Evaluating Primary Care Provider Knowledge of Combined Hormonal Contraceptive Side Effects Following Pharmacist-Provided Education

Introduction

An estimated 100 million women currently use combined hormonal contraceptives (CHCs), with 80% of women considered ever-users of CHCs.[1] CHCs include low-dose combined oral contraceptives, the combined hormonal patch, and the combined vaginal ring. Each of these methods contain both estrogen and progestin components. Commonly known as "the pill," combined oral contraceptives are taken daily for the prevention of pregnancy. The combined hormonal patch is applied to the skin for one week at a time for a total of three weeks in a row, followed by a fourth week during which a patch is not worn and menstruation occurs. The vaginal ring is inserted into the vagina for three weeks, then removed for one week before inserting a new ring.[2] Common side effects of CHCs include weight gain, breast tenderness, breakthrough bleeding, changes in mood, sexual effects, skin changes and nausea.[3] The acronym "**ACHES**" describes side effects of concern with CHCs: **A**bdominal pain, **C**hest pain, **H**eadache, **E**ye problems and **S**evere calf or thigh pain. The ACHES acronym is a quick tool a provider can utilize to determine if a patient may be experiencing severe adverse effects that could warrant change in therapy.[4]

While some side effects can diminish with continued use of CHCs, some side effects will not resolve completely and can be a reason that a patient and provider choose to discontinue the medication.[3,5] In one study, almost 65% of women who discontinued their CHCs did so due to experiencing side effects and 13.1% discontinued their CHCs due to worry about side effects.[6] Potential or actual adverse drug events (ADEs) can be a cause for concern for both patients and providers and can impact continuation of CHCs.

Although CHCs are widely prescribed in primary care, providers identify a need for education on deciding which formulation to prescribe and managing side effect.[7] Several studies have evaluated how educational sessions can improve rates of ADE reporting.[8,9] After an intervention, there can be a substantial increase in ADE reporting rates up to 1 year after the intervention.[8] Along with education interventions, pharmacist involvement has been shown to prevent medication errors, to reduce preventable ADEs and to save costs. The rates of ADE decrease and the number of pharmacist interventions increase when a pharmacist is on the team and located within the unit.[10]

At Campus Health Services at the University of North Carolina at Chapel Hill, pharmacists collaborate with primary care providers daily. A pharmacy resident in present in the primary care clinic at least eight hours each week, during which they are able to see patients alongside the primary care provider to provide medication and immunization recommendations. Educational seminars are given weekly by a variety of providers in the building, including pharmacy staff and primary care staff. These seminars are used to introduce new information or re-inforce prior knowledge to improve patient care. In this seminar, a pharmacy resident will re-inforce the importance of assessing and documenting adverse effects associated with CHCs.

Objectives

The first objective was to evaluate the change in provider knowledge regarding contraceptives and awareness of primary provided resources. The second objective of this project was to evaluate

documentation of side effects ("ACHES") when initiating CHCs in a primary care clinic, before and after a pharmacist-provided continuing education seminar.

Methods

Study Design and Setting: This project was conducted with providers in a primary care clinic in a college health setting. A pre- and post-survey was distributed to providers attending an educational seminar. A chart review was conducted, comparing documentation before and after the educational seminar.

Participants and Procedures – Educational Seminar: Prescribers in the primary care clinic were invited to attend a one-hour live continuing education seminar. Prescribers were included if they were 18 years of age or older, English-speaking, work full-time or part-time in the primary care clinic and attended the live seminar or watched the recorded presentation within 1 week after the live date. Prescribers were excluded if they do not practice in the primary care clinic and did not attend the live seminar or watch the recorded presentation within 1 week after the live date. The educational seminar was recorded and provided to an invited prescriber if they were unable to attend the live offering.

A continuing education session was developed by a pharmacist. The program addressed CHC pharmacotherapy, including available products, pharmacology, common side effects and concerning side effects and documentation of side effects according to the ACHES acronym. The program was delivered live, electronically via Zoom. At the beginning of the education session, an electronic survey link was shared with participants. The 15-item questionnaire included (1) ADE assessment, (2) ADE documentation, (3) a provider's understanding of ADE related to CHCs, and (4) a provider's confidence in adjusting therapy based on ADE. After the seminar was completed, a post-survey was distributed for providers to complete within two weeks.

Participants and Procedures – Chart Review: Charts were included for review if they were for patients receiving combination hormonal contraceptives from a primary care provider within the clinic, without contraindication to receiving combined hormonal contraceptive, age >18 years. Charts were included for review if they were for patients who receive their CHCs from a provider outside of primary care at Campus Health or are using other forms of hormonal contraception (IUD, implant, depo).

Additionally, a retrospective chart review was performed on a random sample of patients that qualify for the study from before and after the education session. Charts were reviewed to see if side effects of combined hormonal contraceptives were documented and compared from pre- and post- education session.

Data prior to the seminar (November 1, 2019 through March 31, 2020) was compared to data after the seminar (November 1, 2020 through March 31, 2021). Data collected includes: appointment date, appointment type, medication name and dose, blood pressure, side effect complaints, assessment of ACHES, documentation of ACHES, and side effect counseling. A chi-squared test was used to determine the statistical significance of differences in assessment and counseling of ACHES between the pre-seminar and post-seminar visits.

Results and Discussion

Educational Seminar

The pre-education survey received a total of 16 responses, 6 of which met inclusion criteria. The post-education survey received a total of eight responses, seven of which met inclusion criteria. When comparing the pre- and post-education surveys, four participants completed both surveys. Of the four participants, two were physicians, one was a physician assistant and one was a nurse practitioner. The mean number of years in practice was 7.5, with a range of 14.5 years. The mean number of years in practice at Campus Health was 2 years, with a range of 2 years.

Knowledge of ACHES improved after the education seminar. Also improved was provider confidence in adjust CHC dose or medication if a patient was experiencing ADEs. Providers' awareness of CHC related resources was strong at baseline and did not improve after the education seminar.

These results are not surprising, given that the pharmacy staff is highly integrated into the primary care clinics at Campus Health. Pharmacists are heavily utilized in many patient encounters and answer provider questions frequently, many related to CHCs. Pharmacists educate providers on these resources and show them where the resources can be found so that they may be utilized even when a pharmacist may not be physically present in the clinic.

Chart Review

After excluding providers who were not present for both time intervals of pre- and post-seminar, there was a total of 184 visits in the pre-seminar review and a total of 87 visits in the post-seminar review. ACHES was assessed in 64 (34.78%) visits before the seminar compared to 25 (28.74%) visits after the seminar. ACHES was used to counsel patients on severe adverse reactions of CHCs in 86 (46.74%) visits before the seminar compared to 43 (49.43%) visits after the seminar. While ACHES was not always used as a counseling tool, a majority of patients received some sort of counseling on side effects of CHCs at their visits both before (n=152; 82.61%) and after (n=66; 75.86%) the education seminar. The note template was used for 94 (51.09%) visits before the seminar and 22 (25.29%) visits after the seminar.

The limitations of this study include the impact of COVID-19 on the number and type of patient visits. All visits from November 1, 2019 through March 31, 2020 were in-person office visits. The majority of the visits from November 1, 2020 through March 31, 2021 were telehealth appointments. There was also a decrease in the number of visits from November 1, 2020 through March 31, 2021 due to the lack of patients who were physically present on-campus. While the results do not show a positive outcome after the education seminar, this may be related to lack of patient appointments and changes in practice with telehealth appointments. Before the COVID-19 pandemic, these education seminars were delivered in-person in a conference room. Since social distancing protocols have been put in place, these seminars are being delivered via Zoom, which may not have enabled discussions that were as engaging as present previously via in-person delivery.

Conclusion

While the providers at Campus Health are already knowledgeable about CHCs and the resources available to them, education from a pharmacist helped to reinforce these topics and resource awareness. Education seminars like this one can be helpful in reinforcing pertinent counseling points on commonly prescribed medications and tools that can help providers quickly assess and counsel patients.

References

1. Brynhildsen J. Combined hormonal contraceptives: prescribing patterns, compliance, and benefits versus risks. *Therap Adv Drug Safety*. 2014;5(5):201-213.
2. The American College of Obstetricians and Gynecologists. Birth Control. Available from https://www.acog.org/patient-resources/faqs/especially-for-teens/birth-control. Accessed September 9, 2020.
3. Barr N. Managing adverse effects of hormonal contraceptives. *Am Fam Physician*. 2010;82(12):1499-1506.
4. Seibert C, et al. Prescribing oral contraceptives for women older than 35 years of age. *Ann Intern Med.* 2003;138:54-64.
5. Westhoff C, Heartwell S, Edwards S, et al. Oral contraceptive discontinuation: do side effects matter? *Am J Obstet Gynecol*. 2007;196(4):412.e-1-7.
6. Moreau C, Cleland K, Trussell J. Contraceptive discontinuation attributed to method dissatisfaction in the United States. *Contraception*. 2007;76(4):267-272.
7. Zhang S, Sridhar A. Oral contraceptive preference and prescription patterns among primary care residents in an academic medical center. *Obstetrics & Gynecology*. 2017;129(5):62.
8. Figueiras A, Herdeiro M, Polonia J, et al. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. *JAMA*. 2006;296(9):1086-1093.
9. Tabali M, Jeschke E, Bockelbrink A, et al. Educational intervention to improve physician reporting of adverse drug reactions (ADRs) in a primary care setting in complementary and alternative medicine. *BMC Public Health*. 2009;9:274.
10. Chen C, Hsiao F, Shen L, Wu C. The cost-saving effect and prevention of medication errors by clinical pharmacist intervention in a nephrology unit. *Medicine (Baltimore).* 2017;96(34):e7883.

Appendix 1: Provider Pre-Survey

1. Please enter a unique identifier using the first 3 letters of your middle name and last 4 digits of your phone number (Ex. JEA 7212)
2. Credentials (NP, MD, PA, etc.)
3. Years in Practice
4. Years in Practice at Campus Health
5. What is your primary practice setting?
    a. Primary Care
    b. Gynecology
    c. Sports Medicine
    d. CAPS
    e. Same Day Care
    f. Other (free text)
6. How often do you counsel patients on the adverse effects of oral contraceptives when prescribing for the first time?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
7. How often do you counsel patients on the adverse effects of oral contraceptives at a follow up visit?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
8. Do you know what the acronym ACHES stands for in regard to combined hormonal contraceptives?
    a. Yes
    b. No
9. Do you use the acronym ACHES in regard to CHC adverse effects?
    a. Yes
    b. No

    If yes to question 9, how often do you use the acronym ACHES to counsel patients on ADE from CHCs?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
10. How often do you use a template to document your CHC visits?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
11. How confident are you in adjusting a patient's OCP dose or medication if they are experiencing adverse effects?

    a. Very confident
    b. Mostly confident
    c. Somewhat confident
    d. Not confident at all
12. Which Campus Health provided resources for oral contraceptive dosing and education are you aware of?
    a. Women's health/gynecology drug formulary
    b. Hormonal Contraceptive chart
    c. OCP Androgen Potential chart
    d. Pill, Patch, Ring Booklet
13. What Campus Health provided resources for oral contraceptive dosing and education do you use?
    a. Women's health/gynecology drug formulary
    b. Hormonal Contraceptive chart
    c. OCP Androgen Potential chart
    d. Pill, Patch, Ring Booklet
14. How often do you use these resources?
    a. For every visit
    b. For most visits
    c. For some visits
    d. Never

Appendix 2: Provider Post-Survey

1. Please enter a unique identifier using the first 3 letters of your middle name and last 4 digits of your phone number (Ex. JEA 7212)
2. Credentials (NP, MD, PA, etc.)
3. Years in Practice
4. Years in Practice at Campus Health
5. What is your primary practice setting?
    a. Primary Care
    b. Gynecology
    c. Sports Medicine
    d. CAPS
    e. Same Day Care
    f. Other (free text)
6. How often do you counsel patients on the adverse effects of oral contraceptives when prescribing for the first time?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
7. How often do you counsel patients on the adverse effects of oral contraceptives at a follow up visit?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
8. Do you know what the acronym ACHES stands for in regards to CHCs?
    a. Yes
    b. No
9. Do you use the acronym ACHES in regards to CHC adverse effects?
    a. Yes
    b. No

If yes to question 9, how often do you use the acronym ACHES to counsel patients on ADE from CHCs?

    a. Always
    b. Most of the time
    c. Some of the time
    d. Never

10. How often do you use a template to document your CHC visits?
    a. Always
    b. Most of the time
    c. Some of the time
    d. Never
11. How confident are you in adjusting a patient's OCP dose or medication if they are experiencing adverse effects?
    a. Very confident
    b. Mostly confident
    c. Somewhat confident
    d. Not confident at all

12. Which Campus Health provided resources for oral contraceptive dosing and education are you aware of?
    a. Women's health/gynecology drug formulary
    b. Hormonal contraceptive chart
    c. OCP Androgen Potential chart
    d. Pill, Patch, Ring Booklet
13. What Campus Health provided resources for oral contraceptive dosing and education do you use?
    a. Women's health/gynecology drug formulary
    b. Hormonal contraceptive chart
    c. OCP Androgen Potential chart
    d. Pill, Patch, Ring Booklet
14. How often do you use these resources?
    a. For every visit
    b. For most visits
    c. For some visits
    d. Never
15. How would you rate the overall content of this presentation?
    a. Excellent
    b. Good
    c. Fair
    d. Poor
16. What was the best aspect of this presentation?
    a. Free text
17. What parts of the presentation could be improved?
    a. Free text
18. Is there anything else you would like to add about the presentation or this survey?
    a. Free text