TEACHERS' TOPICS

A Cardiovascular Pharmacotherapy Elective Course to Enhance Pharmacy Students' Literature Evaluation Skills and Ability to Apply Clinical Evidence

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Objectives. To design and implement a cardiovascular pharmacotherapy elective course to enhance pharmacy students' ability to evaluate medical literature and apply clinical evidence.

Design. In weekly class sessions, students were provided an overview of the important literature supporting therapeutic guidelines for the management of major cardiovascular diseases. Students worked in groups to complete outside-of-class assignments involving a patient case and then discussed the case in class. During the semester, each student also independently completed a literature search on an assigned topic, summarized the studies found in table format, and presented 1 of the studies to the class.

Assessment. Students' grades on weekly patient case assignments steadily increased over the semester. Also, the average grade on the final examination was higher than the grade on the midterm take-home examination. On the course evaluation, students rated the course favorably in terms of improvement of confidence in evaluating the primary literature and applying it to practice.

Conclusion. Completion of the cardiovascular pharmacotherapy elective increased pharmacy students' level of confidence in evaluating literature and applying clinical evidence in making patient care decisions.

Keywords: cardiovascular disease, pharmacotherapy, evidence-based medicine, elective course

INTRODUCTION

Traditional pharmacotherapeutics curriculum generally presented pharmacy students with treatment guidelines and a disease management approach without providing in-depth discussion of the clinical evidence supporting the therapeutic recommendations. Because of time limitations and the amount of materials that needed to be covered, often only the treatment overview was presented and issues regarding therapy selection, dosing, and monitoring were not discussed in depth. Sometimes, students were left to explore these areas for the first time in case study workshops or even during clinical practice experiences, which could be overwhelming.

With the shift in health care practice to an interdisciplinary team approach, pharmacists now play a critical role in the evidence-based decision-making process, serving as a source of scientifically valid information, and experts on best practices in the appropriate use of

medications. Thus, the need to develop pharmacy students' skills in literature evaluation and application of clinical evidence in practice is crucial. According to the latest accreditation standards and guidelines published by the Accreditation Council for Pharmacy Education on February 14, 2011, pharmacy graduates must be able to evaluate the quality of basic science and clinical research evidence to appropriately apply study results to practice decisions.¹

The practice of evidence-based medicine was usually introduced to pharmacy students as part of drug information, literature evaluation, research design, or similar courses. The skill set used in acquiring, interpreting, and applying evidence-based medicine practices was formally taught in a required course in only 42% of US colleges and schools of pharmacy.² Furthermore, there were few opportunities in the classroom curriculum to reinforce these skills prior to beginning clinical clerkships. Only a few studies have evaluated these courses.³⁻⁵ Medical students who were given a 2-hour instructional session on evidence-based practice were able to obtain more relevant and complete search results compared to students who did not receive training.³ Likewise, active-learning

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strategies (2-hour weekly literature search activities) in a drug information and literature evaluation course resulted in improvement in pharmacy students' ability and confidence to perform the course objectives.⁴ Third-year medical students who received four 2-hour sessions on evidence-based medicine increased their ability to critically appraise the literature and their tendency to rely on original research articles to solve clinical problems.⁵ It is, therefore, not only important to introduce students to evidence-based practice, but also to incorporate other strategies earlier in the curriculum to reinforce these concepts prior to beginning practice experiences.

Cardiovascular diseases management is probably one of the most evidence-based areas of medicine and pharmacy practice. The results of new clinical studies require pharmacy practice guidelines to be updated every 2 to 3 years. It is important for students to develop and assume responsibility for their own lifelong learning skills in this area. Being able to evaluate clinical evidence and apply the results to practice is an important component. This manuscript describes the development and implementation of a cardiovascular pharmacotherapy elective course to develop these skills.

DESIGN

The overall goal of the cardiovascular pharmacotherapy elective course was to enhance pharmacy students' ability to evaluate medical literature and to apply clinical evidence to practice via the in-depth study of management of cardiovascular diseases. In addition, the course also discussed "clinical pearls" that were not normally discussed in the required curriculum, for example: (1) how to replace and monitor potassium in patients on high-dose diuretics; (2) how to switch from unfractionated heparin to low molecular weight heparin or other antithrombotics; and (3) how to concentrate all intravenous medications so as to minimize fluid intake in a patient with heart failure and fluid overload. Furthermore, besides learning how to manage cardiovascular disease (ie, choosing the optimal regimen, monitoring outcomes and side effects), the course also discussed management of cardiovascular diseases from a public health and health-system perspective (eg, how to prevent common medication errors relating to cardiovascular agents, how to work with patients with different levels of health literacy to improve cardiac health). Upon completion of the course, students would be able to: (1) identify and use treatment guidelines and other important evidence-based information sources of cardiovascular pharmacotherapy; (2) discuss how evidence-based guidelines are developed, and interpret the different gradings/levels of recommendations in major cardiovascular diseases treatment guidelines; (3)

design a pharmaceutical care plan based on specific patient and disease state characteristics and be able to justify the plan using published clinical evidence; and (4) identify and interpret pivotal clinical studies supporting recommendations of gold standard therapies in prevention and management of cardiovascular diseases (eg, use of aspirin, angiotensin converting enzyme (ACE) inhibitor, beta blockers, and HMG-CoA (3-hydroxy-3-methyl-glutaryl-CoA) reductase inhibitors for prevention and treatment of different cardiovascular diseases); (5) design an approach for educating patients, especially those with low health literacy and history of poor compliance, regarding taking their cardiovascular medications; and (6) identify potential medication errors and drug-induced diseases in a given patient scenario, design strategies to prevent these errors, and implement a management plan should errors occur.

The class met 1 afternoon each week for 3 hours during the spring semester. Up to 25 students were allowed to enroll in the course. During class sessions, the instructor spent the first 1 to 1.5 hours providing an overview of the important literature supporting the therapeutic guidelines and recommendations for the management of major cardiovascular diseases. The discussion topics for spring 2011 are listed in Appendix 1. Because treatment guidelines and recommendations for management of cardiovascular diseases change frequently, the topics discussed in the course varied from year to year.

The rest of the class time was spent discussing the patient case that students were assigned to work on outside of class. The cases included questions designed to force students to research the primary literature to justify their answers. Students were asked to work in groups of 5 to complete these assignments, and to be prepared to discuss the cases in class.

At the beginning of the semester, each student also was assigned a different cardiovascular topic (eg, use of ACE inhibitors in heart failure, use of high dose HMG-CoA reductase inhibitors in acute coronary syndrome) and asked to complete a thorough literature search on the primary studies on the subject and summarize these studies in table format (Table 1). Formative assessment was used for this assignment. Students were provided feedback throughout the semester while they were working on the assignment. Students submitted their literature search results and the instructor provided feedback in terms of whether the appropriate studies were identified. Then students worked on the first few studies and submitted a preliminary draft for which the instructor provided feedback.

Each student also was asked to choose 1 study from among all the studies they had retrieved for their writing

Table 1. Format of Writing Assignment on Summarizing Pivotal Clinical Trials of an Assigned Cardiovascular Disease Topic^a

Reference	Study Design	Subjects (N)	Treatment Arms	Primary Endpoints	Duration of Follow-up	Major Results	Limitations
CLARITY-TIMI 28 ^{*b}	Randomized, double-blinded, placebo controlled	N=3491 STEMI	Clopidogrel 300 mg load, then 75 mg qd vs. matching placebo	Occluded artery + death + recurrent MI	30 days	Primary endpoint: 21.7% in placebo, 15% in clopidogrel p<0.05 No increase risk of bleeding	Not powered to detect survival differences. Did not enroll elderly > 75 and those with CABG

Abbreviations: CABG = coronary artery bypass graft.

^a Use of clopidogrel in ST-elevation myocardial infarction.

^b *New Engl J Med.* 2005; 352:1179-89.

assignment to present to the class and explain why that particular study was important in helping to define the treatment. The presentations were given during the last 4 weeks of class.

The final version of the writing assignment was submitted near the end of the semester. After the course coordinator graded all of the students' writing assignments, she compiled the corrected versions of the tables into a single document containing all significant clinical studies for the cardiovascular therapeutic topics covered, and gave a copy to each student. Students could include the packaged data in their portfolio to use as a future learning reference.

Because learning to evaluate primary literature was the core purpose of the course, during the last week of class, the course coordinator (or an invited speaker) presented "hot topics" emerging from the pharmacotherapy-related clinical trials presented in the most recent American Heart Association Annual Scientific Session (occurred November every year) and the American College of Cardiology Annual Scientific Session and Expo (occurred March every year).

For the take-home midterm and final examinations, each student was assigned a different patient case pertaining to a topic that had been discussed in the course. They were asked to formulate a pharmaceutical care plan for the patient and support each of their recommendations with the appropriate treatment guideline and studies from the primary literature. To prevent students from focusing too heavily on treatment guidelines to answer the case questions, one part of the case required the students to research a controversial therapeutic treatment issue that was not addressed in any treatment guidelines. This forced the students to rely on the primary literature to formulate their answers. Appendix 2 presents an example of a take-home examination case.

ASSESSMENT AND EVALUATION

The take-home midterm examination and the final examination each accounted for 20% of the course grade. The literature evaluation and writing assignment accounted for another 20% of the course grade. Five randomly selected group homework cases were graded and counted 30% of the overall grade. Finally, 4 unscheduled quizzes administered throughout the semester counted for 10% of the course grade. If they provided a legitimate excuse, students were allowed to miss 1 of the 4 quizzes. If they missed more than 1 quiz, the student was given a zero for the second quiz missed.

In 2010 and 2011, students' average grades on the group homework assignments steadily increased over the semester (year 2010: 90%, 91%, 94%, 96%, and 98%; year 2011: 89%, 92%, 94%, 96%, and 97%). Likewise, students' average grade on the final examination was higher than the average grade on the midterm examination in 2010 and 2011 (year 2010: midterm, 89%; final, 94%; year 2011: midterm, 93%; final, 95%). (Samples midterm and final examinations demonstrating individual students' progress in their ability to search the literature to support their care plans are available from the author upon request.) The average grade for the final writing assignment was 92% in 2010 and 2011.

Student Evaluation of the Course

At the end of the course, students completed a 9-item evaluation, with responses based on a 5-point Likert scale (1 = strongly disagree and 5 = strongly agree). Mean Likert scale scores were calculated for each response.

The course was offered for the first time in spring semester 2010 and evaluated using the online CoursEval system (ConnectEDU Inc. Boston MA). Ten of the 26 students enrolled in the course completed the course evaluation in 2010, and 8 of the 25 students enrolled completed

the course evaluation in 2011. The average score on each of the 9 items (Table 2) was 5 in 2010 and 2011. Students strongly agreed that their own efforts to learn improved their quality of learning. Overall, students felt that the course increased their level of confidence in literature evaluation and applying information to patient cases. Students also liked the take-home examinations with patient cases that mimicked real practice.

Some students stated that the course coordinator needed to better clarify student responsibilities for the course including the importance of their assuming responsibility for their own learning. Some students also stated that because a relatively large portion of the course relied on group work, the lesser contribution of some group members led to frustration for other group members.

DISCUSSION

Supported by pharmacy education accrediting bodies and benchmark standards, principles of evidence-based pharmacy practice should be distributed throughout required and elective courses.¹ The curriculum at the Massachusetts College of Pharmacy and Health Sciences includes a literature evaluation course in the second year that teaches students basic literature evaluation skills and analytical concepts encountered in the primary literature. A pharmacotherapeutics seminar in the third year and an advanced pharmacy practice experience (APPE) provide students with opportunities to apply these skills to a greater degree. Because of large class sizes, it is challenging to reinforce these skills in most other lecture-based courses in the curriculum. This elective course was designed with the hope to enhance students' literature evaluation and evidence-based application skills.

The amount of clinical evidence published on cardiovascular diseases management is tremendous. Allowing students to evaluate the primary literature and apply their findings to patient cases and providing feedback from practicing clinicians who are content experts helped students develop confidence in understanding and applying clinical evidence to pharmacy practice.

To our knowledge, only 1 other study describing and evaluating the implementation of an evidence-based practice course in a pharmacy curriculum has been published. Bookstaver and colleagues described the development of an evidence-based medicine elective course (2 hours per week for 1 semester, 15 students per class) to improve student performance in APPEs.⁶ The course used case studies, journal club simulations, and student-driven wiki pages to improve students' literature evaluation skills and ability in applying clinical evidence to practice. Experiential preceptors reported that students who had completed the course had stronger skills in applying evidence-based medicine to patient care than other students. We did not perform any measurement on whether skills acquired in our elective were transferable to other courses or practice experience.

The instructor realized during the students' initial submission of their literature search results that only approximately 30% of the students in 2010 and 2011 could produce a search strategy that identified all the pivotal primary clinical studies in their assigned topics. Three reasons why the students were not able to identify all the pivotal studies were identified: they used search terms that were too broad, they only searched for articles published in the last 10 to 15 years, and they limited their searches to PubMed.

Table 2. Student Course Evaluation of a Cardiovascular Pharmacotherapy Elective Course to Enhance Pharmacy Students' Literature Evaluation Skills and Ability to Apply Clinical Evidence^a

Item	2010 (N =10) ^b	2011 (N =8) ^b
My own efforts to learn (eg, preparing for class, study, and/or seeking additional help) improved the quality of my learning in this course.	5.0	5.0
Overall, I have learned from this course.	5.0	5.0
The structure of this course helped me learn the material.	5.0	5.0
Grading methods in this course were consistent with the syllabus.	5.0	5.0
The course increases my level of interest in cardiovascular pharmacotherapy.	5.0	5.0
The cases in the course improve my problem-solving skills.	5.0	5.0
The course improves my ability in evaluating medical literature in cardiovascular diseases.	5.0	5.0
The instructor communicated what I was expected to learn.	5.0	5.0
The instructor was responsive to my questions about course material and, when necessary, willing to communicate with me individually.	5.0	5.0

^a Students rated items on a 5-point Likert scale ranging from 1 = strongly disagree to 5 = strongly agree.

^b Ten of the 26 students enrolled in the course completed the course evaluation in 2010, and 8 of the 25 students enrolled completed the course evaluation in 2011.

Using search terms that were too broad, eg, “angiotensin receptor blockers use in heart failure,” instead of names of specific angiotensin receptor blockers, may have resulted in missing specific articles that were indexed under individual drug names. Also, using broad search terms generated hundreds or thousands of search results and students were at a loss as to how to sort through them to identify pertinent studies.

Despite being told at the beginning of the semester not to do so, students limited the publication time in their searches to the last 10 to 15 years, resulting in failure to retrieve many pivotal clinical trials on cardiovascular disease topics that were published more than 10 years ago. Students may have limited the time range of the search to reduce the number of articles retrieved, suggesting that they may need assistance with how to limit searches without over-restricting search results.

For reasons that are not clear, many students also limited their search to free full-text articles they could obtain from PubMed. This was inappropriate given that our college library subscribes to a wide array of medical and pharmacy journals and most of the pivotal clinical studies needed for the writing assignment topics were available through the college’s resources.

When students submitted their first 2 articles to be used in their writing assignment for feedback, the instructor was able to give them instruction to concisely summarize the study design, inclusion/exclusion criteria, study endpoints, and pertinent results. The majority of students also required assistance addressing the limitations of the studies and the clinical applicability of the study results. Most had to be reminded that they should not read each clinical study in isolation. They needed to understand the background and rationale that led to conducting the study and think about how each particular study fit into the “big picture” for treatment.

The students had completed a required literature evaluation course the year prior to enrolling in this elective so these concepts should not have been foreign to them. However, the study findings illustrate the importance of reinforcing literature search and evaluation concepts and providing formative assessment throughout the pharmacy curriculum. Because students received formative assessment feedback throughout the semester, most of them performed well on the writing assignment.

The course has been offered for 2 years and 51 students have completed it. Students appeared to have improved confidence in their ability to evaluate literature and apply clinical evidence. A few students commented that the course was not what they expected and they preferred a more traditional (lecturing and testing) approach to learning. For future offerings, the course expectations

should be clarified to prospective students. Also, students should understand the importance of assuming responsibility for their own learning and the importance to their future pharmacy practice of acquiring life-long learning skills, such as the ability to evaluate the literature. However, students learn differently and when the course was offered the second time, in-class quizzes were incorporated. The content of the quizzes was based on the patient case to be discussed that week to encourage students to be well-prepared for the case discussion, and to address/alleviate the problem of some group members contributing less to the patient case group assignment than others.

These were the first 2 times that the course was offered, and overall students performed really well in the course. As the course coordinator was experimenting with different strategies and approaches, and because some of the course assignments used formative assessment, a lenient approach was taken in grading students. Having 25 students participate equally in the weekly case discussion was difficult at times. In future offerings, perhaps 1 group of students will be randomly selected each week to lead the case discussion. By doing that, over the course of the semester, everyone would have a chance to participate in the case discussion. Student self-evaluation or peer evaluation could also be incorporated into the course to get better insight on individual students’ level of participation in group assignments and whether they felt that improving their literature evaluation skills helped them over the semester and in other coursework.

CONCLUSION

Completion of an evidence-based cardiovascular pharmacotherapy elective course increased pharmacy students’ confidence in evaluating the medical literature and applying clinical evidence when making patient care decisions. The course has been offered twice and student feedback has been used to improve the course design. Future plans include exploring different strategies to further enhance student participation in class, and using different assessment strategies to track individual student progress in evaluating medical literature, which may include self-reflection and peer evaluation. A similar course structure could be used to develop electives in other therapeutic areas.

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Appendix 1. Course Outline Spring Semester 2011

Week	Topic	Assignments Due
1	Course Overview Evidence based medicine practice and interpreting cardiovascular disease management guidelines.	
2	Case 1: Hypertension management <u>Teaching points:</u> 1. Selection of appropriate antihypertensives 2. Antihypertensives titration, tapering, monitoring, adding and switching of regimens. 3. Management of side effects.	
3	Case 2: Hyperlipidemia management <u>Teaching points:</u> 1. Selection of appropriate antihyperlipidemics 2. Antihyperlipidemics titration, addition and switching to alternative agents. 3. Preventing statins drug interactions (use in special populations: e.g. organ-transplant recipients, HIV patients) 4. Pleiotropic effects: Are statins really better than other agents. 5. Treatment of other inflammatory endpoints (hsCRP, Lp(a))	Case 2 assignment will be collected.
4	Case 3: Acute Coronary Syndromes Part 1 <u>Teaching points:</u> 1. Contrast Dye induced nephropathy management. 2. Dosing of antithrombotic therapy in patients with renal insufficiency and obesity 3. Discontinuing/restarting antithrombotics before and after surgical procedures. 4. Heparin induced thrombocytopenia management	Case 3 assignment will be collected.
5	Case 4: Acute Coronary Syndrome Part 2 <u>Teaching points:</u> 1. Clopidogrel loading doses (300mg vs. 600 mg vs. 900 mg) 2. Aspirin 81 mg vs. 162 mg vs. 325 mg qd. Is there a right dose? 3. Genetic polymorphism and the affects on antiplatelet response 3. New antiplatelet/anticoagulant use in acute coronary syndrome	
6	Case 5: Heart Failure Part 1 <u>Teaching points:</u> 1. Achieving adequate diuresis (including patients who's allergic to sulfur) 2. Adjusting and pushing angiotensin converting enzyme inhibitor/ angiotensin receptor blocker/beta-blockers/aldosterone antagonist doses. 3. Managing electrolytes in heart failure patients. 4. Managing heart failure with preserved ejection fraction.	Case 5 assignment will be collected.
7	Midterm Examination	

(Continued)

Appendix 1. (Continued)

Week	Topic	Assignments Due
8	Case 6: Heart Failure Part 2 Teaching points: 1. Use of inotropes and vasopressors 2. Concentrating IV drugs to minimize fluid intake. 3. The hemodynamic interactions of the heart and lung: Heart failure causing pulmonary hypertension or pulmonary hypertension causing right heart failure.	
9	Case 7: Arrhythmia Teaching points: 1. Selection of antiarrhythmics for different scenarios. 2. Loading and dosing antiarrhythmics and checking QT and drug interactions. 3. Rate vs. rhythm control in atrial fibrillation 4. Anticoagulation in atrial fibrillation	Case 7 assignment will be collected.
10	Case 8: Common medication errors in patients with cardiovascular diseases Part 1 <u>Teaching points:</u> Drug induced cardiovascular diseases (avoidance and management)	Case 8 assignment will be collected.
11	Case 9: Common medication errors in patients with cardiovascular diseases Part 2 <u>Teaching points:</u> 1. Sound alike/look alike cardiovascular agents (e.g. heparin, digoxin/furosemide (look alike), hydralazine/hydroxyzine, clonidine/klonipine) 2. Subtherapeutic doses/overdoses (mg/kg/min vs. mcg/kg/min vs. ng/kg/min vs. mg/min ... etc) 3. Dosing by total body weight or ideal body weight 4. Common cardiovascular drug interactions	**Student presentation of Clinical Study**
12	Case 10: Public health efforts in reducing incidence of cardiovascular disease. <u>Teaching points:</u> 1. Evaluating epidemiology data (how bad is the problem locally and globally) 2. Evaluating studies demonstrating pharmacists making an impact in reducing incidence of cardiovascular disease and patient outcomes.	Case 10 assignment will be collected **Student presentation of Clinical Study**
13	Case 11: Public health efforts in reducing cardiovascular disease (pharmacists' role and potential obstacles) <u>Teaching points:</u> 1. Improving medication compliance 2. Overcoming low health literacy (AHRQ document on Pharmacy Health Literacy Assessment Tool) 3. Improving access to care 4. Important patient education information, what is the bottom line	Writing assignment will be collected. **Student presentation of Clinical Study**
14	Cardiology Late Breaking Clinical Trials Updates (Update students in pertinent cardiovascular clinical trial results presented at the American Heart Association and American College of Cardiology meeting during the past year)	**Student presentation of Clinical Study**
15	Final Examination	

Appendix 2. An Example of a Take Home Examination Case

W.T. is a 42-year-old, 90-kg man with no significant past medical history except drug abuse including cocaine and oxycodone. He is brought to the emergency department (ED) by ambulance complaining of 8 hours of substernal chest pressure at rest. His roommate called 911. En route to the hospital, paramedics administered three sublingual nitroglycerin tablets and aspirin 325 mg orally without relief. The patient denies any recent trauma or bleeding tendencies. His roommate admitted that they were smoking some cocaine after dinner. On physical examination, he is an obese man (5'8", 200 lbs) in moderate distress. His vital signs include blood pressure 160/80 mm Hg and pulse rate 110 beats/minute, and he is afebrile. His physical examination is significant for regular rate and rhythm and normal S1 and S2; his fecal occult blood test is negative. He has no signs of acute heart failure. Electrocardiography (ECG) performed 5 minutes after presentation to the ED reveals normal sinus rhythm with ST-segment elevation (STE) in the inferior leads. His chemistry panel and complete blood cell count are normal, his serum creatinine (SCr) is 1.0 mg/dL, but his cardiac enzymes (creatinine kinase, CK-MB, troponin) are elevated. The hospital does not have a cardiac catheterization laboratory.

1. Please design a pharmaceutical care plan on how this patient's ST-elevation myocardial infarction (STEMI) should be managed. Please be very specific about the dose and frequency and justify your choice with proper references. Please also include monitoring parameters for the drug. When stating monitoring parameters, please be specific on when to check them.

2. The medical students on the team asked you about the use of beta-blockers in this kind of cases. He said that he has heard that beta-blockers with alpha-blockade properties may be better. He was wondering why and was wondering if you can find him any clinical studies supporting that beta-blockers with alpha-blocking property is better.

Please explain to the intern the theoretical benefits of using alpha-beta-blockers in this kind of STEMI, as well as do a literature search to see if there is any clinical trial supporting the use of alpha-beta-blockers in this kind of STEMI.