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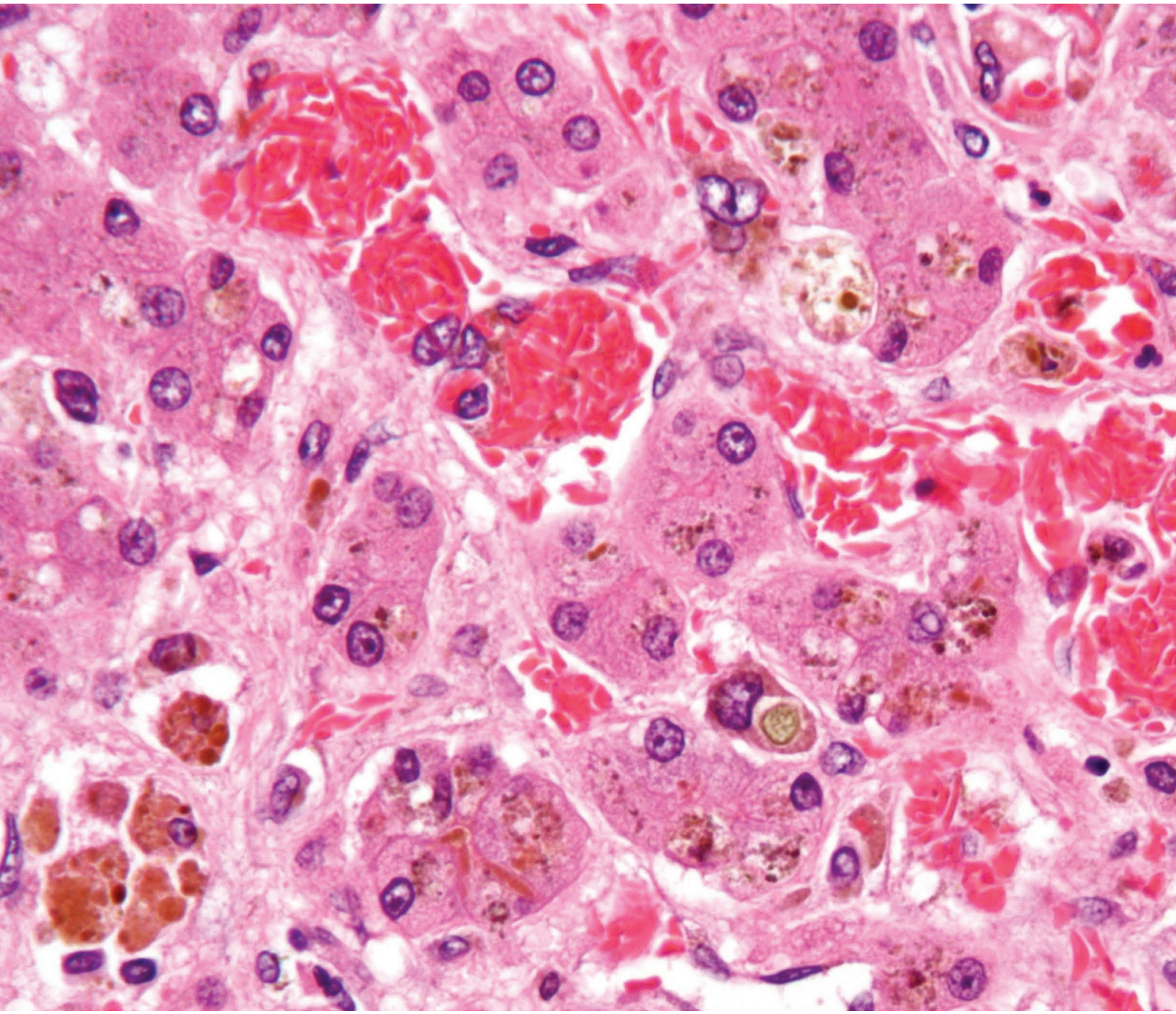

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Mission Statement:

To advance the profession of pharmacy, enabling our members to provide optimal care to those they serve.

President's Letter

As this unprecedented year comes to a close, I want to wish everyone in the NJPhA community a happy holiday season. We are all hopeful that 2021 returns us to "normal" at some point but we all know that we still have a fight ahead of us.

NJPhA started 2020 like any other year, planning for seasonal CE events, planning our annual convention and making sure that our committees had solid plans for the year ahead. Certainly, none of us saw what was coming.

We are constantly surrounded by negative news so I would like to highlight some of the many positives surrounding pharmacy that happened over the year. In all pharmacy workplace settings, we faced short staffing issues due to illness, childcare and family concerns, as well as other reasons. Our members rose to the occasion to address medication shortages, navigate regulatory changes, search for the illusive PPE to keep everyone safe, comply with State/CDC guidelines in the workplace and still continue to do their everyday tasks. As always, our pharmacists, pharmacy technicians and pharmacy staff members were ready to take care of patientneeds and continue to improve outcomes for patients.

Our CEO, Elise Barry, coordinated and lead the weekly Covid-19 conference calls which brought numerous healthcare and regulatory stakeholders together to discuss problems they were facing and to discuss potential solutions. In 30 years of pharmacy practice, I have never seen this many groups of pharmacists, physicians, pharmacy schools, insurance companies and regulatory agencies come together for months on end and calmly discuss the issues at hand. It was very refreshing to see. Kudos Elise for making this happen.

We also had to completely change our largest event of the year, the annual convention, in very short order. The convention was changed from a live event to a virtual event in 3 short months. We saw the reigning Miss America host the student competition on the last day of our convention and the convention as a whole was executed extremely well. Thank you to our NJPhA Convention Chair, Grace Earl and the members of the committee for planning such a great convention.

It has been a privilege and an honor to serve as the 2020 NJPhA President. I would like to thank all of the officers, members and the home office for their support. Thank you to James Ward for his many years of dedicated service as an officer and the best of luck to our incoming President, Grace Earl. Grace will do an excellent job leading the way in 2021.

Sincerely,
Mark Taylor, RPh, MBA
2020 President
2021 Chairman of the Board

From The Editors' Desks...

Dear colleagues,

Thank you for your continued support for the *New Jersey Journal of Pharmacy* – the official peer-reviewed journal of the New Jersey Pharmacists Association. It is our sincere hope that you enjoy the summer edition of our journal. This issue highlights a continuing education article titled "Systemic lupus erythematosus: a brief primer on ethnic and genetic risk associations".

We welcome submissions for the next issue of the *New Jersey Journal of Pharmacy*. If you are interested in submitting a manuscript for publication consideration or serving as a peer reviewer, please email the Journal Committee at njpharmacists@gmail.com.

Elif Özdener-Poyraz, PharmD, BCACP, CDE, AAHIVP
Editor-in-Chief

Malgorzata Slugocki, PharmD, BCPS
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The Journal wishes to acknowledge the following pharmacists who participated as peer reviewers for this issue: Drs. Nicole Ryba, Harold Kirshchenbaum, Ammie Patel, and David Haenick.

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Message from the Chair of the Board of Trustees

Dear NJPhA Members,

Greetings, I hope you are all doing well. Our recent convention in October, held for the first time virtually, was a success and we look to more opportunities to connect with you like this in the near future. Many thanks should be extended to President -elect Grace Earl and her convention committee for all their hard work in bringing to us a new and different way to connect as they did with this convention. Look for upcoming communications regarding our next big event, our annual "March Madness" seminar where there will be many educational opportunities for you to participate in.

This is my last letter to you as Chairman of the Board of Trustees, as my term will be coming to an end in just a few short weeks. It has been an honor to serve the Association and work with such fine pharmacists and technicians, and I appreciate the support you have given to me during my time as a line officer.

Congratulations to our incoming officers, Mark Taylor, Grace Earl, Aakash Gandhi and Rupal Mansukhani, who will serve as the Associations Officers in 2021. I wish them and you a very prosperous year!

I hope you all stay well and thank you again for your support.

Best Regards,
Jim
James Ward RPh
NJPhA Chairman- Board of Trustees

Living The Dream

As a fifty-year registered New Jersey Pharmacist and also a member of the NJPhA for those same fifty years, I want to share some viewpoints through the prism of the current pandemic. My desire to become a pharmacist started in North Bergen, N.J. where I lived for my high school and College days. There was a community pharmacy right across the street from the block on which I lived and even though I had no family member in the medical field to influence me, it was the store that attracted me to this profession. I'm not sure if it was the smell of vitamins, the pretty colored bottles or the white jacket that the pharmacist wore that sealed the deal. Well, it obviously worked and I graduated from St John's University and started my one-year internship (a requirement in those days) at a local pharmacy. The owner immediately demanded that I join the NJPhA and he took me to the monthly county meetings, usually in Jersey City. It was a decision that changed my outlook on pharmacy. I meet a lot of other pharmacist and interns in the group and to this day I still have friendships with those I met so many years ago. You see, that is one of the best things about our association. The friends you make through the association will be with you throughout the remainder of your life. My career path has included many jobs in New Jersey. Mostly in community work, but a few years in nursing home administration and many as an area manager of adult community pharmacies. The constant being; NJPhA. I have had the honor to hold every office of leadership in the association and on that level, even formed closer bonds with fellow officers. I was so much looking forward to this year's one hundred fiftieth celebration. As you could guess, the first convention I attended was the historic one hundredth celebration. In addition, the year I graduated from St Johns college of Pharmacy was also the one hundredth centennial of the University. What a coincidence! So, this year, not only did I miss my fiftieth college reunion and Saint John's one hundred fiftieth centennial, but also the NJPhA one hundred fiftieth convention. The NJPhA Past President council was asked to develop an event to help celebrate our organizational achievement. We spent several days and nights developing an elaborate event but as you all know; the best laid plans of mice and men are sometimes led astray. We will be "zooming" this year with the rest of the world. No matter. It is the spirit of the membership that makes a successful group not the elaborate gala.

In closing, I have decided to retire from my beloved profession this year. Maybe the "Gods" have influenced me by the difficulty we all experienced as front-line workers, be it the N95 masks, the constant disinfecting our hands and work stations, dealing with the anxiety and fears of our clients or maybe just the feeling that "all good things must come to an end." If I can leave you with a message; It is the hope that all of you experience success and daily pride in this wonderful profession as I have. But also remember, that being an active member of our organization has rewards that a no job can offer and will help YOU live the dream!

Professionally yours,
Richard Coniglio R.P.

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A Review of Voxelotor and Crizanlizumab in Sickle Cell Disease

*by Rachel Zabriskie, PharmD Candidate 2021; Sherry Hanna, PharmD Candidate 2021; *Sasha Falbaum, PharmD*

Abstract

Background

Sickle cell disease (SCD) affects approximately 100,000 people in the United States. It is a genetic mutation in which red blood cells clump, polymerize, and change into sickled hemoglobin. This leads to further complications, including anemia, vaso-occlusive pain crisis, and acute chest syndrome. Hydroxyurea has been the mainstay of therapy to treat pain and acute chest syndrome and L-glutamine is thought to help reduce oxidative stress in SCD. The objective of this article is to provide a brief overview of SCD and evaluate the role of therapy of two novel medications approved in 2019: voxelotor and crizanlizumab.

Methods

Medline and Clinicaltrials.gov were utilized to complete a literature search on voxelotor and crizanlizumab. Information was evaluated and summarized based on safety and efficacy from clinical trials and package inserts.

Discussion

Voxelotor and crizanlizumab are indicated in sickle cell disease, however they have differing mechanisms of action and roles in the disease. Voxelotor works by preventing anemia in which the phase 3 trial showed significantly increased hemoglobin levels in the treatment arm versus placebo. In contrast, crizanlizumab reduces the pain and vaso-occlusive crisis associated with the disease as noted in the phase 2 trial, resulting in significantly less pain crises when compared to placebo.

Conclusion

In summary, voxelotor and crizanlizumab appear to be relatively safe and efficacious in the use of sickle cell disease. Choosing which medication to prescribe will depend on the specific patient parameters and whether it is for the prevention of anemia or to reduce pain associated with vaso-occlusive crisis.

Key words: sickle cell disease, voxelotor, crizanlizumab, safety, efficacy

Introduction

Sickle cell disease (SCD) affects approximately 100,000 people in the United States and millions throughout the world according to the Centers for Disease Control and Prevention.[1] In the United States, one out of every 365 Black or African-American babies is born with SCD and one out of 13 Black or African-American newborns is a carrier for the SCD trait.[1] In the first three years of life, one percent of children died due to complications associated with SCD between 1990 and 1994.[1] A retrospective study using the Medicaid Analytic Extracts database found average total medical costs were approximately $35,000 annually.[2] Study participants who experienced greater than three vaso-occlusive crises were found to have a mean total cost of almost $59,000.[2]

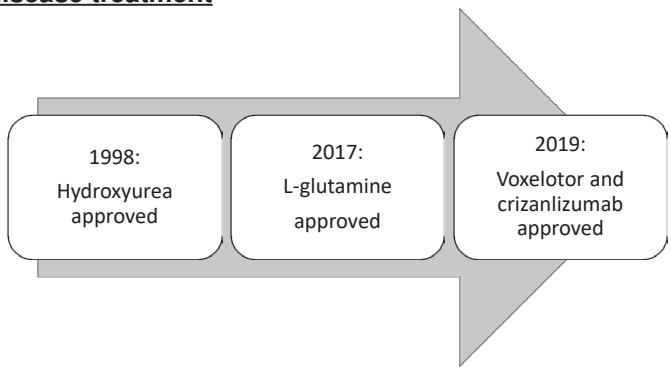
Sickle cell disease, caused by a point mutation in the production of a beta-globin gene, prompts the red blood cells to clump, polymerize, and change into sickle hemoglobin, which is less soluble than normal hemoglobin.[1,3] Sickled hemoglobin will lead to further complications, such as anemia caused by the breakdown of red blood cells, known as hemolysis.[1,3] It can also lead to a vaso-occlusive pain crisis, which occurs when sickled red blood cells clump and block blood flow and oxygen delivery.[1,3] Vaso-occlusion can lead to acute and chronic pain and tissue ischemia or infarction.[1,3] Rizio et al found that approximately 47% of patients experienced four or more vaso-occlusive crises (VOC) in 12 months (N=303) and less than 10% of participants experienced no VOC.[4] Almost two-thirds (63.5%) of participants required mild opioids to control VOC pain at home.[4] Nearly half (44.5%) of patients responded that they required strong opioids to manage pain.[4]

Hydroxyurea has been the mainstay of sickle cell disease management since its approval in 1998. It is a ribonucleotide reductase inhibitor which helps to reduce sickle cell-related pain and acute chest syndrome (ACS).[5] ACS is a pulmonary complication of sickle cell disease and symptoms consist of chest pain, hypoxemia, and dyspnea.[5] Hydroxyurea works by increasing high fetal hemoglobin (HbF) levels.[5] By increasing HbF, hydroxyurea improves clinical outcomes as well as prevents hemoglobin S polymerization and painful vaso-occlusion.[5] However, not all practitioners are well-versed in dosing hydroxyurea as it requires individualized therapy and therefore may take months before a patient will see full benefits.[6] Hydroxyurea also has some serious adverse effects associated with it, including infection, neutropenia, and bleeding.[6]

In 2017, the use of L-glutamine in sickle cell disease was under review. L-glutamine is considered to help reduce oxidative stress, which may contribute to sickling erythrocytes.[7] Sickled erythrocytes contain a lower ratio of oxidation-reduction cofactors as compared to normal erythrocytes.[7] It is thought that the daily administration of L-glutamine would increase the cofactors ratio and ultimately decrease oxidative stress.[7] The results of a phase 3 clinical trial (N=230) conducted by Niihara et al demonstrated 25% fewer pain crises and 33% fewer hospitalizations in the group receiving L-glutamine as compared to placebo.[7]

With the approval of voxelotor (Oxbryta®) and crizanlizumab (Adakveo®) in 2019, there are now newer treatment options in addition to L-glutamine and hydroxyurea for sickle cell patients (see Figure 1 for drug approval timeline).

Figure 1: Timeline of FDA approvals for sickle cell disease treatment



Voxelotor

Pharmacology

Voxelotor is a 500 mg tablet marketed under the trade name Oxbryta® (Global Blood Therapeutics, Inc, South San Francisco, CA). It was FDA-approved under accelerated approval for sickle cell disease in patients 12 years and older.[8] Voxelotor is a hemoglobin S polymerization inhibitor and works by increasing the affinity of hemoglobin S to oxygen; thus, inhibiting red blood cell polymerization and further preventing sickling, hemolysis, and complications of anemia.[8] The recommended dose for voxelotor is 1,500 mg given orally once daily without regard to meals.[8] Dose reduction to 1,000 mg orally once daily is recommended in patients with severe hepatic impairment; however no dose reduction is required in renal impairment.[8] There are several drug interactions with voxelotor which warrant dose adjustments (see Table 1).

Table 1: Dose adjustments for voxelotor[7]

Recommended dosing if…	Voxelotor Dose
Normal	1,500 mg once daily
Severe Hepatic Impairment (Child Pugh C)	1,000 mg once daily
Concomitant use with strong CYP3A4 inhibitors or fluconazole	1,000 mg once daily
Concomitant use with strong or moderate CYP3A4 inducers	2,500 mg once dail

The pharmacokinetics of voxelotor 1,500 mg was evaluated in the plasma and whole blood. It demonstrated linear pharmacokinetics and steady state was reached after 8 days of repeated exposure.[8] Voxelotor was found to be absorbed in the plasma and then distributed mostly to red blood cells because of the preferred binding to hemoglobin.[8] The median time to peak was 2 hours after oral administration and the terminal elimination half-life in the plasma of patients with SCD was 35.5 hours.[8] Voxelotor was primarily metabolized by the oxidation and reduction of phase I and glucuronidation of phase II.[8] Voxelotor's oxidation was mainly affected by CYP3A4, while CYP2C19, CYP2B6, and CYP2C9 played a minor role.[8]

Efficacy

The HOPE trial was a multicenter, international, randomized, double-blind, placebo-controlled, parallel-group phase 3 trial aimed to assess the efficacy and safety of two different doses of voxelotor (1,500 mg and 900 mg) versus placebo in patients with sickle cell disease.[9] The trial enrolled 274 participants between the ages of 12 and 65; and divided them equally into three groups to receive voxelotor 1,500 mg, 900 mg, or placebo. The study followed participants for up to 72 weeks with sickle cell disease who had a hemoglobin between 5.5 and 10.5 g/dL and had anywhere from one to ten vaso-occlusive crises in the past year.[9] About two-thirds of the patients were receiving hydroxyurea at baseline at a stable dose for at least three months before enrollment and were permitted to continue taking it through the duration of the trial.[9] While concomitant use of L-glutamine was allowed in the trial, there were no patients enrolled in the study who were receiving L-glutamine at baseline.[9] Therefore, there are no data on the use of voxelotor concurrently with L-glutamine at this time. The trial excluded patients who were receiving regular red-cell transfusion therapy, received transfusions in the past 60 days, or had been hospitalized for a vaso-occlusive crisis within two weeks of enrollment.[9]

The primary outcome was the percentage of patients who had a hemoglobin response, which was defined as an increase of more than 1.0 g/dL from baseline after 24 weeks.[9] The secondary outcomes were annual events of vaso-occlusive crisis; the change in hemoglobin from baseline to 24 weeks; and a decrease in laboratory markers that assess for hemolysis such as indirect bilirubin, lactate dehydrogenase, and absolute reticulocyte count.[9] At 24 weeks, 51% of the patients in the 1,500 mg voxelotor group, 33% of patients in the 900 mg voxelotor group, and only 7% of patients in the placebo group had a hemoglobin response in the intention-to-treat analysis ($P<0.001$).[9] Moreover, the 1,500 mg voxelotor group resulted in more significant reductions in the indirect bilirubin level than the placebo group at 24 weeks from baseline (mean change, –29.1% vs. –3.2%; $P<0.001$).[9] Other hemolysis laboratory markers also demonstrated more significant reductions in the 1,500 mg voxelotor than the 900 mg voxelotor group or placebo.[9] The study concluded that voxelotor significantly increased hemoglobin levels and reduced markers of hemolysis and can therefore be a potential treatment for sickle cell disease.

Safety

Incidence of adverse events were similar across the three trial groups: 94% of participants in the 1,500 mg group vs. 93% in the 900 mg group vs. 89% in the placebo group. Most adverse events were not related to the trial drug or placebo, as determined by the investigators. The most common adverse reactions occurring in more than 10% of patients treated with voxelotor 1,500 mg versus placebo, respectively, were headache (26% vs. 22%) and diarrhea (20% vs. 10%).[9]

Voxelotor is contraindicated in hypersensitivity reactions to the drug or its excipients. Moreover, voxelotor use can interfere with the measurement of hemoglobin subtypes (HbA, HbS, and HbF) using high-performance liquid chromatography.[8] Accurate measurements can be obtained when patients are not receiving the medication.

Crizanlizumab

Pharmacology

Crizanlizumab is a 100 mg/10 mL single-dose vial under the trade name Adakveo® (Novartis Pharmaceuticals Corp, East Hanover, NJ). It was FDA approved for the reduction of frequency in vaso-occlusive crises in sickle cell patients 16 years of age or older.[10] Crizanlizumab is a humanized IgG2 kappa monoclonal antibody which binds to P-selectin and blocks interactions with its ligands, which in turn blocks the adhesion of HbF to P-selectin.[10-11] This blockade of adhesion reduces the chance of vaso-occlusion by allowing erythrocytes to flow through blood vessels without adhering to endothelial walls and preventing clusters.[11] The recommended dosing of crizanlizumab is 5 mg/kg (using actual body weight) by intravenous infusion using a 0.2-micron inline filter over 30 minutes at Week 0, Week 2, and every 4 weeks thereafter.[10]

Crizanlizumab should be stored in the refrigerator in its original container to protect from light.[10] In order to prepare crizanlizumab for administration, the vials should first be brought to room temperature (no longer than 4 hours) before the start of compounding.[10] It should be diluted to a final volume of 100 mL using either Sodium Chloride Injection, USP or 5% Dextrose Injection, USP.[10] Acceptable infusion bags include those made of polyvinyl chloride, polyethylene, or polypropylene.[10] Before the dose of crizanlizumab is added to the infusion bag, the equivalent volume of diluent should be removed.[10] Only after the diluent has been removed, the desired volume of crizanlizumab may be added to the infusion bag.[10] The infusion bag should be inverted to mix the solution, but should not be shaken.[10] The diluted solution should not be stored at room temperature (25°C) for longer than 4.5 hours or under refrigeration for longer than 24 hours (from the time of beginning the preparation).[10]

Crizanlizumab 5mg/kg was evaluated for pharmacokinetic parameters. In patients with SCD, the terminal elimination half-life was 7.6 days.[10] The anticipated metabolism pathway of crizanlizumab is similar to small peptides by catabolic pathways.[10] It did not appear to have any clinically significant drug interactions with hydroxyurea during clinical trials.[10]

Efficacy

The SUSTAIN trial was a phase 2, multicenter, randomized, placebo-controlled, double-blind trial which was twelve months in duration and based in the United States.[12] The primary outcome was annual rate of sickle cell-related pain crises—this was defined as an acute episode of pain with no other medically determined cause than a vaso-occlusive crisis that required a medical visit with pain management.[12] Total enrollment was 198 participants and patients were divided into three treatment arms: placebo (N=65), low-dose crizanlizumab 2.5 mg/kg (N=66), and high-dose crizanlizumab 5 mg/kg (N=67).[12] Inclusion criteria for the clinical trial included patients aged 16 to 65 who had two to ten sickle-cell related pain crises in the past year and if participants were receiving hydroxyurea or erythropoietin, it must have been prescribed at least six months prior with a stable dose of at least three months.[12] While concomitant use of L-glutamine powder was allowed in the trial, there were no patients enrolled in the study who were taking it at baseline.[12] Therefore, there are no data on the use of crizanlizumab concurrently with L-glutamine at this time. Exclusion criteria included chronic transfusion programs and chronic anticoagulation.[12] Participants who received high-dose crizanlizumab had a statistically significant lower median annual rate of VOC compared to low-dose crizanlizumab and placebo (1.63 vs 2.01 vs. 2.98, respectively; P=0.01).[12] Of the participants receiving high-dose crizanlizumab, 36% did not experience a VOC as compared to 17% on placebo.[12] Months to first VOC was tested as a secondary outcome and high-dose crizanlizumab was found to lengthen time to VOC to 4.1 months as compared to low-dose crizanlizumab (2.2 months) and placebo (1.4 months).[12]

Safety

Crizanlizumab has warnings for infusion-related reactions and should be discontinued for severe reactions.[10] Severe reactions include pruritis, urticaria, fever, chills, or bronchospasms.[10] Crizanlizumab may also interfere with automated platelet counts when blood samples are collected in tubes containing EDTA.[10] This interference may result in unusable or falsely decreased platelet counts due to abnormal platelet clumping.[10] Therefore, it is recommended to run samples within four hours of collection or collect samples in tubes containing citrate.[10] Adverse events of all grades consist of nausea (18%), arthralgia (18%), back pain (15%), and pyrexia (11%).[12] For grades ≥3, one participant experienced arthralgia and pyrexia (N=66).[12]

Place in Therapy

Although hydroxyurea has been the primary treatment for SCD in reducing pain and ACS for over 20 years, it has its limitations as well. For some patients, it may take months to see full benefits of the medication, while others may not tolerate hydroxyurea at all due to adverse effects and are then considered to be treatment failures. L-glutamine may be administered as an alternative to patients who are unable to tolerate hydroxyurea or it may be given in conjunction with hydroxyurea. Treatment with L-glutamine resulted in patients having fewer hospitalizations and pain crises, though the administration of the medication as a powder may be cumbersome for some.

Both voxelotor and crizanlizumab have the same indication of sickle cell disease, though they have entirely different mechanisms of action. Voxelotor works by inhibiting polymerization, thus preventing sickle cell formation, hemolysis, and anemia. It is primarily treating the root cause of the disease, as compared to crizanlizumab, which is mainly used to reduce the pain and vaso-occlusive crisis associated with the disease. The HOPE trial also demonstrated a significant reduction in hemolysis lab markers from baseline, which indicated that voxolotor was effective in reducing hemolysis. There was insufficient data on the reduction of VOC in patients taking voxelotor; however, in the SUSTAIN trial of crizanlizumab, twice as many patients treated with crizanlizumab 5 mg/kg did not experience a VOC as com-

pared to placebo. Moreover, those in the treatment group had delayed median time to first VOC versus those in the placebo group.

Currently there are no ongoing combination studies of voxelotor with crizanlizumab. Global Blood Therapeutics, Inc. has not studied the specific drug interactions between or co-administration of voxelotor and crizanlizumab.[13] Patients in the HOPE study were excluded if they were participating in another clinical trial or had received an investigational agent within 30 days or five half-lives of the date of informed consent.[13] At the time the study was conducted, crizanlizumab was an investigational agent and thus no patients were concurrently receiving voxelotor and crizanlizumab.[13] However, there is lack of data to suggest that the medications cannot be co-administered.[13]

Global Blood Therapeutics offers patient assistant programs for coverage and reimbursement support for voxelotor by enrolling patients into the GBT source. Voxelotor is available via a Managed Distribution Specialty Pharmacy model for patients through CVS Specialty Pharmacy and Accredo Specialty Pharmacy.[13] Moreover, voxelotor is available via a Specialty Distributor, Amerisource Specialty Distributor (ASD Healthcare), for Hospital/IDN Inpatient Pharmacies, VA/DOD, and Kaiser.[13]

Novartis offers the Patient Assistance Now Oncology (PANO) program for crizanlizumab.[14] PANO services allow patients to verify their insurance coverage for manufacturer financial assistance with crizanlizumab.[14] These services are available whether a patient has no insurance, private/employer-based, or government insurance.[14] There is also an option available to patients with private insurance for a universal copay program.[14]

Conclusion

In summary, crizanlizumab can be used more for symptomatic improvement as it reduces VOC, while voxelotor is used strictly for SCD treatment. Furthermore, they have different routes of administration. Voxelotor is an oral tablet, while crizanlizumab is administered intravenously. Choosing which medication to prescribe will depend on the specific patient and provider preference. Nevertheless, both medications are long term treatments.

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Evaluation of a Layered Learning Practice Model Workshop

Nicole Ryba, PharmD, BCPP, BCGP; Vishal Patel, PharmD, BCCCP; Jesse B. Sullivan, BCPS

Learning Objectives:
After participating in this activity, the pharmacist shall be able to:
Pharmacists:

1. **Define the layered learning practice model.**
2. **Describe the benefits of utilizing the layered learning practice model.**

Author disclosures: None of the contributors have anything to disclose related to this educational activity

CEU Hours: 1 contact hour of continuing education credit (0.01 CEU)

Activity Type: Knowledge based

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Abstract

Purpose: To evaluate an educational workshop that utilizes the layered learning practice model in which students, residents, clinical specialists and faculty participate at a large, nonteaching community hospital.

Methods: The layered learning practice model workshop took place at a nonteaching, community hospital on two individual days, over a six-hour period, in July of 2018 and July 2019. Participants included multiple APPE students, two PGY1 residents, one PGY2 critical care resident, clinical specialists and two clinical faculty. Residents were responsible for the presentations and discussions while clinical specialists and faculty facilitated the discussion when needed.

Results: Fourteen students, six residents and six faculty/preceptors participated and completed the post-evaluation surveys. All participants had a strong positive response to the workshop, with the average of the program overall being rated higher than a 4 (5 was the maximum) by each respondent. 72% (n=10) of students stated that the statistics review was the strongest portion of the workshop, and 28% (n=4) rated the discussion on research design the strongest.

Conclusion: The layered learning practice model workshop was beneficial to students and residents. Future directions include optimizing the workshop based on feedback for future students and residents.

Background

The layered learning practice model (LLPM) was originally developed through a partnership between The University of North Carolina (UNC) Eshelman School of Pharmacy and UNC Hospitals as a way to enhance the delivery of pharmaceutical care to patients.[1] This framework for pharmacy practice and education modeled the active learning of medical education. An attending clinical pharmacist takes responsibility for the actions and education of the team, and tasks are distributed to residents and students in layers according to their current level. The method of "see one, do one, teach one" becomes an integrated part of the process, while also extending the reach of the clinical pharmacist and pharmacy department.[2]

In our current era of increased demand for student training sites and residency programs, coupled with pharmacists having less time to devote solely to the act of teaching, the LLPM offers a solution which does not compromise either clinical productivity or learning effectiveness.[3] Examples of LLPM implementation are found in the literature, demonstrating benefits such as increased HCAHPS scores, increased reach of pharmacy services, increased interventions, and minimizing drug costs.[4–7] Despite objective evidence of the clinical benefits, the effect on learning is less quantified.[2]

A study of an oncology elective rotation utilizing a LLPM made up of students, postgraduate year 1 (PGY1), and postgraduate year 2 (PGY2) residents gave participants a pre-posttest assessment of their learning in different content domains. All participants reported an increased in their knowledge base from the experience, the greatest effect exhibited by the students, followed by the residents. Qualitative feedback was also collected. Participants reported positive feelings towards perceived knowledge attainment, improved clinical time management skills, and contributions to patient care and development of clinical and self-management skills. Student participants also reflected on their comfort with learning, as having a resident as their direct preceptor felt less intimidating during their experience.

Another evaluation of a LLPM in an ambulatory care experience showed that introductory pharmacy practice experience (IPPE) and advanced pharmacy practice experience (APPE) students felt the LLPM experience prepared them in a manner described as "above

average" or "excellent" for their next steps, either from IPPE to APPE, or from APPE to independent practice.[8] Participants demonstrated benefits in areas that included reinforcement of knowledge, enhanced understanding of expectations, exposure to multiple teaching styles, and feeling comfortable in their learning environment.

This study aims to evaluate a one-day educational workshop that utilizes the layered learning practice model method in which students, residents, clinical specialists and faculty participate at a large, nonteaching community hospital.

Methods

The layered learning practice model workshop took place at a nonteaching, community hospital on two individual days, over a six-hour period, in July of 2018 and July 2019. Participants included multiple APPE students, including one chosen mini-resident, two PGY1 residents, one PGY2 critical care resident, four clinical specialists and two clinical faculty. The mini-resident was an APPE student who completed four consecutive rotations and one longitudinal project at the institution to prepare them for the residency application process and the residency year itself. The workshop was decided by the faculty to be incorporated as a requirement of the PGY1 residents drug information rotation. The topic of research-design was chosen to fit into this rotation, as well as, due to previous informal feedback of students feeling they had little exposure to this topic. There were two goals of the workshop (1) to educate students by enhancing knowledge on designing practice-based research and (2) to incorporate constructive feedback from all levels of the hierarchy for the mini-residents longitudinal project.

APPE students on site at the time that the workshop took place were the primary audience. Clinical faculty were facilitators of the workshop day and provided feedback as needed. Clinical pharmacy specialists also provided feedback as needed throughout the day. Both were responsible for informally evaluating the retention of the content as the students and residents completed rotations within the institution. The day began with the PGY1 residents presentations. Each PGY1 resident was responsible for one 30-minute lecture with topics surrounding developing a research question, designing a study and finding evidence to support the research. The PGY2 resident was responsible for a one-hour lecture on statistical analysis. After the lectures, time was allotted for the PGY1 residents to discuss their experiences with research as an APPE student, as well as, the PGY2 resident to discuss their experience with research as a PGY1 resident. The day ended with a final presentation that consisted of a short overview of the mini-residents longitudinal project. At the end of the presentation, each participant of the workshop was expected to give feedback on the project.

A post-evaluation survey was distributed to each participant at the end of the workshop. Two surveys were created: an audience survey (students, faculty and clinical specialists) and a resident survey. All surveys consisted of questions that were answered on a Likert-scale (1-5; 5 being "strongly agree") and three open-ended questions. The audience had questions regarding the overall day and learning experiences while the residents had questions centering around their teaching experiences (see Tables 1 and 2). The open-ended questions included (1) what did you most appreciate about the day ("best part"), (2) what is something you would change about the day and (3) any additional opinions/comments. In addition to the three mentioned open-ended questions, the residents also had two additional open-ended questions including (1) how well were you prepared to teach the topic and (2) how well do you think the students were able to learn the material? The audience survey also had two rating scale questions about the length of the workshop (too short, right length, too long) and the level of the workshop (introductory, intermediate, advanced).

Results

During the two years this workshop was run, fourteen students, six residents and six faculty/preceptors participated and completed the post-evaluation surveys. Results of the responses can be found in Table 1 and Table 2. All participants had a strong positive response to the workshop, with the average of the program overall being rated higher than 4 by each respondent. The residents were able to successfully give each presentation to the students, as they were rated 4.9 and 4.2 for knowledge, organization and communication by the students and pharmacists, respectively.

In addition to the Likert scale and rating scale survey questions listed in the table, the audience and residents had open-ended questions in their respective surveys. When looking at the audience section, 72% (n=10) of students stated that the statistics review was the strongest portion of the workshop. The other 28% (n=4) regarded the discussion on research design as the strongest presentation. The majority of responses for future improvements on the workshop revolved around the meeting location and recommendations to include additional examples for research design. Requests were also made to move the workshop earlier in the rotation cycle.

Per the survey and open-ended responses, residents believed they were able to successfully teach the material to the students, with an average score of 4 out of 5. Per responses, majority felt this was largely contributed to the use of realistic, but straightforward examples that allowed the students to participate in an open group discussion. Prior preparation was cited as a reason for improved presentation ability, however 50% (n=3) requested additional preparation on teaching techniques and strategies to better improve their own ability on the responses. This was reflected as well in the low numerical responses with ability to engage the learners and preparedness teaching-wise to teach the topic (3.6 out of 5, both). Per open-ended responses, the residents stated that having completed their last professional year of pharmacy school recently, their teaching was strengthened by easily being able to identify what the students were looking for and wanted to learn about.

Discussion

The layered learning practice workshop was a well-received learning experience by both students and residents, demonstrated by the high average scores answered to the statement "I would recommend this workshop to my colleagues" (4.9 and 4.5, respectively). The workshop material was also something that students and residents felt that they could apply to their future roles as they progressed

Table 1. Survey Responses

Question	Average Student Responses (n=14)	Average Resident Responses (n=6)	Average Preceptor Responses (n=6)
I would recommend this workshop to my colleagues	4.9	4.5	N/A
The workshop was applicable to my role in the profession	4.8	4.8	N/A
"Research Question and Design" presentation was interesting	4.3	4.8	4.3
"Research Question and Design" presentation was relevant to my current role	4.5	4.6	4.1
"Finding the Evidence" presentation was interesting	4.5	4.4	4
"Finding the Evidence" presentation was relevant to my current role	4.6	4.6	4.3
"Statistic Review" presentation was interesting	4.7	4.6	4
"Statistic Review" presentation was relevant to my current role	4.6	5	4.5
The instructor was a good communicator	4.9	4.4	4.2
The material was presented in an organized manner	4.9	4.6	4.2
The instructor was knowledgeable on the topic	4.9	4.6	4.2
Quality of presenters	4.7	4.3	4.3
Quality of presentation times	4.5	4.1	4
Quality of meeting space	4.0	3.3	3
Quality of handouts	4.4	4.3	4
Quality of program overall	4.6	4.5	4.3
Length of workshop (# of responses)			
Too Short	0	0	0
Right Length	13	6	4
Too Long	1	0	2
Level of workshop (# of responses)			
Introductory	4	0	4
Intermediate	10	5	2
Advanced	0	1	0

through their careers as demonstrated by a high average response to the statement "the workshop was applicable to my role in the profession" (4.8, both groups).

According to the students, the statistics overview was the most beneficial part of the workshop day. They also deemed the residents effective by rating them high for knowledge, organization and communication, though, this was slightly lower when looking at the preceptor scores. In literature, research has been reported to cause pharmacy students anxiety; academic support from lecturers and colleagues combined with their individual effort has helped to reduce this stress.9 This emphasizes the importance of continually reinforcing research design and literature knowledge, including statistics, throughout a student's career. Research design may be an area of weakness, as demonstrated by our sample, as not all pharmacy students are exposed to actively participating in completing research. Current data supports that students who are involved in programs that have dedicated courses that focus solely on research are more confident outside the classroom in completing these tasks and have successful publications.[10,11]

Residents felt that students were able to effectively learn the material and that they themselves were prepared knowledge-wise to deliver their respective presentations. However, they felt they were lacking in appropriate teaching skills and ability to engage the learners as demonstrated by the low average scores. The LLPM workshop was delivered early during the residency year as residents are assumed to have the knowledge needed to present the material. Residency training incorporates teaching skills throughout the year and need for improved teaching skills could be expected early in the year. This emphasizes the need for continued teaching certificate programs, as literature supports that these programs help graduates excel in their positions.[12]

Clinical pharmacy specialists and faculty overall had lower rated scores versus the rest of the respondents when rating the residents' presentations. This is to be expected as preceptors have differing expectations from residents versus students. For our clinical pharmacy

Table 2. Resident Specific Survey Response

Question	Average Response
The students were able to effectively learn the material	4
I was well prepared knowledge-wise to teach this topic	4.3
I was well prepared teaching-wise to teach this topic	3.6
I was given enough time to prepare the educational material	4.3
I was effectively able to engage the learners	3.6
I was able to identify areas of improvement in my teaching style	4.5

specialists and faculty purposes, this workshop can be utilized informally to individually help each preceptor determine the residents baseline teaching skills for the year and could potentially help prepare activities accordingly.

The main limitation of our study was the limited number of participants. Performing additional years of this workshop could assist with better understanding of how students perceived the benefit. Two different residency years (PGY1/PGY2) delivered the presentations, though expected, this could present differing baseline knowledge. Being that PGY2 residents were included and most PGY1 programs offer teaching certificates, the completion of a teaching certificate may have better prepared the PGY2 presenters, though this information was not collected. Students also most likely differed in baseline knowledge, as participants came from different schools of pharmacy; however, all still found the workshop very beneficial to their learning.

Conclusion

All participants in the layered learning practice model workshop found the day to be beneficial. The layers of the workshop included education to the students and teaching skills for the residents combined with feedback and facilitation from the pharmacists. It also allowed the faculty and clinical specialists to informally evaluate baseline knowledge of all participants to individualize their learning experiences. A LLPM workshop could be utilized in many different settings. This type of workshop day could be beneficial for any topic and of use to all learners and facilitators. Future directions include utilizing the feedback to optimize the workshop for additional students and residents.

About The Author

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Evaluation of newer FDA-approved medications for incorporation into NIOSH List of Hazardous Drugs 2020.

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Purpose

To identify novel drugs approved by the Food and Drug Administration (FDA) for hazardous potential.

Methods

A list of drug approved by the FDA since 2016 was obtained from the FDA website. Drugs were excluded if they were removed from the market post-approval. Package inserts were obtained from the manufacturer's websites. Definition of "hazardous drugs" was obtained from the National Institute for Occupational Safety and Health (NIOSH). Boxed warnings and sections 5, 18, 12, 13, and 16 of the package inserts were reviewed for the following words: carcinogenicity, teratogenicity, developmental or reproductive toxicity, organ toxicity, genotoxicity, or structure and toxicit profiles that mimic existing drugs determined hazardous. If deemed hazardous, drugs were put into one of three tables: antineoplastics, non-antineoplastics hazardous drugs or drugs with reproductive effects. Package insert review was performed independently by two student pharmacists and disagreements were reviewed by a third student pharmacist, with discussion with faculty mentor as needed.

Results

193 novel drugs were approved Jan 1, 2016 through May 8, 2020. Two drugs were excluded from study due to being withdrawn from market. 191 medications met inclusion criteria. 157 (82%)were classified as hazardous drugs: 52 (27%) antineoplastics, 26 (14%) non-antineoplastic hazardous drugs, and 79 (41%) hazardous drugs with primarily adverse reproductive effects. 34 (18%) did not meet criteria to be listed as hazardous.

Conclusion

The majority of new drugs are considered hazardous according to NIOSH. Hazardous drug information and education should be included in continuing education regarding newly approved medication.

Management of acute overdose of valproic acid with levocarnitine: a case report

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Introduction

This case report describes a 62 year old female who was admitted for an intentional acute overdose of valproic acid and was treated with levocarnitine. Valproic acid treats partial/generalized seizures and acute mania and is used for bipolar disorder and migraine headaches. Acute valproic acid intoxication can result in central nervous system depression, serious toxicity, and death. The route of metabolism is by glucuronic acid conjugation and mitochondrial beta-oxidation, which may be inhibited by high-dose therapy of valproic acid. VPA enters the mitochondria through carnitine-dependent long chain fatty acid transport system that generates valproyl-CoA, which is then esterified with L-carnitine to form valproyl-carnitine. This metabolite is lost in the urine. VPA found in cytosol is metabolized via omega-oxidation which leads to hyperammonemia and other metabolic abnormalities

Case

The patient presented to our emergency department at 8:38 am on day 1. Patient self-reporting that she attempted to overdose by taking five tablets in the morning on day 1 Depakote 500 mg instead two tablets. Patient presented with suicidal thoughts, normal vital signs, serum creatinine, LFTs, Valproic acid levels were 148 ug/mL and serum ammonia levels were 206 umol/L. Levo-carnitine 6 grams in 1030 mL of 0.9% NaCl was infused intravenously over 30 minutes. Five hours after infusion, valproic acid levels were 162 ug/mL, ammonia levels were 108 umol/L. There were no repeated doses of Levocarnitine given. The patient is no longer confused, alert and does not have any active complaints on Day 1 at 23:05. She was discharged home on day.

A Retrospective Review of COVID-19 Patients treated with tocilizumab (Actemra) at a Community Hospital

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Purpose

Tocilizumab is a monoclonal antibody interleukin-6 (IL-6) receptor antagonist indicated for the treatment of rheumatoid arthritis, cytokine release syndrome (CRS) and giant cell arteritis. Its use emerged as a potential treatment for CRS

associated with COVID-19. The purpose of this study is to evaluate the effectiveness of tocilizumab in reducing inflammatory markers, mortality and mechanical ventilation.

Methods

We conducted a retrospective chart review of 181 patients who received at least one does of intravenous tocilizumab 400 mg or 800 mg between March 25, 2020 and May 15, 2020 for suspected COVID-19 at a 318-bed community hospital. Patient demographics, inflammatory markers, drug regimens and patient outcomes were collected.

Results

Of the 181 patients included, ninety-one percent of patients received tocilizumab 400 mg IV and nine percent received tocilizumab 800 mg IV. One hundred patients were discharged, 78 passed away and 3 were still admitted. When comparing patients who received tocilizumab, best outcomes were observed in patients who did not use hydroxychloroquine or remdesivir concurrently 60% versus 54% versus 32% respectively. After receiving tocilizumab dose, the mean decrease in C-reactive protein was 2.81 mg/L, while ferritin and D-dimer increased by 55.4 mcg/L and 957.7 ng/L respectively. Seventy patients were intubated during their admission, 32 before the initial dose and 38 patients after initial dose.

Conclusion

When given for COVID-19, tocilizumab did not show improvement in inflammatory markers. Controlled trials are needed to determine the benefits of tocilizumab in hospitalized patients with COVID-19.

The Severity of Adverse Effects Related to Withdrawal Induced by Pre-Hospital Naloxone Administration in the Event of an Opioid Overdose

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Introduction

Naloxone, a mu-opioid receptor antagonist, is used as a harm-reduction strategy to prevent opioid overdose-related deaths. Policy changes around the country promote pre-hospital administration of naloxone by laypersons in the event of an opioid-related overdose to reduce risk of mortality. The trend to increase access to laypersons is associated with the notion that these individuals are the first ones at the scene. However, there exists a risk of adverse effects related to precipitated withdrawal due to the quick onset of action and then clearance of naloxone. Outcomes of an opioid overdose after reversal by naloxone depend on many factors. In our research we aim to evaluate whether there is a difference in severity of adverse effects related to precipitated withdrawal between layperson and medical first responder pre-hospital administration of administration of naloxone in the event of an opioid overdose. Our secondary objective is to identify the patient demographics that are associated with higher risk of more severe adverse effects of naloxone-precipitated withdrawal.

Methods

We conducted a single center, retrospective cohort study, between January 2016 and June 2019. The electronic medical record system with a consecutive convenience sampling design was used to identify records of patients who presented to the ED with a suspected opioid overdose.

Conclusion

We found no significant difference in severity of adverse effects related to precipitated withdrawal between layperson and medical first responder pre-hospital administration of administration of naloxone in the event of an opioid overdose.

Pharmacy's preference in use of brand names for generic drugs

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Introduction

Every drug makes its debut to the pharmaceutical market with a brand name along with a generic name. Using either a brand or generic name can place the drug in preference of certain patients, insurers, and pharmacists based on various considerations. While the majority of patients prefer generic drugs due to lower cost, some patients insist on the brand name drugs, believing in superiority. For insurers, generic drugs are usually preferred. From a medication safety standpoint, use of either generic or brand name can prevent a different type of medication error. Using generic names can prevent therapeutic duplication of dispensing both generic and brand name drugs, whereas using brand names can clarify dispensing medications of the same molecular entity but different brands for different indications.

Objective

To determine active licensed pharmacist's preference on use of brand names over generic names, or vice versa. To ascertain background factors that determine this choice.

Methods

An initial screening of 75 community pharmacists was conducted. Forty-seven pharmacists were selected and completed the final in the survey with a 94% response rate.

Results

Approximately 66% of pharmacists preferred to dispense a generic with a brand name in practice; 34% did not care if the generic had a brand name.

Conclusion

Brand awareness for patients and specific drug identification for pharmacists were top considerations for preference in using brand names. However, there are reimbursement issues and possible confusion for pharmacists due to unnecessary brand names, which were in disfavor of using both brand and generic names.

The Positive Association Between Proton Pump Inhibitors and Clostridium difficile infection

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Background

Proton pump inhibitors (PPIs) are among the most common used medications by patients due to its availability over the counter and frequent prescribing by physicians to treat and alleviate symptoms of gastroesophageal reflux disease. Recently, the FDA issued a warning with respect to the utilization of PPIs and risk of developing Clostridium difficile infections (CDI). The most common known medications to cause CDI are antibiotics. However, available studies suggest an association and increase in risk for CDI with PPI use as well.

Objective

The purpose of this research is to review and summarize data currently available on the association between PPIs and CD.

Methods

To search for eligible studies, EBSCO engines were investigated using proton pump inhibitors or PPIs and Clostridium difficile or C. diff. as search terms.

Results

Out of 333 studies, 8 meta-analyses and systematic reviews met the inclusion criteria. They included studies conducted in the US, Europe, Asia and Canada on inpatient and outpatient adults. And the final result for all 8 studies showed a statistically significant association between PPIs and CDI ranging from mild to high risk.

Conclusion

Currently available data suggest a positive association between PPIs and CDI.

Applying the new Lactation Labeling to non-antineoplastic drugs approved by the FDA since 2016

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Purpose
To categorize novel drugs approved by the Food and Drug Administration (FDA) into categories according to risk during lactation by applying the New Pregnancy and Lactation Labeling 2016.

Methods
A list of drugs approved by the FDA since 2016 was obtained from the FDA website. Drugs were excluded if they were removed from the market post-approval, if they are not approved to be used in women of childbearing age, or if they are in AHFS Class 10:00 (Antineoplastic Agent). Package inserts were obtained from the manufacturer's websites and reviewed for Section 8 according to the New Pregnancy and Lactation Labeling 2016. Drugs were put into one of five tables: present in human milk –no harm; present in human milk –harm; present in animal milk –no harm; present in animal milk –harm; insufficient data. Package insert review was performed independently by two student pharmacists and disagreements were reviewed by a third student pharmacist, with discussion with faculty mentor as needed.

Results
193 novel drugs were approved Jan 1, 2016 through May 8, 2020. 137 drugs met inclusion criteria. Of those reviewed, 6 (4.4%) are acceptable during lactation, 34 (24.8%) are not recommended while breastfeeding, 97 (70.8%) have insufficient data.

Conclusion
The majority of medications have no definitive answer on whether it is acceptable to breastfeed while on said drug. Risk versus benefit, primary literature evaluations, and shared decision-making between clinicians and patients are required when these drugs may be needed

Lessons Learned: Data-Driven Changes to a School's Co-Curricular Program Development

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Introduction
Fairleigh Dickinson University School of Pharmacy and Health Sciences (FDU SOP&HS) developed and implemented a co-curricular program to facilitate student learning and reinforce ACPE Standards 3 and 4. The objective of this poster is to highlight changes made after the first year of the co-curricular program derived from student learning outcomes assessment and program evaluation.

Methods

FDU SOP&HS formalized its co-curricular program in AY2018-19 around its core tenets and select CAPE outcomes. Program requirements were established to optimize student engagement and attainment of competencies in domains 2, 3, and 4. An assessment and evaluation plan was written, and CampusLabs was deployed as a software solution. Datawere collected from multiple sources using multiple methods. Quantitative and qualitative data analysis resulted in descriptive statistics and key themes. A report was generated detailing insights about each cohort and the overall program, and formed the basis of improvement initiatives enacted for AY2019-20.

Results

Changes made to the co-curricular program in response to student feedback, included offering more and varied co-curricular activities, increased marketing of CAPE outcomes for each domain and refining activity scheduling to optimize student attendance given timing of their classes. Changes in response to faculty feedback included disseminating co-curricular activities calendar at the beginning of the semester, and arranging blocks of time to facilitate faculty-student advising. Based on positive findings of student engagement and learning, we extended program requirements to students in their final year.

Conclusion

Data analysis generated evidence of a robust, student-centered co-curricular program. Program refinements were made, which emphasizes the importance of timely data collection from multiple program stakeholders to catalyze implementation of meaningful changes.

2020 Award Recipients

Bowl of Hygeia Award
For an outstanding record of community service that, apart from the practice of pharmacy, reflects well on the profession.

Recipient
Edward Rucki, RPh, CCP

NJPhA Lifetime Achievement Award
For lifetime achievement to the profession of pharmacy and to NJPhA.

Recipient
Loretta Brickman, RPh

Rosario J. Mannino Award
For meritorious service to the profession of pharmacy and the New Jersey Pharmacists Association, given in honor of President-Emeritus Rosario J. Mannino.

Recipient
Carmela Silvestri, PharmD, CCP, FASCP

Donald J. Wernik Academic Achievement Award
Presented to an academician who has performed outstanding service for our profession and NJPhA.

Recipient
Lucio Volino, PharmD, CTTS

Independent Pharmacist of the Year Award
This award is presented to a practicing pharmacist who has demonstrated exemplary service to their patients and the community.

Recipient
Brian Pinto, RPh

Mortar and Pestle Award
The award is given to an individual who is not a pharmacist, but who by virtue of his or her activity, has contributed to the profession of pharmacy and the public-at-large.

Recipient
Senator Thomas H. Kean, Jr.

William H. McNeill Award
This award recognizes outstanding community service work by an NJPhA member in the preceding year or years.

Recipient
Azuka Obianwu, PharmD

Pharmacist Mutual Distinguished Young Pharmacist Award
Presented for meritorious service to the profession of pharmacy and NJPhA during the first 10 years of practice.

Recipient
Andrew Mina, PharmD, BCCCP

NCPA Pharmacy Leadership Award
Recognizes the leadership qualities of the incoming state president.

Recipient
Recipient: Grace Earl, PharmD, BCACP

The advancement of pharmacists as healthcare providers will not occur by accident; it must occur by design. Incremental progress is made every day--it is a slow and tedious process. We can start small but we must think BIG! Complete integration into the healthcare team is a long-term interest not a short-term demand. Turn the process into a best practice.

Extending best wishes for 2021 and for the renewed sense of purpose each new year brings!

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Elise Barry, CFRE, MS
Chief Executive Office, NJPhA