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LECOM Point

WELCOME TO LECOM POINT, A DRUG INFORMATION SOURCE THAT IS DIRECT AND TO THE POINT

LECOM CDIR 2.0

We're going monthly! Starting with this issue, plan to see the Point online and in your email box every month. If there are topics you'd like to see discussed, please send us an email: cdir@lecom.edu

The LECOM Center for Drug Information and Research (CDIR) was established with a mission to provide students, faculty, preceptors, and the public with timely, independent, best-evidence analysis and commentary on pharmaceuticals and healthcare policy as it relates to pharmaceuticals. Our aim is to take advantage of our virtual world and develop an online drug resource accessible to anyone via the Internet.

For the LECOM community, the CDIR acts as a direct resource for our medical, pharmacy and dental providers, faculty and preceptors who need answers to specific drug information questions.

The CDIR website is being updated with new content frequently. Users can sign-up for our Twitter updates and RSS feeds. As we work to develop our virtual presence, the CDIR team will provide this newsletter as a service to the entire LECOM family.

Feel free to contact us with drug information questions, general questions or comments at cdir@lecom.edu.

Future wave of chemotherapy?

The FDA recently approved Pfizer to market Xalkori (crizotinib), targeted to treat patients with late stage, non-small-cell lung cancer (NSCLC) who express mutations of the anaplastic lymphoma kinase (ALK) gene.[1] Concurrently, the FDA has also approved a companion diagnostic test to help determine if the patient expresses the ALK gene mutation. This represents a rather new and exciting trend in chemotherapy treatment as Xalkori is the 2nd targeted chemotherapy agent approved by the FDA along with a test this year (Genentech Inc.'s Zelboraf™ used for late-stage melanoma in patients with BRAF V600E mutation was approved along with a companion test in August 2011).

EML4-ALK is a genetic mutation representing the fusion of the echinoderm microtubule-associated protein-like 4 (EML4) and ALK genes.[2] It is estimated that 2-7% of patients with NSCLC have EML4-ALK mutations, representing about 10,000 patients in the United States alone.[3] Patients expressing EML4-ALK mutations are resistant to treatment with currently available growth factor receptor inhibitors (ie. Tarceva®, erlotinib), however, it has been shown in clinical trials that treatment with crizotinib (an ALK inhibitor) has improved response rates to nearly 60% of patients, compared to ~10% of patients treated with second line chemotherapy.[2]

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One of the challenges facing practitioners had been that no standard FDA-approved test for detecting EML4-ALK mutations was available per the NCCN guidelines for NSCLC. Now with the new FDA approval of the Vysis ALK Break Apart FISH Probe kit as a companion test, providers will now have a gold-standard tool to use in determining patient qualification for this new medication.

One of the issues that will certainly arise is the cost of targeted therapies. It is estimated that treatment with Xalkori will cost roughly $9600/month.[4] This is far out of the financial reach of the vast majority of patients, although Pfizer is currently offering a patient assistance program for uninsured or underinsured patients which may help a greater number of patients have access to the drug. The high cost associated with this new drug is not unique. The previously mentioned Zelboraf comes with its own steep price tag of $56,400 for a 6-month course of treatment.[5] Even considering planned patient assistance programs, it is clear that these new, innovative genomic-based targeted therapies will come at a significant cost, making accessibility to the general population limited at best. While these therapies surely represent advances in our understanding of the role of genomics in providing patient-specific therapy, only time will tell if the benefits will outweigh the costs enough to continue advancing medicine in this direction.

References

Insulin Pump Review

The use of insulin pumps to control blood sugar in persons with diabetes is rising. An estimated 375,000 patients use insulin pumps worldwide.[1] Insulin pump use in patients with type 2 diabetes is increasing, with more patients relying on insulin therapy for control every day. With the rise in use, many insurance companies are starting to cover insulin pumps and supplies. Coupled with data that show fewer complications with tight blood sugar control, insulin pumps can be beneficial in certain patients with diabetes requiring insulin therapy.[2]

Insulin pumps work by providing a constant, basal flow of rapid acting insulin (Humalog®, Novolog®, or Apidra®) into the patient's body. The flow of insulin is adjusted by the patient's healthcare provider, taking into consideration the patient's daily insulin need as well as insulin sensitivity. Most pumps also allow for short bursts (boluses) of insulin to be administered to cover for mealtime increases in blood sugar.

There are a number of insulin pump systems available in the United States. It is important to consider all features of a pump before choosing one for a patient. Price is often a deciding factor. It is difficult to price pumps for individuals since most insurance companies have contracted prices for each pump. The cash price for most pumps usually ranges from $5,000 - $7,000 for the pump alone. Infusion sets and tubing cost around $12 each and need to be changed every 2-3 days, adding to the patient's total cost. All of the pumps and infusion sets are similarly priced. As an alternative, the OmniPod tubeless pump system can be purchased for ~$600 but requires the tubeless system to be purchased for ~$35 each.

The OmniPod tubeless pump system uses a Personal Diabetes Manager (PDM) device, similar to a PDA or a smart phone, to communicate wirelessly with a waterproof, tubeless, "pod" that is placed on the body.[3] The pod has an automatic inserter to place a catheter under the patient's skin for insulin delivery. The PDM is programmed with a set basal rate to deliver insulin to the patient. The patient can also program a bolus amount of insulin to cover meals. Once programmed, the PDM can be placed in a drawer or bag while the pod automatically delivers the scheduled amount of insulin. This allows the patient freedom from carrying the insulin pump device with attached tubing. The PDM however does need to be within 2 feet of the pod when communicating changes in insulin doses. The pod is also a bit larger than other infusion sets, which can make it visible through clothing and bulky when physically active.

The PDM also has a number of applications that help the patient calculate the necessary amount of insulin to cover blood sugars and meals. It has a built-in glucometer and food library to help with these calculations. It also integrates with many different available continuous glucose monitoring (CGM) systems, that must be purchased separately, which can reduce finger sticks throughout the day. CGM systems measure blood sugar throughout the day through a probe inserted just under the skin. They allow for patients to track their blood sugar over time, looking for trends in rising or falling blood sugars. These values can be used to adjust insulin and food intake before a critically high or low blood sugar value occurs.

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The One Touch Ping is the newest insulin pump from Animas.[4] It is a waterproof insulin pump. The Ping, much like the OmniPod, has a meter-remote that communicates wirelessly with the pump. This remote also has applications and can remotely dose insulin from the pump. The Ping can interface completely with a CGM system, purchased separately, as well.

The Medtronic MiniMed Paradigm offers completely integrated CGM with their extra accessories. The patient can purchase a glucose sensor that is placed in the skin to continuously monitor blood glucose. This information is directly transmitted to the MiniMed and can warn patients of impending highs and lows. Although water resistant, the company does not recommend that the patient bathe or swim with the pump attached. Unlike the units above, this unit lacks a food library to help the patient calculate mealtime insulin doses.

The amount of insulin a pump can hold and the minimum and maximum dosing amounts are important factors in choosing a pump. The MiniMed holds 300 units while both the OmniPod and Ping can hold at most 200 units. Larger volumes allow for more time between filling the pumps' reservoirs (for people travelling or working long hours).

The OmniPod can dose in increments of 0.5 units. The Ping and MiniMed both can dose at increments of 0.25 units, giving better ability to control blood sugar. The maximum amount that the Ping, OmniPod, and MiniMed can dose at one time are 25, 30, and 35 units respectively. Larger maximum doses can be less time consuming for patients, especially those type 2 patients who might need large amounts of insulin per dose.

Most insulin pumps interact with home computers to give the patient access to graphs and other data collected. This data can then be taken to a provider's office for analysis. Both the Ping and MiniMed are PC and Mac compatible. The OmniPod's software is only PC compatible.

Choosing the right insulin pump involves taking each patient's individual situation into account. Working with the patient to choose the best system for them can give the patient new freedoms and can have a major impact on the patient's overall quality of life.

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LECOM SCHOOL OF PHARMACY
CENTER FOR DRUG INFORMATION AND RESEARCH

LECOM is a single school of pharmacy operating out of two locations. Consistent with LECOM's core value of creating student-centered education, two distinct learning pathways are offered for the Pharm.D. degree providing students the option of choosing a pathway most suited to their learning needs. In Erie, PA, an accelerated three-year pathway is offered enabling students to complete the Pharm.D degree in three calendar years; in Bradenton, FL, a traditional four-year pathway is offered. Both curricula offer the same spectrum of didactic courses, credit hours, and experiential education and experiences. The full array of supporting services exists at both campuses. Physical facilities, at each campus, are state-of-the art and of sufficient volume to meet all educational and administrative functions.

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