Evaluation of efficiency and safety for delivery of rapid acting insulin between *Comfort-in*™ and conventional pen needle.

Aim

This clinical study has the aim for showing the same difference in the pharmacokinetic and pharmacodynamic profile between *Comfort-in*™ and conventional pen needle when the rapid-acting insulin analogue apart (Humalog®) injected prior to a standardized meal in patients with diabetes.

Clinical profile

Patient		**Glucose monitoring**	
Gender	Male	Last A1C	8.5%
Age	54	Fasting	225 mg/dL
Weight	95kgs	**Lipid profile**	
Height	178cm	Total	194mg/dL
BMI	31	LDL	120mg/dL
Liver function		HDL	31mg/dL
ALT	26	Triglycerides	210
AST	37	**Eye exam**	
Blood pressure		Background diabetic retinopathy	
high	155/90 mmHg	**Others**	
Cardiovascular condition		High cholesterol. (High LDL and Low HDL) so required for control of blood vessel	
Normal		Hypertension 1hr Exercise everyday and eating by diet program for 1 year	

- Patient's average blood glucose level was 155 mg/dl, with a widely variable range of 103-277 mg/dl (Table I)
- This patient was using Novorapid® insulin (rapid onset-fast acting) and Lantus (long-acting) but she has needle phobia stress so difficulties for insulin treatment.
- Other physical status is in normal range.

(Table I). Patient's glucose monitoring (mg/dl)

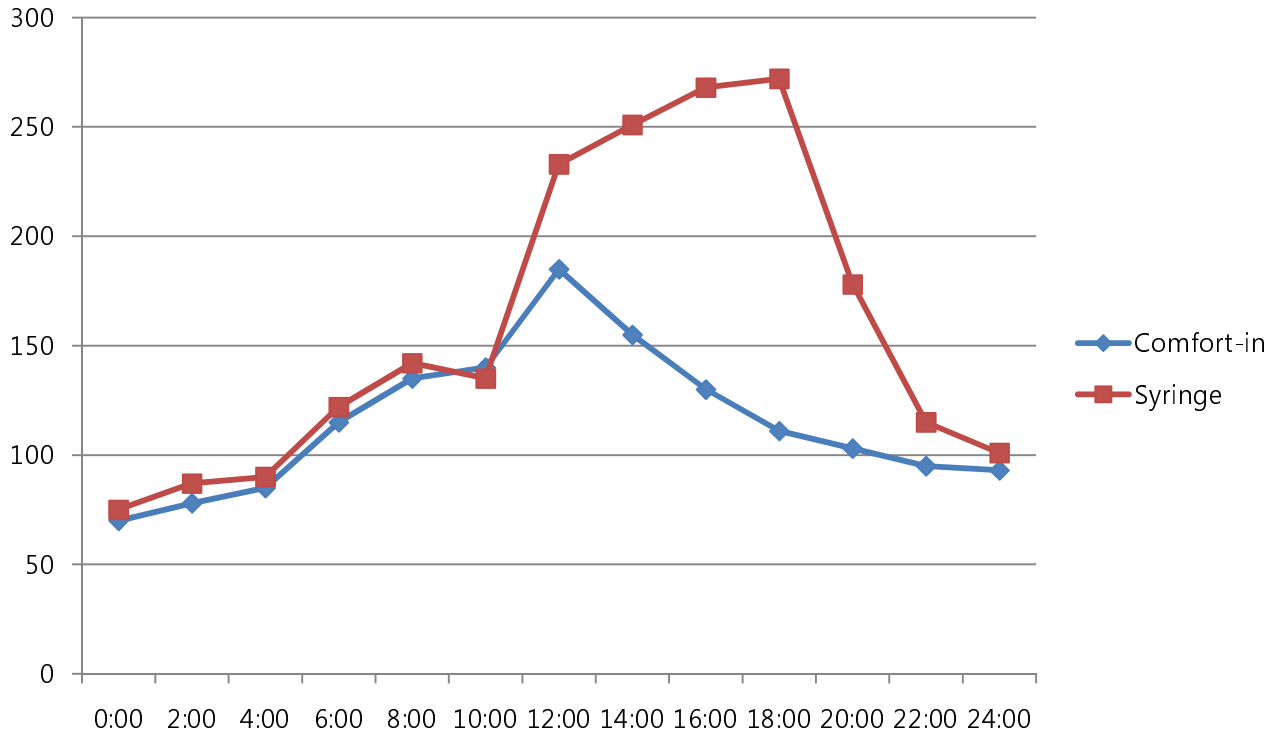
Date	8:00 AM	11:00 AM	14:00 PM	17:00PM	20:00 PM	23:00PM	Average
16 SEP 2012	140	171	211	262	185	101	178
17 SEP 2012	145	175	253	270	181	113	189
18 SEP 2012	155	183	225	268	175	111	186
19 SEP 2012	149	179	248	273	173	**103**	187
20 SEP 2012	151	186	251	**277**	185	109	193

Method

- Mini CGMS (Continuous Glucose Subcutaneous Monitoring) for 48 hours.
- 4 times by regular insulin per day and long-acting insulin at bedtime.
- Insulin device for comparison
  - ① One day: Insulin pen, Humalog ® 100U for breakfast, lunch & dinner time and Lantus Solostar(long-acting) at bedtime
  - ② Second day: *Comfort-in*™ for 2nd day study
- Injecting time:
  1) Insulin pen: 30 min. before eating
  2) *Comfort-in*™: Immediately injecting before eating

Figure 1

Glucose monitoring in every 2 hours for 48 hours to see the comparison between conventional insulin pen and *Comfort-in*™



Comments

I. Demonstration according to mini CSGM for 48 hours by *Comfort-in*™

- This patient has hypertension and high cholesterol so we had to consider for side-effect by jet injection system.
- The result itself is quite better than what we expected but the clinical test's period is too short to prove the new device (needle free injection system)
- Therefore, the study by A1C in minimum 2 months' evaluation should be required.

Result

- According to the 48 hours glucose monitoring, we found that the glucose control is similar to insulin pen without sudden change of glucose blood level.
- Moreover, faster absorption of insulin into the body (abdominal part) is confirmed
- Especially, the lower level of blood glucose after meals stands out from the result.

Conclusion

- *Comfort-in*™ is fully accepted by type II diabetic patients from this study.
- *Comfort-in*™ was proved well in this test to reduce hyperglycemic peaks more after meals than the result of insulin pen without increase or sudden decrease in hyperglycemic episodes.

Clinical inspiration

- The part of study is made from MiniMed Continuous glucose monitoring system (CGMS) :
- "Evaluation of efficiency and safety for delivery of rapid acting insulin between *Comfort-in*™ and conventional pen needle." Conducted by S.H. Lee, M.D.,
- Humalog ® is registered trademark.
- Lantus solostar is registered trademark of Sanofi Aventis Co.Ltd.
- Above two insulin are using popularly in Korea and can make immediate comparison result for this study.

Reference

1) Luijf YM, DeVries JH. Dosing accuracy of insulin pens versus conventional syringes and vials. diabetes Technol Ther 2010;12 (Suppl. 1):S73–S77
2) Pehling GB, Gerich JE. Comparison of plasma insulin profiles after subcutaneous administration of insulin by jet spray and conventional needle injection in patients with insulin-dependent diabetes mellitus. Mayo Clin Proc 1984; 59: 751-754.
3) Thurman JE. Insulin pen injection devices for management of patients with type 2 diabetes: considerations based on an endocrinologist's practical experience in the United States. Endocr Pract 2007;13:672–678

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