Are children with type 1 diabetes obese: What can we do?

QI Project
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Traditional View of Diabetes

<table>
<thead>
<tr>
<th>Type 1 Diabetes (T1DM)</th>
<th>Type 2 Diabetes (T2DM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset- “Juvenile”</td>
<td>Onset- “Adult”</td>
</tr>
<tr>
<td>Lean</td>
<td>Obese</td>
</tr>
<tr>
<td>Beta cell failure-autoimmune</td>
<td>Insulin resistance + Beta cell dysfunction</td>
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<td>Insulin Dependent</td>
<td>Non-Insulin Dependent</td>
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</table>

Age-adjusted Prevalence of Obesity and Diagnosed Diabetes Among U.S. Adults Aged 18 Years or Older

Obesity (%BMI ≥ 30 kg/m²)

<table>
<thead>
<tr>
<th>Year</th>
<th>Obesity 1994</th>
<th>Obesity 2000</th>
<th>Obesity 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>1994</td>
<td>&lt;4.5%</td>
<td>4.5%–5.9%</td>
<td>&lt;4.5%</td>
</tr>
<tr>
<td>2000</td>
<td>6.0%–7.4%</td>
<td>7.5%–8.9%</td>
<td>8.0%–9.4%</td>
</tr>
<tr>
<td>2010</td>
<td>8.0%–9.4%</td>
<td>9.5%–10.9%</td>
<td>10.0%–11.4%</td>
</tr>
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</table>

Figure 1. Trends in obesity among children and adolescents: United States, 1993–2006

Change in Traditional View of Diabetes

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Obesity in Children with T1DM- An Ongoing Problem?

- Retrospective study: Jan 1979- Dec 1998
- Children and adolescents < 19 years
- Antibody positive
- Prevalence of BMI > 85%: comparable to the general population

Libman et al. Diabetes Care 2003
Why are we concerned about weight in children here?

- A trend for children with T1DM to be “heavier” at diagnosis
- Increased cardiovascular risk
- Accelerator Hypothesis—
  - Earlier age of onset of childhood diabetes
  - Cause of increase incidence of T1DM

Wilkin T. Pediatr Diabetes 2012

Previous retrospective study result

- 1998-2001
- On NPH/Regular insulin BID
  - At diagnosis
    - Overweight: 13.5%
    - Obese: 7.2%
  - At 71-139 days
    - Overweight: 31.7%
    - Obese: 15.9%

Newfield RS et al. Pediatr Diabetes 2009
Effect of New Insulin Regimen !!!

**BASAL – BOLUS INSULIN**

- **INSULIN PUMPS**
- **INSULIN PENS**

? Change in Focus

- Daily carbohydrates (CHO), protein, and fat intake percentages are “prescribed” by the nutritionists.
- A focus on CHO counting.
- Inadequate attention paid to CHO “quality” and/or overall energy intake.
- Families may misinterpret “CHO-free” foods as “calorie-free”.

Effect of New Insulin Regimen !!!

**INSULIN PENS USERS**

- May “bundle up” and consume high amounts of CHO at one time to reduce number of insulin shots.

Effect of New Insulin Regimen !!!

**INSULIN PUMP USERS**

- May think they have a “free ride”
- Keep bolusing with insulin as needed.

WCHOB experience

<table>
<thead>
<tr>
<th>BMI Percentile</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>At diagnosis</td>
<td>24.3%</td>
</tr>
<tr>
<td>At 1 year</td>
<td>36.5%</td>
</tr>
<tr>
<td>NHANES 2008-2009, 2-19 years</td>
<td>31.7%</td>
</tr>
</tbody>
</table>

BMI ≥85% in youth with T1DM

- Bethin et al
- Retrospective data
- Jan 2008- June 2009
- Data on visits in the 1st year after diagnosis
- Basal-Bolus insulin

Following BMI Trends

BMI Sympercent [BMI Percentile] =
100 x natural log(BMI/BMI at 50th percentile)

BMI -z : 1.645
BMI -z : 1.036
BMI -z : 0

Following BMI Trends

• Percent over BMI / Percent overweight =
  \[\frac{[\text{BMI} - \text{BMI at 50th percentile}] / \text{BMI at 50th percentile}}{\times 100}\]

Hypothesis

➢ Youth with new onset T1DM may present with BMI above the 85th percentile.

➢ Higher than recommended energy intake may be present in youth with T1DM after diagnosis.

➢ Enhanced nutritional counseling of newly diagnosed youth with T1DM along with their family may affect their BMI trajectory after the initiation of insulin therapy

LMS/ Z-score system

<table>
<thead>
<tr>
<th>Percentile</th>
<th>50</th>
<th>85</th>
<th>95</th>
<th>97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut-off for</td>
<td>Overweight</td>
<td>Obese</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI -z</td>
<td>0</td>
<td>1</td>
<td>1.645</td>
<td>2</td>
</tr>
</tbody>
</table>

Converts BMI values to normally distributed z-scores, based on:
• median (M), coefficient of variation (S) and skewness (L),
• values appropriate for the child's age and sex.

\[Z = \frac{(\text{Measurement} / M)^L - 1}{L} x S, L \neq 0\] or
\[Z = \frac{\log((\text{Measurement} / M))}{S}, L = 0\]

http://www.phsim.man.ac.uk/ChildObesity/MethodReferences.aspx


Following BMI Trends

• BMI Sypercent: Least consistent for comparison

• LMS z-score: In heavier children, BMI changes are attenuated

• Percent over BMI (%OB) / Percent overweight: Best to detect BMI changes in heavier children

Specific Aim

To evaluate the effect of enhanced nutritional counseling on the change in BMI-Z score and %OB in youth newly diagnosed with T1DM over the 6 months following initiation of insulin therapy, as compared to subjects receiving standard dietary counseling.
Secondary Aims

1. Determine the prevalence of obesity in youth [2-19 years] with T1DM at diagnosis.
2. Compare the BMI-z and %OB [Pre-diagnosis vs. 6 months after diagnosis]
3. Assess the awareness of daily energy and CHO intake goals.
4. Assess the nutritional intake.

Inclusion Criteria

• All youth in the age group 2-19 years with new-onset T1DM
• Positive for at least one autoantibody marker for T1DM

Exclusion Criteria

• Celiac disease diagnosed by biopsy.
• Use of chronic medication which can affect appetite
  • oral steroids > 5 days or
  • medications for ADHD

Study Design

• Prospective Randomized Interventional trial
• Randomization:
  • Random number table
  • Block randomization – blocks of 4

Study Design Flow sheet

At initial diagnosis:
- Positive Ab confirmed and insulin therapy initiate.
- Diabetes education and nutritional counseling
- Consent and assent
- Data Collection at diagnosis
- Pre-diagnosis data from primary care provider - pre-illness BMI
- Parental weight, height and BMI [when parents willing to be measured]

At first clinic visit (2 weeks post diagnosis):
- Weight, height, BMI, BMI-z, percent over BMI, HbA1c and insulin dose.
- Questionnaire - recall daily energy requirement and CHO intake recommended at diagnosis
- Randomization to: Enhanced nutritional counseling (ENC) or Standard dietary counseling (SDC)

In between the clinic visits:
Enhanced Nutritional Counseling (ENC) Group:
- Starting at 6 weeks after diagnosis
- Dietary counseling:
  - 3-day food record
  - Focus:
    • age appropriate caloric intake
    • portion size.
    • CHO quality
    • subjects and their parents
- Monthly via study coordinator

In between the clinic visits:
Standard Nutritional Counseling (SDC) group
Nutritional concerns addressed by the primary endocrinologist’s team or the nutritionist as needed
At each clinic visits for subjects in both groups (3 monthly intervals)

- Diabetes related patient care - by the primary endocrinologist and the nutritionist.
- Data Collection: Weight, Height, BMI, BMI-Z, Percent over BMI, Tanner stage, daily total insulin dose (U/Kg), HbA1c
- Questionnaires - Assess the family’s comfort level with management of T1DM
- Parental weight, height and BMI (when parents willing to be measured)

Food Journals
- Food Journal
- Food Journal - Electronic

Sample Size
- 51 subjects in ENC
- 51 subjects in SDC
- Power = 80%
- α error= 5%
- detect a difference in BMI- Z of 0.5 between the groups
- SD of BMI-Z [previous study] = 0.9
- Apriori calculation
- Based on Primary Aim

Statistical Analysis
- Student’s t-test and χ² test for continuous and discrete variables
- Repeated measure ANOVA- as appropriate
- Linear regression- adjustment for baseline BMI-z / percent over BMI- as needed.

Recruitment

Families Approached [N=63]  
July 2011- April 2012

- Celiac Disease [N=6]
- Refused [N=2]
- T1DM Ab Negative [N=2]

Final Number Included [N=53]

Results

<table>
<thead>
<tr>
<th></th>
<th>Pre-diagnosis [n=50]</th>
<th>Diagnosis [n=53]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [years]</td>
<td>8 ± 4</td>
<td>9.1 ± 4.1</td>
</tr>
<tr>
<td>Male : Female</td>
<td>-</td>
<td>24:29</td>
</tr>
<tr>
<td>Tanner Stage</td>
<td>-</td>
<td>1 (1,4)</td>
</tr>
<tr>
<td>BMI- Z</td>
<td>0.9 ± 1.1</td>
<td>0.6 ± 1.2</td>
</tr>
<tr>
<td>Percent Over BMI</td>
<td>19.5 ± 24.3</td>
<td>15.2 ± 25.1</td>
</tr>
<tr>
<td>Insulin Dose [Units/Kg/day]</td>
<td>-</td>
<td>0.8 ± 0.2</td>
</tr>
<tr>
<td>HbA1c</td>
<td>-</td>
<td>11.3 ± 2.1</td>
</tr>
</tbody>
</table>
Hypothesis

➢ Youth with new onset T1DM may present with BMI above the 85th percentile.
➢ Higher than recommended energy intake may be present in T1DM patients after diagnosis.
➢ Enhanced nutritional counseling of newly diagnosed youth with T1DM along with their family may affect their BMI trajectory after the initiation of insulin therapy.

Prevalence of Obesity in Youth with T1DM

Prevalence of Overweight Youth with T1DM

Parental Overweight Status

<table>
<thead>
<tr>
<th>Parent</th>
<th>Overweight Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=23</td>
<td></td>
</tr>
<tr>
<td>N=39</td>
<td></td>
</tr>
<tr>
<td>BMI Father</td>
<td>Families with &gt;1 overweight parent: 14.9%</td>
</tr>
<tr>
<td></td>
<td>Families with normal parental weights: 85.1%</td>
</tr>
<tr>
<td>BMI Mother</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Hypothesis 1 Conclusion

- Significant proportion of youth with T1DM are overweight at diagnosis—despite associated weight loss
- Overweight and obesity is comparable to the National data

Hypothesis

- Youth with new onset T1DM may present with BMI above the 85th percentile.
- Higher than recommended energy intake may be present in T1DM patients after diagnosis.
- Enhanced nutritional counseling of newly diagnosed youth with T1DM along with their family may affect their BMI trajectory after the initiation of insulin therapy

Recall of Energy and CHO Goals

- Percentage of families correctly recalling the recommended daily energy and CHO requirement

3-Day Food Record – Pre-Intervention

Hypothesis 2 Conclusion

- Most families do not express understanding of the daily recommended energy requirement
- Correctly recall the recommended daily CHO intake.
- Daily energy intake > recommended goals—significant percentage.
- CHO intake exceeded—a small percentage.
- Quality of CHO: recommended intake of fruits and vegetables not met in majority

Hypothesis

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- Higher than recommended energy intake may be present in T1DM patients after diagnosis.
- Enhanced nutritional counseling of newly diagnosed youth with T1DM along with their family may affect their BMI trajectory after the initiation of insulin therapy
Change In Energy Intake
[All Subjects]

Excess Energy Intake / Day

<table>
<thead>
<tr>
<th>Excess Energy Intake</th>
<th>Pre-Intervention</th>
<th>Post-Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>-39</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-40.5</td>
<td></td>
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</tbody>
</table>

P > 0.05

Change in Energy Intake [Subjects With Excess Pre-Intervention Intake]

Excess Energy Intake / Day

<table>
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<th>Excess Energy Intake</th>
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<th>Post-Intervention</th>
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<tbody>
<tr>
<td>184.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-175</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P = 0.016
Hypothesis 3 Conclusion

- Contrary to current notion- At 6-7 months after diagnosis, BMI-Z may exceed pre-illness BMI-Z
- Enhanced Nutritional Counseling- with focus on energy intake and quality of CHO- may be effective in this population

Caveat

- Single provider initiated process
- Extremely labor intensive
- Motivated population- recently diagnosed T1DM

HbA1c Change

<table>
<thead>
<tr>
<th></th>
<th>SDC</th>
<th>ENC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>4.5</td>
<td>4.6</td>
</tr>
<tr>
<td>2 Weeks</td>
<td>4.3</td>
<td>4.4</td>
</tr>
<tr>
<td>3-4 Months</td>
<td>4.2</td>
<td>4.3</td>
</tr>
<tr>
<td>6-7 Months</td>
<td>4.1</td>
<td>4.2</td>
</tr>
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<th>SDC</th>
<th>ENC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>5.0</td>
<td>5.1</td>
</tr>
<tr>
<td>2 Weeks</td>
<td>4.9</td>
<td>5.0</td>
</tr>
<tr>
<td>3-4 Months</td>
<td>4.8</td>
<td>4.9</td>
</tr>
<tr>
<td>6-7 Months</td>
<td>4.7</td>
<td>4.8</td>
</tr>
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Insulin Dose [Units/Kg] Change

<table>
<thead>
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<th></th>
<th>SDC</th>
<th>ENC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>0.2</td>
<td>0.3</td>
</tr>
<tr>
<td>2 Weeks</td>
<td>0.1</td>
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Future Plans

- Complete follow-up
- Follow BMI trajectory, HbA1c, insulin dose change till 12 months?
- Inculcate enhanced nutritional counseling into practice?
- Assess other biochemical parameters and cardiovascular risk markers
- Assess patients’ comfort with diabetes care

Acknowledgements

- Teresa Quattrin MD
- Kathleen Bethin MD, PhD
- All my colleagues in the division of Endocrinology and Diabetes
- Michelle Ecker RD, CDE
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- Community Pediatricians
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