she is getting inconsistent information from different HCPs in the practice
• Admits to not taking her medication regularly

Which of the following options do you believe would most improve Surita’s diabetes management?

1. Assess barriers with the patient to determine reasons for her nonadherence with medication and lifestyle recommendations
2. Recommend consultation/sessions with diabetes educator
3. Screen for depression
4. Intensify glycemic control therapy
5. Transfer patient to another practice to improve your practice’s pay-for-performance scores
6. Other
Progressive, Multifactorial Pathophysiology Sets the Stage for Clinical Inertia in Type 2 Diabetes

Loss of β-cell Function Begins Long Before the Diagnosis of Type 2 Diabetes

- TZDs may preserve β-cell function*, slow progression from IGT to diabetes
- Incretin-based therapies may preserve β-cell mass*


*Based on mathematical and/or animal models.

“Ominous Octet” Contributes to Hyperglycemia

Many, if not all, are consequences of increased insulin resistance.

Ability to Achieve Glycemic Control With Monotherapy Decreases Over Time

- Diet
- SU
- MET*
- Insulin

Diet
SU
MET*
Insulin

*Limited to overweight patients.


Definition of Clinical Inertia

- General
  - Recognition of the problem, but failure to act
  - Failure to initiate or intensify therapy when indicated

- Functional*
  - Proportion of patients with elevated measures of glycemic control who do not receive therapeutic intensification

*Definition specific to glycemic control in patients with type 2 diabetes and a potential measure of healthcare quality.

Physician Behaviors Contribute to Clinical Inertia
American Diabetes Association Guidelines: Therapeutic Intensification for Glycemic Control

- Statement on recent trial results (ACCORD, ADVANCE, VADT)
  - Glycemic target still A1C < 7%
  - Emphasis on individualized therapy
- Initiate or change therapy at A1C ≥ 7%
- More or less stringent goals appropriate for some patients
  - More stringent: short diabetes duration, long life expectancy, no significant cardiovascular disease
  - Less stringent: hypoglycemia, advanced complications, extensive comorbid conditions, long-standing diabetes with difficulty achieving treatment goals

American Association of Clinical Endocrinologists Guidelines: Therapeutic Intensification for Glycemic Control

- A1C goal ≤ 6.5%
- Initiate monotherapy at A1C of 6% to 7% or combination therapy at A1C of 7% to 8%
- Intensify every 2 to 3 months until glycemic goals are met

Clinical Inertia is Common in Type 2 Diabetes

Studies reveal that therapy is intensified for < 50% of patients with A1C above target.

<table>
<thead>
<tr>
<th>Study</th>
<th>A1C Target (%)</th>
<th>Intensification Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant et al (N = 2086)</td>
<td>&lt; 7.0</td>
<td>33</td>
</tr>
<tr>
<td>Schmittdiel et al (N = 64,821)</td>
<td>≤ 7.0</td>
<td>47</td>
</tr>
<tr>
<td>Shah et al (primary care) (N = 568)</td>
<td>≤ 8.0</td>
<td>37</td>
</tr>
<tr>
<td>Shah et al (specialist care) (N = 568)</td>
<td>≤ 8.0</td>
<td>45</td>
</tr>
</tbody>
</table>

Missed Intensification Opportunities Result in Poorer Glucose Control

- A1C difference vs intensified group (%)
- N = 133 (13 not appropriately intensified)
- 24-month study

More Clinical Items and Less Time During Primary Care Visits

- More items per visit...
  - 1997: 4.4, 2005: 7.0
  - 1997: 4.0, 2005: 3.6
- Less time per item!
  - 1997: 4.5, 2005: 2.0

Clinical Inertia Physician Contributions

- Lack of knowledge
  - Diabetes is a complex, progressive, multifactorial disease state
  - Multiple evidence-based practice guidelines
  - Multiple therapeutic options
- Burden of management tasks

* Significant change from 1997 to 2005.

**Reference Citations:**
As a provider, what is your biggest reason for clinical inertia in managing type 2 diabetes?

1. Lack of knowledge of clinical treatment guidelines and therapeutic goals
2. Lack of knowledge of medication indications and safety
3. Perception of poor patient acceptance of additional therapy
4. Lack of adequate time due to volume of patients required to support salary and staff
5. Poor access to diabetes education
6. Other

Factors Associated with First-Fill Adherence Rates for Diabetes Medications

- **N = 1132**
  - Patients prescribed a diabetes medication for first time between 2002 and 2006
  - Retrospective review of electronic health records and pharmacy claims
- **Primary outcome**: Naive prescription filled by patient within 30 days of prescription order date
- **Results**
  - Overall first-fill adherence was 85%
  - Several factors associated with first-fill adherence

Clinical Inertia Patient Contributions

- **Poor treatment adherence**
  - Regimen complexity
  - Lack of perception of treatment benefits
  - Adverse effects
  - Cost
  - Poor emotional well-being
  - Practical issues (remembering doses, reading labels, obtaining refills)

Clinical Inertia Patient Contributions

- **Poor understanding**
  - Importance of self-management
  - Disease consequences
  - Therapeutic program and options
- **Concerns regarding intensification**
  - Injections
  - Side effects
  - Feelings of failure and guilt
Patient and Physician Behaviors are Related

Poor Medication Adherence Correlates With Lower Therapeutic Intensification

- Minimize cost
- Methods to improve adherence (pill organizers, easily readable labels, memory systems, etc.)
- Simplify regimens
- Discuss adverse effects
- Clarify treatment benefits
- Verify recall and comprehension regarding new information
- Motivational techniques
- Proactive contact, surveillance, and reminders

Approaches to Overcoming Clinical Inertia Patient Behaviors

1. Discuss importance of adherence, benefits of therapy using motivational techniques
2. Adjust therapy to accommodate patient barriers to adherence (side effects, number of pills/doses, price, etc.)
3. Recommend strategies to improve adherence (pill reminder/organizer, mail order refill, medication assistance programs, etc.)
4. Schedule longer and/or more frequent office visits
5. Schedule consultation with diabetes educator
6. Referral to an endocrinologist

Performance Feedback Improves Treatment Intensification (IPCAAD Study)

- Greater A1C improvements for feedback + reminder vs control

Approaches to Overcoming Clinical Inertia: Clinical Operations

Three Interventions Improve Diabetes Care in a Primary Care Clinic

- 3 interventions
  - 30-minute appointments every 3 months
  - Reminder telephone calls to patients
  - Appointment
  - Bring medications and logbooks
  - Arrange for blood work
  - Standardized diabetes care flow sheet from Canadian Diabetes Association
- 3 staff members
  - 1 physician
  - 1 nurse
  - 1 secretary
- 3-year study
Significant differences between open access and standard clinics included patient characteristics (age, race, comorbidity index, insulin use, and use of managed care) and support staff to MD ratio.

No significant differences observed for health care utilization.

Management Intervention

Three Interventions Improve Diabetes Care in a Primary Care Clinic

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Reference Group (n = 35)</th>
<th>Intervention Group (n = 33)</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>Aspirin Use (%)</td>
<td>24</td>
<td>65</td>
<td>.10</td>
</tr>
<tr>
<td>ATC (%)</td>
<td>7.7</td>
<td>7.4</td>
<td>.24</td>
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<tr>
<td>LDL-C (mmol/L)</td>
<td>121</td>
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<tr>
<th>Indicator</th>
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<tbody>
<tr>
<td>Reinitiation (%)</td>
<td>19.3</td>
<td>12.2</td>
<td>&lt; .01</td>
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<tr>
<td>Time to Reinitiation (Days)</td>
<td>59.5</td>
<td>42.2</td>
<td>&lt; .05</td>
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Significant differences observed for health care utilization.

Open (Advanced) Access vs Standard Scheduling in Diabetes Management

- Comparison of open access (same-day, not prebooked) and standard (prebooked) scheduling
  - Retrospective study
  - One year before and 1 year after open access implementation

- N = 4069
  - Adult patients with type 2 diabetes
  - Wishard Advantage Health Plan* participants

- Outcome measures
  - Processes of care (testing for A1C, LDL, urine microalbumin)
  - Intermediate outcomes (A1C, LDL, SBP)
  - Health care utilization (hospitalizations, ER/urgent care/primary care visits)

Overcoming Clinical Inertia in Your Practice

- Elicit feedback on performance from partners and specialists
- Implement patient-specific reminders
- Utilize standardized flow sheets
- Exploit clinical information systems for data management
- Delegate responsibilities to other HCPs

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Management Intervention

Targeted, Technology-Driven Disease Management Intervention

- 155 patients who were nonadherent to medication identified through pharmacy claims data
- Care managers informed of nonadherence
- Care managers received focused training on:
  - Techniques for medication behavior change
  - Readiness to change
  - Motivational Interviewing
  - Active listening
  - Common barriers to adherence
  - Available resources
    - Side affect management
    - Mail order benefits
    - Drug adherence programs
    - Medication organizers
    - Reminder systems

Interpretation of positive adherence: T = 46

Reference Group (n = 35)

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Intermediate Outcomes

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<th>Test Type</th>
<th>African Americans</th>
<th>Other</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>A1C (%)</td>
<td>5.3</td>
<td>5.2</td>
<td>.12</td>
</tr>
<tr>
<td>BP (mmHg)</td>
<td>120</td>
<td>121</td>
<td>.91</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>3.5</td>
<td>3.6</td>
<td>.77</td>
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<tr>
<th>Test Type</th>
<th>Probability of Testing (Odds ratio)</th>
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<tr>
<td>A1C (%)</td>
<td>2.2</td>
</tr>
<tr>
<td>BP (mmHg)</td>
<td>1.1</td>
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<tr>
<td>LDL (mmol/L)</td>
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Significant differences observed for health care utilization.

*Probability of Testing (Odds ratio) = 2.2

Significant differences observed for health care utilization.

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Other barriers to adherence include:
- Side affect management
- Mail order benefits
- Drug adherence programs
- Medication organizers
- Reminder systems

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†Clinically meaningful difference = .05.

‡Clinically meaningful difference = .10.

§Clinically meaningful difference = .01.

¶Clinically meaningful difference = .01.
Learning Organization

“…Organization that has developed the capacity to continuously adapt and change because all members take an active role in identifying and resolving work related issues…”


Case Study: Overcoming Clinical Inertia with Surita Patel – 3 months later

• Actions following previous office visit
  – Surita was referred to a diabetes educator for information regarding self-management
  – Phone call reminders of appointments and necessary test results (including SMBG) were initiated

• This office visit
  – Surita kept her appointment and brought SMBG and lab results
  – Her current A1C is 7.7%, and she has lost 3 lbs
  – She is taking her medication regularly, although side effects are uncomfortable
    • Metformin causes occasional GI upset
    • Feels bloated with glipizide
  – She is encouraged by her weight loss and would like to lose more

How would you modify Surita’s regimen to improve glycemic control, promote adherence, and address underlying diabetes pathophysiology?

1. Stop MET and SU due to side effects and initiate different therapy
2. Add TZD
3. Add GLP-1 agonist
4. Add DPP-4 inhibitor
5. Start insulin
6. Other