

*Injection Techniques Questionnaire (ITQ)
WorldWide Results*

2014-2015

Insulin Usage



BACKGROUND

***Lipohypertrophy in Diabetes
or
„How much does a lipo cost?“***

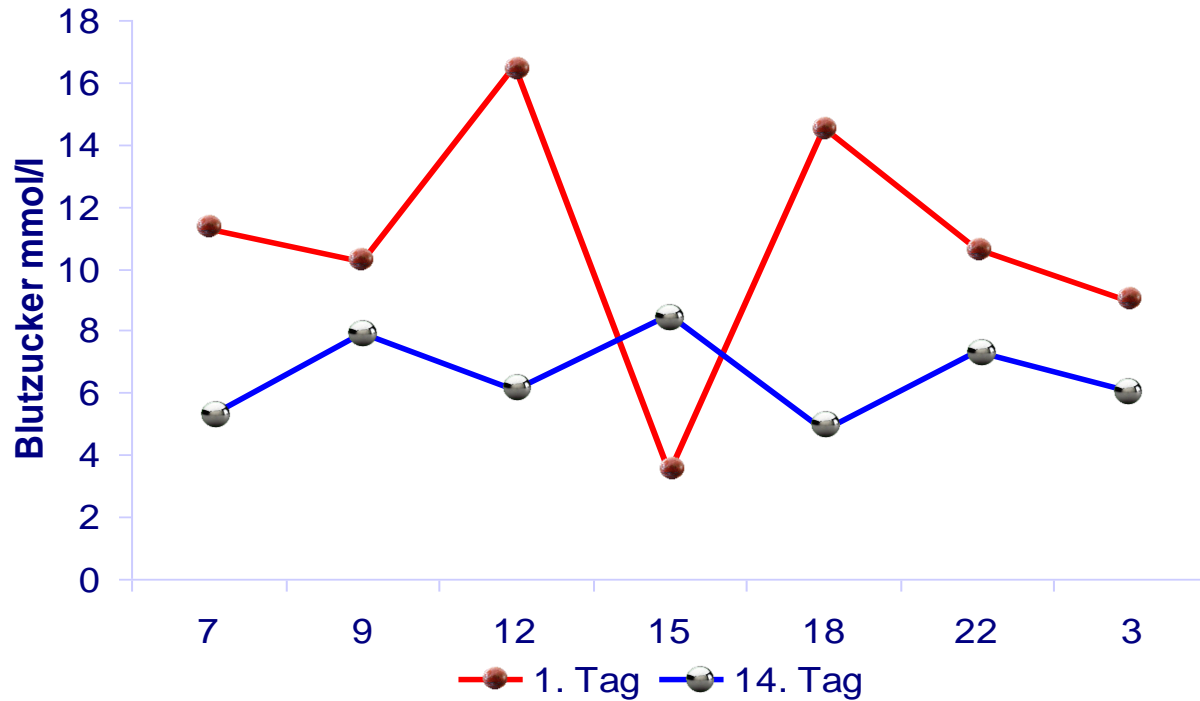
Dr. Treichel, Magdeburg

Studies have shown that the individual dose of insulin increases significantly when insulin is injected into lipohypertrophic tissue in order to achieve satisfying results for diabetes control.*

*(*Franzen I, J. Ludvigsson, Linköping 1997 Specific Instructions Gave Reduction of Lipomas and Improved Metabolic Control in Diabetic Children, Diabetologia Vol 40, Supplement 1: A615 (1997)*

Results

- Intra-day variations of BG values were reduced.
- BG values generally went down to the proposed range.
- The individual daily insulin dose needed had to be reduced significantly.



Cost of Therapy

Patient A

| (per year) | Basal | Humalog | Pen Needles | Sum | Co-Payment |
|-----------------------------|----------------|--------------|----------------|----------------|--------------|
| prior to IT training | 2.005 € | 1.499 € | 45 € | 3.550 € | 275 € |
| after IT training | 573 € | 551 € | 498 € | 1.622 € | 128 € |
| difference (savings) | 1.432 € | 948 € | (453 €) | 1.928 € | 147 € |



ELSEVIER
MASSON

Available online at
SciVerse ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en

& Diabetes
Metabolism

Diabetes & Metabolism 39 (2013) 445–453

Original article

Prevalence and risk factors of lipohypertrophy in insulin-injecting patients with diabetes

M. Blanco^a, M.T. Hernández^b, K.W. Strauss^{c,*}, M. Amaya^d

^a *Novartis Pharma, Barcelona, Spain*

^b *A.G.S. Campo de Gibraltar, Algeciras, Cádiz, Spain*

^c *BD, POB 13, Erembodegem-Dorp 86, 9320 Erembodegem-Aalst, Belgium*

^d *Diabetes Service Puerta de Europa, Hospital Algeciras, Cádiz, Spain*

Received 25 March 2013; received in revised form 5 May 2013; accepted 12 May 2013

LH and Total Insulin Dose

| | Lipohypertrophy | |
|--------------------------|-----------------|----|
| Dose category | Yes | No |
| Total Dose (mean IU/day) | 56 | 41 |
| Total Dose DM 1 | 50 | 42 |
| Total Dose DM 2 | 62 | 41 |

Health Economic Costs

- This **15 IU difference** multiplied over the number of daily injections into LH
- Assuming a cost of 0.0243 euros/IU
- Total annual cost to the Spanish health care system of over **122 million euros.**

Cost of Additional Insulin Attributable to Injecting into LH

| | PATIENTS INJECTING | NUMBER OF | TOTAL ADDITIONAL IU | TOTAL ADDITIONAL IU | ANNUAL FINANCIAL |
|--------------|--------------------|-----------------------|---------------------|---------------------|------------------|
| | INSULIN in SPAIN | ADDITIONAL IU PER DAY | CONSUMED PER DAY | CONSUMED PER YEAR | IMPACT EURO* |
| DM 1 | 139,500 | 8 | 1,116,000 | 407,340,000 | 9,474,728 |
| DM 2 | 634,000 | 21 | 13,314,000 | 4,859,610,000 | 113,034,529 |
| TOTAL | 773,500 | 15 | 14,430,000 | 5,266,950,000 | 122,509,257 |

*assumes an average cost of 1 IU insulin in Spain of 0.02326 euros

**COMPARATIVE
STATISTICS: DEMOGRAPHICS**

Is TDD related to DM type?

| | | TDD | | |
|---------|------|------|----|------|
| | | Mean | SD | N |
| DM type | T1DM | 48 | 25 | 2512 |
| | T2DM | 49 | 35 | 5030 |
| | GDM | 22 | 23 | 81 |

TDD by Country in IU(1)

| Country | Mean | SD | N |
|--------------|------|----|-----|
| USA | 39 | 41 | 304 |
| Canada | 69 | 52 | 302 |
| Russia | 45 | 25 | 109 |
| South Africa | 53 | 33 | 149 |
| Netherlands | 70 | 38 | 75 |
| Belgium | 55 | 32 | 146 |
| France | 59 | 35 | 234 |
| Spain | 51 | 26 | 198 |
| Italy | 46 | 24 | 337 |
| Switzerland | 51 | 46 | 71 |
| Austria | 42 | 24 | 113 |

TDD by Country in IU (2)

| Country | Mean | SD | N |
|-----------|------|----|-----|
| UK | 63 | 41 | 409 |
| Denmark | 56 | 24 | 14 |
| Sweden | 59 | 31 | 102 |
| Poland | 44 | 20 | 101 |
| Germany | 57 | 33 | 447 |
| Perú | 22 | 10 | 24 |
| Mexico | 39 | 23 | 134 |
| Argentina | 45 | 20 | 73 |
| Brazil | 45 | 30 | 242 |
| Chile | 62 | 29 | 20 |
| Colombia | 37 | 19 | 45 |

TDD by Country in IU (3)

| Country | Mean | SD | N |
|-------------|------|----|------|
| Venezuela | 35 | 16 | 25 |
| Malaysia | 53 | 24 | 50 |
| Australia | 63 | 36 | 81 |
| Indonesia | 27 | 19 | 124 |
| Philippines | 43 | 26 | 70 |
| Singapore | 44 | 15 | 23 |
| S. Korea | 41 | 23 | 179 |
| China | 32 | 16 | 491 |
| Turkey | 54 | 29 | 1251 |
| India | 36 | 23 | 982 |
| Ireland | 59 | 21 | 36 |

TDD by Country in IU (4)

| Country | Mean | SD | N |
|----------------------|------|----|------|
| Finland | 59 | 34 | 92 |
| Czech Republic | 57 | 32 | 126 |
| Nicaragua | 26 | 11 | 16 |
| Taiwan | 44 | 41 | 92 |
| Saudi Arabia | 41 | 26 | 410 |
| United Arab Emirates | 50 | 32 | 59 |
| TOTAL | 48 | 32 | 7756 |

**COMPARATIVE
STATISTICS: ASSOCIATIONS**

Is Needle Length associated with total daily dose (TDD) of insulin?

| Needle Length | Mean TDD | N | Std. Deviation |
|---------------|----------|------|----------------|
| 4 | 44.9 | 2031 | 31.6 |
| 5 | 47.6 | 1454 | 31.6 |
| 6 | 47.0 | 1466 | 29.6 |
| 8 | 54.0 | 1993 | 33.6 |
| Total | 48.5 | 6944 | 32.0 |

TDD less with 4, $p < 0.000$

What could explain this?

- 4mm used more frequently in younger patients and T1DM, both of whom use lower doses
- LH rates are lower with 4mm needles (for various reasons, not necessarily causative) and insulin use in LH- subjects are lower
- 4mm used more frequently in intensively treated patients (T1DM and T2DM), who use less insulin overall

What is the association between pain and TDD?

| PAIN | Mean TDD | N | SD |
|--------------|-----------------|----------|-----------|
| Yes | 51.0 | 3569 | 33.2 |
| No | 46.1 | 3484 | 31.3 |
| Total | 48.6 | 7053 | 32.3 |

$\Delta = 4.9$ IU

p < 0.000

Is TDD associated with Device?

| | Mean | Std. Deviation | N |
|----------------------|------|----------------|------|
| Syringe | 41 | 27 | 1028 |
| Pen | 49 | 32 | 6027 |
| Other (pump) | 42 | 21 | 110 |
| Pen + Syringe | 57 | 37 | 206 |

p < 0.000

Is TDD associated with site of injection?

| | | TDD | | |
|-------------------|---------------|------|----|------|
| | | Mean | SD | N |
| Site of Injection | Abdomen alone | 47 | 34 | 2029 |
| | Thigh alone | 36 | 28 | 250 |
| | Arm alone | 41 | 27 | 174 |
| | Abdomen/Thigh | 51 | 33 | 1549 |
| | Abdomen/Arm | 48 | 34 | 490 |
| | Thigh/Arm | 48 | 26 | 306 |
| | Abd/Thigh/Arm | 53 | 29 | 1281 |
| | All 4 | 46 | 27 | 646 |

Is TDD related to Leakage from Site?

| Leakage from Site | Mean TDD | SD | N |
|-------------------|----------|----|------|
| Yes | 51 | 32 | 2819 |
| No | 46 | 32 | 4777 |
| Total | 48 | 32 | 7596 |

$\Delta = 5 \text{ IU}$

$p < 0.000$

Is TDD related to Reconstituting Cloudy Insulin?

| Reconstitute | Mean TDD | SD | N |
|--------------|----------|----|------|
| Yes | 46 | 28 | 2879 |
| No | 49 | 34 | 1161 |
| Total | 47 | 30 | 4040 |

$\Delta = 3 \text{ IU}$

$p = 0.026$

Is TDD related to Skipping Injections?

| Skip Injections | Mean TDD | SD | N |
|-----------------|----------|----|------|
| Yes | 50 | 31 | 3699 |
| No | 46 | 32 | 3938 |
| Total | 48 | 32 | 7637 |

$\Delta = 4 \text{ IU}$

$p < 0.000$

Is TDD related to Hyperglycemia?

| Hypers | Mean TDD | SD | N |
|--------|----------|----|------|
| Yes | 53 | 33 | 3728 |
| No | 43 | 30 | 3753 |
| Total | 48 | 32 | 7481 |

$\Delta = 10$ IU

$p < 0.000$

Is TDD related to Hypoglycemia?

| Hypos | Mean TDD | SD | N |
|-------|----------|----|------|
| Yes | 52 | 32 | 4339 |
| No | 43 | 31 | 3288 |
| Total | 48 | 32 | 7627 |

$\Delta = 9 \text{ IU}$

$p < 0.000$

**COMPARATIVE
STATISTICS: OUTCOMES**

What is the association between LH and the total daily dose of insulin (TDD)?

| LH | Mean TDD | N | SD |
|-------|----------|------|------|
| Yes | 55.2 | 2192 | 33.0 |
| No | 45.1 | 4889 | 31.5 |
| Total | 48.2 | 7081 | 32.3 |

$\Delta = 10.2 \text{ IU}$

T1DM

T2DM

| LH | Mean TDD | N | SD |
|-------|----------|------|------|
| Yes | 51.2 | 1007 | 25.9 |
| No | 45.9 | 1286 | 24.5 |
| Total | 48.2 | 2293 | 25.3 |

$\Delta = 5.4 \text{ IU}$

| LH | Mean TDD | N | SD |
|-------|----------|------|------|
| Yes | 58.8 | 1159 | 38.0 |
| No | 45.2 | 3457 | 33.6 |
| Total | 48.6 | 4616 | 35.2 |

$\Delta = 13.5 \text{ IU}$

p for all <0.000

What is the association between Injecting into LH and TDD?

| Inject into LH | Mean TDD | N | SD |
|----------------|----------|------|------|
| Yes | 56.1 | 1644 | 33.2 |
| No | 47.1 | 2064 | 32.2 |
| Total | 51.1 | 3708 | 32.9 |

$\Delta = 9.0$ IU

$p < 0.000$

What is the association between LH and the TDD by Insulin type?

Rapid Analogues

| LH | Mean TDD | N | SD |
|-------|----------|------|------|
| Yes | 34.4 | 928 | 22.0 |
| No | 29.9 | 884 | 21.6 |
| Total | 32.2 | 1812 | 21.9 |

$\Delta = 4.5$ IU

Basal Analogues

| LH | Mean TDD | N | SD |
|-------|----------|------|------|
| Yes | 28.7 | 1149 | 19.0 |
| No | 27.2 | 1228 | 22.0 |
| Total | 27.9 | 2377 | 20.6 |

$\Delta = 1.5$ IU

Premixes

| LH | Mean TDD | N | SD |
|-------|----------|-----|------|
| Yes | 49.9 | 319 | 30.2 |
| No | 40.0 | 479 | 22.9 |
| Total | 44.0 | 798 | 26.5 |

$\Delta = 9.8$ IU

p for all <0.000

Findings

Insulin Consumption:

- Strong association between the presence of LH and the total daily dose (TDD) of insulin, with over 10 IU of insulin on average being consumed in the LH+ population vs LH-.
 - In T2DM patients, this average TDD difference is 13.5 IU.
 - In T1DM patients, the average TDD difference is 5.4 IU.

Findings

Insulin Consumption:

- These differences were seen for different types of insulin:
 - fast-acting analogue (mean of 4.4 IU more),
 - basal analogue (mean of 1.5 IU more)
 - and premix (mean of 9.8 IU more).

Findings

Insulin Consumption:

- All currently used families of insulins are associated with the risk of LH.
- It is difficult to determine if any one type of insulin has higher risks.
- Even newer analogues show a prevalence of LH in double digits

Is TDD related to Correct Rotation?

| Correct Rotation | Mean TDD | SD | N |
|------------------|----------|----|------|
| Yes | 47 | 31 | 5220 |
| No | 51 | 33 | 2164 |
| Total | 48 | 32 | 7384 |

$\Delta = 4 \text{ IU}$

$p < 0.000$

Conclusions

- The average TDD is approximately the same between T1DM and T2DM (48-49 IU), with greater variability of dosage in patients with T2DM.
- There is huge variability in mean TDD and SD country to country.
- Lower TDD are associated with use of 4 mm needles, syringe use, use of limbs as sole injection sites and correct rotation of injections.
- Higher TDD are associated with leakage from the site, failing to reconstitute cloudy insulin, skipping injections, hypo- and hyperglycemia, injection pain, the presence of LH and injecting into LH.