



Summer, 2006, Volume 6

Chartwell Diversified Services, Inc.

Thoughts to Ponder . . .

- * I can earn nursing CE credits by reading this newsletter??
- * What's new in insulin therapy?
- * The only approved FDA fish oil supplement
- * What are the challenges facing patients new to home parenteral nutrition?
- * The latest update on immunoglobulin therapy

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Continuing Education (CE) Highlights

The following SELF-Study programs are now updated and available on disk for your convenience:

- [Cultural Awareness](#)
- [Autoimmune Therapies in the Home](#)
- [Vascular Access Devices](#)
- [Nutrition Screening and Assessment](#)
- [Parenteral Nutrition](#)
- [Enteral Nutrition](#)

These programs will soon be available on our website:

<http://www.chartwelldsi.com>

A NEW self-study program is available now as well—**DRUG UP-**

DATE 2006—2 contact hours.

Please let me know if you would like a copy of the program.

You may be noticing some slight changes in ANCC credit hours for the various programs. ANCC has changed the credit hour base from 50 minutes to 60 minutes = 1 CE credit hour. This will not make a significant difference in credit hours and will be easier to calculate available hours on education material.

I also want to thank everyone for

sending materials back once the program is completed. This helps out tremendously and saves \$\$\$\$\$.

EARN 1.0 hour of nursing CE CREDIT (ANCC and CA) by reading this NEWSLETTER—Complete the quiz and evaluation sent with this newsletter file. Return the information to me at khammond@chartwelldsi.com. I will then send a certificate to you!

Drug Update

Two new drugs of interest from The Medical Letter, July 17, 2006 Vol. 48 (Issue 1239):

Exubera-Pfizer

Exubera is an inhaled, dry-powdered form of rapid-acting human insulin approved by the FDA for treatment of type 1 or type 2 diabetes in adults.

Exubera is available in "blisters" which contain 1 or 3 mg of dry powdered insulin (equivalent to 3 units or 8 units, respectively) of subcutaneous injected regular insulin. A handheld inhaler is used to administer the medication. Since the blisters are only available in 1 or 3 mg, several different blisters may be necessary to meet the prescribed amount. Once the insulin is inhaled, approximately 30% of the medication remains in the blister or inhaler, 20% reaches the oropharynx, 10% reaches the airways, and 40% reaches deep into the lung.

Due to the rapid onset of inhaled insulin, it should not be administered any earlier than 10 minutes before a meal.

A mild to moderate cough can occur as an adverse reaction. This type of reaction can occur within a few minutes of inhalation and resolves once the medication is discontinued. Long term safety issues for the pulmonary system is not known at this time.

Overall, patients tested were satisfied with this method of insulin administration and chose to continue therapy rather than use subcutaneous administration.

Omacor (Reliant)

Did you know that Omacor is the only fish oil supplement approved by the FDA? It is only available by prescription for the treatment of hypertriglyceridemia (≥ 500 mg/dL). Clinical Studies using fish oil include acute and chronic coronary disease, Type 2 diabetes, hypercholesterolemia, and hypertriglyceridemia.

There are other fish oil supplements available over the counter as dietary supplements but they are not regulated for purity or content. The US Pharmacopeia (www.usp.org) is the official standard-setting body for supplements and drugs. They have been testing some of the OTC fish oil products for verification of labeled content.

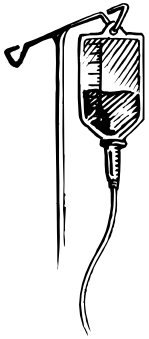
Adverse effects from fish oil include eructation, dyspepsia, and unpleasant aftertaste. Patients with diabetes taking large doses have noted problems with glycemic control. Large doses can also inhibit platelet aggregation and increase bleeding time.

Consumption of fish in the diet may be beneficial for healthy people. There is no evidence that fish oil supplements prevent cardiovascular disease in the general population.

Examination of Factors that Lead to Complications for New Home Parenteral Nutrition Patients

From: *Journal of Infusion Nursing*

March/April 2006 Vol. 29, No. 2:74-80



Home parenteral nutrition (HPN) therapy has been a life-sustaining therapy for many people since its beginning. Many adults and children have been able to maintain a long and productive life with this therapy. However, HPN as with parenteral nutrition therapy in the acute care setting, carries the risk of infection along with mechanical and metabolic complications.

A study was conducted by the Cleveland Clinic Foundation in regard to patients who received parenteral nutrition in the home setting. Factors that led to complications within the first 90 days of receiving home parenteral nutrition (HPN) were studied.

Of the 97 patients studied, 29 patients had a diagnosis of cancer, 16 patients had Crohn's disease, 13 patients had graft versus host disease after allogenic bone marrow transplant, 2 patients with enterocutaneous fistula, 1 patient with intestinal ischemia, 1 patient with radiation enteritis, and 35 with other diagnoses.

The main indications for HPN included malabsorption, bowel obstruction, and fistulas. Most patients had Hickman catheters but ports and peripherally inserted central catheters were also placed.

Additional complex needs for these patients included home IV antibiotic therapy, wound care, ostomy or fistula care, pain management, and others who required physical or occupational therapy.

Complications that occurred within the first 90 days of therapy at home included infections, and mechanical and metabolic disorders. Infections accounted for 25 or 56.8% of the total complications. Catheter-related bloodstream infections (CR-BSI) accounted for 22 of the 25 infections. The other three infectious complications were 1 Hickman tunnel infection and 2 exit-site infections.

Mechanical complications accounted for 11 or 25% of the total complications. Sources of the mechanical complications included a catheter falling out, 1 that migrated out of position, 3 catheters that became occluded, 4 catheters that broke, and 2 catheter-related bleeding episodes.

Metabolic complications occurred for 8 or 18.2% of the total complications. Among the metabolic complications noted, there were 4 alterations in hydration, 1 blood sugar abnormality, 2 electrolyte abnormalities, and 1 bleeding complication possibly related to a lack of vitamin K in the formulation.

Other complications noted were 1 inadequate training, 4 noncompliance related issues, 3 prescribing errors, 4 healthcare worker errors, and 3 equipment malfunctions.

It appears that 1/3 of the patients had complications while receiving HPN in the first 90 days of therapy. Among the complications noted, 1/3 of them may have been preventable. Having a single-lumen catheter and the presence of an ostomy or fistula were two factors that seemed to predispose patients to complications.

Infectious complications, particularly (CR-BSI), were the most common. Conditions requiring HPN often increase the risk for infection of the vascular access device. There was also a trend for more complications for those who had an ostomy or fistula which may occur related to the possible contamination resulting from the manipulation of the ostomy device and close proximity of the venous access device. The presence of an ostomy or shortened bowel itself can lead to metabolic complications. But, in spite of the associated risks and complications for those with ostomies, HPN has provided a means to nourish and decrease the overall mortality rate in this group of patients.



Immunoglobulin Therapy: Intravenous and Subcutaneous: An Update

Immunoglobulin therapy is the administration of immune globulins containing antibodies to patients who may have inherited and acquired immunodeficiency disorders. Immunoglobulin preparations are produced from plasma collected from 5,000 to 10,000 people. Immunoglobulin is a highly purified solution of human IgG and is the most widely used component of plasma used in the world. Immunoglobulins can be administered by intravenous, intramuscular, or subcutaneous route.

The FDA has approved IVIG for primary immune deficiency, secondary immune deficiency (pediatric HIV infection, bone marrow transplant idiopathic/immune-mediated thrombocytopenia), chronic lymphocytic leukemia, and Kawasaki disease. The use of IVIG has expanded to neurological disorders including Guillain-Barre syndrome, chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, myasthenia gravis and dermatomyositis. It is also used for dermatologic conditions such as autoimmune blistering skin disease.

Intravenous products currently available include Gamunex (Talecris), Gammagard S/D (Baxter), Gammagard Liquid (Baxter), Carimune NF (ZLB Behring), Panglobulin NF (American Red Cross), Polygam S/D (American Red Cross), Flebogamma (Grifois), Octagam (Octapharma), and Iveegam EN (Baxter). Gammar-P I.V. (ZLB Behring) is no longer being manufactured and once the already-manufactured supply ends will no longer be available. The manufacture of Panglobulin NF and Polygam S/D is scheduled to stop by the end of this year. Iveegam EN will no longer be available as of January 1, 2007. Please see the attached document accompanying this newsletter to review a comparison chart on the various products.

Decreased reimbursement for IVIG products occurred by government legislation in 2005 resulting in more patients having to receive hospital care. This in turn led to patients not being able to afford co-pays, limited product availability, and prolonged treatment times of 6 to 8 hours.

Home infusion of IVIG provides an alternative for some patients receiving IVIG. The first infusion is usually given in a controlled setting and if stable, can transition to home. Of course, a complete home assessment is completed before a final decision is made.

Since every patient is affected differently by immunoglobulin and each product is slightly different in composition, it is not recommended to switch products during therapy. Before initiating therapy, patient assessment for IgA deficiency has to be determined. Those with an IgA deficiency can build antibodies against foreign IgA (anti-IgA antibodies) in the IVIG product. As a result, a patient can have an anaphylactic IgE reaction. Each product will list the amount of IgA contained in the solution. Gammagard S/D and Polygam S/D by Baxter Healthcare currently contain the lowest amounts of IgA.

A review of the medical history is essential before initiating therapy. Especially important to assess is kidney function, history of diabetes, hypertension, stroke risk, thromboembolic events including pulmonary embolism, deep vein thrombosis, hemolytic anemia, and myocardial infarction.

Any of these risk factors may pose a risk to therapy. Products that contain a low osmolarity (5% products) are recommended for those with a history of stroke, clotting disorders or risk of thromboembolism. Awareness of other medications that the patient is taking should be taken into account and noted for any nephrotoxicity.

In 1990, a "black box" label by the FDA warned of IVIG products containing carbohydrates, glucose, sodium, and other stabilizers when infused at a rapid rate had the potential for causing renal tubular necrosis. This is especially important with those who have a preexisting renal concern.

In January of this year, the FDA approved the first subcutaneous IgG product, Vivaglobin 16% (ZLB Behring), for use in patients with primary immunodeficiency disease states.

Subcutaneous immunoglobulin is advantageous for those patients (adults and children) who have poor venous access, severe adverse reactions, and for whom intravenous administration has been cost prohibitive. Subcutaneous administration is an alternative for pregnant antibody-deficient patients. Other advantages include the convenience of home administration, no need for venous access, few side effects as compared to IVIG, more stable IgG concentrations, increased autonomy, and rare systemic reactions. On the other hand, disadvantages include frequent dosing, complete compliance for self-injection, and localized reactions. It is contraindicated in patients with bleeding disorders, thrombocytopenia, or those receiving anticoagulant therapy.

Overall, subcutaneous administration of immunoglobulin is a positive alternative to monthly infusions of IVIG. It is well tolerated and safe. Of course, patients greatly appreciate the alternative and the ability to receive a therapy that might otherwise be unavailable to them. The competently trained infusion nurse is the patient's resource in the home setting.

For patients who have had a prior anaphylactic or allergic reactions to IM or IV immunoglobulin, premedication with acetaminophen, oral diphenhydramine, and/or IV hydrocortisone may be necessary. An EpiPen should also be kept on hand.

The most commonly used adult dose of subcutaneous immunoglobulin referenced is approximately 100 mg/kg per week. The most common method of administration is via an IV syringe infusion pump. The Intravenous Nursing Society (INS) has established guidelines for the administration of subcutaneous immunoglobulin. Rate and infusion vary with some of the literature citing a slower initiation rate with a gradual increase as tolerated. A final infusion rate of 20 to 25 mL/hour was most commonly used.

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Information contained in this newsletter is meant to serve as an educational tool. As always, clinical judgment should be exercised in determining the appropriate therapy for specific cases.

Upcoming Meetings:

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| September 16-19 | American Dietetic Association Food and Nutrition Expo Honolulu, HI |
| September 17-19 | American College of Clinical Pharmacology Cambridge, MA |
| November 17 | Autoimmune Diseases of Connective Tissue Washington DC |
| November 18 –19 | Fall National Academy of Infusion Nursing Washington DC |
| December 3-7 | 41st Annual Midyear Meeting of the American Society of Health System Pharmacists Anaheim, CA |

(Cont. from page 3) Side effects of subcutaneous immunoglobulin can include localized reactions at the injection site including swelling, erythema, itching, soreness, or induration at the site. These side effects usually resolve within 24 hours. There have been no reports of infections or abscesses reported.

References:

Duff K. You can make a difference in the administration of intravenous immunoglobulin therapy. 2006 Journal of Infusion Nursing 29 (3S):S5-S14.

Kirmse J. Subcutaneous administration of immunoglobulin. 2006 Journal of Infusion Nursing 29 (3S):S15-S20).

Koski CL. Intravenous immunoglobulin use for neurologic disease. 2006 Journal of Infusion Nursing 29 (3S):S21-S28).

RECIPE: Vine Ripe Salsa



Soon all of those vine ripe tomatoes will be available. Here is a quick, delicious, and healthy recipe packed with vitamin C, antioxidants, lycopene, phytochemicals, and fiber:

Ingredients:

- 5-6 vine ripe tomatoes, washed
- 1/4 cup chopped cilantro
- 1 clove minced garlic
- Juice of 1 lime
- 1/2 fresh jalapeño chopped without seeds (add seeds for more heat)
- Dash of salt, pepper

Combine all ingredients in a bowl. Add to food processor and prepare to desired consistency.

Enjoy with favorite foods!