P-991

High Treatment Satisfaction with 3-day Insulin Patch is Independent of Patient Demographics: A Post-Hoc Analysis

Mark Peyrot,[1] Don Johns,[2] Buddug R. Rees,[3] Robert Rook,[4] Jay L. Warner,[5] & Brian Levy[6]

[1]Loyola University Maryland, Department of Sociology, Baltimore, Maryland
[2]Independent Statistical Consultant, Indianapolis, IN
[3]Buddug Consulting, Wales, UK
[4]Praxico Consulting Group, Boston, MA
[5]CeQur Corporation, Marlborough, MA
[6]Calibra Medical, Wayne, PA

APM-02-0033 Rev.A
Effective Date: 2020-06-01

Conflicts of Interest and Financial Relationships Disclosures:

M. Peyrot: Advisory Panel; Self; Eli Lilly and Company. Consultant; Self; CeQur Corporation, Eli Lilly and Company. Research Support; Spouse/Partner; Eli Lilly and Company.

D. Johns: Consultant; Self; CeQur Corporation

B.R. Rees: Consultant; Self; CeQur Corporation.

R. Rook: Consultant; Self; CeQur Corporation.

J.L. Warner: Employee; Self; CeQur Corporation.

B.L. Levy: Consultant; Self; CeQur Corporation, Digma Medical, iGlucose, LifeScan, Inc., QuiO Technologies.

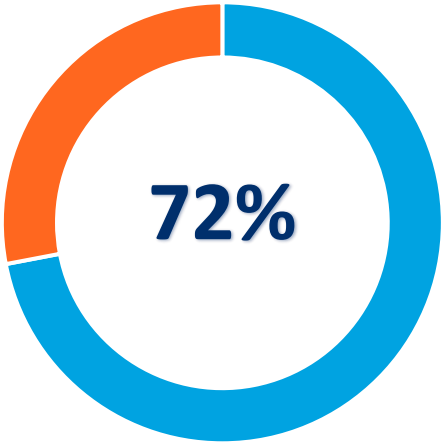
Background

Progression of Type 2 Diabetes Treatment

- Due to natural progression of type 2 diabetes, maintenance of glycemic targets requires a stepwise approach to treatment in order to achieve and maintain glycemic control and avoid complications[1,2]
  - Comprehensive lifestyle modifications combined with metformin
  - Addition of up to 3 oral medications or GLP-1 RA injection
  - Addition of basal (long-acting) insulin
  - Addition of mealtime (fast-acting) insulin
- Addition of medications may require termination or modification of existing medication regimen

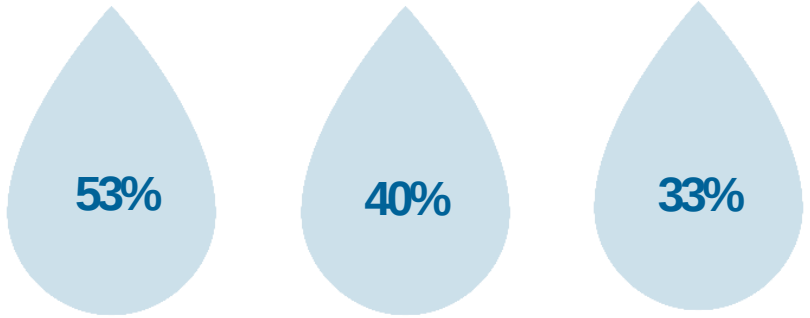
Background

- Known barriers to insulin use:
  - Multiple injections
  - Interference with daily activities
  - Injection pain
  - Embarrassment
  - Impaired quality of life



of people on multiple daily injections (≥ 3 injections/day) do not take insulin outside the home[3]

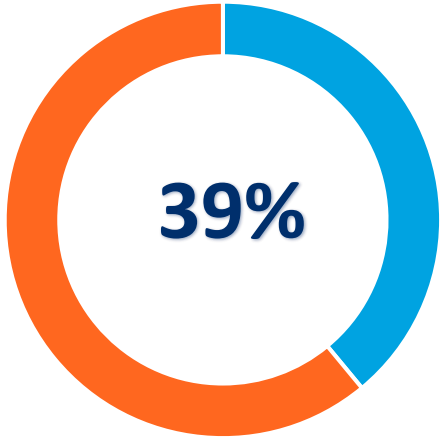
- Missed doses:



forgot to dose[4]

forgot their insulin[4]

skipped on purpose[4]

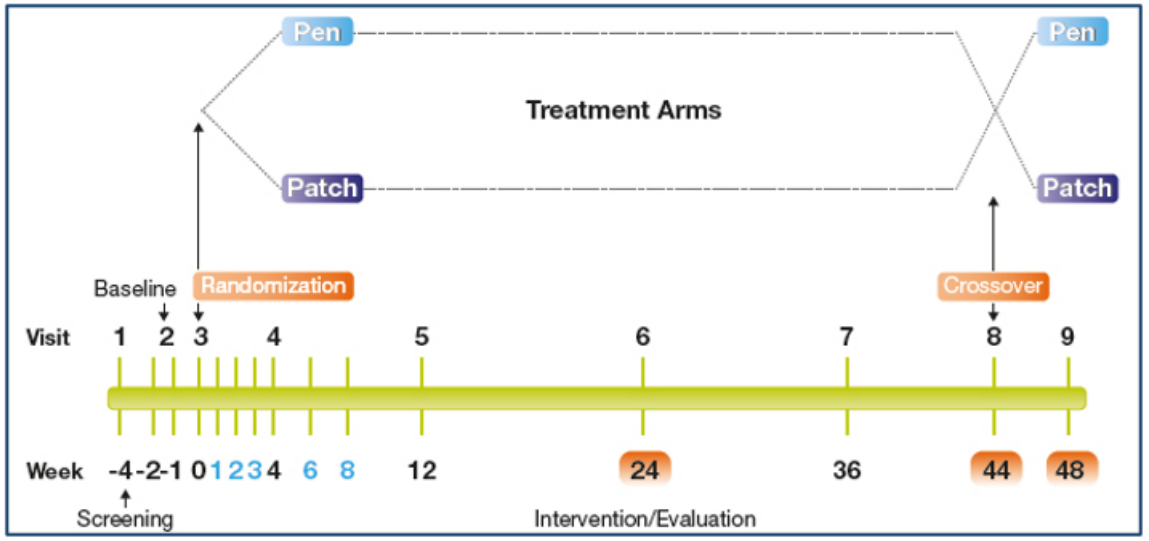


If 39% of all meal-related boluses are missed, the A1C can be negatively impacted by 1.8%[4]

Background

- A 3-day wearable insulin Patch may lessen known barriers to mealtime dosing by being: convenient, discreet, and providing injection-free dosing
- Dosing administered in 2-unit increments
- 2-button safety mechanism ensures that dosing only occurs when intended – designed to prevent accidental dosing
- Buttons lock to notify: stay in “squeezed” position when Patch is empty or cannula is occluded
- Adhesive designed to keep Patch on skin for up to 3 days
- Water resistant to a depth of 1 meter for up to 30 minutes

Study Methods & Published Clinical Outcomes[5]



- Multi country 48 week crossover study (n=278, age 22-75) for people with type 2 diabetes
- Randomized 1:1 to either a 3-day wearable insulin Patch or to pen injections
- Participants were instructed how to perform self-titration of mealtime insulin.
- Transitioned subjects from basal-only to basal insulin plus mealtime insulin dosing
- Published data showed the Patch was equivalent to pen in all clinical measures, including A1C,[5] self-monitoring blood glucose (SMBG) values,[5] and time in range (TIR)[6] with similar hypoglycemic events[5]

Patient Preference Data[5]

% Favorable response (95% CI)[a,b]	Insulin Patch group (n=123)	Insulin pen group (n=109)	P value for comparison
Taking mealtime insulin was easy	92.7 (88.8, 96.5)	78.0 (71.5, 84.5)	P<0.01
Always had mealtime insulin with me	91.2 (86.8, 95.5)	72.5 (65.3, 79.8)	P<0.001
Taking mealtime insulin was painless	90.2 (85.8, 94.6)	70.4 (63.1, 77.6)	P<0.001
Could do things on the spur of the moment	87.0 (82.0, 92.0)	66.7 (59.2, 74.1)	P<0.001
Dosed without attracting attention	93.5 (89.8, 97.2)	68.8 (61.5, 76.1)	P<0.0001
Felt comfortable using it socially	89.3 (84.7, 93.9)	71.0 (63.8, 78.2)	P<0.001
Recommend for mealtime insulin	91.0 (86.7, 95.2)	78.9 (72.5, 85.3)	P=0.01

[a]"Favorable" defined as 4 or 5 on a Likert scale of 1–5 for each statement (1=strongly disagree, 2=disagree, 3=neutral, 4 = agree, 5 = strongly agree).
[b]Higher % is better (higher proportion of patients agreeing [4] or strongly agreeing [5] with statement).
CI=confidence interval

- The Patch had several advantages over pen in terms of barriers to insulin administration[5]
- The Patch was recommended more often than the pen for mealtime insulin[5]

Post-Hoc Analysis Rationale and Methods

- Original analyses of patient reported outcomes was generalized and could be enhanced by post-hoc analysis of treatment satisfaction within patient subgroups based on baseline demographic and clinical characteristics
- We performed post-hoc analysis of between-arm changes in overall treatment satisfaction in subgroups based on age, sex, and baseline body mass index (BMI)
- Subjects included 27% aged ≥ 65 (n=35), 39% female (n=108), and 66% BMI >30 – ≤ 40 kg/m^2 (n=92)
- Insulin Delivery System Rating Questionnaire (IDSRQ) Overall Satisfaction was analyzed by testing for interactions of insulin delivery method (Patch vs pen) with age, sex, and BMI

Post-Hoc Analysis Results

	Total	Gender		Age		Baseline BMI		
		Female	Male	<65 yrs	≥65 yrs	Normal BMI >18.5	Overweight BMI >25	Obese BMI >30
Patch	n=136	n=56	n=80	n=96	n=35	n=7	n=37	n=92
OS Change	-0.7	-0.7	-0.8	-0.8	-0.6	-0.3	-0.9	-0.7
Pen	n=138	n=52	n=86	n=93	n=38	n=5	n=35	n=98
OS Change	-0.5	-0.5	-0.4	-0.5	-0.4	0.0	-0.4	-0.5

OS Overall Satisfaction, Scoring 1-4, lower score is better.
BMI Body Mass Index.
274 subjects provided OS data at baseline and week 24.

- Within the overall study, sample participants were more satisfied with the Patch than pen ($p<0.01$)[5]
- There were no significant ($p<0.05$) interactions between baseline patient characteristics and insulin delivery method; participants in every subgroup were more satisfied with the Patch than pen

Conclusions

- Patients with T2D reported fewer barriers and more advantages in using the Patch than pen for insulin delivery; this may reduce missed insulin doses, especially mid-day administration away from home
- Study participants were more satisfied in using the Patch than pen for insulin delivery; this may contribute to sustained maintenance of mealtime insulin therapy
- Post-hoc analysis indicated that subjects in every age, gender, and BMI subgroup were more satisfied with the Patch than pen; resistance to new technology was not seen among subjects above age 65 years
- The wearable insulin Patch was well-tolerated by all patient subgroups and may be appropriate for all subgroups

References

1. *9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2020.* Diabetes Care, 2020. **43**(Supplement 1) p. S98-S110.
2. Holman, R.R., et al., *Three-year efficacy of complex insulin regimens in type 2 diabetes.* N Engl J Med, 2009. **361**(18): p. 1736-47.
3. Randløv, J. and J.U. Poulsen, *How Much Do Forgotten Insulin Injections Matter to Hemoglobin A1c in People with Diabetes? a Simulation Study.* Journal of Diabetes Science and Technology, 2008. **2**(2): p. 229-235.
4. Grabner, M., et al., *Using observational data to inform the design of a prospective effectiveness study for a novel insulin delivery device.* ClinicoEconomics and Outcomes Research, 2013. **5**: p. 471+.
5. Bergenstal, R.M., et al., *Implementation of Basal-Bolus Therapy in Type 2 Diabetes: A Randomized Controlled Trial Comparing Bolus Insulin Delivery Using an Insulin Patch with an Insulin Pen.* Diabetes Technol Ther, 2019. **21**(5): p. 273-285.
6. Johnson, M.L., et al., *Comparing patch vs pen bolus insulin delivery in type 2 diabetes using continuous glucose monitoring metrics and profiles*, in *78th Scientific Sessions of the American Diabetes Association*. 2018: Orlando, FL.