

Comparing ITCA 650, continuous subcutaneous delivery of exenatide via DUROS® device, vs. twice daily exenatide injections in metformin-treated type 2 diabetes

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Disclosures

- Grants/Research Support (via Veterans Medical Research Foundation/ University of California San Diego): Amylin, Bristol-Myers Squibb/ AstraZeneca, Johnson & Johnson, National Institutes of Health-NIMH & NIDDK, Novartis Pharmaceuticals
- Consultant: Amylin, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Isis, Intarcia, Novo Nordisk, Roche, Sanofi-Aventis, Takeda
- Shareholder: Amylin Pharmaceuticals, Inc. (Pension Stock)

GLP-1 Therapy Evolution - Novel Injection-Free Continuous Delivery Option

*6 – 12 Months
GLP-1 Therapy
(ITCA 650)*

Sustained Glucose &
Weight Reductions
100% Compliance
No Injections
Improved Tolerability

*Earlier &
Broader Use*

*Better Patient
Outcomes*

*Weekly
GLP-1 Therapy*

Fewer Injections
Improved HbA1c Drop
Enhanced Tolerability

*Injectables
Often
Relegated to
3rd – 4th line
use*

*Daily
GLP-1 Therapy*

Potent A1c Reduction
Effective Weight Loss
Low Hypoglycemia Risk

ITCA 650 – DUROS[®] Continuous Delivery of Exenatide

- Implantable osmotic mini-pump
- Continuous subcutaneous delivery of exenatide
 - reduces persistent nausea
 - ensures adherence
 - provides consistent glycemic control
- Delivery for up to 12 months from a single device
- Inserted in a 10 minute in-office reimbursed procedure
 - performed by MD, PA or NP



ITCA 650 Phase 2 Type 2 Diabetic Subjects

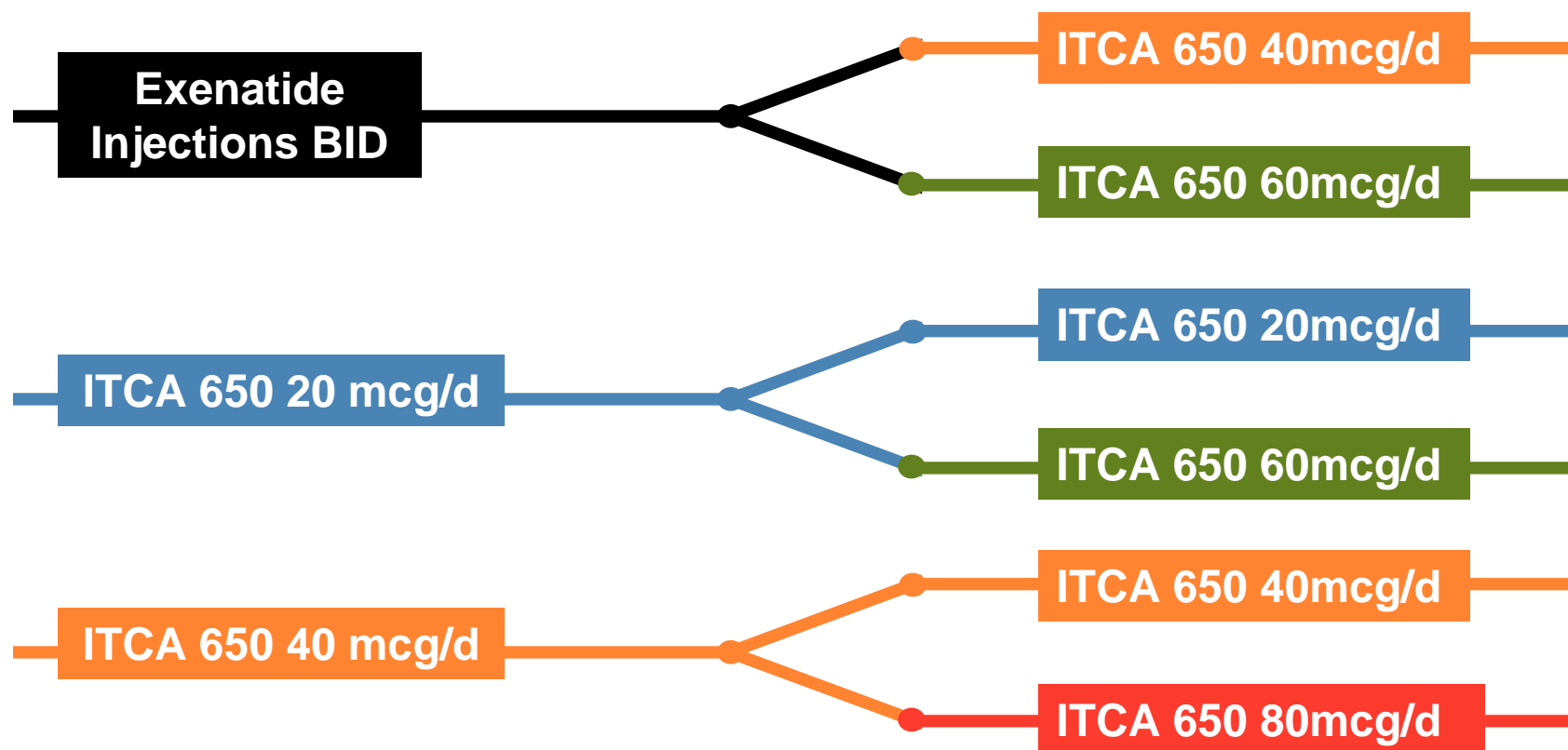
- Multi-center, randomized, open label, US trial
 - 50 sites, 150 patients
 - metformin-only background therapy
- Study weeks 1 - 12
 - ITCA 650 20 & 40 mcg/day
 - vs. active control of exenatide BID injection therapy
- Study weeks 13 - 24
 - switch all exenatide injection subjects to ITCA 650
 - dose escalate ½ of ITCA subjects to 60 or 80 mcg/day

Phase 2 Design

Metformin monotherapy, HbA1c ≥ 7 - ≤ 10

Weeks 1 - 12

Weeks 13 - 24

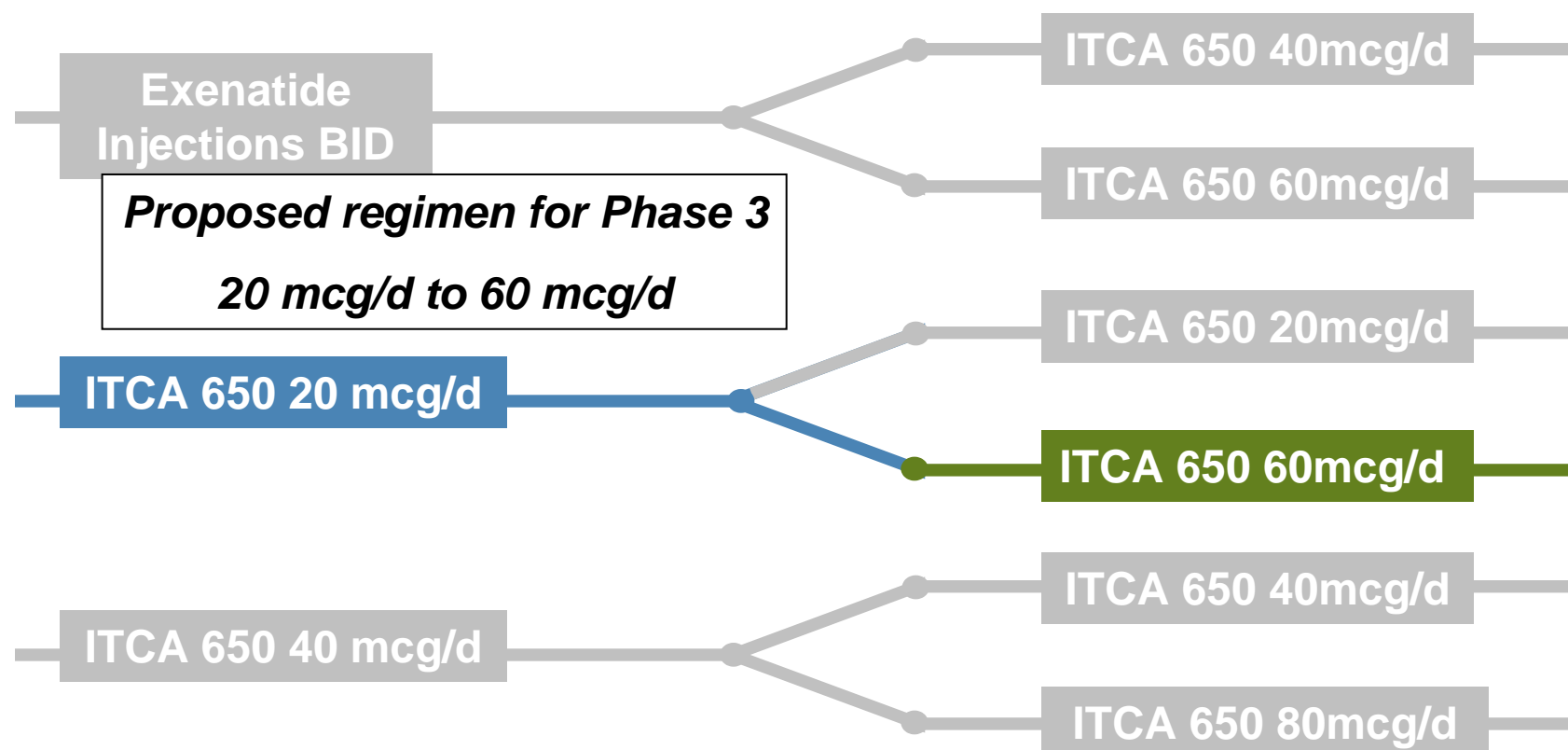


Phase 2 Design

Metformin monotherapy, HbA1c $\geq 7 - \leq 10$

Weeks 1 - 12

Weeks 13 - 24



Patient Demographics

Representative T2D, Mean HbA1c ~ 8.0%

	Exenatide injections N=53	ITCA 650 20 mcg/d N=51	ITCA 650 40 mcg/d N=51
Age (yrs)	53.8	54.0	53.3
Gender (M/F)	29/24	25/26	23/28
Duration of diabetes (yrs)	5.2	6.2	8.4
HbA1c (%)	8.0	7.9	8.0
Weight (kg)	93.4	93.5	91.5
BMI (kg/m ²)	33.0	33.5	31.8

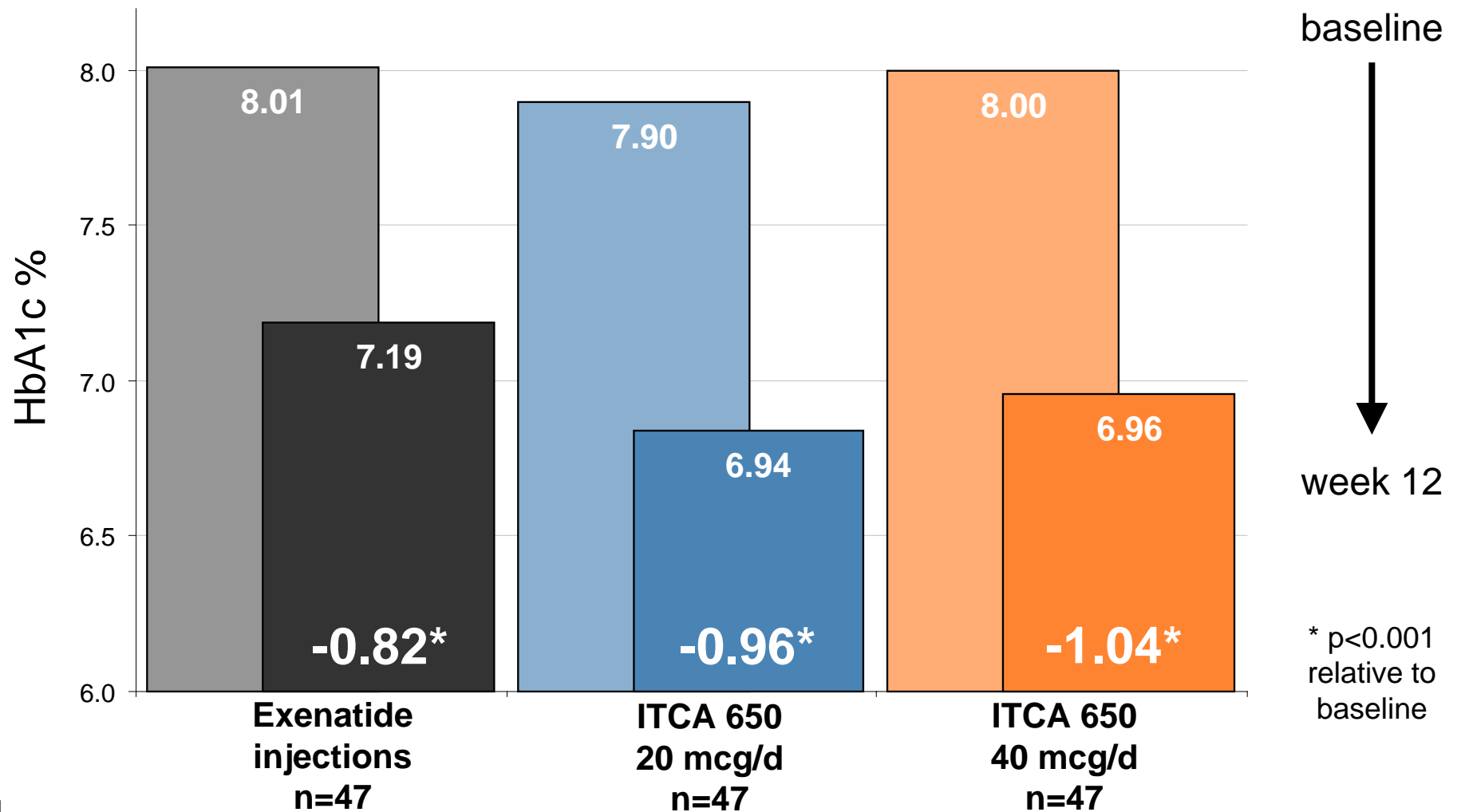
Overall Study Disposition

	ITCA 650	Exenatide Injections
Weeks 1-12		
Completion rate	93%	89%
Withdrawals due to nausea	3.9%	5.7%
Withdrawals prior to re-randomization		7.7%

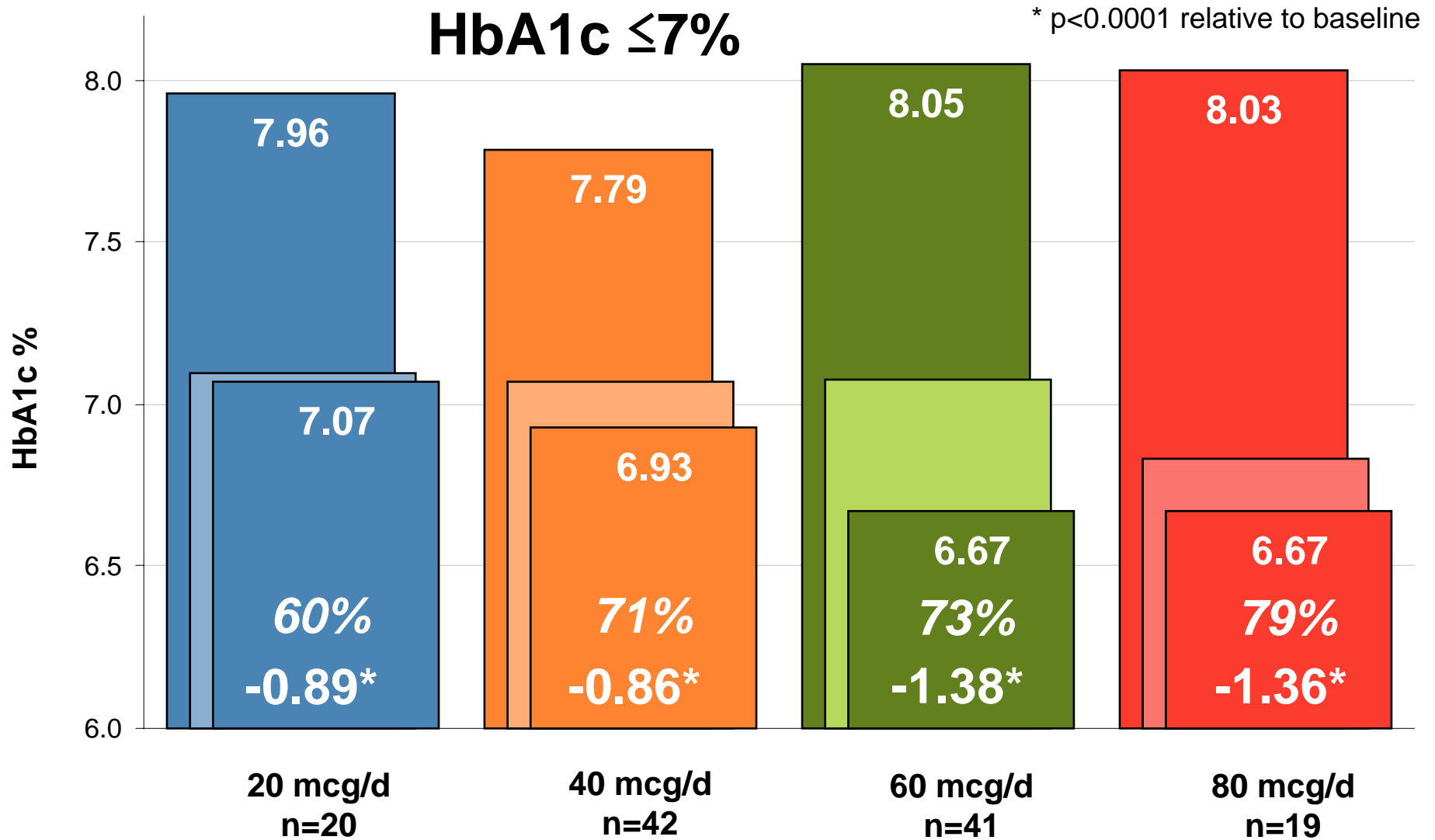
Overall Study Disposition

	ITCA 650	Exenatide Injections
Weeks 1-12		
Completion rate	93%	89%
Withdrawals due to nausea	3.9%	5.7%
Withdrawals prior to re-randomization		7.7%
Weeks 13-24		
Completion rate	95%	NA
Withdrawals due to nausea	<1%	NA

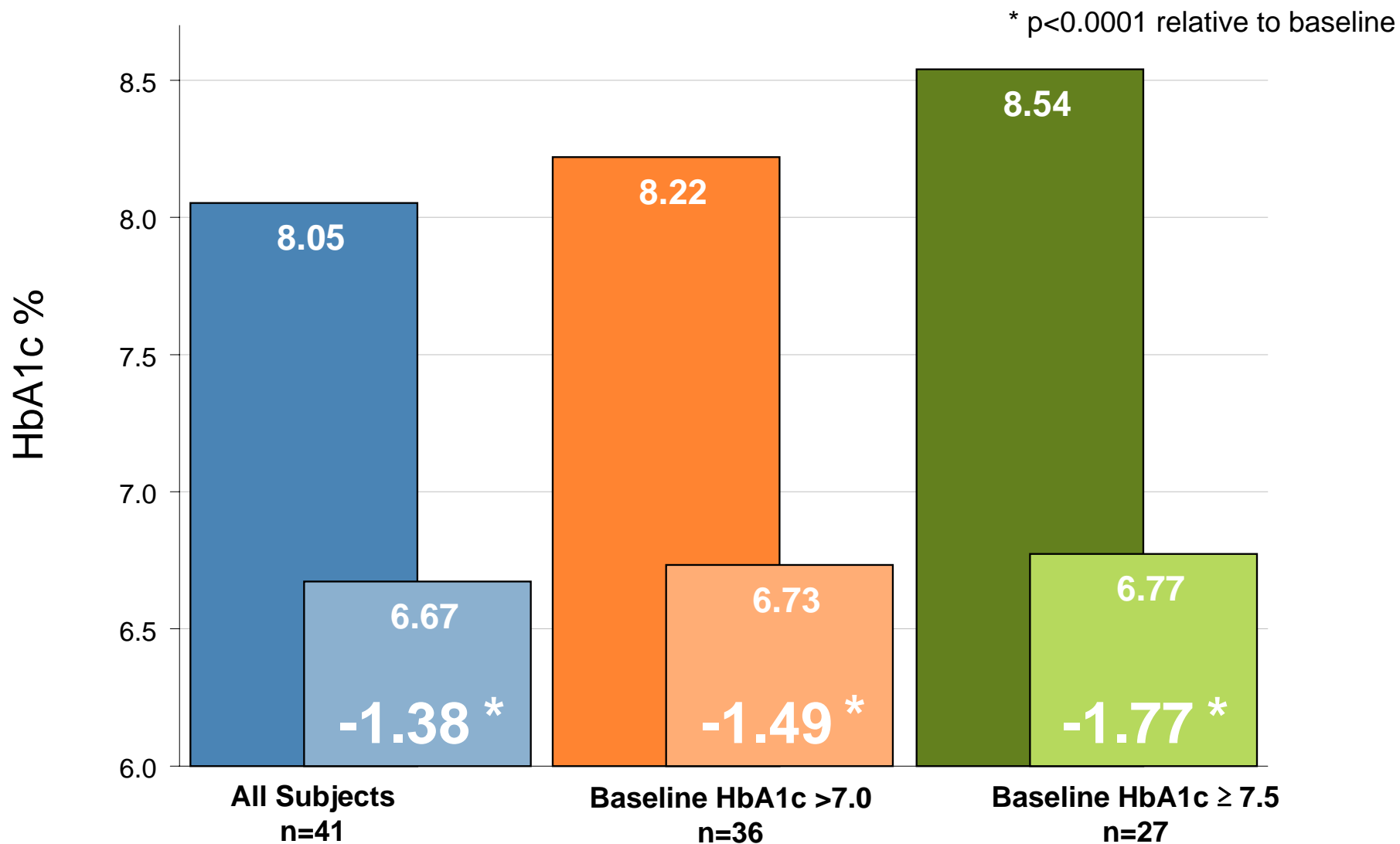
Change in HbA1c at Week 12



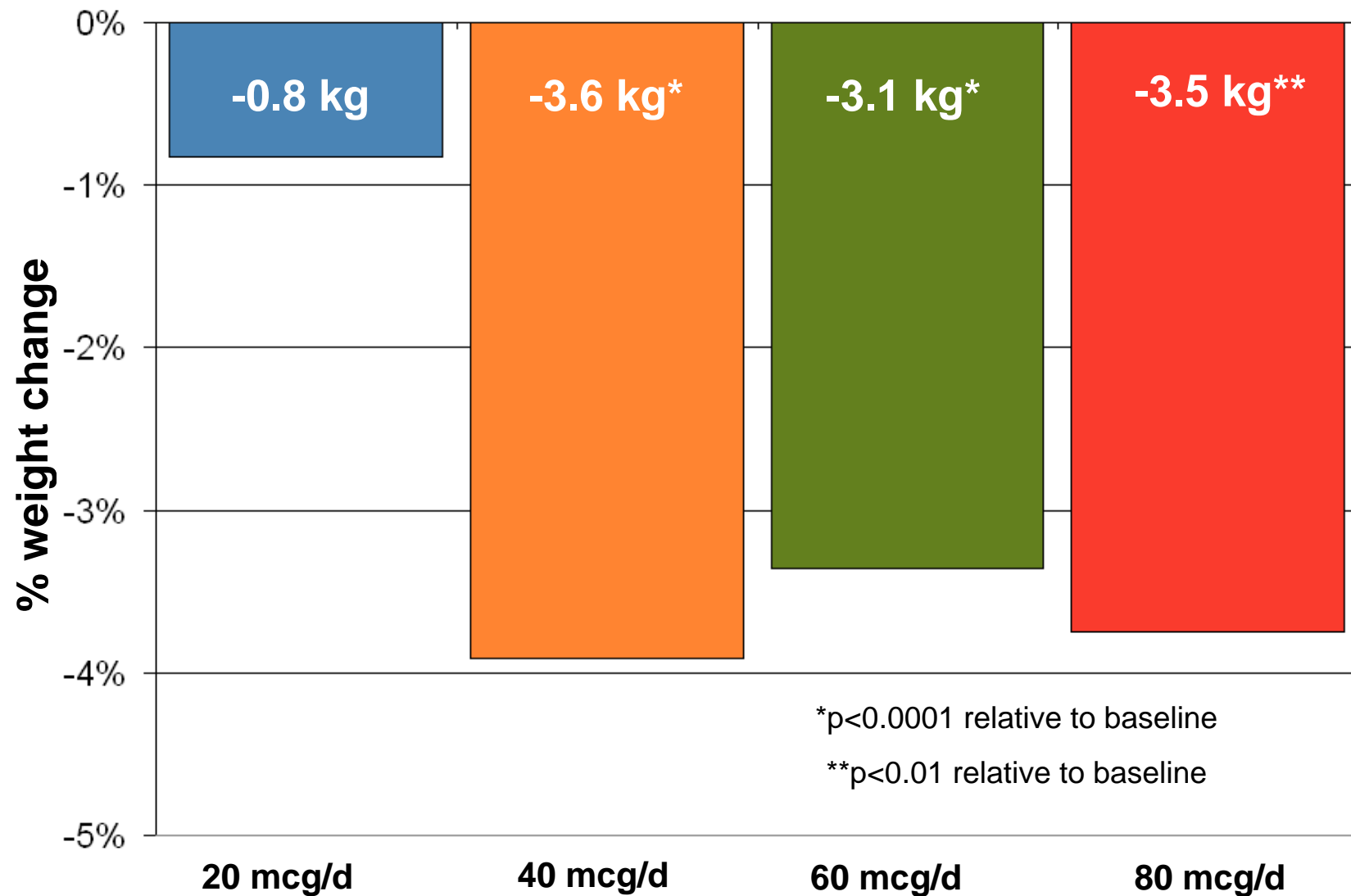
Change in HbA1c at Weeks 12 and 24



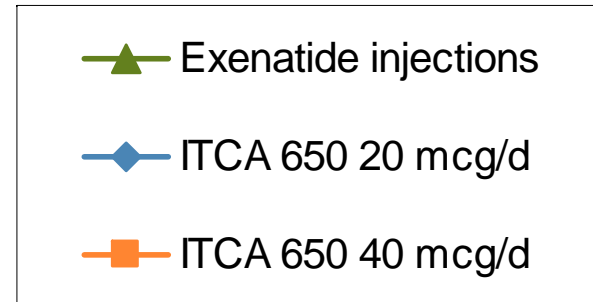
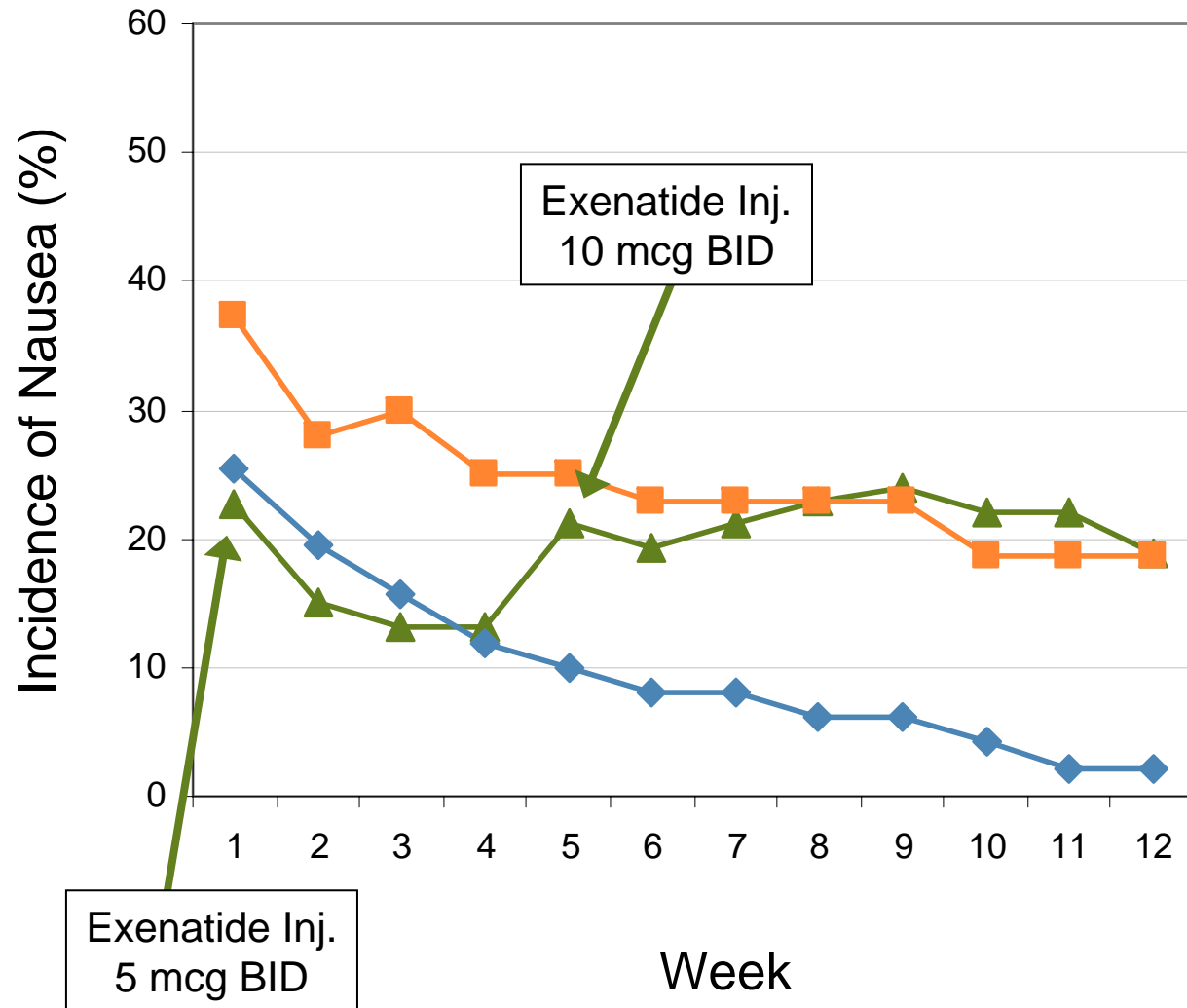
ITCA 650 Performance: Higher Baseline Subjects on 60 mcg/d



Change in Weight at Week 24



Improved Tolerability with ITCA 650 20 mcg/d vs. Exenatide Injection During Weeks 1 - 12

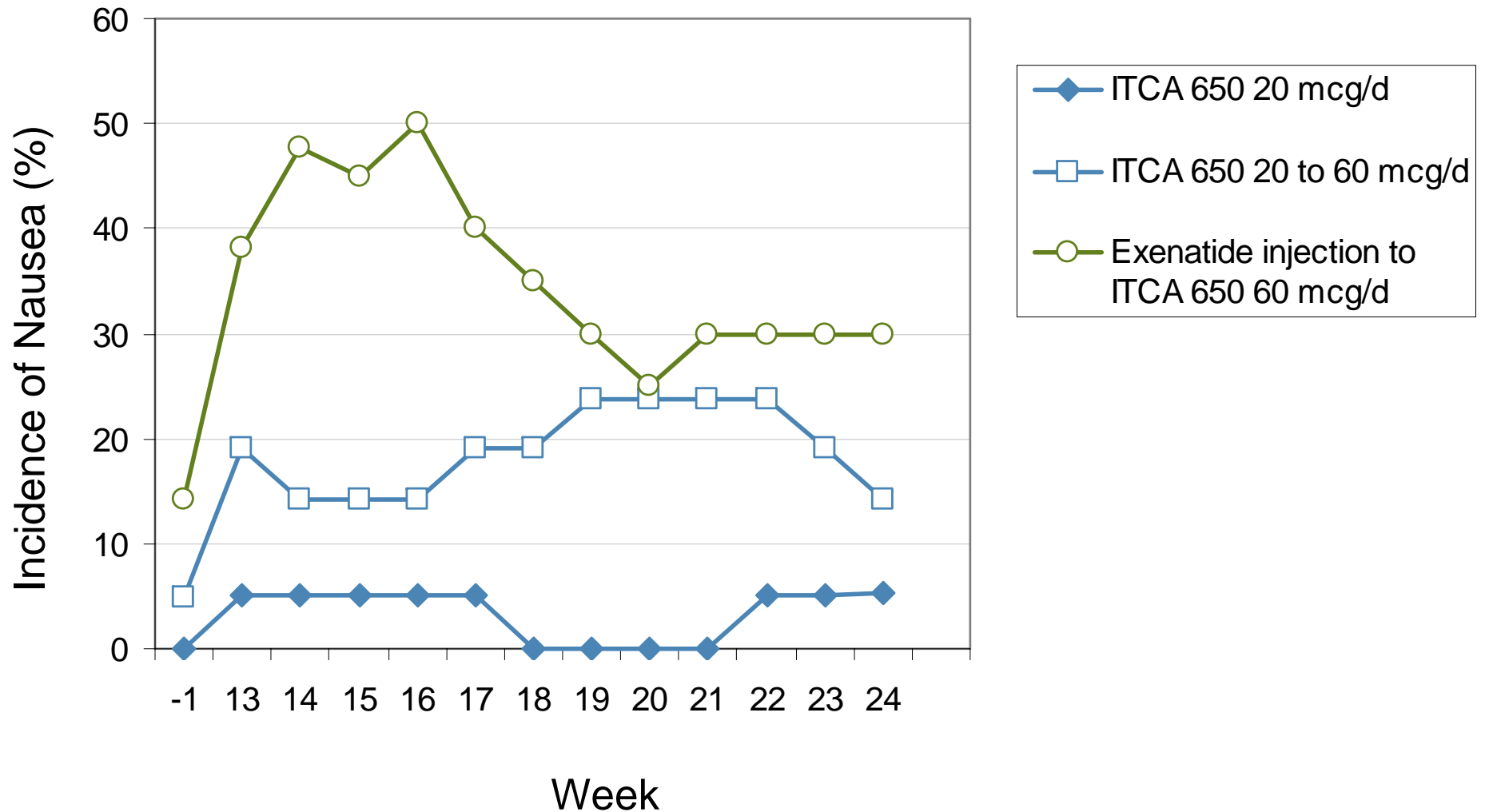


Mean duration of nausea

ITCA 650 20 mcg/d – 17 days

Exenatide Inj. – 47.7 days

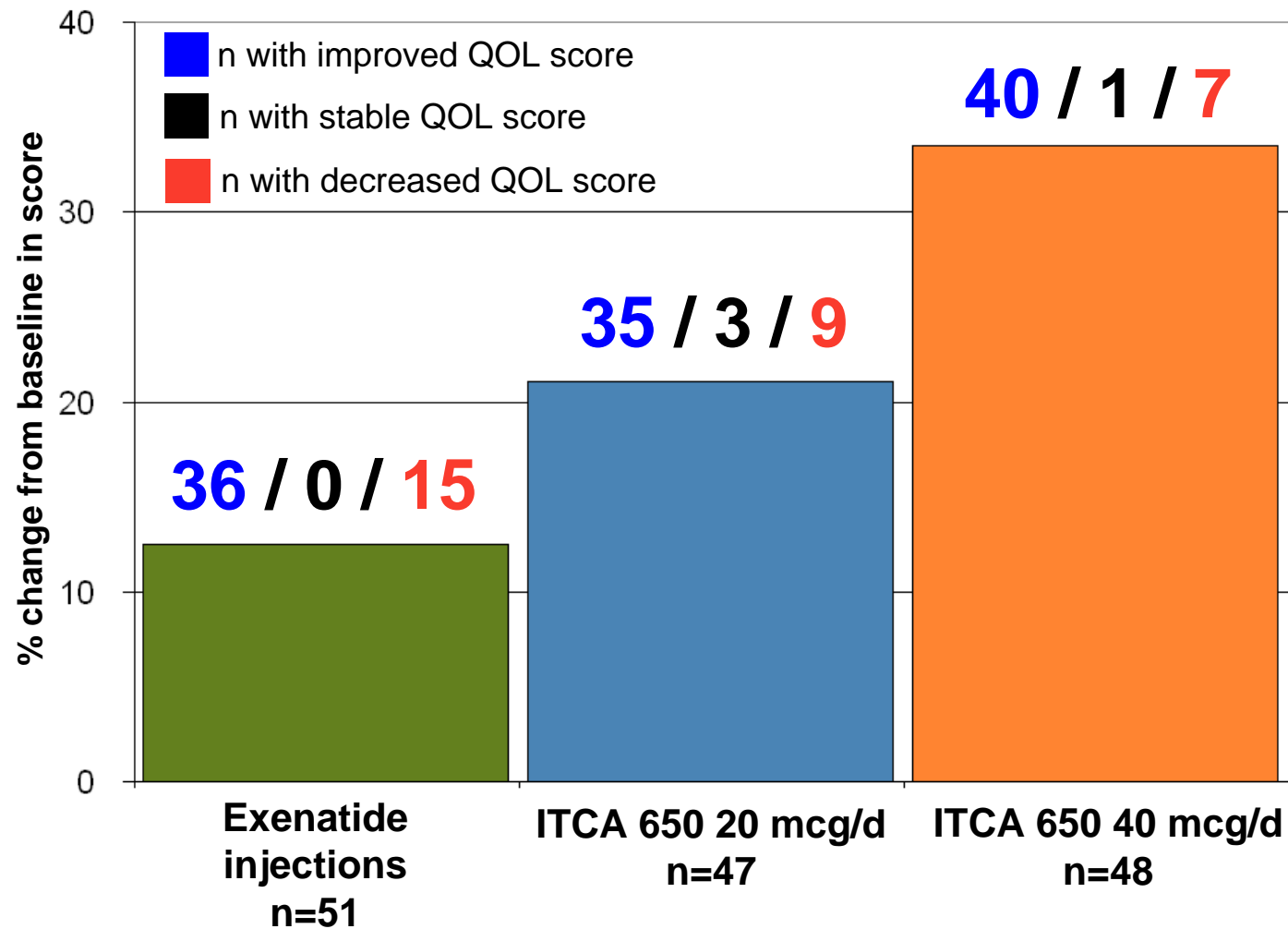
Dose Escalation to ITCA 650 60 mcg/d is Well-Tolerated During Weeks 13 - 24



Tolerability & Persistence on ITCA 650 Treatment

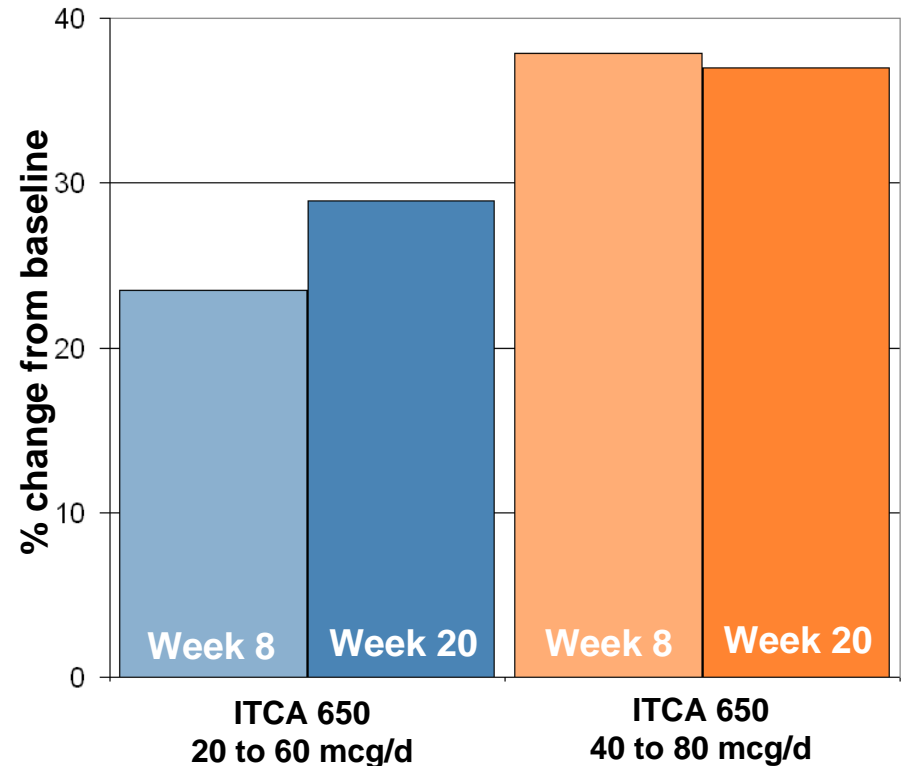
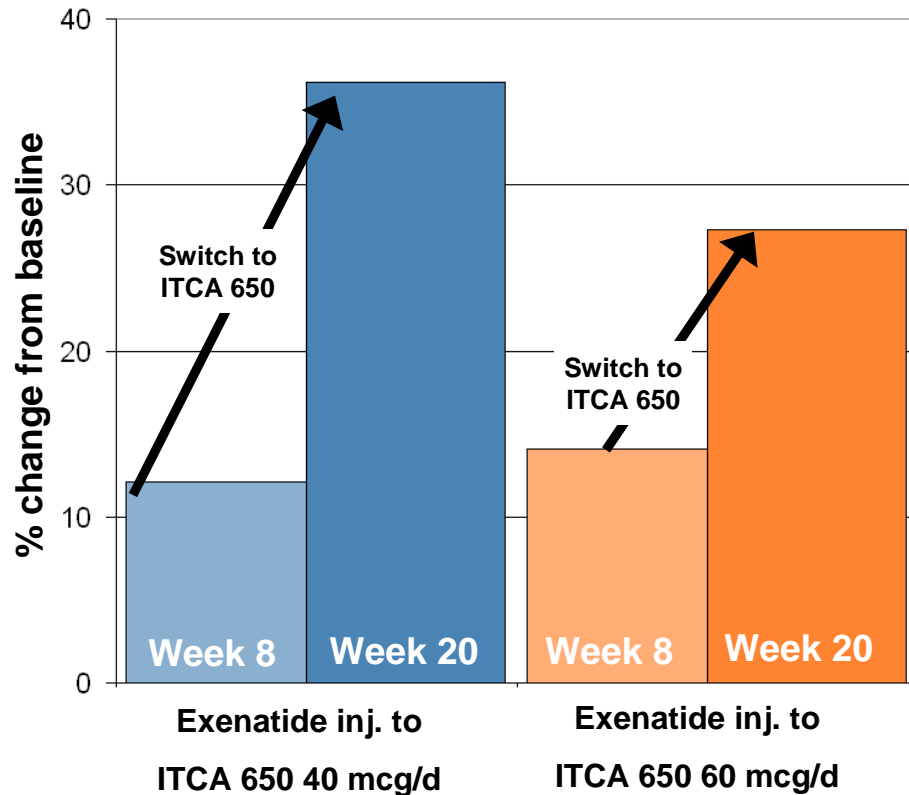
- ITCA 650 20 to 60 mcg/d
 - no withdrawals
 - six subjects reported nausea during weeks 13 - 24
 - four also reported nausea during weeks 1-12
 - four were at sites participating in the continuation phase, all four elected to continue treatment
 - no reports of vomiting
- Optional continuation treatment
 - weeks 24 - 48
 - 85% of eligible subjects elected to continue treatment

Improved Quality of Life Demonstrated with ITCA 650 at Week 8



Anderson, RT, Girman, CJ, et al. *Diabetes Care* 32:51, 2009

Quality of Life Assessment Change from Week 8 to Week 20



ITCA 650 Conclusions

- ITCA 650 at 20 mcg/d, escalating to 60 mcg/d, resulted in the best tolerability and activity profile
- Significant reductions in HbA1c and weight at 24 weeks
- Improvement in patient-reported QOL
 - greater with ITCA 650 vs. exenatide injection
 - increased when switching from exenatide injection to ITCA 650
- Unique potential for long-term optimal treatment of T2D
 - the first GLP-1 therapy that ensures compliance without self injection

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