



**18th Biennial Medical Conference
of the
Hellenic Medical Society of New York**

**Astir Palace, Nafsika Conference Center
Vouliagmeni, Athens, Greece
17-18 June 2006**



**Conference Chairman
George D. Dangas
President, Hellenic Medical Society of New York**



President's Message

On behalf of the Hellenic Medical Society of New York and as Chairman of its 18th Biennial Conference, I would like to extend an official welcome to the entire faculty and all other participants and attendees of this Scientific Conference.

Scientific topics include cardiovascular disease (both cardiac and peripheral vascular), diabetes, metabolic syndrome, adolescent medicine, surgery, orthopedics, pharmacological and minimally invasive therapy, history of medicine and medical education.

The program has a diverse, multi-specialty character, branching out to many subjects of interest, and complemented by the remarkable geographic diversity of the faculty. Both of these facts underline the universal features of medical education in the present era, as well as the broad appeal of scientific events organized by the Hellenic Medical Society of New York.

The program offers official accreditation for Continuing Medical Education per the standard process of our Society through a pathway paved by Dr. Jack Sotirakis. We would like to thank Dr. Sotirakis for his involvement. Additionally, we would like to thank Hope Rubel of the Cardiovascular Research Foundation, a non-profit organization based in New York City, for providing the graphic design of this program booklet.

Astir Palace in Vouliagmeni is the classic upscale resort in the metropolitan Athens area and I am confident that it will provide the appropriate environment for scientific and social interaction between the faculty and attendees. This type of interaction will be highly beneficial to the general goals of the Hellenic Medical Society of New York that have always included international participation and collaboration with Greek doctors and the healthcare administration.

Again, I extend a warm welcome to all attending this conference!

New York City, June 1, 2006

George D. Dangas, MD, PhD

Conference Chairman
President of the Hellenic Medical Society of New York

CME Information

CME Accreditation and Designation

St. Francis Hospital is accredited by the Medical Society of the State of New York (MSSNY) to sponsor continuing medical education for physicians.

St. Francis Hospital designates this continuing medical educational activity for a maximum of six (6) Category 1 credit hours towards the Physician Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Documentation of awarded credit is provided for registered attendees in exchange for completed activity evaluations. Certificates of attendance are provided to all registered attendees.

The Hellenic Medical Society of New York has appointed Dr George Carayiannopoulos as on-site Director of Continuing Medical Education for this activity.

Learning Objectives

This conference will focus on emerging therapies and diagnostic trends of various diseases involving interventional cardiology. In addition to these advancements, speakers will review the current state of adolescent medicine in Greece, the impact of ancient medicine on orthopedics, and the role of websites in addressing lower back pain. Main objectives for participants will be to:

- Evaluate the effectiveness of advanced treatments for aggressive cholesterol reduction, acute myocardial infarctions and therapies to improve limb salvage in critical limb ischemia patients.
- Identify cardio biomarkers and analyze their predicative role in the diagnosis of atherosclerotic disease.
- Conduct in-depth analysis of cardiac arrhythmias.
- Discuss the progression of lower extremity arterial disease in coronary artery disease patients
- Analyze emerging therapies for postprandial glycemic control.

- Consider the success of intensity-modulated radiation therapy and chemotherapy in the treatment of anal cancer.
- Explore new approaches to adolescent medicine in Greece.
- Examine the influence of ancient medicine on modern orthopedics.

Activity Evaluation

Evaluation by questionnaire will address content, presentation, possible bias, and future educational needs.

Disclosure

It is the policy of the Hellenic Medical Society of New York and St. Francis Hospital to ensure balance, independence, objectivity, and scientific rigor in all of its sponsored educational programs.

Discussion of off-label product usage is made at the sole discretion of the faculty and is not endorsed by the Hellenic Medical Society of New York and St. Francis Hospital.

Faculty participating in continuing medical education activities are required to disclose to the program audience any real or apparent conflict of interest related to the content of their presentation(s). Faculty not complying with this policy are not permitted to participate in this activity.

This educational activity has no commercial support.



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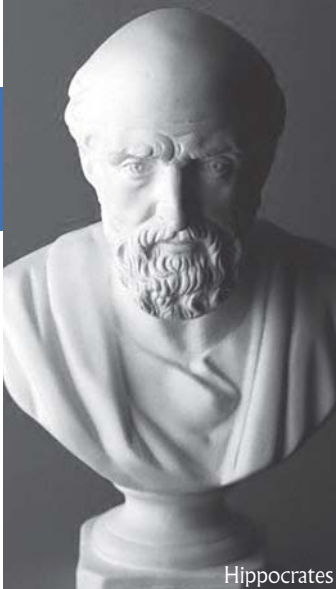
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The Hippocratic Oath

I swear by Apollo Physician, by Aesclepius, by Health, by Heal-all, and by all the gods and goddesses, making them witnesses, that I will carry out, according to my ability and judgment, this oath and this indenture:

To regard my teacher in this art as equal to my parents; to make him partner in my livelihood, and when he is in need of money to share mine with him; to consider his offspring equal to my brothers; to teach them this art, if they require to learn it, without fee or indenture; and to impart precept, oral instruction, and all the other learning, to my sons, to the sons of my teacher, and to pupils who have signed the indenture and sworn obedience to the physicians' Law, but to none other.

I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them. I will not give poison to anyone though asked to do so, nor will I suggest such a plan. Similarly I will not give a pessary to a woman to cause abortion. But in purity and in holiness I will guide my life and my art. I will not use the knife either on sufferers from stone, but I will give place to such as are craftsmen therein.

Into whatsoever houses I enter, I will do so to help the sick, keeping myself free from all intentional wrong-doing and harm, especially from fornication with woman or man, bond or free. Whatsoever in the course of practice I see or hear (or even outside my practice in social intercourse) that ought never to be published abroad, I will not divulge, but consider such things to be holy secrets.

Now if I keep this oath and break it not, may I enjoy honour, in my life and art, among all men for all time; but if I transgress and forswear myself, may the opposite befall me.

Translated during the 1940s by Drs. Lantzounis and Nittis.

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AGENDA

Astir Palace, Nafsika
Conference Center

Saturday, June 17, 2006

Session I

9:00 AM - 12:00 PM

Moderators: Dr. Dennis Caralis, Dr. Antonio Colombo, Dr. Jeffrey W. Moses

- 9:00-9:30 Dr. Dennis Caralis
Lower Extremity Arterial Disease in Coronary Artery Disease Patients
- 9:30-10:00 Dr. Steven Kavros
Improving Limb Salvage with Intermittent Pneumatic Compression in Patients with Critical Limb Ischemia: The Mayo Clinic Experience (1998-2004)
- 10:00-10:30 Dr. James Christodoulou
Aggressive Cholesterol Reduction: Update 2006
- 10:30-11:00 Dr. George Dangas
Cardio Biomarkers for the Prediction and Diagnosis of Atherosclerotic Disease
- 11:00-11:30 Dr. Roxana Mehran
Percutaneous Coronary Intervention for Acute Myocardial Infarction
- 11:30-12:00 Dr. James Coromilas
Patient Selection for Automatic Implantable Defibrillators

Session II

2:00 PM - 5:00 PM

Moderators: Dr. George Maragos, Dr. Spyros Mezitis

- 2:00-2:20 Dr. Dimitrios Karadaglis
The Contribution of Ancient Medicine to Modern Orthopaedics
- 2:20-2:35 Dr. Dimitrios Karadaglis
Low Back Pain on the Web: An Assessment of Quality and Popularity of Websites
- 2:35-2:50 Dr. George Varsos
IMRT and Chemotherapy Used to Successfully Treat Anal Cancer
- 3:00-3:20 Dr. George Maragos
Adolescent Medicine in Greece Today. Current Perspectives and Approaches
- 3:20-3:40 Break
- 3:40-4:00 Dr. Spyros Mezitis
Emerging Therapies Affecting Postprandial Glycemic Control - Background
- 4:00-4:20 Dr. Spyros Mezitis
Emerging Therapies Affecting Postprandial Glycemic Control – GLP-1R Agonists, DPP-IV Inhibitors
- 4:20-4:40 Dr. Spyros Mezitis
Emerging Therapies Affecting Postprandial Glycemic Control – Amylin and Insulin
- 4:40-5:00 Discussion

Sunday, June 18, 2006

Session III

12:00 PM - 2:00 PM Conference Deductions
Joint session with the entire faculty to discuss the messages learned from the present conference as well as to brainstorm around the goals, main subjects and venues of future medical conferences of the HMS



Claudication and Coronary Artery Disease

D. Caralis

Claudication due to Lower Extremity Arterial Disease (LEAD) is an independent risk factor for Coronary Artery Disease (CAD) mortality.

LEAD is an independent risk factor for CAD and a prognosticator of cardiovascular mortality. Cardiovascular death rates are higher in men than in women. In patients with LEAD, morbidity from coronary heart disease and stroke is increased: 2.5 times more likely to present with morbidity from all forms of cardiovascular disease compared to subjects who do not have LEAD. There is a graded effect of the Ankle Brachial Index (ABI) survival. The 10-year survival estimates among those patients with an ABI less than 0.4-0.85 had a survival rate of 51%; whereas three out of four patients with an ABI greater than 0.85 survive 10 years.



Aggressive Cholesterol Reduction: Update 2006

J. Christodoulou

Recent studies have confirmed the ATPIII guidelines that "lower is better." The TNT, REVERSAL, and ASTEROID studies will be reviewed and their clinical impact discussed. The role of combination and high potency statins will be highlighted as well as their potential role in arteriosclerotic coronary artery disease regression via IVUS imaging.



Cardiac Biomarkers for the Prediction and Diagnosis of Atherosclerotic Disease and Its Complications

G. Dangas, R. Mehran, J. Moses, A. Colombo

Inflammation has been implicated in all stages of cardiovascular disease. This has driven a very fruitful search for new biomarkers, which potentially can be used as tools in the diagnosis and prognosis of atherothrombotic disease. While these new markers might prove useful in predicting the onset of atherosclerosis in healthy individuals, the utility of biomarkers in risk assessment for events in those patients with established disease and/or those with acute coronary syndrome requires further work. Effective biomarkers must be standardized, logistically simple to analyze, and clinically useful. Understanding what impact sex, age, ethnicity, and comorbid conditions may have on biomarkers is also of importance. Unfortunately, many of the candidate markers have yet to satisfy these requirements.



Rescue Angioplasty for Acute Myocardial Infarction

R. Mehran, G. Dangas, J. Moses, A. Colombo

Objectives: To examine the contemporary results of rescue percutaneous coronary intervention (PCI) after failed thrombolytic therapy, and to investigate whether use of a distal microcirculatory protection device in this setting can improve angiographic and clinical outcomes and reduce infarct size.

Background: Though rescue PCI is commonly performed after failed thrombolytic therapy, acute procedural success rates are lower than after primary PCI. The value of distal protection devices during rescue PCI has not been studied.

Methods: The Enhanced Myocardial Efficacy and Removal by Aspiration of Liberated Debris trial was a prospective, multicenter trial of distal microcirculatory protection randomized as an adjunct in 501 STEMI patients, stratified for those undergoing rescue (n=93) or primary (n=408) PCI.

Results: Compared to primary PCI, rescue PCI patients had a higher risk hemodynamic profile at baseline (elevated mean respiratory rate and heart rate, with lower mean systolic and diastolic arterial pressure). Compared to primary PCI, rescue PCI patients had higher baseline rates of TIMI-3 flow (38.2% vs 15.9%, p<0.0001), but lower rates of post PCI TIMI-3 flow (80.9% vs 92.6%, p=0.002). However, no differences in the primary endpoints of complete ST-segment resolution (STR) at 30 minutes (79.6% vs 84.0%, p=0.69) or infarct size (median 13.0 vs 11.0, p=0.21), or 6 month mortality (2.2% vs 3.7%, p=0.56) were present between rescue and primary PCI patients. In rescue PCI patients' randomization to distal protection did not significantly affect infarct size, STR, mortality or other clinical events.

Conclusions: Despite reduced rates of TIMI-3 flow, patients undergoing rescue PCI compared to primary PCI have similar myocardial perfusion, infarct size and clinical outcomes. Further study may be warranted to determine whether distal microcirculatory protection devices may be of benefit in select patients undergoing rescue PCI.



Patient Selection for Automatic Implantable Defibrillators

J. Coromilas

Implantable cardioverter defibrillators (ICD) are now indicated for primary prophylaxis in patients with significant left ventricular dysfunction and either prior MI or NYHA Class II or III CHF. This indication is based primarily on the findings of the MADIT II and SCDHeft clinical trials and is supported by findings from other, smaller trials. These recommendations have tremendous social and economic implications given the millions of people who meet the above broad criteria for primary prophylaxis with an ICD. However, further analysis of data from these trials suggests that the benefit of ICD may not be realized by all the patients now covered by these guidelines. In SCDHeft, the benefit of ICD seemed to be largely limited to patients in Class II rather than Class III patients. This finding is corroborated by the finding that no benefit is apparent in patients who were unable to walk at least 900 feet on a 6 minute walk test. Similarly, based on data presented to CMS by MADIT II and careful review of a recent publication from this group concerning the role of EPS study in the identification of highest risk patients, it appears that much of the benefit in MADIT II may have occurred in patients who had inducible sustained ventricular tachycardia. The benefit of ICD in patients with MI and inducible sustained VT had been previously demonstrated in the MADIT I and MUSTT clinical trials. Finally, it appears that a negative T wave alternans study may also identify a sub-group of patients who meet the established primary prophylaxis criteria but are at extremely low risk for sudden cardiac death. While caution must be used in interpreting retrospective subgroup analysis, these findings should form the basis for future studies to identify the subset of patients with LV dysfunction who are at highest risk for sudden cardiac death.



Background: Intermittent pneumatic compression (IPC) has been shown to be an effective method of lower limb arterial leg flow enhancement in patients with peripheral arterial disease and to ameliorate arterial claudication. The purpose of this study was to evaluate the clinical role of IPC in the treatment of non-healing foot wounds with associated tissue loss and in assisting limb salvage in patients with chronic critical ischemia.

Methods: The study was performed in a multidisciplinary wound healing clinic, including orthopedic and vascular surgeons, and physicians. The study comprised 2 groups: group 1 consisted of 24 patients, median age 70 (IQR: 68.7-71.3) years, who received IPC prior to and after partial foot amputation (toe or metatarsal) [IPC Group]; group 2 consisted of 24 patients, median age 69 (IQR: 65.7-70.3) years, who did not receive IPC treatment implementation prior to or after partial foot amputation [Control Group]. Laboratory assessment entailed measurement of the ankle brachial indices (ABI), transcutaneous oximetry (TcPO₂), duplex graft surveillance, and radiography. Surgical outcomes were considered favorable if complete healing occurred and the limb was salvaged. An unfavorable outcome was noted if the patient had to undergo a below knee amputation (BKA) subsequent to failure of healing of the local amputation. Patients enrolled in the study were followed-up for 18 months. All patients received a standard wound care regimen consisting of weekly debridement and biologic dressings for antimicrobial effect. IPC was used for six hours per day and patients were encouraged to pump three times per day, two hours per session. Calf compression was every 20 seconds (three times per minute), a rapid rise of pressure to 95 mmHg with a 2 second hold. Patients with recent (6 months) deep vein thrombosis or calf wounds were excluded from the study.

Results: Baseline differences in the age, sex, male/female ratio, risk factors (diabetes, smoking, hypertension, dyslipidemia, renal impairment) and in the ABIs, TcPO₂, and the extent and type of prior arterial reconstruction between the 2 groups were not significant. In the control group, 20 patients (83%) failed to heal their local foot amputation and had to undergo a BKA; the remaining 4 (17%, 95% Confidence Interval: 0.59% to 32.7%) had complete healing and limb salvage. In the IPC group, 14 patients (58%, 95% Confidence Interval: 37.1% to 79.6%) had complete healing after the local foot amputation and subsequent limb salvage. Ten patients (42%) in this group underwent BKA after failing healing of the local foot amputation. Both wound healing and limb salvage were significantly better in the IPC group (p<0.01). When compared with those who received IPC, the odds ratio of limb loss in patients who did not have the benefit of IPC was 7.0.

Conclusion: Our study data reveal that patients with chronic critical limb ischemia who undergo local foot amputation improve significantly the wound healing and thus their chances of limb salvage when IPC is used as an adjunct to a standard wound care regimen. By enhancing the arterial calf and foot inflow, IPC may promote the healing process at the amputation site, when sound treatment alternatives in current practice have been exhausted. Our data is in support of large-scale studies aiming to substantiate not only the clinical benefit but also the underlying mechanisms of IPC in the pathophysiology of chronic critical limb ischemia.



INTRODUCTION

Medical education today aims not only to physicians but also to the general population as part of health maintenance. It is well recognized that the internet is the major source of medical information for the average health information seeker yet the quality of this information has been often criticised inaccurate or even misleading.

We studied the relationship between popularity and quality of websites providing information about low back pain on the Internet.

MATERIAL AND METHOD

A study of websites was conducted in 2002 visiting the top 50 websites returned by Google in response to the query: "low back pain". The quality of the information they provided was assessed using the JAMA benchmarks for website quality and the Health on the Net (HoN) criteria. The popularity of the websites was assessed by their ranking provided by Google and by the number of links related to each site (URL). We revisited and reassessed the same sites 3 years later. The Pearson's Chi square test was used for statistical analysis of the results.

RESULTS

12 of the most popular sites in 2002 were not present in 2005 and they redirected the search. 8 sites have improved their rank in 2005, 2 remained the same and 38 have deteriorated. The number of links for each website has also reduced from 18 to 2 (median values).

11 sites have improved their quality and 25 remained the same. The Health on the Net seal appeared in 8 websites in 2002 and in 12 in 2005. No statistically significant improvement was found in the fulfilment of the JAMA benchmarks between 2002 and 2005. We found no relationship between the popularity and quality of low back pain websites.

DISCUSSION/CONCLUSION

The number of patients seeking medical information and advice on the Internet is constantly increasing yet the quality of the information provided is usually sub optimal. This confusion may affect the patient's understanding of their condition and also the trust to their doctor.

This study demonstrates the need for the careful designing of websites providing medical information and perhaps the need for their monitoring by medical authorities.



IMRT and Chemotherapy Used to Successfully Treat Anal Cancer

G. Varsos

Anal cancer accounts for 3% of anorectal tumors in the United States. They are frequently associated with a history of hemorrhoids, fistulae, fissures, leukoplakia, condilomata and AIDS. They are more common in women and homosexual males. Human pappilloma viruses 16, 18 and 33 have all been identified to be more frequently found in patients with anal carcinoma.

The standard treatment for carcinoma of the anus traditionally was surgical extirpation most often leaving the patient with a permanent colostomy. A landmark study was published by Nigro et al from Wayne State University that 23/28 patients with anal cancer achieved permanent local control with radiation and chemotherapy using 5FU and Mitomycin. Since that time this type of treatment has become widely used for patients with anal carcinoma.

We have treated seven consecutive patients with anal carcinoma using intensity modulated radiation therapy (IMRT) and chemotherapy at the advanced radiation Oncology free-standing center in conjunction with the Mount Sinai Hospital of Queens. To our knowledge this is the first report of the use of IMRT for anal cancer. We achieved a complete response in 6 patients the one failure went on to surgical salvage.

IMRT is a method of planning and delivery of radiation that is available because of recent computer technological advances. It allows the treating physician to deliver radiation to tumors and exclude sensitive normal tissue from the field of treatment with great accuracy. The technique utilizes a dynamic multiple of Collimator that moves 80 to 120 segments during the treatment and allows control of beam intensity within one field of treatment. The treatment has both decreased the incidence of complications and enabled the delivery of higher doses to tumors than ever before.

We found that IMRT is easily used for anal radiation. We observed minimal side-effects which is very important in because patients treated with chemo-radiation has an increased incidence of both acute and long term reactions. We believe that protocols similar to ours could be employed in both University and Community hospitals.



Improving the Educational Value of Clinical Audit

V. G. Hadjianastassiou, D. Karadaglis, M. Gavalas

OBJECTIVES

Clinical Audit is a recognised and method of medical education. The feedback is conventionally given in the format of an average performance of the department relative to established guidelines. The impersonality of this feedback format may compromise audit educational value. The aim of the study was to compare personal, peer-comparison feedback, an effective method of changing physician practice, to the 'conventional' departmental one.

METHODS

Eleven junior doctors working at a central London Accident & Emergency department were audited in terms of the adequacy of their documentation process. The study comprised patients presenting with closed head injury, acute asthma and chest pain of possible cardiac origin. Personal peer-comparison feedback and average departmental feedback was given for the first two groups, respectively. No feedback was given for the chest pain group, acting as a control group. The outcome measure was documentation of the minimum variables, as specified by departmental and national guidelines.

RESULTS

The peer-comparison feedback group showed a significant improvement (p-value<0.0001) in two out of three target variables audited, in contrast to the departmental feedback group and the control group which did not show a significant improvement in any of the variables.

CONCLUSION

The educational value of audit feedback is better achieved by personal, confidential peer-comparison feedback rather than feedback in groups of doctors. This pilot study should form the basis of a larger study (more doctors, wider range of conditions) to establish unequivocally the best format for educational feedback.



The Contribution of Ancient Medicine to Modern Orthopaedics

D. Karadaglis

The modern orthopaedic surgeon is bombarded daily with new information. This applies to new surgical techniques and approaches (minimally invasive surgery), new medications, new methods of treatment, and new instruments. There is also a constant flow of new policies and guidelines. All these can easily confuse the modern surgeon and distract him from his aim, the treatment of a patient, rather than the management of mere symptoms or even radiographic images of a disease. Another increasingly serious problem of today's surgeon is to understand the limits of modern surgery as well as the limits of his personal abilities and skills and advise his patient regarding their expectations.

Today, it is more important than ever for the new orthopaedic surgeon to look back to the origins of the profession in order to find the foundations of this art, which surprisingly have remained unchanged through centuries. The basic principles of:

- Good training,
- Sound diagnosis prior to any treatment,
- Good communication with the patient and other colleagues,
- Disease prevention,
- Rehabilitation,
- Continuous education and teaching and;
- Most importantly an ethical code

have been well established by the ancient, Greek and Roman surgeons. These principles had been forgotten during the dark ages and gradually "reinvented" in our times after long and laborious research and study.

The Iliad, the various books of the Corpus Hippocrates and Gallen's work from Greece are some of the sources of invaluable information about the origins and the shape of surgery. The modern surgeon has a lot to gain from studying these papers regarding the above mentioned principles and most importantly to understand that he has to continue and enrich this ancient tradition. He will also become better equipped to meet the continuous challenges and dilemmas of his current practice.



Adolescent Medicine in Greece Today. Current Perspectives and Approaches

G. Maragos

Adolescents comprise 15 % of the population at present in Greece and it is estimated that in a very short period of time this percentage would be increased to 35 %, mainly due to the population movements from the developing countries to the more affluent. This segment of the population is notoriously known for the high risk health behaviors and the special medical services, preventive and otherwise needed in order to promote and cope with the diversified health problems it is faced with. Accidents, homicide and suicide are the leading causes of death in adolescents today. Added to this important list are problems related to sexuality and reproductive health, substance abuse, psychological and physical abuse, fleeing from the house, quitting from school and in situ family problems. The nature of these problems and the basic framework of morbidity and mortality are amenable to prevention and effectively coped with, in more than 75 % of the cases, with timely provided, to both parents and adolescents, consultation and the anticipated guidance, for each stage of adolescence (Guidelines Adolescents Preventive Medicine Services, GAPS)

Basic to this endeavor, of early prevention and coping of the adolescents turmoil is the promptness, availability of physicians and nurses willing to care for adolescents, their education on the subject of adolescents health problem, and the proper clinical setting.

In order to approach the major problem of adolescent health in Greece, the Hellenic Society of Adolescent Medicine was founded in 1992 in Athens with the basic goal to educate, promote health services to adolescents and improve the overall spectrum of health facilities available to adolescents in this country. During the past 15 years a significant amount of work has been done in this direction. Lectures, international conclave, publications on the subject, post graduate programs in adolescent medicine, clinics and a number of hospitalized clinical facilities have been advanced. In addition to Athens the effort is being spread to the provinces with a major undertaken in Thessaloniki, 4th pediatric University clinic, where a two year post-graduate course in adolescent medicine is being running very successfully. It is estimated that in the near future the comprehensive health program on adolescents would be further solidified and soon a residency program in this discipline would be incorporated into the pediatric postgraduate education in Greece as well.



Emerging Therapies Affecting Postprandial Glycemic Control

S. Mezitis

Current antidiabetic pharmacologic therapies are frequently associated with inadequate control of postprandial hyperglycemia, hypoglycemia, weight gain, and loss of efficacy over time. Postprandial hyperglycemia contributes to the abnormal glycemic exposure of tissues, limits efforts to reduce A1C to the normal 4-6% range, and may increase the risk for cardiovascular events. Rapid and sustained insulin secretion during and after eating is necessary to limit postprandial hyperglycemia. The "incretin effect" was discovered showing a two to three times greater secretion of insulin after oral administration of glucose compared to intravenous administration. Gut-related factors (incretins) isolated are the glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide 1 (GLP-1). Furthermore, gastrointestinal related mechanisms contributing to postprandial hyperglycemia in diabetes include lack of glucagon suppression, slow gastric emptying and decreased satiety that are improved upon by the incretins. GIP will not be further discussed because the diabetic beta-cell is relatively resistant to GIP action.

GLP-1 is a 30-amino acid gut peptide produced in enteroendocrine L cells located in the distal ileum and colon. Enzymatic inactivation by dipeptidyl peptidase IV (DPP-IV) and renal clearance contribute to a very short circulating half-life of several minutes for native GLP-1. Pharmacologic strategies for enhancing GLP-1 action in human diabetic patients have focused on developing degradation-resistant GLP-1 receptor agonists or potentiating endogenous levels of circulating GLP-1 via inhibition of DPP-IV activity.

Furthermore, insulin analogues have been developed in both subcutaneous and oral form to mimic postprandial insulin secretion.

REF: Emerging Therapies Mimicking the Effects of Amylin and Glucagon-Like Peptide 1, Riddle M. and Drucker D: Diabetes Care 29:435-449, 2006.



Emerging Therapies Affecting Postprandial Glycemic Control – GLP-1R Agonists, DPP-IV Inhibitors

S. Mezitis

Exenatide-4 was isolated from the venom of a lizard in the Southwest United States that exhibits 53% amino acid homology to native human GLP-1, is resistant to DPP-IV action, and is a GLP-1 receptor agonist. The synthetic form exenatide (Byetta) is a 39-amino acid GLP-1 receptor agonist showing A1C decline and weight loss in three large 6-month trials testing the addition of exenatide 10 mcg injections twice a day before meals to metformin alone, sulfonylurea alone, or metformin and a sulfonylurea together. The placebo-adjusted decline of A1C from baseline levels of 8.2-8.6% was 1% in each trial and the weight loss ranged from 0.9 - 2.5 kg. The U.S. Food and Drug Administration has approved exenatide for use in type 2 diabetes not optimally controlled with metformin and/or sulfonylurea. After 26 weeks of therapy with exenatide or insulin glargine in patients failing to achieve optimal glycemic control on metformin and a sulfonylurea, mean A1C reduction (1.1%) was comparable in both groups, but patients treated with exenatide had a mean weight loss of 2.3 kg versus 1.8 kg weight gain in the glargine group. Mild nausea and rare vomiting have been reported with exenatide.

Vildagliptin is an orally administered DPP-IV inhibitor that in a 12-week placebo controlled study 50 mg daily in 107 type 2 diabetic patients taking metformin showed an A1C reduction of 0.7% from mean baseline values averaging 7.8%. Weight changes were not observed.

REF: Therapeutic Options in Development for Management of Diabetes: Pharmacologic Agents and New Technologies, Lebovitz, Harold: Endocrine Practice 12:142-147, 2006.



Emerging Therapies Affecting Postprandial Glycemic Control – Amylin and Insulin

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Islet amyloid polypeptide or amylin is a 37-amino acid peptide co-secreted together with insulin from islet beta-cells. Plasma levels of amylin increase with nutritional stimuli and by glucagon, GLP-1, and cholinergic agonists. The acute glucoregulatory actions of exogenous amylin include inhibition of gastric emptying, glucagon secretion, and short-term food intake. The amylin analog pramlintide (Symlin) with three amino acid substitutions does not cause amyloid deposits, possesses the biological potency of native amylin, and has been approved by the U.S. Food and Drug Administration (FDA) for use in type 1 and type 2 diabetes receiving insulin. Published results from four 52-week trials, two in type 1 (60 mcg qid injections 15 minutes before a meal) and two in type 2 diabetes (150 mcg tid and 120 mcg bid injections), resulted in similar placebo-adjusted A1C reductions (0.3 -0.4%) and weight loss (1.5 - 2.5 kg). Pramlintide needs to be started at a lower dose in type 1 (15 mcg tid) versus type 2 (60 mcg tid before meals) and mealtime insulin should be halved. Hypoglycemia and nausea decrease after 4 weeks of treatment.

Insulin therapy is critical for achieving target glycemic control in all patients with type 1 and many patients with type 2 diabetes. Rapid-acting insulin analogs control postprandial hyperglycemia. Insulin glulisine (Apidra) was recently FDA approved and it may have advantages over lispro, aspart by not causing weight gain and acting faster.

The first inhaled insulin preparation (Exubera) has been FDA approved as a bolus/prandial insulin. Clinical trials show Exubera to be as effective as bolus subcutaneous insulin to control postprandial glucose excursions. The cumbersome device, dosage requirements, and unknown long-term pulmonary safety are concerning.

REF: Amylin Replacement with Pramlintide as an Adjunct to Insulin Therapy Improves Long-Term Glycaemic and Weight Control in Type 1 Diabetes Mellitus: A 1-year Randomized Controlled Trial, Ratner et al, Diabet Med. 21:1204-1212, 2004.

Inhaled Insulin: Exubera, Odegard and Capoccia, Ann Pharmacother. 39:843-853, 2005.



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