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Compatibility of the Omnican® Pen Needles with Insulin Pens, Humapen® and Novopen®

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Abstract

This study was carried out to assess accuracy of Omnican® insulin pen needles (29G and 30G) by measuring the weight of insulin delivered in each of 10 depressions of the plunger comparing these using other pen-injectors (Humapen® and Novopen®) for each gauge. We found that the needle-to needle variation was not statistically significant when the needles were used to dispense insulin using either of the insulin pens (Humapen® and Novopen®). HumaPen® insulin pen was found to deliver the insulin closer to set target volume using either gauge (29G and 30G) of the Omnican® needles in some of the insulin ranges used in this study.

Introduction

In diabetic patients requiring insulin for control, it is important to ensure that the dosage prescribed is the dose delivered to the patient. Variation in dose delivery may lead to poor control (either hyperglycemia or hypoglycemia) of diabetes. One reason for the variation is due to the inaccurate measurements in dispensing due to poor delivery devices.

Many adults who are diabetic may require insulin daily injections. Insulin injection can be a problem be it in the adolescents or children. There are reports that question the accuracy of patients and health professionals in preparing the split-mix of insulin therapy[1]. This problem has become more acute in the U.K., where the more dilute U40/ml and U80/ml insulin were withdrawn and have been replaced with the U100/ml insulin[2]. Although this simplified treatment and reduced the potential for dosage errors, it meant that insulin had to be dispensed in extremely small volumes. Consequently, the use of conventional syringes to administer insulin becomes less possible as the syringes have an unacceptable large error[3].

In the U.K., a variety of pen-injector devises such as NovoPen®[4,5] and HumaPen®[6] were used to ensure that small doses are administered more accurately. In addition, these pens minimised potential dosage errors. Patients who have used some of the pen-injectors have expressed satisfaction in using this device to administer their daily insulin injections. The patients felt more at ease using the pen-injectors to administer insulin and it also gave them flexibility of lifestyle.

There are several studies[7, 8] that recommend the use of multiple daily injections with insulin pens in children and adolescents with diabetes.

In this study we assessed the repeatability and reproducibility of two gauges of Omnican® pen needles using two well-established insulin pens, HumaPen®[6] and NovoPen®[5].

Materials and methods

Insulin pens NovoPen® and Eli Lily's HumaPen® were used for testing in the study. Both pens and the corresponding insulin cartridges were obtained from the respective suppliers.

Omnican® needles Omnican® needles gauge 29 and 30 were tested in the study. The needles were provided by B. Braun Medical Supplies (M) Sdn. Bhd.

Volunteers Random selection of thirty volunteers of which fifteen were females, aged 40 years and above. Just prior to the study, all the volunteers were taught on how to use the NovoPen® and HumaPen® insulin pen.

Experimental design
Two gauges (29G and 30G) of the Omnican® pen needle and two insulin pens (HumaPen® and NovoPen®) were tested. For each needle gauge the volunteers were asked to dispense 1-10 depressions per needle gauge of the plunger and this was compared with similar measurements using other pen-injectors for each gauge. For both needle gauges and insulin pens, four insulin volumes were tested i.e. 60 units (one depressions per needle per pen), 20 units (five depressions per needle per pen) and 15 units (ten depressions per needle per pen). The volunteers dispensed the relevant amount of insulin into pre-weighed tubes. Three trials were done for all the tested ranges, pens and also needles. The tubes were weighed immediately and the amount of insulin dispensed calculated.

Statistical analysis Gauge Repeatability and Reproducibility (GRR) with Nested Design method[9] model was chosen. The data obtained from the study were analysed using the Analysis of Variance (ANOVA) method.

Results

The summary of results is shown in **Table-1.** The tolerance applied is based on target value ± 5%. The results show that there is no significant needle-to-needle variations when the both types of needles (29G and 30G) are used to dispense insulin with both the insulin pens tested (Humapen® and Novopen®).

Table 1

Gauge	Tolerance	% Needle-To-Needle Variation	p-value *(needle variation)**
HP60	(0.6 ± 0.03) g	11.68%	0.408
NP60	(0.6 ± 0.03) g	0.00%	0.794
HP20	(1.0 ±0.05) g	28.47%	0.710
NP20	(1.0 ± 0.05) g	0.00%	0.584
HP15	(1.50 ± 0.075) g	23.53%	0.204
NP15	(1.50 ± 0.075) g	0.00%	0.997

(Note: * As p>0.05, the contribution of needle-to-needle variation is not significant with reference to the indicated tolerance. Variations due to user and insulin pens are not included.)

Table 1: Summary of results.
Two Omnican® pen needle gauges (29G and 30G) and two insulin pens, HumaPen® (HP) and NovoPen® (NP) were tested. The volunteers were asked to dispense 1-10 depressions of the insulin pen and this was compared with similar measurements using other pen-injector for each gauge. The insulin volumes tested were 60 units, 20 units and 15 units. The data obtained was analysed using the ANOVA and GRR statistical method. The tolerance applied is based on (target value ± 5%).

(Note: Numbers after HP and NP refer to the volume of insulin dispensed, e.g. HP60 = 60 units of insulin using the HumaPen®; NP15 = 15 units of insulin using the NovoPen®)

Table 2

Method	Target value (insulin units)	HumaPen® (29G)		NovoPen® (29G)		ANOVA
		Average	S.D.	Average	S.D.	
60	0.60	0.594	0.011	0.598	0.011	0.199
20	1.00	0.994	0.010	0.989	0.015	0.124
15	1.50	1.495	0.022	1.464	0.030	0.000*

Method	Target value (insulin units)	HumaPen® (30G)		NovoPen® (30G)		ANOVA
		Average	S.D.	Average	S.D.	
60	0.60	0.596	0.008	0.594	0.009	0.474
20	1.00	0.999	0.013	0.989	0.012	0.003*
15	1.50	1.489	0.019	1.464	0.025	0.000*

(Note: * Statistically significant as $p < 0.05$)

Table 2: The above results are obtained via one-factor ANOVA. The factor being studied is the insulin pens i.e. HumaPen® (HP) and NovoPen® (NP) pens.

The ability of the HumaPen® to deliver insulin nearer to the set target set value was shown to be statistically significant (see Table-2) when the pen was used to deliver 15 units of insulin using the both the Omnican® needles. With the 29G needle, the HumaPen® was also able to deliver closer to set target value when it was used to dispense 20 units of insulin (see Table-2)

Discussion

The GRR with Nested Design was chosen and ANOVA method was used to analyse the data for two reasons. The first being that the needles used in this trial are 'nested' to the users. This is different from the conventional GRR study where the gauges are shared among the users. This study simulates the actual situation when the pens are to be used by diabetic patients where sharing of needles does not usually take place. The second reason for choosing this

approach was that the GRR (ANOVA) method provides variance components for 'needle to needle' variation in addition to the repeatability and reproducibility variations. Based on the p-value obtained from ANOVA results at significance level of 0.05, the needle-to-needle variation is not significant when the needles (30G & 29G) are used for dispensing volumes of insulin i.e. 60, 20 and 15 units using either of the insulin pens tested (see Table-1). Variations due to users and insulin pens were not included in the scope of this study. Nevertheless, the user variations in using the gauges (pen and needles) may be improved when they get familiar with the gauges. The ability of the HumaPen® to deliver nearer to set target value was also shown to be statistically significant with some of the insulin volume tested (see Table-2).

Based on the results from this study, we would recommend that it is compatible for all volume of insulin up to 15 units dispensed using both the gauges of the Omnican pen needles with NovoPen® and HumaPen®. With the results of the data in mind, we could extrapolate that we can use both gauges of the Omnican® pen needles for dispensing lower volume of insulin. We will be conducting further testing for ranges between 15 and 5 units of insulin and also to study the impact of insulin pen and user variation in using the Omnican® needles. In conclusion, we observed consistency in the dispensing of insulin using the both gauges (30G and 29G) Omnican® needles using the NovoPen® while we found that the HumaPen® was able to deliver insulin nearer to the set target values (see Table-2).

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