National Medical Association

FAMILY MEDICINE

DIABETES UPDATES LUNCHEON SYMPOSIUM

Integrating GLP-1 Inhibitors Into a Comprehensive Diabetes Care Management Regimen – The Incretin Experience

SYLLABUS

Monday, August 3, 2015

12:40 – 3:00 p.m. | Room 420B

COBO Center

Detroit, Michigan

Supported by educational grants from **Janssen, Merck Sharp & Dohme Corp, and Novo Nordisk**

Faculty Disclosures

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Consulting / Speakers' Bureau:
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[1]*This speaker declares no relevant relationship with commercial entities.*

New Models of Care in the Management of Type 2 Diabetes: Focus on Incretin Therapies

Introduction

We know that Diabetes has reached epidemic proportions, both worldwide and nationally. According to the American Diabetes Association, the prevalence of Diabetes in 2012, was 29.1 million Americans, or 9.3% of the population. 8.1 million of these Americans were undiagnosed.[1] The incidence of diabetes in 2012 was 1.7 million new diagnoses/year; in 2010 it was 1.9 million.[2]

Diabetes not only affects the quality of life of people with the disease, but also presents a tremendous economic burden on our health care system. Diabetes, including diagnosed and undiagnosed diabetes, pre diabetes, and gestational diabetes mellitus (GDM) and their complications, accounted for $218 billion in direct and indirect costs in 2007 alone.[3] Much of the economic burden of diabetes is related to its complications, including blindness, amputation, kidney failure, heart attack, and stroke.

Gaps/Needs Assessment

African American patients are more likely than white patients to have diabetes. The risk of diabetes is 77% higher among African Americans than among non-Hispanic white Americans.[4] The rates of diagnosis of diabetes in non-Hispanic African Americans is 18.7% compared to 7.1% of non-Hispanic white Americans. That is 4.9 million African American adults with diagnosed or undiagnosed diabetes.[5] In 2006, African-American men were 2.2 times more likely to start treatment for ESRD related to diabetes than non-Hispanic white men. In the same year, African Americans with diabetes were 1.5 times more likely to be hospitalized and 2.3 times more likely to die from diabetes than non-Hispanic whites.[6] African Americans are almost 50% more likely to develop diabetic retinopathy than non-Hispanic whites.[7]

References:

1. http://www.diabetes.org/diabetes-basics/statistics/#sthash.dsck9TDB.dpuf
2. http://www.diabetes.org/diabetes-basics/statistics/#sthash.FXE5LhiB.dpuf
3. Dall TM, Zhang Y, Chen YJ, Quick WW, Yang WG, Fogli J: The economic burden of diabetes. Health Aff 29:297–303, 2010
4. Centers for Disease Control and Prevention: National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States. Atlanta, Ga., U.S. Department of Health and Human Services, 2011
5. National Diabetes Information Clearinghouse. National diabetes statistics, 2011 [article online]. Available from http://www.diabetes.niddk.nih.gov/dm/pubs/statistics. Accessed 7 March 2012
6. U.S. Department of Health and Human Services Office of Minority Health: Diabetes and African Americans [article online]. Available fromhttp://minorityhealth.hhs.gov/templates/content.aspx?lvl=2&lvlID=51&ID=3017. Accessed 23 January 2012
7. American Diabetes Association: African Americans & complications [article online]. Available from http://www.diabetes.org/living-with-diabetes/complications/african-americans-and-complications.html. Accessed 7 March 2012

Intended Audience

This program is intended for primary care and family medicine physicians, endocrinologists, internists, nurse practitioners and other healthcare professionals interested in diabetes.

Objectives

Upon completion of this session, participants should be able to:

1. Summarize the efficacy, safety, and tolerability of GLP-1 agonists.
2. Identify patients who would benefit from GLP-1 agonist therapy and those for whom it may not be appropriate.
3. Describe in patient-appropriate terms how GLP-1 agonists can improve glycemic control.
4. Compare and contrast GLP-1 agonists, other incretin-based therapies, and traditional oral agents.
5. Develop evidence-based treatment plans to incorporate incretin therapies in combination with oral agents and insulin for optimal glycemic control

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Program Agenda

MONDAY, AUGUST 3, 2015

12:40 – 1:00	Registration and Luncheon
1:00 – 1:10 **Moderator**	**Introduction and Program Overview/Pre-Test** **Warren A. Jones, M.D.** Endowed Chair in Health Disparities Research Dillard University New Orleans, Louisiana Professor Emeritus of Family Medicine University of Mississippi School of Medicine Chair Emeritus, NMA Family Medicine Section Ridgeland, Mississippi
1:10 – 1:35	**Characteristics and Functions of Endogenous Incretins: Review of Current ADA/AACE Diabetes Guidelines** **Morris L. Brown, M.D.** Associate Clinical Professor of Family Medicine Wright State University Medical School Providence Medical Group Dayton, Ohio
1:35 – 1:40	Audience Interaction/Questions and Answers
1:40 – 2:05	**Review of Clinical Evidence Supporting the Beneficial Effects of Incretins on Body Weight and the Cardiovascular System** **Kwabena Adubofour, M.D.** Associate Clinical Professor Department of Internal Medicine University of California-Davis Medical Center Sacramento, California Medical Director East Main Clinic and Stockton Diabetes Intervention Center Stockton, California
2:05 – 2:10	Audience Interaction/Questions and Answers
2:10 – 2:35	**Using Incretin-Based Treatments as Monotherapy and in Combination with Anti-Diabetes Medications** **James R. Gavin, III, M.D. Ph.D.** Clinical Professor of Medicine Endocrinology Division Department of Internal Medicine Emory University School of Medicine Atlanta, Georgia
2:35 – 2:40	Audience Interaction/Questions and Answers
2:40 – 3:00	**Panel Discussion/Post-Test/Audience Interaction with Faculty** **Kwabena Adubofour, M.D.** **Morris L. Brown, M.D.** **James Gavin, Jr., M.D., PhD** **Warren A. Jones, M.D.**

Warren A. Jones, M.D.

Endowed Chair in Health Disparities Research
Dillard University
New Orleans, Louisiana
Professor Emeritus of Family Medicine
University of Mississippi School of Medicine
Chair Emeritus, NMA Family Medicine Section
Ridgeland, Mississippi

Moderator

Warren A. Jones, M.D., a family physician and retired Captain in the U.S. Navy, is the Endowed Chair of Health Disparities Research and Professor of Chemistry at Dillard University in New Orleans, LA. He was most recently the Director of Healthcare Quality and Disparities at Provider Resources, Inc. He was the founding Executive Director of the Mississippi Institute for Improvement of Geographic Minority Health at the University of Mississippi Medical Center where he is a Professor Emeritus of Family Medicine and has also been a Distinguished Professor of Health Policy, Professor of Family Medicine and a Professor of Anesthesiology. He is a previous Associate Vice Chancellor for Multicultural Affairs at the University of Mississippi and past Director of the Mississippi Area Health Education Centers (AHEC).

He was previously the Executive Director of the Division of Medicaid in the Office of the Governor of Mississippi, the state's health program for 25% Mississippi's total population. He currently serves on the congressionally Mandated Advisory Committee on Disability compensation for the Veterans Administration. He has also served on the congressionally mandated Council of Councils at the National Institutes of Health (NIH). He has also served as Chair Designee of the National Advisory Council to the NIH's National Institute on Minority Health and Health Disparities (NIMHD). He has served on the Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group (TAG) to the Secretary of Health and Human Services and on the National Commission for Prevention Priorities. He has completed his service on the Advisory Panel on Outreach and Education for the Centers for Medicare and Medicaid Services. He also has served on the Board of Trustees for his Alma Mater, Dillard University in New Orleans, LA. He currently serves as a Trustee at St. Andrews Episcopal School in Ridgeland, MS. He Chairs the Board of Directors for the American Health Information Management Association Foundation (AHIMA) and serves on the Board of the Diabetes Foundation of Mississippi.

Dr. Jones is a past President of the American Academy of Family Physicians, an 118,300-member primary care specialty society. He has also served Chair of the AAFP's Board of Directors and President-elect of the Academy. He is the Chair Emeritus of the Family Medicine Section of the National Medical Association (NMA). He has also Chair of the Maternal Child Council, Past Chair of the Family Medicine Section and Aerospace & Military Medicine Section of the NMA. He also served on the Minority Affairs Governing Council for the American Medical Association (AMA). He was most recently a Co-Lead for the Behavioral Health Subgroup of the Eunice Kennedy Shriver-National Institute of Child Health and Human Development Visioning Project.

Jones retired from the United States Navy and his position as the first African American Medical Director of the over 10 million member TRICARE Military Health Program, the military's health insurance program

in 2001. He previously served as Director of Medical and Clinical services for the Pacific region of TRICARE coordinating care for U.S. service members and their families from Alaska to Madagascar.

Jones has served on the *President's Select Panel* on Surviving and Living after Cancer, the Chiropractic Implementation Committee for the U.S. Secretary of Veterans Affairs and on the Secretary's *Chiropractic Advisory Committee*. In addition, Jones was a member of the *Expert Panel for the Medicaid Disease Management Initiative* for the Center for Health Care Strategies, the Robert Wood Johnson Foundation and the Kaiser Permanente Foundation,. He was a member of the Key Stakeholders Advisory Board to the Evidence Based Research Center for the Agency for Healthcare Research and Quality (AHRQ). He is currently a member of the Board of Directors of the Mississippi Diabetes Foundation and has previously served on the Board of the National Health Council and the National Advisory Council to *Rewarding Results*, an advisory panel to the Robert Wood Johnson Foundation and the California Health Foundation which led to the development of the Pay for Performance initiative in health care. He is also a member of the expert panel for the Innovations in *Prevention Awards*, sponsored by Health and Human Services Secretary, Tommy Thompson.

Jones received his undergraduate degree in chemistry from Dillard University in New Orleans. He received his medical degree from Louisiana State University School of Medicine in 1978, and completed a family medicine residency at the Naval Hospital in Pensacola, Fla. Jones also earned a fellowship in Adolescent Medicine at the Naval Hospital in San Diego. Jones is a Fellow of the AAFP, an earned degree awarded to family physicians for distinguished service and continuing medical education.

Jones has extensive military and medical teaching experience, which includes serving as special assistant to the U.S. Navy Surgeon General and was Chair of the Department of Family Medicine at the Naval Hospital in Charleston, S.C. Jones has received numerous military honors including the Defense Superior Service Medal and the Navy Commendation Medal for superior performance. He received the Meritorious Service Medal three times. He was recently honored as the Outstanding Black Educator in Mississippi by the Board of the Institutions of Higher Learning. He is married to the former Gennie Lacy of Pickens, MS and has six children: Aaron, Keith, Winston, Deanna, Cassandra and Madison.

Morris L. Brown, M.D.

Associate Clinical Professor of Family Medicine
Wright State University Medical School
Providence Medical Group
Dayton, Ohio

Morris L. Brown, M.D., is a Family Practice physician who has practiced in the Dayton area for over 35 years. Dr. Brown earned his medical degree from Meharry Medical School in Nashville, Tennessee. Upon completing an internship at the Wright-Patterson Air Force Base in Ohio, he served as a Captain in the Medical Corps and Chief of Flight Medicine in the United States Air Force. Subsequently, he completed residency training in family practice at Miami Valley Hospital in Dayton, Ohio.

Dr. Brown is certified by the American Board of Family Practice. He currently serves on the Board of CareSource and The Physicians Charitable Foundation. He is the Medical Director for three area nursing and rehabilitations centers and one of the Medical Directors for Hospice of the Miami Valley. Dr. Brown served as President of the Gem City Medical, Dental and Pharmaceutical Association and as Treasurer of the Montgomery County Medical Society. Currently he serves as Associate Professor Wright State Medical School.

He continues to be an advocate for his patients and the community while serving as member of a pharmaceutical minority Advisory Board, local non- profit initiatives, seeing patients at his private practice Dayton Primary & Urgent Care, providing care at the 24 hours St E's Urgent Care and the weekly radio program on WDAO 'Health Living.

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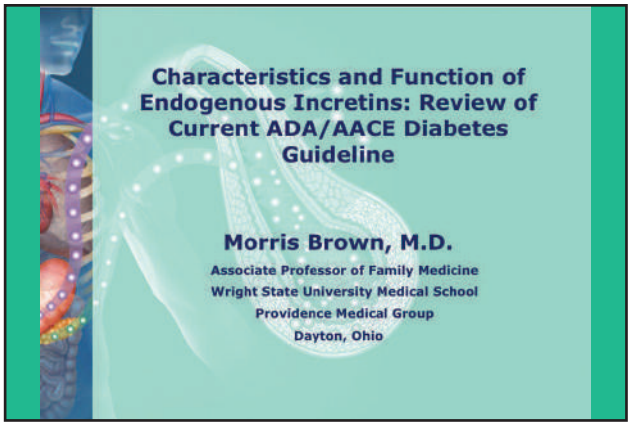

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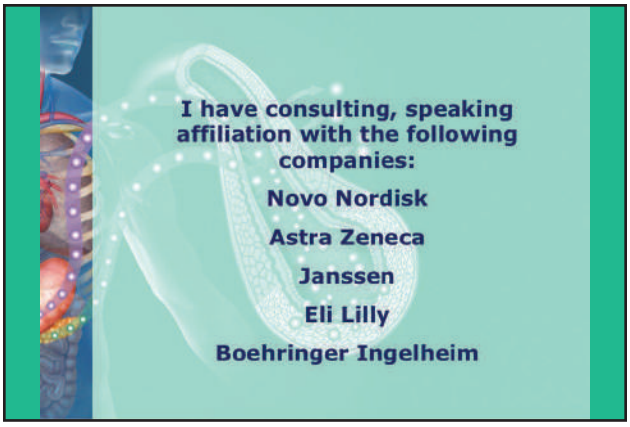

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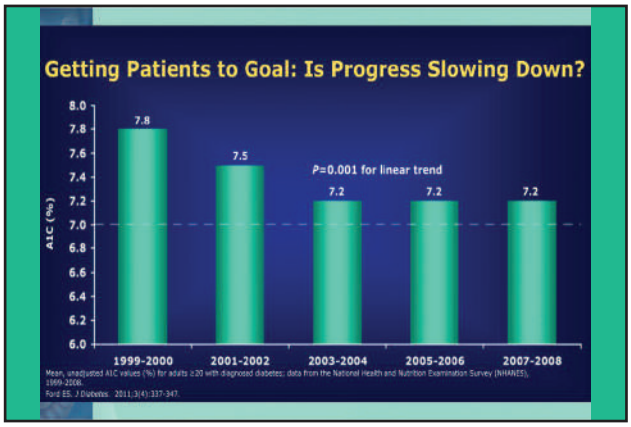

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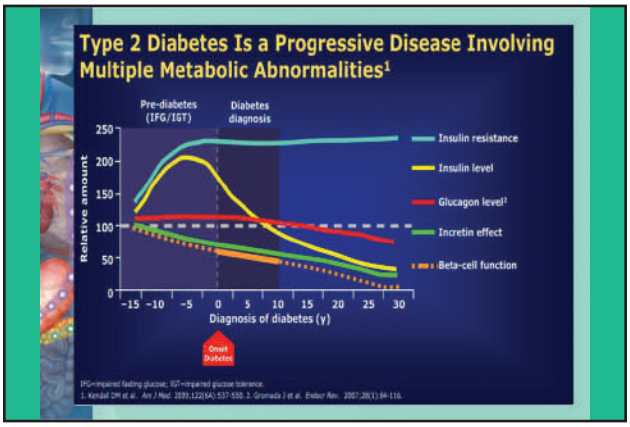

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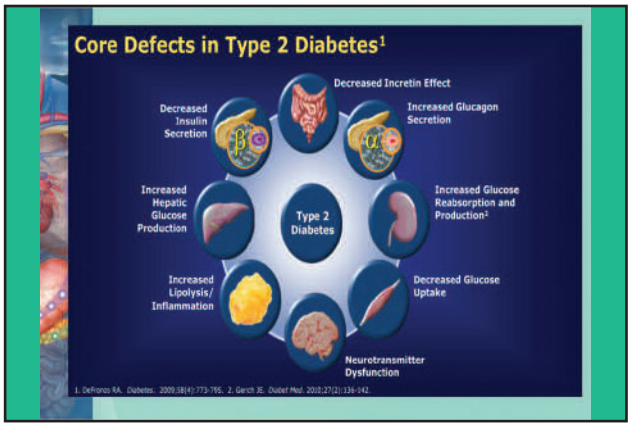

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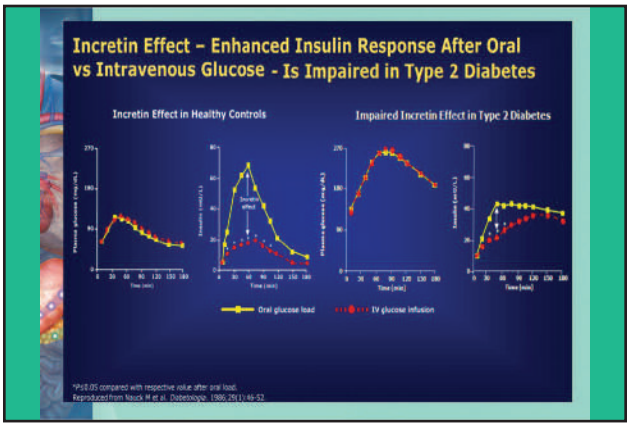

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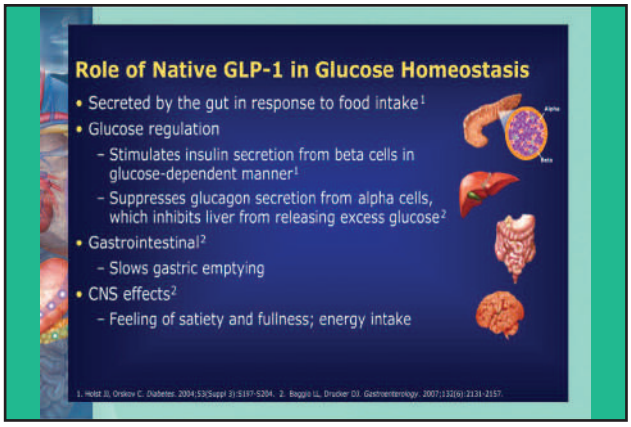

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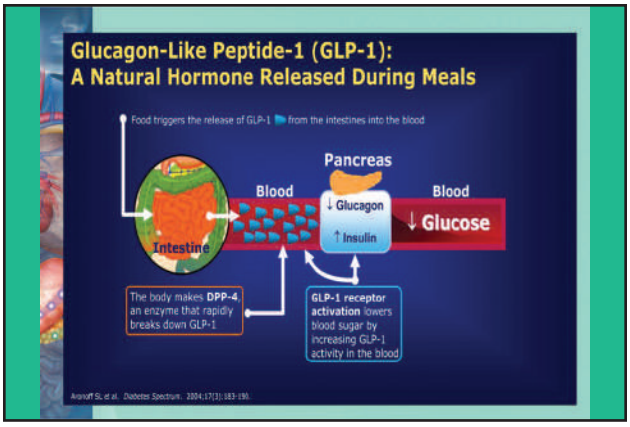

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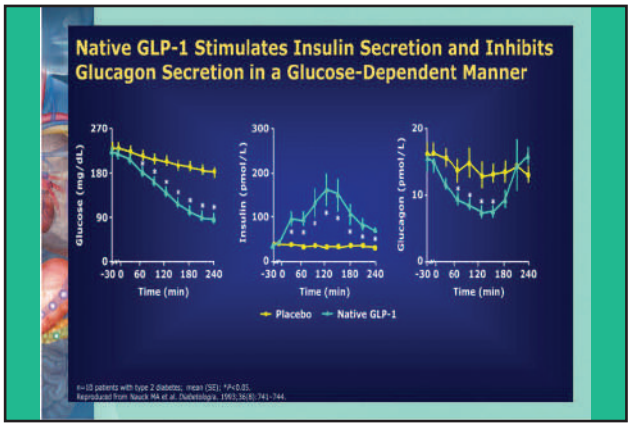

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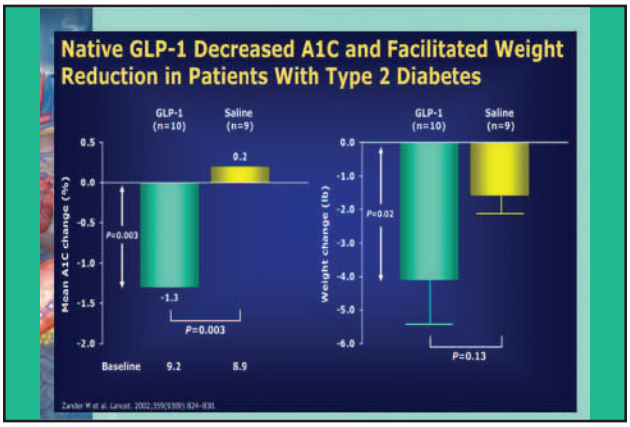

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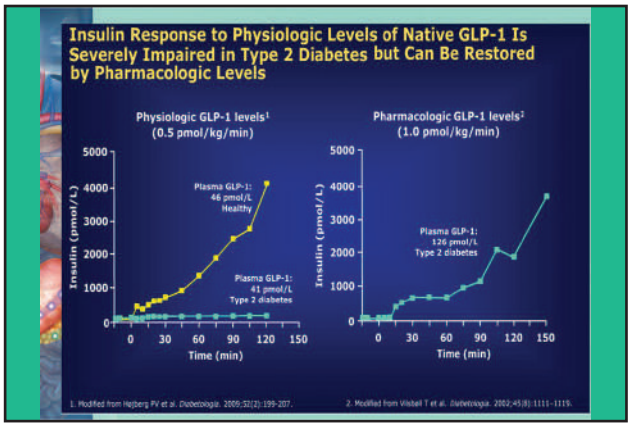

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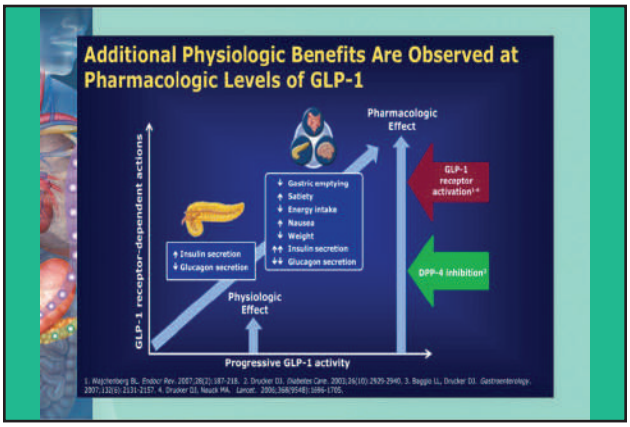

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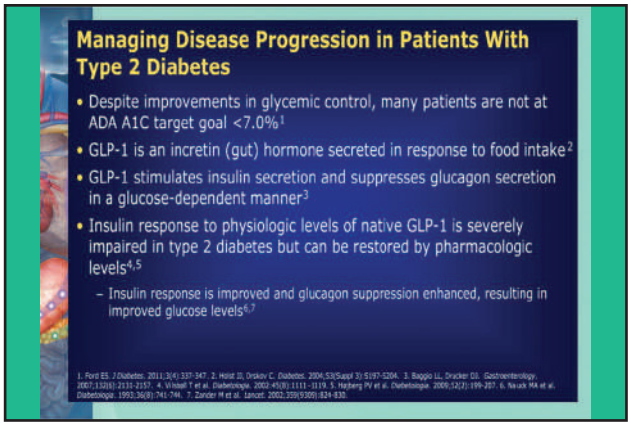

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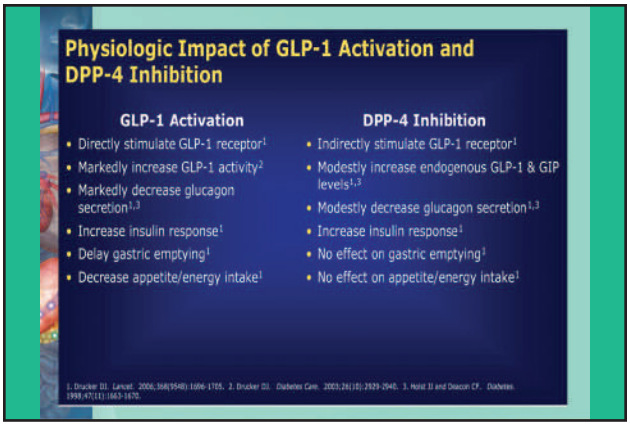

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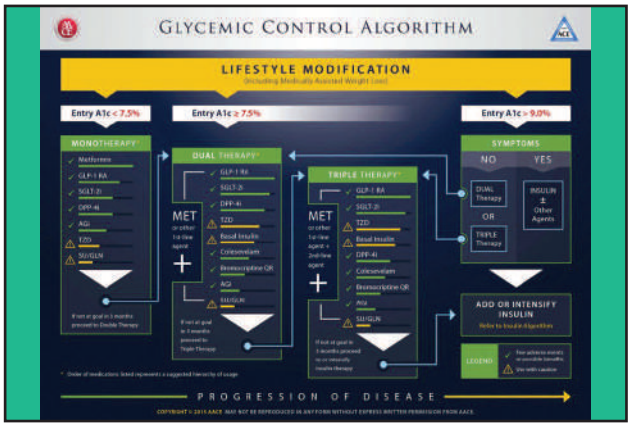

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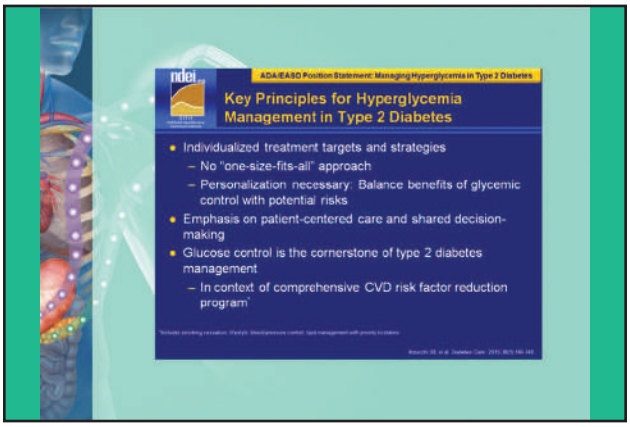

Kwabena Adubofour, M.D.

Associate Clinical Professor
Department of Internal Medicine
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Sacramento, California
Medical Director
East Main Clinic and Stockton Diabetes Intervention Center
Stockton, California

Kwabena Adubofour, M.D. is the Medical Director of East Main Clinic and Stockton Diabetes Intervention Center in Stockton, California. The clinic is active in the private practice of internal medicine and diabetes care.

He is the founder and current chair of the scientific and technical committee of the San Joaquin County Diabetes Society. The society seeks to improve the lives of individuals living with diabetes in San Joaquin County and holds an annual diabetes conference aimed at health care professionals involved in the day to day care of patients with diabetes.

Dr. Adubofour is also the current chair of Decision Medicine. Decision Medicine is a summer internship program of the San Joaquin County Medical Society and is designed to encourage high school students to pursue careers in the medical profession.

He has served as a preceptor at the level of Clinical Professor at the Division of General Internal Medicine, Department of Medicine, University of California Davis Medical Center in Sacramento.

Dr. Adubofour finished medical school at the University of Ghana Medical School in Accra, Ghana. He completed his residency in internal medicine at the Kaiser Permanente Medical Center in Oakland where he was also Chief resident in internal medicine.

Adubofour completed a fellowship in clinical pharmacology at the Division of Clinical Pharmacology, Stanford University Medical Center in Palo Alto.

Slide 1

REVIEW OF CLINICAL EVIDENCE SUPPORTING THE BENEFICIAL EFFECTS OF INCRETINS ON BODY WEIGHT AND THE CARDIOVASCULAR SYSTEM

KWABENA O.M. ADUBOFOUR, MD, FACP
MEDICAL DIRECTOR, EAST MAIN CLINIC AND STOCKTON DIABETES INTERVENTION CENTER

Slide 2

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Disclosures: Have previously served on speakers bureau and advisory boards for Novo-Nordisk, AstraZeneca

Slide 3

DIABETES AND CARDIOVASCULAR DISEASE

Slide 4

Diabetes and Cardiovascular Disease

- Patients with T2D have a several fold increased risk of developing cardiovascular disease when compared to non-diabetic controls.
- Myocardial Infarction and stroke are responsible for 75% of all deaths in patients with diabetes.

Slide 5

Diabetes and Cardiovascular Disease

- Patients with diabetes present with a 2-4X increased incidence of death from coronary artery disease.
- Patients with diabetes are considered for cardiovascular disease secondary prevention because their risk is similar to that reported in patients without diabetes who have already suffered a myocardial infarction.

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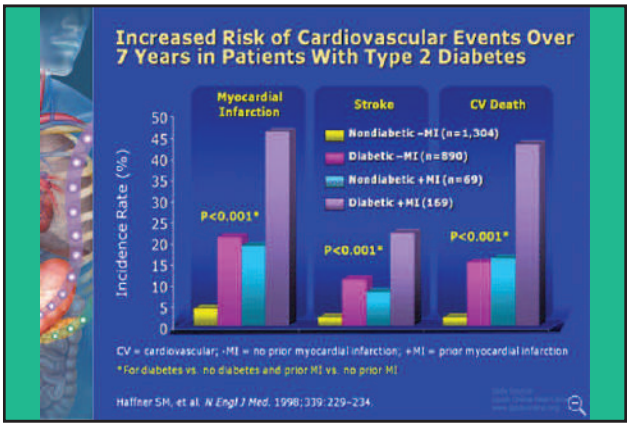

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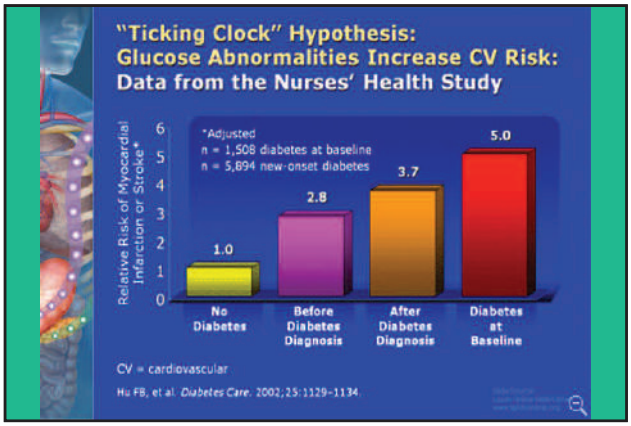

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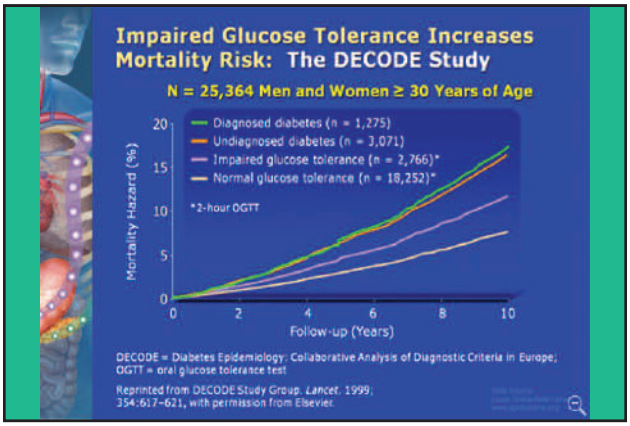

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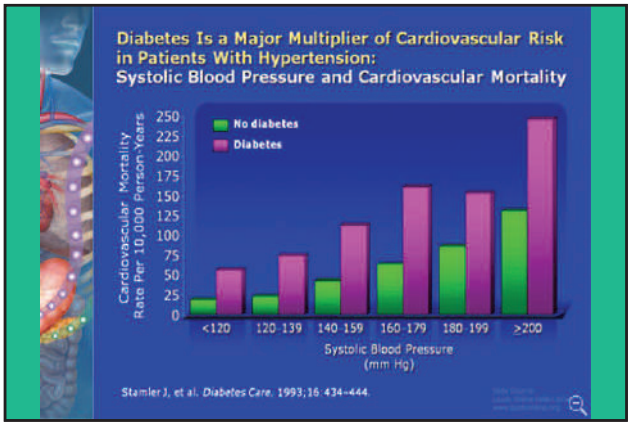

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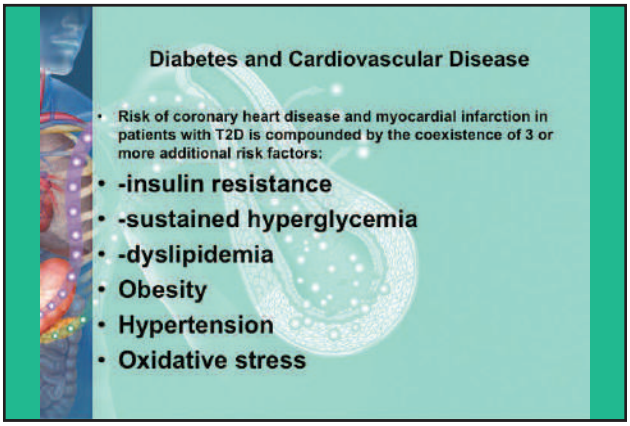

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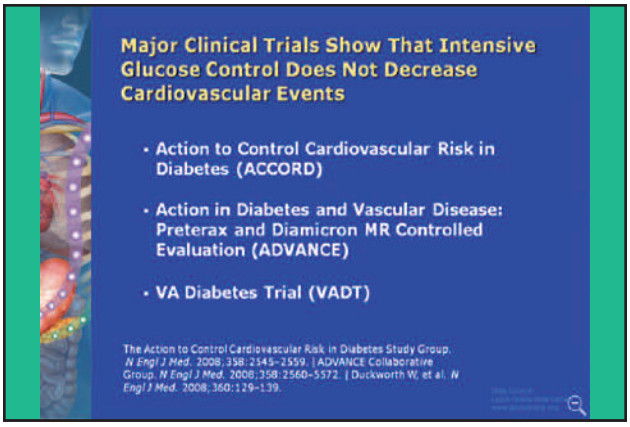

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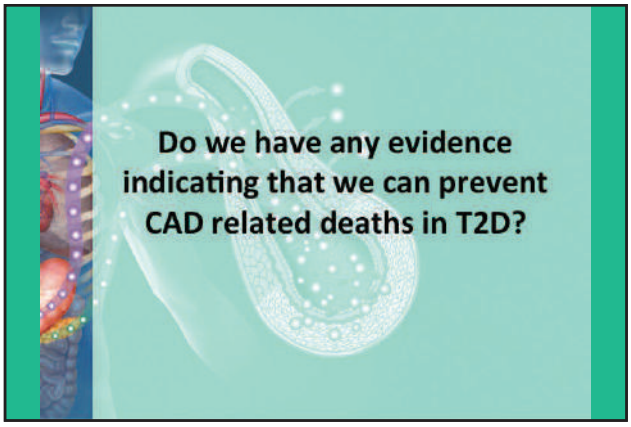

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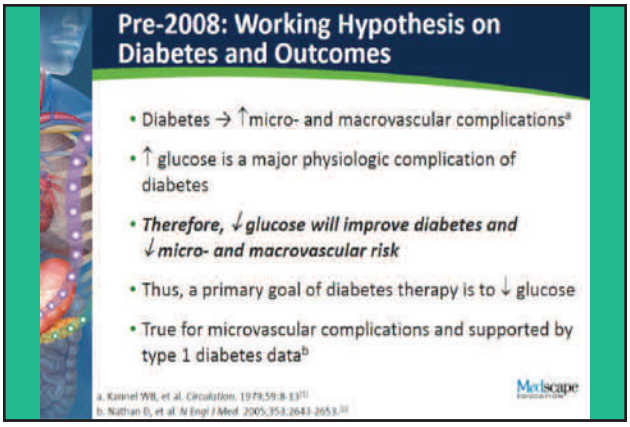

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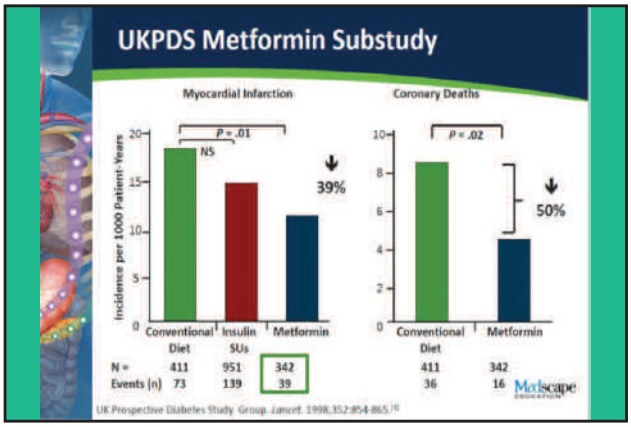

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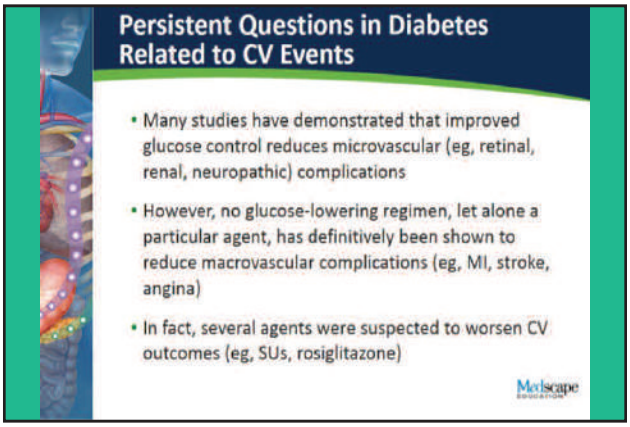

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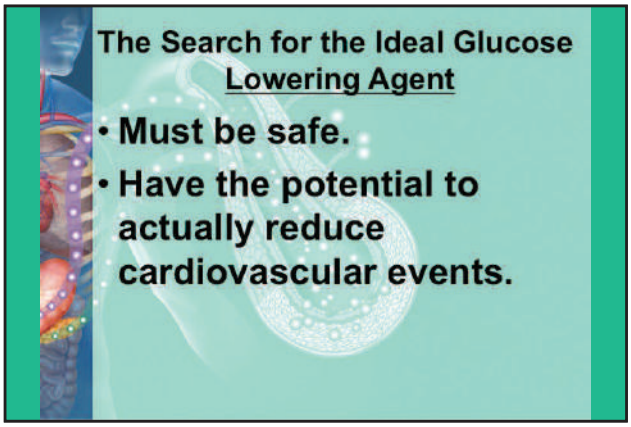

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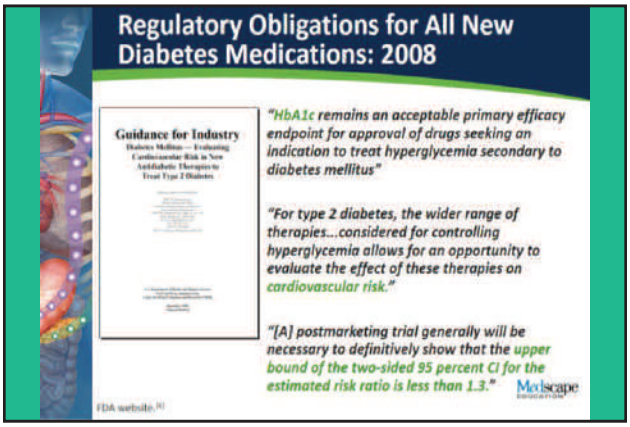

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INCRETINS: DPP-4 Inhibitors and GLP-1 Agonists and Cardiovascular Disease

What is the evidence to date

Slide 20

Glucagon-like peptide 1 (GLP-1)

- The observation that intrajejunal glucose promotes greater insulin release than intravenous glucose administration was reported 50 years ago by Mcintyre et al.
- Perley and Kipnis estimated the intestinal component accounts for 50% - 70% of the total insulin secreted after an oral glucose load.
- The "incretin effect" was coined by Creuzfeld and Ebert in 1985 to designate this phenonmenon.

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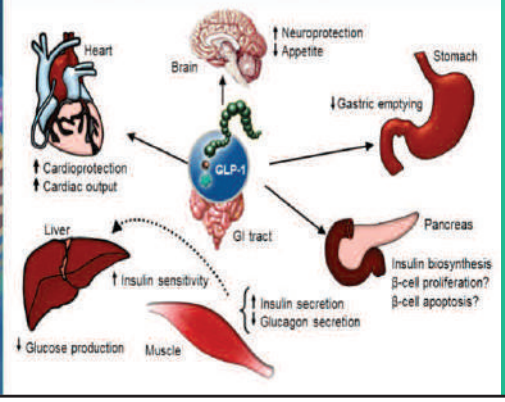

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Primary Objective

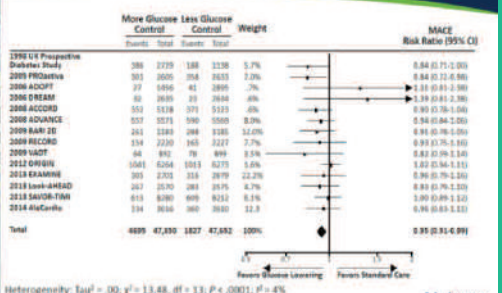
- To determine whether, when added to background therapy, DPP-4 inhibitors would be noninferior to placebo for the composite end point of CV death, nonfatal MI, or nonfatal ischemic stroke (upper 95% CI of HR < 1.3)
- And, if noninferiority were met, to determine whether DPP-4 inhibitors would be superior to placebo

Medscape

Scirica BM, et al. *N Engl J Med*. 2013;369:1317-1326.[5]

Slide 23

Risk for MACE With Glucose-Lowering Drugs or Strategies vs Standard Care



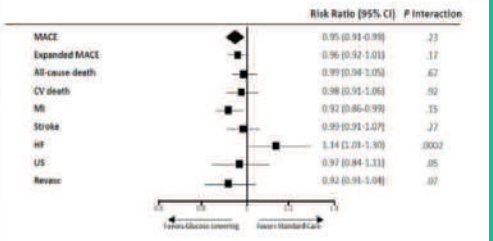
Heterogeneity: $\tau^2 = .00$; $\chi^2 = 13.48$, $df = 13$; $P < .0001$; $I^2 = 4\%$
Test for overall effect: $Z = 2.47$; $P = .014$

Medscape

Udell JA, et al. *Lancet Diabetes Endocrinol*. 2015;3:356-366.[8]

Slide 24

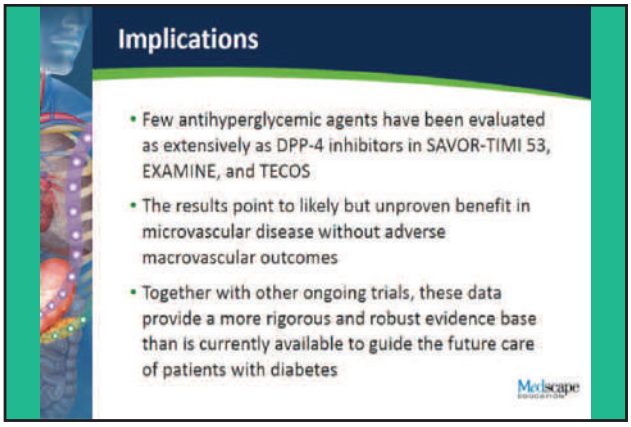
Major Adverse CV Events and Individual CV Events With Glucose-Lowering Drugs or Strategies vs Standard Care



Medscape

Udell JA, et al. *Lancet Diabetes Endocrinol*. 2015;3:356-366.[8]

Slide 25



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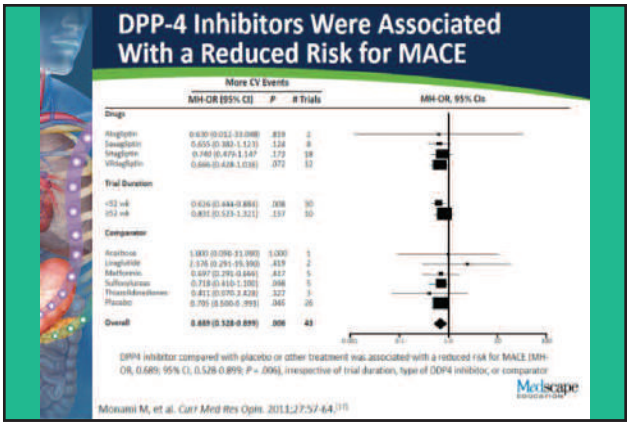

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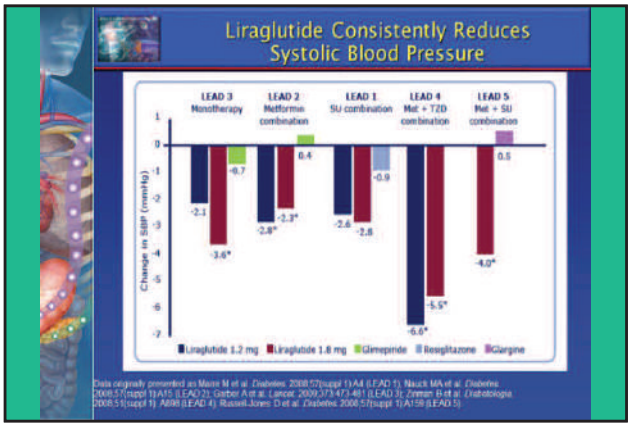

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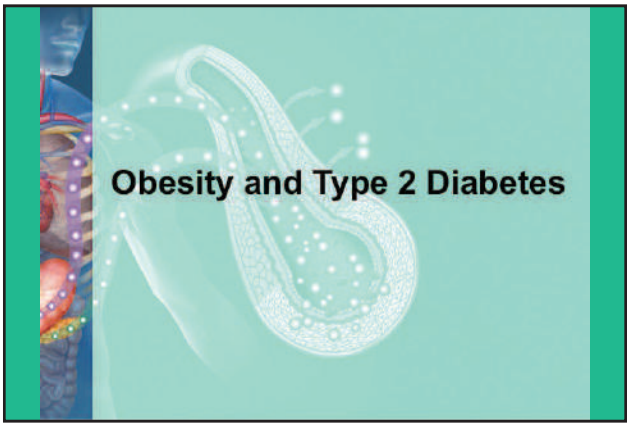

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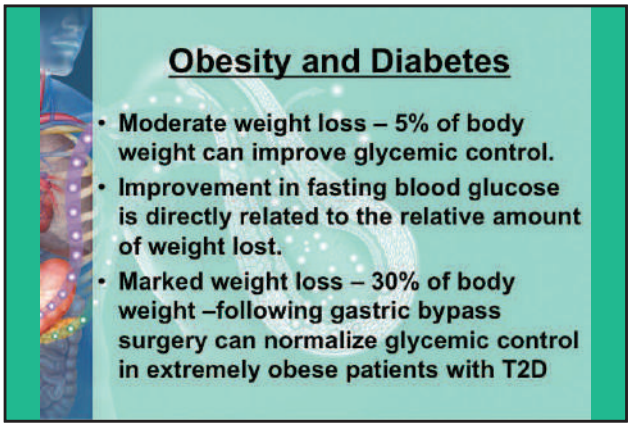

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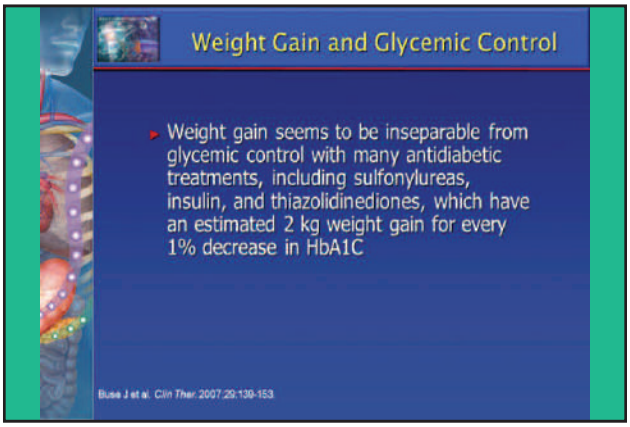

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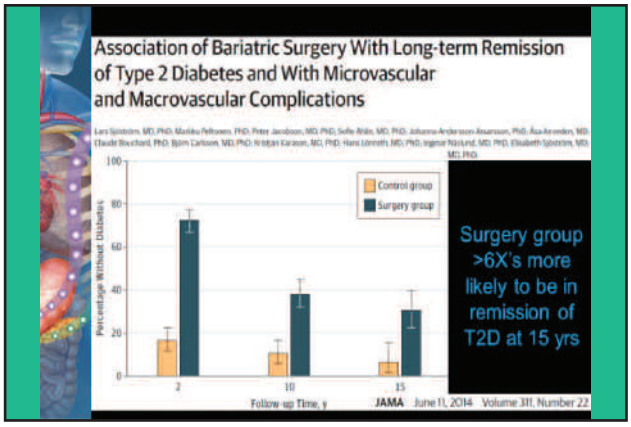

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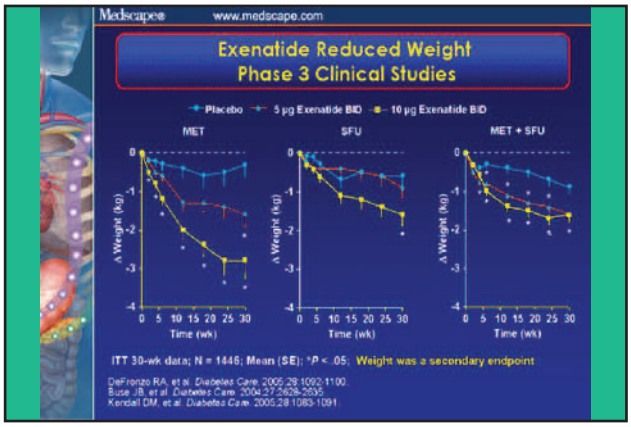

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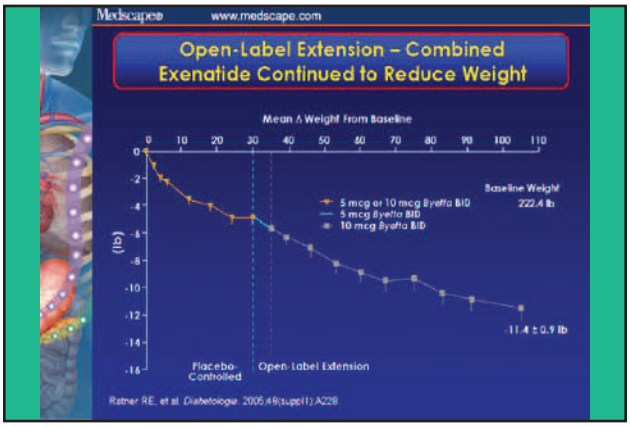

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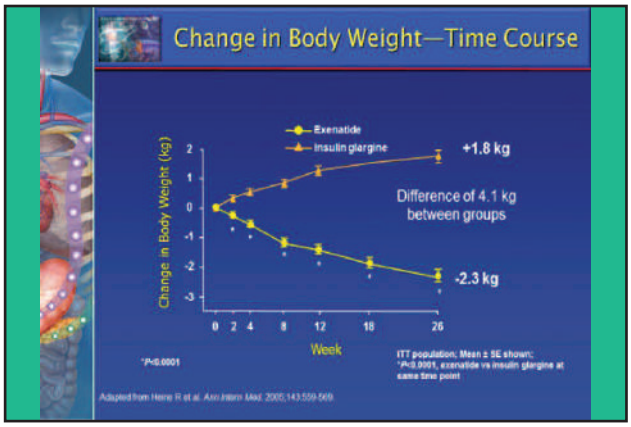

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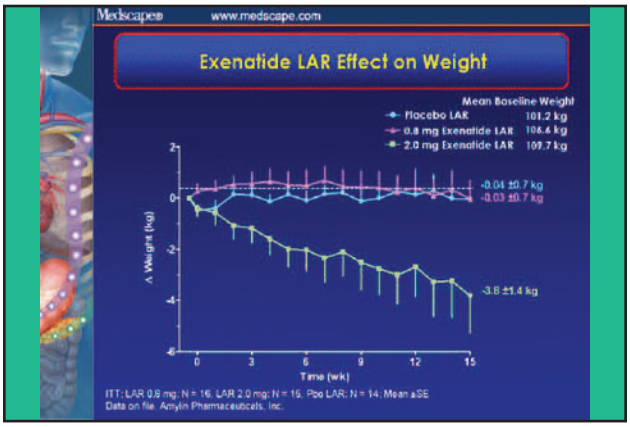

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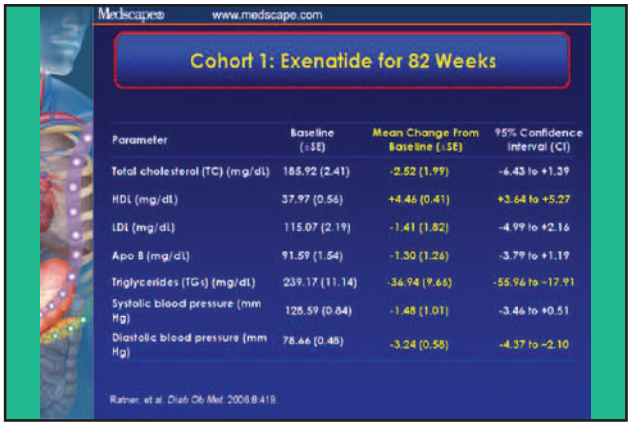

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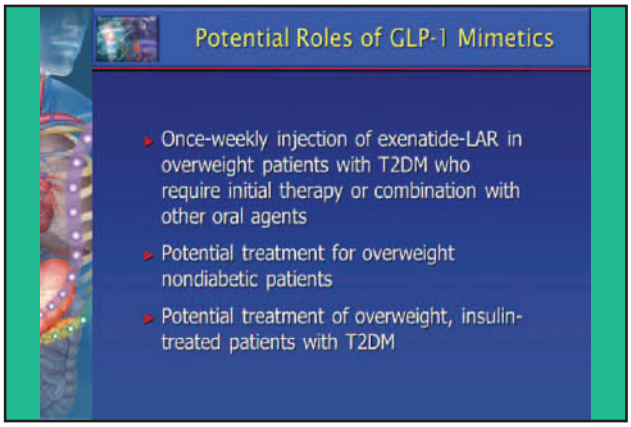

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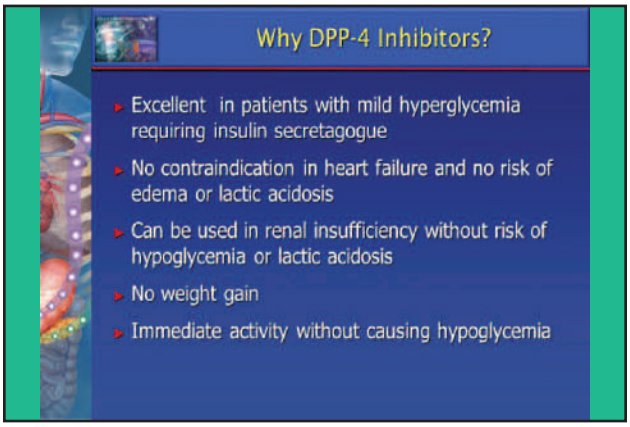

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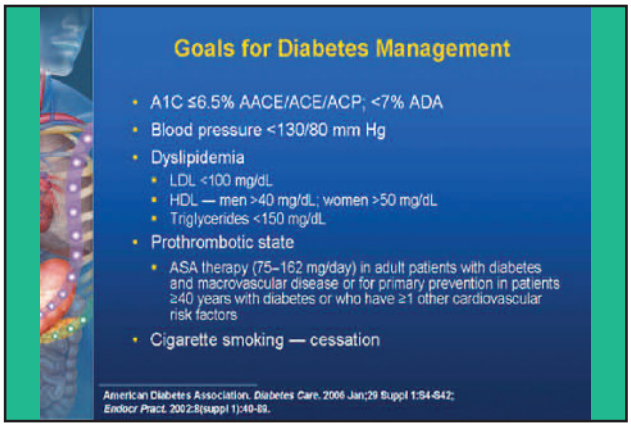


James R. Gavin III, M.D., PhD

Clinical Professor of Medicine
Endocrinology Division
Department of Internal Medicine
Emory University School of Medicine
Atlanta, Georgia

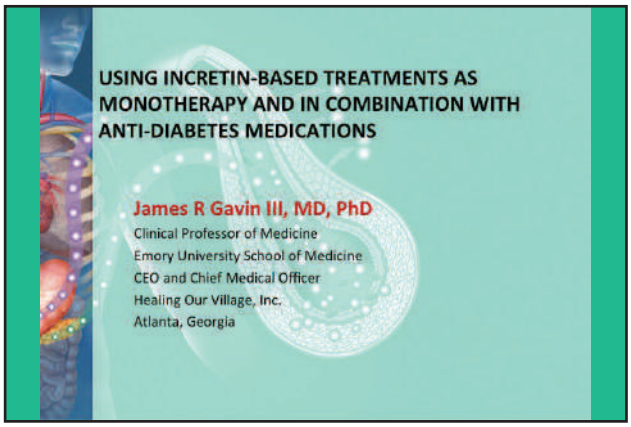
James R. Gavin III, MD, PhD is clinical professor of medicine at Emory University School of Medicine in Atlanta, Georgia, and Clinical Professor of Medicine at the Indiana University School of Medicine, Indianapolis, Indiana. He currently serves as Chief Executive Officer and Chief Medical Officer of Healing Our Village, Inc. Prior to this, he served as president and chief executive officer of MicroIslet, Inc., San Diego, California, from January 2006 to July, 2007, and was president of the Morehouse School of Medicine in Atlanta from 2002-2005. He served as senior scientific officer at the Howard Hughes Medical Institute (HHMI) from 1991 to 2002 and as director of the HHMI–National Institutes of Health Research Scholars Program from 2000 to 2002. Before joining the senior staff of HHMI, Dr Gavin was a professor and chief of the Diabetes Section, acting chief of the Section on Endocrinology, Metabolism, and Hypertension, and William K. Warren Professor for Diabetes Studies at the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma. He previously served as an associate professor of medicine at Washington University School of Medicine in St. Louis, Missouri. Dr Gavin served as a lieutenant commander in the US Public Health Service from 1971 to 1973 and continues to serve as a reserve officer.

Dr Gavin belongs to a number of organizations, including the Institute of Medicine of the National Academies of Sciences, the American Diabetes Association (ADA), the American Association of Clinical Endocrinologists (AACE), the American Society of Clinical Investigation (ASCI), the American Association of Physicians (AAP), the National Medical Association (NMA), the Sigma Pi Phi Leadership Fraternity, and the Downtown Atlanta Rotary Club. He is a past president of the ADA and was voted Clinician of the Year in Diabetes by the ADA in 1991. He has served on many advisory boards and on the editorial boards of the American Journal of Physiology and the American Journal of Medical Sciences. He is on the board of trustees for Emory University, Livingstone College, and Trustee Emeritus for the Robert Wood Johnson Foundation. In addition, he is immediate past national program director of the Harold Amos Faculty Development Program of the Robert Wood Johnson Foundation. Dr Gavin is also past chairman of the National Diabetes Education Program (NDEP) and a past member of the Board of Scientific Councilors for the Intramural Research Program of NIDDK at the NIH. He also serves as chairman of the Data Safety Monitoring Board for the VA Cooperative Diabetes Study (VADT). He is co-chair of the Advisory Committee to the Associate Director of Intramural Research of the NIDDK, and serves as Chairman of the Board for the Partnership for a Healthier America.

Dr Gavin has published more than 230 articles and abstracts in such publications as Science, Journal of Applied Physiology, Diabetes, and the American Journal of Physiology. He is coauthor of two books: Healing Our Village: A Self-Care Guide for Diabetes Control (written with L. Coleman) and Dr. Gavin's Health Guide for African Americans (written with S. Landrum). Among the many honors Dr Gavin has received are the Daniel Hale Williams Award, the E.E. Just Award, the Herbert Nickens Award, the Daniel Savage Memorial Award, the Emory University Medal for Distinguished Achievement, the Banting Medal for Distinguished Service from the ADA, the Distinguished Alumni Award from the Duke University School of Medicine, the F.C. Greenwood Award from the RCMI of NCRR at NIH and the Internist of the Year Award from the National Medical Association. He was named a "Living Legend in Diabetes" by the American Association of Diabetes Educators (AADE) in 2009, and was named one of the "175 Emory History Makers" on the occasion of the celebration of the University's 175th Anniversary. He was designated an inaugural Senior Fellow of the W. Montague Cobb Research Institute of the NMA.

Dr Gavin graduated from Livingstone College in Salisbury, North Carolina, with a degree in chemistry. He earned his PhD in biochemistry from Emory University and his MD degree from Duke University School of Medicine, Durham, North Carolina. He and his wife, Dr. Annie Gavin, are the parents of three adult sons.

Slide 1



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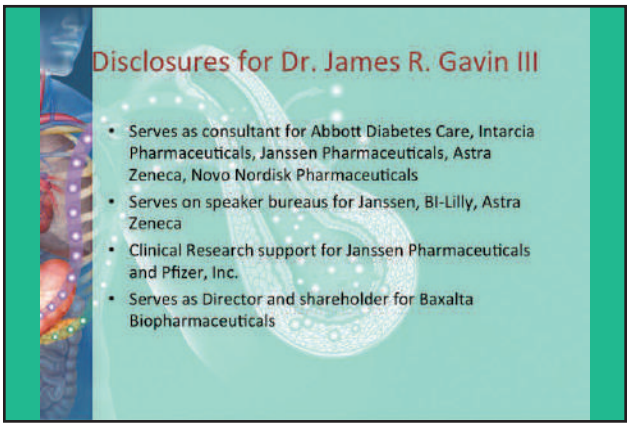

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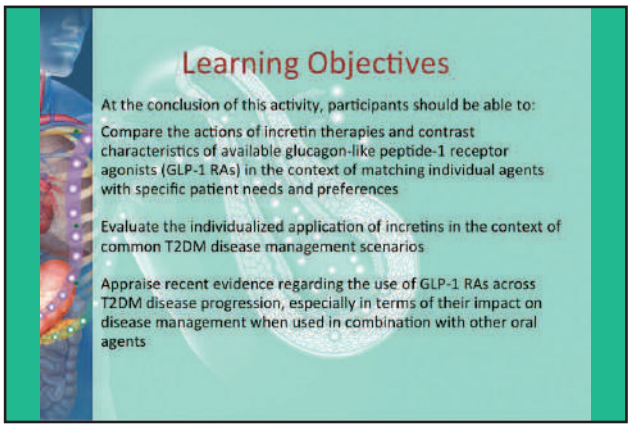

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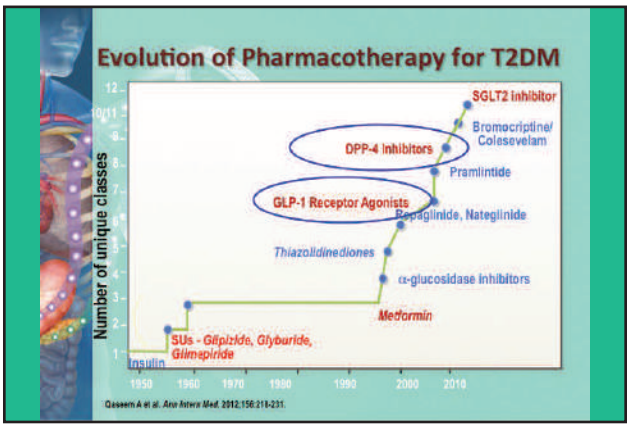

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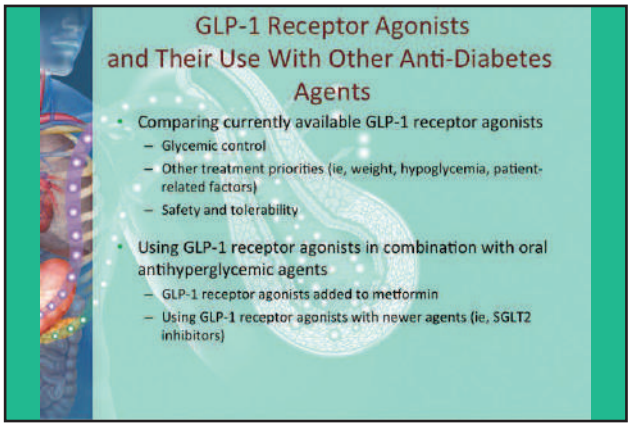

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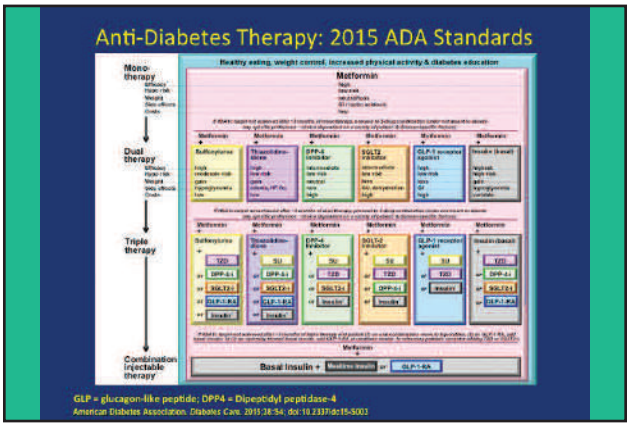

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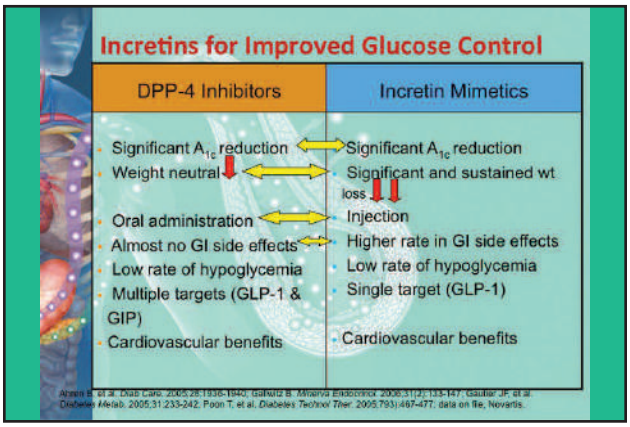

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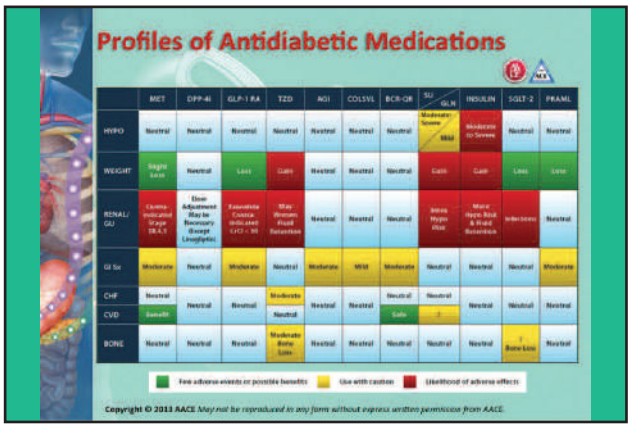

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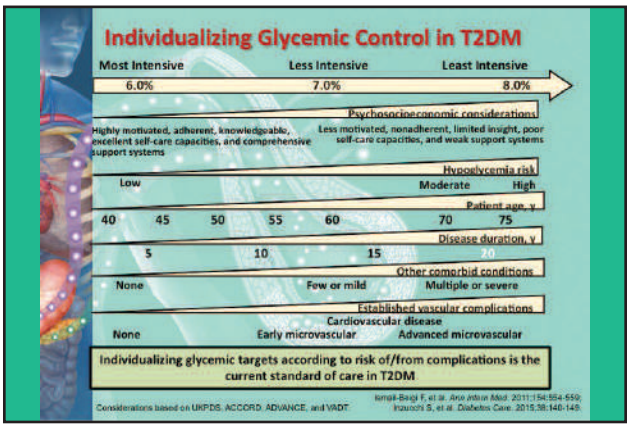

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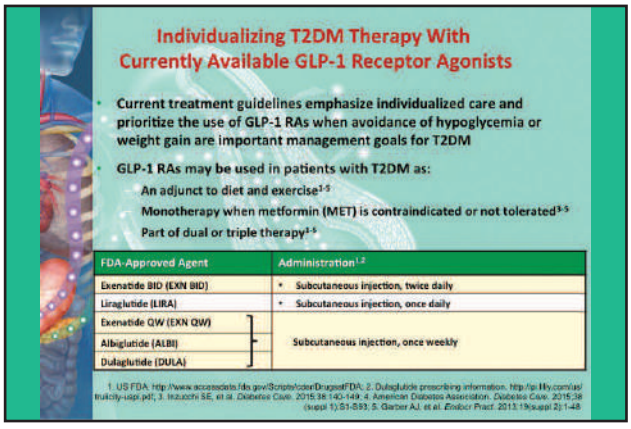

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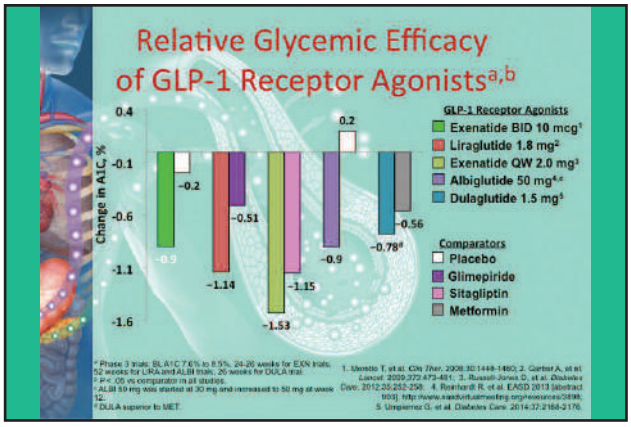

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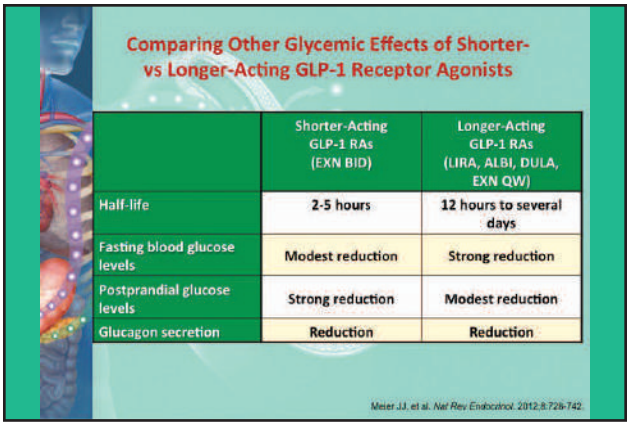

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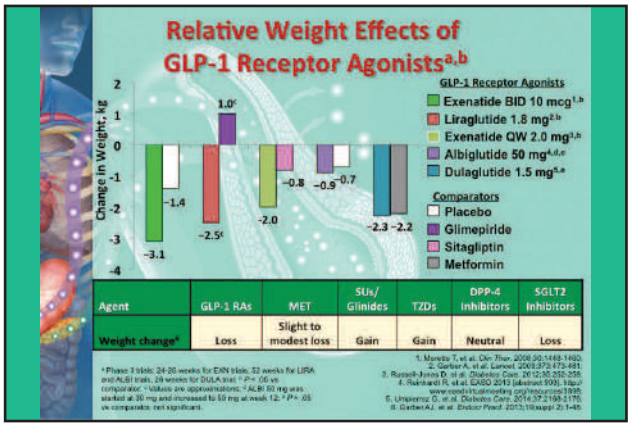

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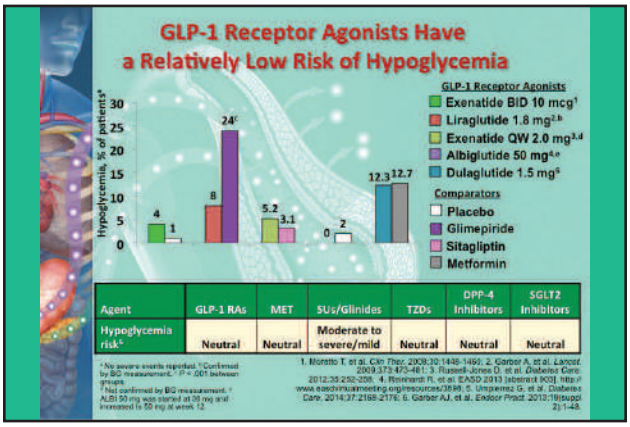

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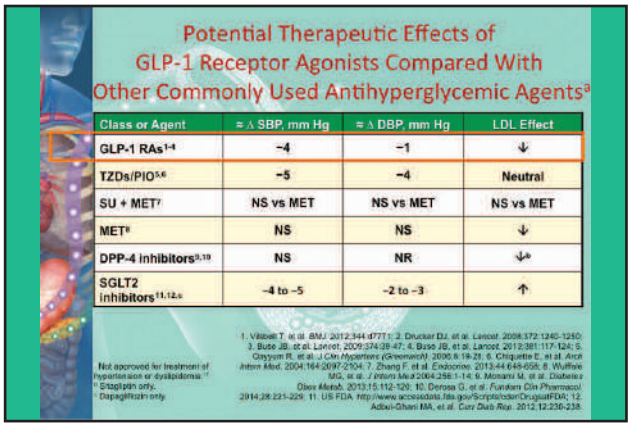

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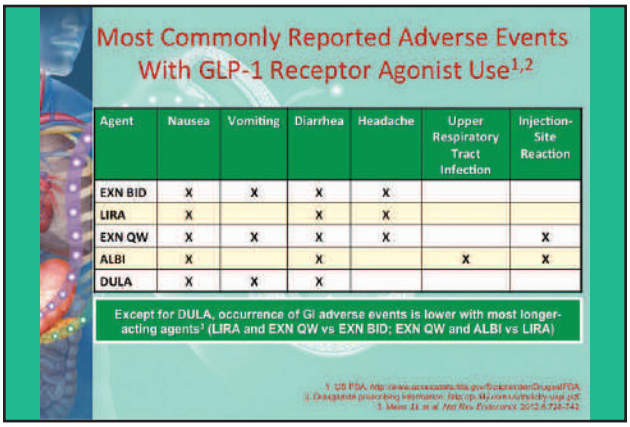

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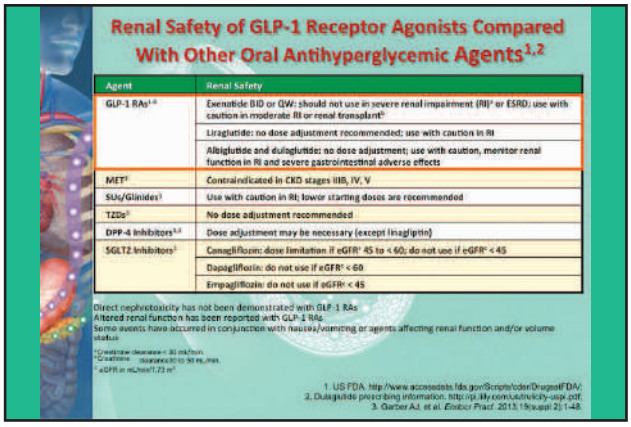

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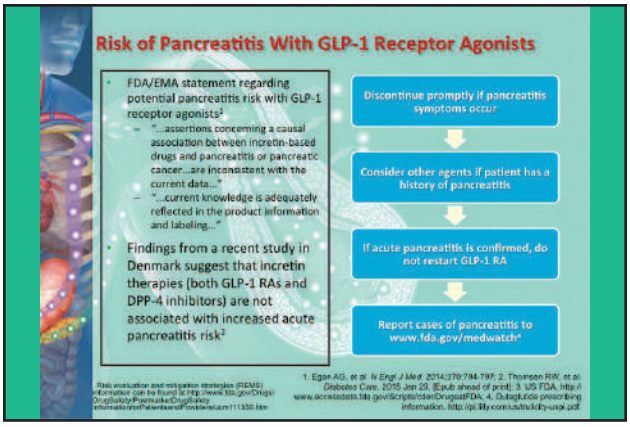

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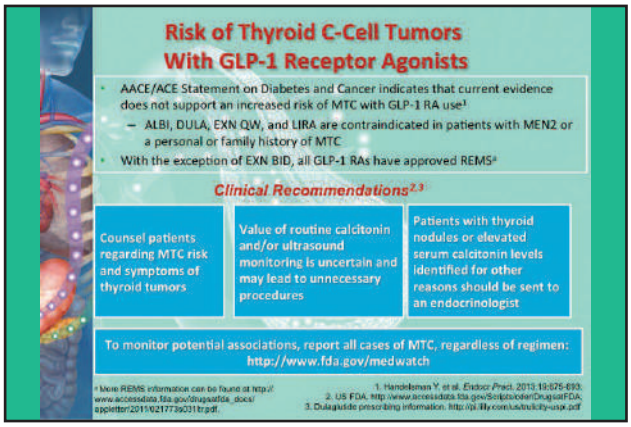

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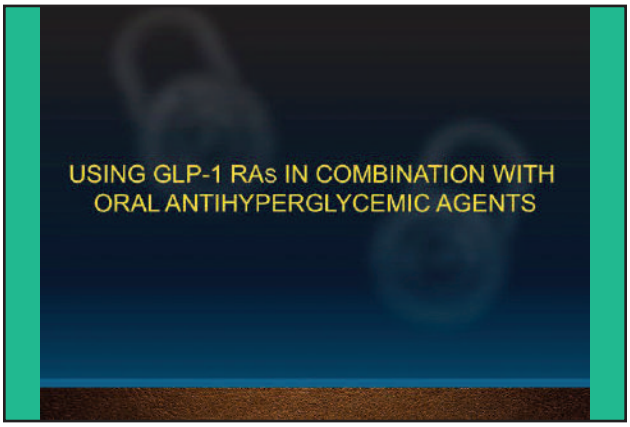

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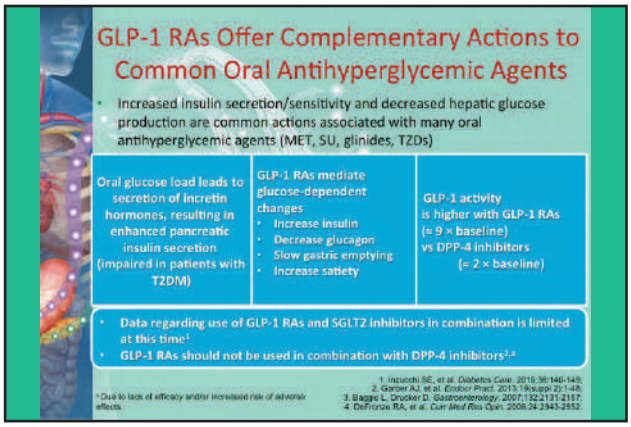

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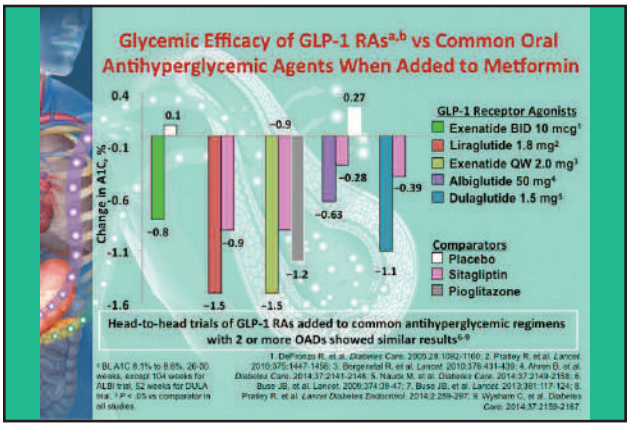

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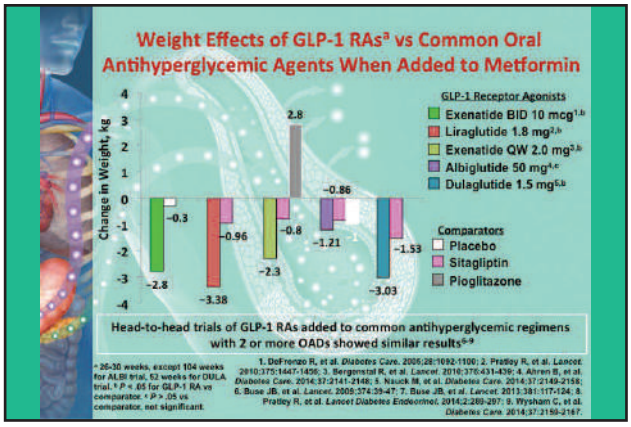

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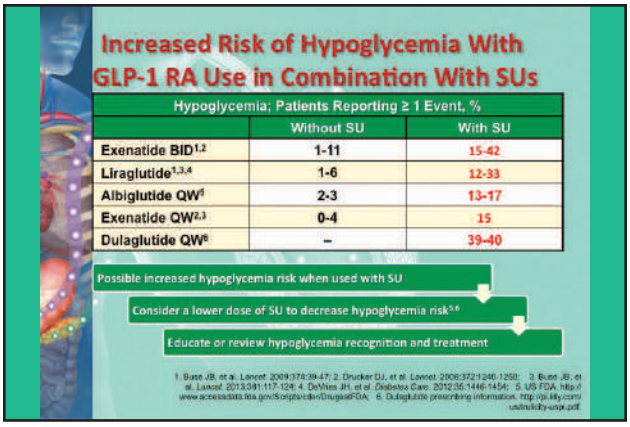

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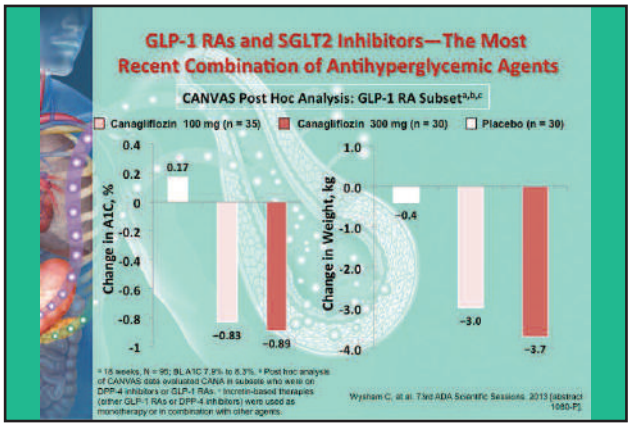

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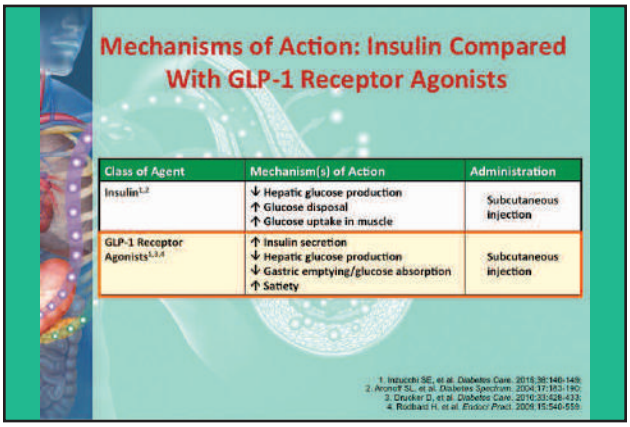

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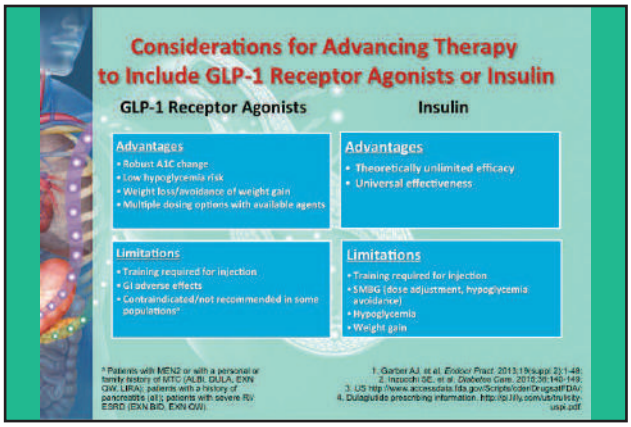

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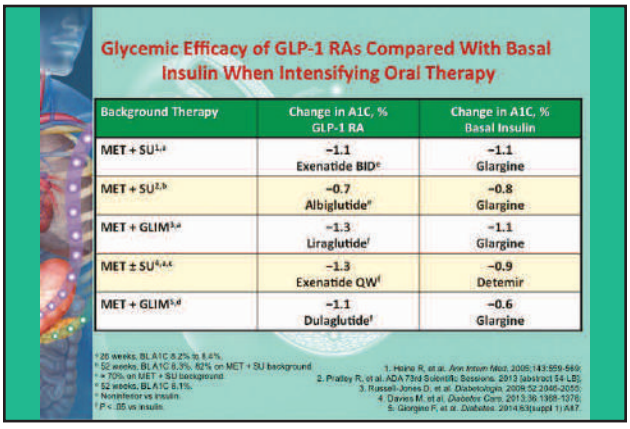

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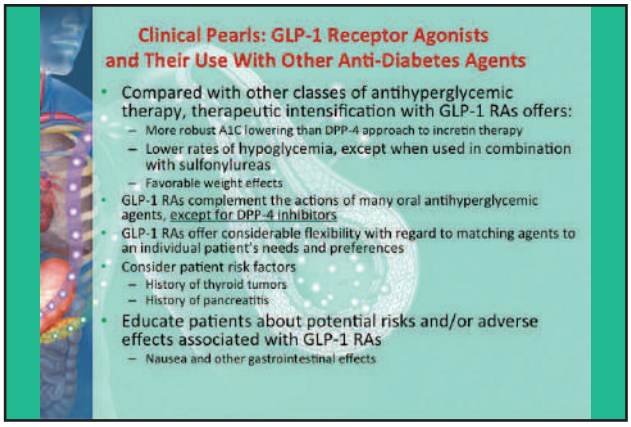
Clinical Pearls: GLP-1 Receptor Agonists and Their Use With Other Anti-Diabetes Agents
Compared with other classes of antihyperglycemic therapy, therapeutic intensification with GLP-1 RAs offers:
More robust A1C lowering than DPP-4 approach to incretin therapy
Lower rates of hypoglycemia, except when used in combination with sulfonylureas
Favorable weight effects
GLP-1 RAs complement the actions of many oral antihyperglycemic agents, except for DPP-4 inhibitors
GLP-1 RAs offer considerable flexibility with regard to matching agents to an individual patient's needs and preferences
Consider patient risk factors
History of thyroid tumors
History of pancreatitis
Educate patients about potential risks and/or adverse effects associated with GLP-1 RAs
Nausea and other gastrointestinal effects

NOTES

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