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| **Capacità e competenze personali acquisite nel corso della vita e carriera ma non necessariamente riconosciute da certificati e diplomi ufficiali** | - Dal 1985 ad oggi ha partecipato in qualità di discente a numerosi corsi, congressi e convegni per il proprio aggiornamento professionale.<br>- Dal giugno 2003 ad oggi ha partecipato in qualità di progettista, responsabile scientifico, moderatore, docente, tutor in numerosi corsi di aggiornamento professionale e congressi regionali e nazionali promossi dalle principali società scientifiche di Endocrinologia (AME –SIE -ANIED) e Diabetologia (SID - AMD - OSDI).<br>Autore Poster su "Valutazione dei livelli di empatia tra gli studenti del Master di Endocrinologia e Malattie del Metabolismo" del Dipartimento di Medicina Interna Università di Torino.<br>- Una Pubblicazione su rivista internazionale "Journal of Clinical & Translational Endocrinology" (In allegato). |

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**Ulteriori informazioni**

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- Da marzo 2017 a 2019 componente della commissione regionale della rete Endocrino-Diabetologica – Regione Piemonte.

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Research Paper

# Optimizing insulin injection technique and its effect on blood glucose control☆

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ABSTRACT

*Purpose:* The purpose of the study is to assess whether proper Injection Technique (IT) is associated with improved glucose control over a three month period.
*Methods.* Patients ($N = 346$) with diabetes from 18 ambulatory centers throughout northern Italy who had been injecting insulin ≥ four years answered a questionnaire about their IT. The nurse then examined the patient's injection sites for the presence of lipohypertrophy (LH), followed by an individualized training session in which sub-optimal IT practices highlighted in the questionnaire were addressed. All patients were taught to rotate sites correctly to avoid LH and were begun on 4 mm pen needles to avoid intramuscular (IM) injections. They were instructed not to reuse needles.
*Results:* Nearly 49% of patients were found to have LH at study entry. After three months, patients had mean reductions in HbA1c of 0.58% (0.50%–0.66%, 95% CI), in fasting blood glucose of 14 mg/dL (10.2–17.8 mg/dL, 95% CI) and in total daily insulin dose of 2.0 IU (1.4–2.5 IU, 95% CI) all with $p < 0.05$. Follow-up questionnaires showed significant numbers of patients recognized the importance of IT and were performing their injections more correctly. The majority found the 4 mm needle convenient and comfortable.
*Conclusions:* Targeted individualized training in IT, including the switch to a 4 mm needle, is associated with improved glucose control, greater satisfaction with therapy, better and simpler injection practices and possibly lower consumption of insulin after only a three month period.


## Introduction

Most physician visits with insulin-injecting patients involve discussions about glucose control and dose adjustments, but very little time is spent on improving Injection Technique (IT). However IT may in certain cases be just as important to diabetes management as the type of insulin or dosage used.

This study was the outgrowth of a survey performed in 21 hospitals in northern Italy in 2011 by the ANIED Group — *Associazione Nazionale Infermieri in Endocrinologia e Diabetologia* (National Association of Nurses in Diabetology and Endocrinology; see Acknowledgments section) [1]. That study, termed the Swansdown Survey and done in the same centers as our study, involved 472 injecting patients and consisted of training to improve their injecting technique. Patients were using a variety of needle lengths (12.7 mm [1.2%], 8 mm [37.7], 6 mm [35.4%], 5 mm [18.4%], 4 mm [7.6%], unknown [5%]). No needle length changes were proscribed by the study. Patients were followed up at 3 and 6 months for effects of the training on their glucose control and injection technique knowledge. No significant changes were found in HbA1c or fasting glucose levels, but understanding of injections was improved. The Survey had initially revealed that the greatest educational needs were in older patients who had been injecting insulin for over ten years and who had outdated practices. By study conclusion a majority of patients showed improved understanding of injecting devices (including shorter, finer-gauge needles), the care and maintenance of injection sites, the means for avoiding complications such as lipohypertrophy (LH) and the necessity for rotating injection sites. As a result of this


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**Table 2**
Key study questions[a]

| |
|---|
| How many injections do you give per day? |
| What injection sites do you use? |
| When do you give your injections? |
| What needle length do you use? |
| Do you use the pinch-up technique? |
| If so, when do you release the pinch? |
| How long do you leave the needle in the skin after the injection? |
| Does the injection cause bleeding or bruising? |
| How often do you use the same needle? |
| At what angle do you insert the needle? 45°, 90° or other? |
| How would you describe the experience of injection in terms of pain? |
| [b]How important was it for you to use a short needle? |
| [b]What did using a 4 mm × 32 g needle feel like? |

[a] This is a selection of questions; the full questionnaire is available on request.
[b] These questions were only posed at the end.

Nurses in all centers received standardized training on how to evaluate for LH and how to train patients on IT. Each patient was taught the correct way to inject using a 4 mm PN and were told they would be evaluated after the first 3 months in order to assess their IT, changes in clinical parameters, the state of their injection sites and their psychological reaction to and clinical impact of the 4 mm PN (see final questions in Table 2).

Every patient was informed that data from their questionnaire would be maintained in strict confidentiality, with only his/her doctor and nurse having access to their identity. They were told that it was not important to give the correct answer ("this is not an examination!") and that they should not try to give the answer they thought their nurse or doctor might want to know. It was reinforced that to help them optimize their care it was extremely important to give accurate, true answers. No patient was paid for participating or otherwise rewarded. They were informed that the reason for doing the study was to help them optimize their own therapy, to uncover issues which individually-tailored training could address and that the global information from the study would help them and other patients by providing an improved educational approach.

HbA1c values from the 18 centers were obtained from instruments which were calibrated every month and underwent an optical control every time they were moved. The instruments were qualified for use in the diagnosis of diabetes and were shown to give equivalent readings across centers.

Patients gave verbal consent to participate and the study was conducted in accordance with Good Clinical Practice, the clinical trials directives of the EU and the 1964 Declaration of Helsinki and its six revisions. The study started in January, 2012 when the nurses were trained. Patient recruitment began in February, 2012 and lasted to April, 2012 and 3-month follow up lasted from May, 2012 to July, 2012.

SPSS software (IBM Corporation, Armonk NY, USA, version 19) was used to analyze the data. Mean, median, standard deviation, minimum, maximum and standard error around the mean were measured for the entire population. Comparisons of parameters were performed using $\chi$-square, ANOVA, log linear models and multivariate analysis. The threshold for statistical significance was $\alpha = 0.05$.

**Table 3A**
Overall patient demographics

| | N | Mean | Std. deviation | Minimum | Maximum |
|---|---|---|---|---|---|
| Age (years) | 346 | **55.5** | 18.6 | 11.0 | 85.0 |
| Age at insulin inception (years) | 325 | **42.2** | 21.4 | 1.0 | 80.0 |
| Years on insulin | 332 | **13.0** | 9.8 | 0.5 | 50.0 |
| Injections/Day | 342 | **3.71** | 0.89 | 1.0 | 7.0 |

**Table 3B**
Parameters at study entry

| | N | % |
|---|---|---|
| Females/Males | 166/176 | 48.1/51.9 |
| Visible lipohypertrophy | 124 | 35.7 |
| Visible lipoatrophy | 18 | 5.2 |
| Palpable lipohypertrophy | 159 | 45.8 |
| Total lipohypertrophy[a] | 169 | 48.7 |
| 5 mm needle used | 111 | 33.3 |
| 6 mm needle used | 139 | 41.7 |
| 8 mm needle used | 79 | 23.7 |
| 12.7 mm needle used | 4 | 1.2 |
| Abdomen used primarily for injections | 163 | 47.0 |
| Thigh used primarily for injections | 83 | 23.9 |
| Buttocks used primarily for injections | 14 | 4.0 |
| Arm used primarily for injections | 79 | 21.8 |

[a] Those with both visible and palpable lipohypertrophy are only counted once.

## Results

A total of 346 patients were included in the study. Demographic data are given in Tables 3A and 3B and the key clinical parameter changes in Tables 4A and 4B.

Age and gender parameters, years on insulin, total daily doses (TDD) of insulin and injections/day were all in keeping with previous studies in patients with diabetes [3,4,11,12]. At study entry patients were found to be using a variety of needle lengths, with a majority on PN ≤ 6 mm long; none used the 4 mm PN. Most patients used the four conventional injection sites (abdomen, thighs, upper arm and buttocks) although the buttock was used much less frequently than the others. A number of patients were found to be injecting in sites other than these four. Figure 1 illustrates some of these unusual practices which were addressed during individualized training.

By visual inspection at study entry nurses found LH in 35.7% of patients and by palpation, in 45.8% (Figure 2). The overall LH percentage when visual and touch evaluations were combined was 48.7%. Those with both visible and palpable LH were only counted once in determining the latter percentage.

After three months, patients had mean reductions in HbA1c of 0.58% (0.50%–0.66%, 95% CI), in fasting blood glucose of 14 mg/dL (10.2–17.8 mg/dL, 95% CI) and in total daily insulin dose of 2.0 IU (1.4–2.5 IU, 95% CI) with a $p < 0.05$ for all differences (Table 4A). Body mass index (BMI) decreased slightly over the three months of the study but this change was not statistically significant. LH rates were unchanged at three months. Follow-up HbA1c data were available on only 259 of the 346 subjects (74.9%) included at baseline (Table 1). However analysis of the demographic and clinical data on the 259 was compared to that of the 346 and similar results were obtained for HbA1c, fasting blood glucose and total insulin doses.

**Table 4A**
Clinical parameters at study entry and at three months

| Clinical parameter | n | Mean | Δ | SD | Minimum | Maximum |
|---|---|---|---|---|---|---|
| HbA1c at entry | 346 | **8.49** | | 2.86 | 5.2 | 14.0 |
| HbA1c at 3 months | 259 | **7.91** | −0.58* | 1.30 | 5.1 | 14.1 |
| FBG (mg/dL)at entry | 249 | **186.7** | | 49.9 | 90 | 410 |
| FBG (mg/dL)at 3 months | 182 | **172.5** | −14.2* | 42.3 | 81 | 358 |
| TDD (IU) insulin at entry | 326 | **50.5** | | 24.7 | 9 | 159 |
| TDD (IU) insulin at 3 months | 256 | **48.5** | −2.0* | 24.8 | 9 | 150 |
| BMI[a] at entry | 304 | **28.2** | | 7.77 | 17.0 | 103.0 |
| BMI at 3 months | 235 | **27.7** | −0.5 | 8.20 | 16.5 | 102.0 |

*$p < 0.05$.
[a] BMI = height (in meters)/(weight in kg)$^2$.

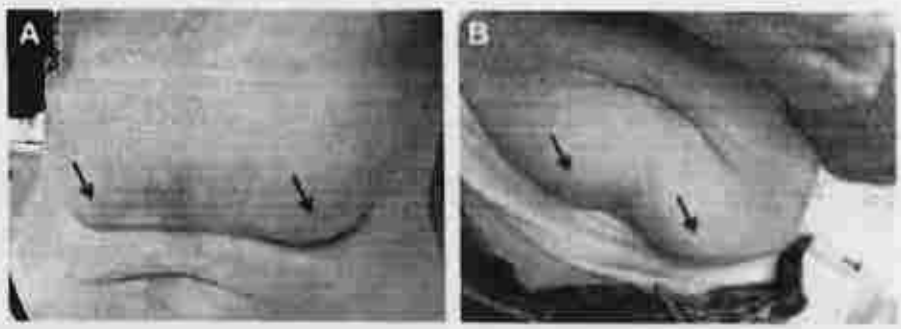


**Figure 2.** Examples of visible lipohypertrophy (A. Bilateral upper abdomen; B. Bilateral lower abdomen); see arrows.

1.6–2.5 mm, even in obese patients [19]. Therefore, a 4-mm needle is more than long enough to pass through the skin and enter the SC space.

However the distance from the skin surface to the muscle varies widely both from one person to another and within the usual injection sites in a single individual [8,14,19,20]. These results have given pause to those who once advocated routinely using longer needles (≥8 mm). In many normal to lean adults and in most children there is a substantial risk of IM injections with such needles. Even in obese patients who inject into the limbs (arms or legs) such risks are not trivial. Hence we have seen in recent years a shift to shorter needles. This was the rationale of ANIED in shifting all injecting patients in the Piedmont region of northern Italy over to the 4 mm PN, in the context of an educational IT intervention.

The 4 mm PN has been tested in a number of clinical trials to date [2–4,6,9] and has proven its safety and efficacy in both adults and children, as well as in persons spanning a range of BMIs, including in the obese. Hirsch et al. [2], for example, showed similar glycemic control (as measured by fructosamine values) during all stages of a 3-week two-period crossover study that compared the BD 32-gauge, 4-mm insulin PN with 31-gauge 5-mm and 31-gauge 8-mm needles [2]. In a follow-up randomized, controlled crossover study with 3-month treatment periods using HbA1c to measure control, the same results with the 4 mm PN were confirmed in an obese (BMI ≥ 30 kg/m$^2$) diabetic population, many taking very large insulin doses [21,22].

The latest consensus injection recommendations [10] state that 4 mm PN 'may be used by any adult patient including obese ones and do not generally require the lifting of a skin fold' and that children and adolescents 'should use' such needles. We found that educational interventions regarding IT coupled with a switch to the 4 mm PN are associated with improved glucose control in a relatively short period of time.

The weight of each of these interventions in the overall outcomes was not evaluated. Limitations of our study include the lack of a control group and the sequential nature (pre-post) of our analyses; furthermore, we do not yet have long-term data. We did not include a control group in this study because we felt obliged to give the same best-practice advice to all our patients. In fact IT review and a switch to a shorter needle is standard practice by the nurses and doctors in the participating centers. Lack of a control prevents absolute certainty that the 4 mm needle and IT training were the exclusive causes of the clinical improvements we observed. Lack of chronic follow-up data limits our knowledge as to how sustainable these improvements might be.

Another important limitation is that we have follow-up HbA1c data on only 259 of the 346 subjects (74.9%) included at baseline. Nevertheless, analysis of the data on the 259 was compared to that of the 346 and similar results were obtained, suggesting that results from the former can be extrapolated to the latter. Hypoglycemia was not assessed because of our inability to certify glucose values when hypoglycemic symptoms appeared; not all patients were using meters. Our findings however warrant further study in a prospective, randomized controlled clinical investigation. Follow-up for this trial was only planned for 3 months, but it has continued and will be the subject of an additional analysis and possible future paper.

The implications of our study are striking. Patients and professionals do not have to wait for months and years to see improvements in the most important clinical parameters when appropriate IT training and devices are provided. These improvements can be expected early enough in the course of insulin therapy to provide motivation for continuous improvement.

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