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Amiodarone-Induced Peripheral Phlebitis: Implementation of Practice Guideline to Decrease Incidence

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Abstract

Amiodarone is used in the management of ventricular and atrial arrhythmias, and the drug of choice among many cardiothoracic surgeons to manage post-operative arrhythmias. Atrial fibrillation with rapid ventricular response, is the most common arrhythmia treated with amiodarone in a telemetry unit in one medical center located in northern California. Nurses have noted a high incidence rate of phlebitis related to amiodarone infusion even when the current hospital guidelines are being followed. Data were collected over six months and included 35 patients, each infusion via a different intravenous site was considered another occurrence, for a total of 40 infusions. There were 16 cases of phlebitis that developed which was a 40% incidence rate. Some patients had more than one episode of phlebitis. A multidisciplinary team was formed to introduce practice change. Interventions focused on education of staff and implementation of evidence-based practice guidelines for infusion. Data collection of phlebitis incidence was performed post-intervention over four weeks that included 4 patients with a total of 7 infusions. Each infusion was considered as a separate occurrence. There were 3 cases of phlebitis, with one patient accounting for two cases. The result is a 43% incidence rate of phlebitis. A follow-up study is necessary after six-months of data collection post-intervention in order to make a more balanced analysis of the result, and this continuation of data collection is in progress.

Keywords: Amiodarone, phlebitis, guideline, side effects, infusion, thrombophlebitis.
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**Problem Description**

Managing arrhythmias in a cardiac unit can pose a significant challenge for nurses and physicians in their daily practice. The life-threatening nature of the problem makes it critical to have a drug that can be infused readily and can manage the arrhythmias effectively. First discovered in 1961, Amiodarone is a Vaughan Williams class III anti-arrhythmic drug commonly used in the setting of managing unstable atrial and ventricular arrhythmias (Brady Boyce & Homer Yee, 2012). Approved by the Food and Drug Administration (FDA) in 1985, the increased use of amiodarone has also been linked to phlebitis. The approval of the FDA is limited to the treatment of ventricular fibrillation and ventricular tachycardia. However, the off-label use of amiodarone in managing atrial arrhythmias, such as atrial fibrillation in the postoperative period, has gained popularity among cardiac surgeons, (Hannibal, 2016).

Endorsed by consensus guidelines published by the American College of Cardiology (ACC), the American Heart Association (AHA), and the European Society of Cardiology (ESC) in the treatment of atrial fibrillation, the guidelines also acknowledge that one of the common side effects when infused peripherally is phlebitis (Spiering, 2014). With its increased use in many cardiac-care units, a high incidence of amiodarone-related phlebitis has also been noted, prompting three major nursing journals in the last few years to address this issue (Hannibal, 2016). With an increasing number of patients presenting for hospital admission with atrial fibrillation, or having atrial fibrillation post-cardiac surgery, combined with the drive to manage...
atrial arrhythmias to avoid complications such as stroke, the likelihood that healthcare institutions will continue to use amiodarone to manage such diagnoses is high.

Phlebitis is defined as an inflammation of the vein wall characterized by pain, edema, erythema, streak formation and/or a palpable cord (Washington & Barrett, 2012). The Infusion Nurses Society (INS) phlebitis scale is widely used in the clinical setting to grade the severity of phlebitis, in a range from 0 to 4, with 4 being the most severe. An additional phlebitis scale; the visual phlebitis scale is another alternative assessment tool widely used in grading the severity of phlebitis (see appendix A for both phlebitis scales). According to INS (2011), the rate of phlebitis should be 5% or less in any given population of patients receiving peripheral infusions. The 2016 INS Intravenous Therapy Standards of Practice identified four categories of phlebitis: chemical, mechanical, bacterial, and phlebitis driven by patient characteristics. The INS also acknowledged post-infusion phlebitis that can develop due to any of the same causes. Amiodarone-related phlebitis, in particular, can be categorized under chemical phlebitis. The chemical features of amiodarone, such as its acidity, have been thought to be a major culprit in phlebitis formation with amiodarone infusion (Spiering, 2014).

It has been noted that there is a direct connection between pH and osmolarity of an infusate contributing to phlebitis formation. In the case of amiodarone, it is hypothesized that the acidic pH level (ranging from 3.4-4.5 in some literature) is more responsible for phlebitis rather than the osmolarity (Spiering, 2014). Pharmaceutical companies are well aware of the complication of phlebitis when amiodarone is infused peripherally. Information on how to avoid phlebitis is included in the prescribing information from the various manufacturers, and has included recommendations for using an in-line filter to reduce particulate formation, use of
central venous catheter for infusions longer than one hour, and if the drug concentration is 2 milligram(mg)/milliliter (ml) and higher (Baxter Healthcare Corporation, 2018). Ideally, it is recommended that all infusions should be given via central venous catheter due to phlebitis as a known side effect. However, this is not always feasible since intravenous amiodarone is usually prescribed during emergencies or when patients develop arrhythmias where timing is not always predictable. In many cases, a central line is not always readily available for all patients.

In addition to pH and osmolarity contributing to phlebitis, the preservatives added to amiodarone and the drug’s inherent tendency to precipitate when it enters the blood stream have also been hypothesized as causative factors. The conventional amiodarone preparation contains preservatives such as polysorbate 80 and benzyl alcohol, both thought to contribute to phlebitis formation. Some pharmaceutical companies have done their best to eliminate such preservatives in their packaging. With regard to precipitation of amiodarone once diluted or in contact with the bloodstream, a study by Ward and Yalkowsky (1993) using animal subjects found that rapidly forming needle-shaped crystals adhere to the intima of the vein causing trauma to the vascular endothelium when amiodarone is infused. Smaller volume infusions did not illicit the same inflammatory response, but as the volume of amiodarone infused increased, so did the severity of thrombophlebitis. It is then hypothesized that even when the amiodarone infusion was diluted, the amount of precipitation still exceeded the solubility of the drug in the bloodstream (Mowry & Hartman, 2011).

Phlebitis has been well-known as a side effect of amiodarone infusion for many years and thus, hospitals across the country have conducted studies to improve practice and minimize it. In
2014, Spiering, a cardiology clinical nurse specialist at Providence Saint Vincent Medical Center in Oregon at the time, conducted a study and published the results in the Journal of Infusion Nursing. The study found that the implementation of amiodarone peripheral infusion guidelines significantly decreased the incidence rate of phlebitis from 85% pre-guidelines down to 38% post-guidelines, representing a 47% improvement. It also showed reduced severity of phlebitis after the guidelines were implemented. The study was conducted in response to nurses reporting a high incidence of phlebitis in a telemetry unit, causing pain and infection in patients, and often delaying discharge. There were no existing guidelines for amiodarone infusion at the facility before the study. Study patients were identified from those admitted to a single institution, using an observational convenience sample consisting of 34 patients over a six-month period. A multidisciplinary team was formed including nurses, cardiologists, pharmacists, and the intravenous (IV) therapy team, and an approval from the Institutional Review Board (IRB) was obtained. Multiple peer-reviewed research articles were used in the development of the guidelines.

The effective guidelines included use of dedicated lines, separate filters for boluses and infusions, patient instruction to notify a nurse immediately in case of pain or redness at the site, inspection of the IV site during change of shift report, and discontinuation of catheter at the first sign of pain and redness. Although the guidelines appear to be successful in decreasing the incidence of amiodarone-related phlebitis, the sample size was small and the population used were strictly adult cardiac patients. Therefore, the study may not be generalizable to the rest of the hospital population. There is also a question of whether or not the decrease in phlebitis can be attributed to the guideline themselves, or was merely a response to an increased awareness and understanding of amiodarone complications on the part of staff.
In a study published in *Critical Care Journal*, Brady Boyce & Homer Yee (2012) conducted a study to determine the rate and severity of phlebitis related to peripheral infusion of amiodarone and to evaluate the magnitude of the problem at Mount Auburn Hospital in Massachusetts. Nurses were reporting a high incidence of phlebitis even when existing guidelines for drug administration was being followed. Those guidelines included having amiodarone prepared in a glass bottle from pharmacy, and the use of an in-line filter in case of drug precipitation. The study included a review of the current literature and of the hospital’s current policy and procedures. The hospital’s IRB was consulted, and a multidisciplinary team was formed including nurses, an IV therapy nurse, a cardiovascular nurse specialist, a pharmacist, and a research advisor.

Using a descriptive design, data was collected over a six-month period using a convenience sampling of 12 patients. Each infusion of amiodarone was treated as a separate occurrence, for a total of 24 infusions. A collection tool drafted by the multi-disciplinary team was used to aid in determining variables that would affect phlebitis development. This tool was then submitted and reviewed by the nursing research council prior to its use and face validation was established. The study was stopped after six months due a high rate of phlebitis, and a plan for action to prevent further harm to patients was initiated immediately. The study showed various grades of phlebitis developed in eight patients (67%), and phlebitis developed at 12 of the 24 infusion sites (50%). This was a far higher rate than that reported in the literature, which is between 7-23% (Brady Boyce & Homer Yee, 2012). The high rate of phlebitis warranted a plan to increase awareness and education for nurses and other medical staff, as well as a change in the policy and practice guidelines and subsequent implementation of those changes.
These changes to practice included involvement of the IV therapy nurse to monitor infusion sites, annual competency testing for nurses regarding amiodarone infusion, increasing the frequency of IV site assessment, use of in-line filters during infusion, and reminding physicians about the risk of phlebitis associated with amiodarone infusion to alert them to carefully consider the length of infusion and possible conversion to oral route of administration. The small sample size was identified as one of the limitations of the study, although it was enough to make changes to policy and practice guidelines promptly. The result, even from a small sample, combined with the known common side effect of amiodarone, triggered the appropriate response by the medical center to consider patient safety as their top priority. There is, however, no outcome study or follow up data mentioned in the study to determine whether the changes made decreased the incidence of phlebitis at this facility.

Another study published in *American Journal of Critical Care* by Norton, et al. (2013) at Stanford University in California, examined the magnitude of the problem of amiodarone-related phlebitis in a critical care unit (CCU). Staff recognized the problems of amiodarone-related phlebitis when infused peripherally even when the current recommendations of drug administration were being followed. The current protocol of the facility at the time of the study called for use of an in-line filter, central line for higher concentration of the drug, and only used peripheral lines for lower drug concentrations. The guidelines were insufficient as evidenced by the high incidence of phlebitis and the need for refinement was recognized.

A retrospective descriptive study over an 18-month period was conducted with a total sample of 105 patients. The study found the incidence of phlebitis to be 40% with a 50% recurrence rate. All cases of phlebitis occurred in patients who received a total dose of 3 grams peripherally, and one quarter of the cases developed phlebitis at dosages less than 1 gram per
dose, with complications occurring within 24 hours of treatment (Norton, et al., 2013). Results of the study clearly warranted a change in practice policy which included continuing use of an in-line filter, using the largest peripheral vein for infusion, converting to oral dosing within 24 hours of IV administration, insertion of percutaneous central catheter if infusion exceeded 24 hours, creation of pharmacy order set, and mandatory assessment of the IV site by nurses. The study emphasized that an outcome study would be needed to measure the effectiveness of the changes adopted in their practice policy.

Rationale

Intravenous amiodarone is widely used in the management of rapid control of arrhythmias in the author’s microsystem, a telemetry unit located in northern California. The high utilization of intravenous amiodarone in the management of arrhythmias has brought attention to an accompanying high rate of phlebitis related to the infusion. The author tracked and collected data in collaboration with charge nurses in her unit and has shown a 40% incidence rate over a six-month period in 35 patients with repeat occurrence of phlebitis in some. A total of 40 infusions resulted in 16 case of phlebitis. The high incidence rate of phlebitis has caused pain and discomfort to patients, extending hospital length of stay (LOS), thereby, increasing cost, and contributes to lower score on patient satisfaction survey. According to HealthCare.gov (2018), the average cost of a three-day hospital stay is around $30,000. Prolonged length of hospital stay due to phlebitis complication can significantly contribute to high cost in healthcare expenditure. In severe cases, sepsis can develop, further extending length of hospital stay and causes suffering of patient.
Currently, the only practice guidelines at the author’s microsystem are the use of a 0.22 micron in-line filter when administering amiodarone, and the mandatory use of central lines for infusions of concentrations exceeding 2 mg/ml. In addition, there is no available policy and procedure related to amiodarone infusion with regard to management of intravenous complications, such as phlebitis and medication extravasation. The hospital currently uses pre-mixed amiodarone intravenous bags from the hospital’s chosen pharmaceutical supplier with a concentration of 0.5 mg/mL for intravenous bolus, and 1.8mg/ml for continuous infusion. The ongoing high incidence of amiodarone-related phlebitis at a northern California medical center, telemetry unit, warrants attention to address such complication. Using the graphic cause and effect diagram, also known as an “Ishikawa diagram,” the author laid out the possible reasons for the high incidence of amiodarone-related phlebitis in her microsystem (see appendix B for the Ishikawa diagram).

With the increasing demands for evidence-based approaches on healthcare practice, it is important for clinicians to base their decisions on the best available scientific evidence. A key step in finding answers based on evidence-based practice is framing the clinical question in an organized manner to find the answer. PICOT is a strategy and is widely used in framing clinical and research questions, and aids in formulating questions clearly and concisely. First introduced in 1995 only as PICO, it was eventually expanded by adding the letter “T,” hence, eventually became known as PICOT (Davies, 2011). The acronym stands for the following: P - patient or problem, I - intervention, C - comparison, O - outcome, and T - for time. By utilizing this framework, the author formulated a clinical practice question aimed at improving clinical practice and patient care in a cardiac microsystem. The formulated question the author designed
using the PICOT framework for her planned practice improvement is: “In cardiac patients developing peripheral phlebitis during amiodarone infusion, how does the implementation of expanded evidence-based-practice (EBP) guideline compared to the current hospital infusion guidelines will affect the incidence rate of phlebitis over a period of four weeks?” Through interventions such as educational program and implementation of EBP guideline related to amiodarone infusion, the author’s expectation is that the incidence rate of phlebitis will decrease and lead to better patient outcomes.

**Specific Aim**

By introducing evidence based-change of practice guideline to improve patient care delivery, the goal is, by August 2018, the implementation of expanded amiodarone infusion guidelines in a telemetry unit will result in a 20% decrease in the incidence of peripheral phlebitis related to amiodarone infusion.

**Context**

The author’s microsystem is a cardiac-driven unit, with a 30-bed capacity, located in Northern California. It is a multi-specialty unit with the primary focus in caring for patients needing services ranging from coronary/cardiac interventions, cardiothoracic surgeries, cardiac device implants, care post myocardial infarction, and care of various cardiac-related symptoms. The average length of stay of four to five days. Patient-to-nurse ratio is usually 4:1, but changes to 3:1 when the patient assignment involves recovering patients with post coronary artery interventions, trans-catheter aortic valve replacements (TAVR), and cardiac ablations (see Appendix C for microsystem profile). The make-up of employees and patients reflect the city’s wide demographics of varying cultural backgrounds. Patients and staff are culturally and
AMIODARONE-INDUCED PHLEBITIS

The diverse composition of staff is beneficial in delivering culturally-sensitive care for most patients.

With the primary medical care focus on cardiac-related diagnoses, amiodarone infusion is a common occurrence in this microsystem. Current hospital infusion guidelines regarding amiodarone infusion consist of the use of in-line filter, and central line requirement for drug concentration of 2mg/ml. These guidelines are actively being followed by staff, however, the incidence rate of phlebitis remains noticeably high, prompting the author to conclude that the current guideline is insufficient to prevent the occurrence of amiodarone-related phlebitis. Further intervention is needed to alleviate such a problem.

**Intervention and Methods**

Quality improvement (QI) methods have been a common trend in healthcare to support the delivery of quality care that is also timely, safe, and effective, as well as cost efficient. Of the many QI tools and methods, the Plan-Do-Study-Act (PDSA) cycle is the method for quality improvement the author has chosen to use for the planned change of practice. The PDSA cycle, first introduced to Dr. Deming by his mentor, Walter Shewhart of the famous Bell Laboratories in New York, is a systematic process for acquiring valuable learning and knowledge for the continual improvement of a product, process, or service (The W. Edwards Deming Institute, 2018).

PDSA method offers the benefit of learning as quickly as possible whether an intervention works and thus allowing the system to make adjustments accordingly to achieve the desired improvement (Reed & Card, 2016). Unlike controlled trials, PDSA allows the flexibility of new learning to be built in to the experimental process where, if problems are identified with
the original plan, then the theory is easily revisable to fit the new learning and one can then proceed to test its effectiveness in achieving the planned change. Using this method allows continual identification of further problems that might need to be addressed. The adaptability of PDSA is an important feature that is valuable in this current complex state of healthcare systems where change has become constant (see appendix D for the PDSA cycle for the improvement project).

The planning stage started with assessment and recognition of the problem in the microsystem. The author discussed the evident problem with the manager/preceptor and the planned evidence based-change of practice project plan. The author recruited team members with varying key roles that consisted of three charge nurses from different shifts, an intravenous nurse, and a pharmacist. Charge nurses are tasked with assisting the author in disseminating information to staff on their respective shifts about the planned change in practice. The charge nurses were assigned to assist in gathering and recording amiodarone infusions and any phlebitis incidences in a designated log book. The author set up an informational interview with the intravenous (IV) nurse to discuss intravenous lines, vein anatomic variations and other subjects related to intravenous therapy. The pharmacist was tasked to serve as an expert for information regarding amiodarone infusion, facility infusion guidelines, and pharmaceutical-related prescribing information. The author was responsible for literature searches and designing a knowledge assessment of staff related to educational program. A Gantt chart was constructed to provide a detailed timeline of the change in practice project (see appendix E). Together with the team assembled, the author and team members proceeded to the next phase of PDSA cycle; the “Do” phase.

Acting on the planned practice change required constant discussions with team members.
Charge nurses reminded staff during huddles about the improvement projects, and also recorded demographic information about patients and their amiodarone infusion dates, sites, and gauge sizes of intravenous catheter used. Most importantly, when patient developed phlebitis, grading of phlebitis was recorded using the INS phlebitis scale in the log book. The IV nurse recommended further exploration of INS practice regarding phlebitis management. She assisted in discussing causes of phlebitis, treatment, and the most current best practice recommendations. She also discussed ideal locations for intravenous sites, and gauge size of catheter ideal for infusing acidic substances, such as amiodarone. Her recommendations were consistent and validated by INS during the author’s literature search.

The Pharmacist provided amiodarone infusion guideline recommendations based on the pharmaceutical prescribing information, and discussed the current packaging and the pharmaceutical company used by the hospital as the supplier. The information aided the author in structuring the literature search and helped narrow the focus to that particular supplier. In addition, current hospital infusion guidelines were also discussed by the pharmacist with the author. The author performed literature searches regarding amiodarone infusion, phlebitis, and extended the search to include amiodarone extravasation. Literature review was performed using CINAHL, Cochrane, Google Scholar, PubMed, and 1Findr. The author accessed and reviewed various guidelines, policy and procedures at her institution related to infusion causing phlebitis or extravasation. The author was able to establish communication via e-mail with one author, discussing her published amiodarone infusion guideline (see appendix F) and requested permission to adapt her published infusion guideline for educational purposes, to which she graciously agreed. (M. Spiering, personal communication, June 14, 2018).

To accurately grasp the level of knowledge staff have regarding amiodarone infusion, the
author distributed a baseline amiodarone nursing knowledge assessment (see appendix G for the knowledge assessment questionnaire). The author then assembled all the information and prepared an educational poster used to educate staff about amiodarone infusion and phlebitis. Backed by literature search and EBP, the poster was then used to educate staff and displayed in the nursing unit for staff viewing and reference. Education was provided to all nursing staff across three different shifts discussing amiodarone and phlebitis, emphasizing the EBP infusion guideline implementation shown in the poster, and providing answers and feedback to staff over the course of several weeks. In addition, the author simultaneously had ongoing discussions with team members on how to best record and maintain the amiodarone log book in a format that was easy to access and record information. This format was modified recording according to feedback from team members and other staff. In addition, the author provided staff assistance in evaluation of phlebitis incidences on some patients, and seized the opportunity to include patients in educating them about amiodarone infusion by encouraging their participation in the prevention of amiodarone-related phlebitis complications. Patients were instructed to notify staff immediately for any early signs and symptoms of phlebitis, such as pain and redness to infusion site.

**Study of the Intervention**

In order to identify whether or not interventions are effective for any process improvement project, it is important to study the efficacy and potential generalizability of these interventions for improving practice in healthcare. Continually utilizing the PDSA method for change of practice project, the letter “S,” which stands for “study”, is appropriately assigned and can be utilized as a guide for what is next in a sequence of steps in evaluating practice improvement interventions that were enacted. To study the reliability and effectiveness of
interventions, the author first measured the baseline nursing knowledge of nursing staff related to amiodarone infusion before the educational program and guidelines were implemented. The author then re-measured their knowledge after four weeks of the educational program by using the same survey questions that were initially distributed at the baseline knowledge assessment. This measure provides an opportunity to evaluate differences in knowledge acquisition, and whether or not this will translate to change in nursing practice, which could lead to eventual decrease in incidence rate of amiodarone-related phlebitis in the microsystem.

Another method in addition to studying and evaluating interventions was to compare the number of cases of amiodarone-related phlebitis before and after the educational program and guideline implementation. By comparing the incidence rates, any changes in the phlebitis rate could be attributed to the interventions that were initiated. However, it can be difficult to determine whether an improvement in incidence rate is related to guideline implementation, or due to increased understanding and awareness of the amiodarone side effects on the part of staff; or both. The result revealed an increased in incidence rate post-interventions. However, it is important to consider the imbalance in the length of time data collection that was performed. The discrepancy is due to limitation in time allotted for this improvement project, which only allowed four weeks to collect data post educational program and guideline implementation due to the academic deadline set by the educational institution. The author however, has extended the data collection to go over a six-month period to match the data collection time pre-and post-intervention.

The last stage of PDSA cycle, “Act,” required the team to constantly reflect and analyze the interventions and the results being collected, adjusting the protocols as they saw fit in order to improve the process. With the tracking of amiodarone-related phlebitis, for example, the log
book was continuously updated to make it user-friendly for staff to log amiodarone infusions and phlebitis formation over the course of four weeks. The team provided support and feedback, as well as reinforced staff education, since initial results post-intervention have remained above goal. They have also reexamined the process further to identify any opportunities for improvement. Adjustments have been made to adapt in differences in staff’s learning needs and style. Ongoing plans to re-evaluate the effectiveness of adjustments are in works. The PDSA cycle is an ongoing process, making changes as needed to improve the process, with the goal of staff’s adaptation to process improvements in order to eventually become more efficient as these improvements slowly become embedded to the microsystem. The success of the planned change relies on staff compliance once it is implemented. Results of the interventions are discussed further in the following sections of this manuscript.

**Measures**

To determine whether or not there were any changes to nursing knowledge regarding amiodarone and phlebitis, a survey of 56 nursing staff from three different shifts was conducted, assessing their knowledge regarding amiodarone infusion and phlebitis before and after the educational program. The questionnaire was designed by the author based on her observations of the knowledge needed in her microsystem, and what was used in literature in addressing staff’s knowledge deficit related to amiodarone infusion. The author designed the survey questions factoring in the current limited hospital guideline in place. The same survey questions were administered to nursing staff again after the educational program to determine any changes in the knowledge level of staff regarding amiodarone infusion and phlebitis. Results were then gathered and broken down into the specific questions that were used in the survey. Baseline nursing staff knowledge assessment results (see appendix H) were presented in graphical format for ease in
interpretation. Post-educational program nursing staff knowledge assessment results were also presented graphically (see appendix I) for consistency in data presentation. The author also compared the incidence rate of amiodarone related phlebitis before and after the educational program and with the implementation of infusion guideline. This is to determine whether knowledge level of staff and implementation of an infusion guideline are factors in any changes to the incidence rate of phlebitis.

There are no available metrics specific to amiodarone-related phlebitis in the microsystem. However, the development of phlebitis can affect patient satisfaction, length of stay due to complication, and cost containment; all considered metrics that matter in any healthcare industry, including in this microsystem. Benchmarking was performed with other medical and academic institutions using published literature and studies of the incidence rates, improvement processes, and outcomes. There is no current national benchmark specific to amiodarone-related phlebitis, however, INS (2011) has indicated that phlebitis rate in any given population should only be 5% or less when receiving peripheral infusion.

To identify any improvements, the team collected data after educational program and guideline implementation, tracking all amiodarone infusions in the microsystem. Data collection included the following information: patient demographics, medical record number, diagnosis, amiodarone infusion timeframes, IV sites information, and phlebitis scale utilization. Data regarding amiodarone infusion and phlebitis incidence rate post-educational program and guideline implementation were gathered over the course of four weeks. Results were then compared to data of amiodarone infusion and phlebitis rate incidence collected before educational program and infusion guideline implementation.
Analysis/Discussion

Quantitative and qualitative methods were used in the improvement project to obtain the data necessary to draw conclusions. The survey questions for assessing both baseline and post-educational program nursing knowledge were designed as qualitative measures, but, in order to analyze the answers more easily, a numerical value was assigned and made the analysis quantifiable. The graphical representation and display of the results were another method of presenting the data quantitatively. In addition, a multiple-choice question was utilized to select an answer that best described the nursing staffs’ preference involving infusion site and IV gauge.

The data collected regarding the rate of phlebitis incidence prior to educational program and guideline implementation were collected over a period of six months. This data showed a 40% rate of amiodarone related phlebitis. On the other hand, the data collected post-educational program and guideline implementation was only over a period of 4 weeks, and showed a 43% incidence rate of phlebitis. The result revealed a higher incidence, opposite of the goal of lower incidence. It is however too early and premature to drew a final conclusion of the interventions’ effectiveness, since the data collection was done on a very short time after the interventions were initiated, and sample population is still small. An outcomes study is in progress and an analysis of the true effectiveness of the study is pending.

Ethical Considerations

Ethics Approval

The study was done without approval from the Medical Center’s Institutional Review Board (IRB). Patient confidentiality was maintained and protected using medical record numbers, diagnosis, and other demographics-related information as identifiers.
Competing Interests

The author reports no potential conflicts of interests in this quality improvement project.

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Results

The educational program for nursing staff and implementation of EBP infusion guideline related to amiodarone resulted in increased understanding of nursing staff. However, the incidence rate of phlebitis remained high and above goal, and is not reflected in the early results of the study. The incidence rate pre-interventions were collected over a six-month period, showing a 40% versus over four-weeks post-interventions showing a 43% phlebitis incidence rate. It is however, important to note that the initial result is not a true indication of the effectiveness of the interventions, due to time limitation in data collection post-intervention and sample size of the population. The author has extended the data collection to go over a six-month period. The ability to draw a balanced comparison and to arrive at a final conclusion are not possible at this time. An outcomes evaluation will be made six months after the interventions were enacted to truly assess the effectiveness of the quality improvement project.

Summary

A key to resolving the high incidence of amiodarone-related phlebitis is the utilization of EBP standards and addressing knowledge deficits of staff. By increasing knowledge and utilizing EBP guideline, the goal was to promote early detection, apply knowledge learned, and encourage vigilance in monitoring IV sites during infusion. The author is confident that the educational program and the implementation of amiodarone infusion best practice remains the key to
resolving high incidence of phlebitis in her microsystem. Although the initial result has not shown any impact in lowering the incidence, the author believes that eventually, the interventions will be successful, and will be reflected in the final outcomes study that is currently pending. By slowly introducing staff and immersing them to EBP approaches, improvement project can be successful and can only lead to a better health outcome.

**Interpretation**

After implementation of quality improvement interventions, initially, the incidence rate of phlebitis remained high. Similar studies reported that an improvement in phlebitis rate when implementation of infusion guidelines and staff education were adopted. Others have made successful similar efforts after recognizing the problem, while others have adopted changes in their practice protocol with outcome study pending at the time of publication. Knowledge of staff regarding amiodarone infusion in the microsystem improved, as was reflected in their post educational survey results. However, improved knowledge did not equate to a lower phlebitis rate, at of this writing. On the other hand, the final outcome cannot be analyzed fully until six months of data has been collected to see whether the interventions were truly effective. The engagement and the sustainability of staff compliance with the infusion guideline will also be a factor that will be determined over time. If successful, replication of the improvement project processes can be instituted at other cardiac-focused units.

**Limitations**

Initial results in this quality improvement project are not comparable to pre-intervention data due to the unequal time in data collection after implementation of intervention. The sample size is small and the length of time for data collection is very short. An effort to extend the data collection over six-month period is in progress to determine the real impact of the intervention
and evaluate the outcome of study. Another possible limitation to the study is distinguishing whether any improvement in the trend of phlebitis incidence in the future is a direct result of the infusion guideline implementation, or a result of increase awareness of staff about the side-effects of amiodarone infusion. However, it is also possible that it could be related to both reasons. The result of the project is limited and not generalizable beyond the adult cardiac population.

**Conclusion**

Managing amiodarone-related phlebitis poses a challenge in a cardiac-focused microsystem. The frequency of using amiodarone to manage arrhythmias continues, and the need to control the high incidence of amiodarone-related phlebitis remains pervasive. Attempts to alleviate such issues have been addressed, and the nursing profession is instrumental in attempting to find solutions to decrease the incidence, as evidence by the availability of multiple published nursing-led research addressing the issue. Nurses are in key positions to detect, educate, and intervene when there is an obvious breakdown in care management affecting the delivery of quality care. The nursing profession has evolved over time, and nursing research focusing on the delivery of quality care based on evidence based-practice is the trend specific to nursing in healthcare.

In response to quality care issues, a role was created in the nursing profession; the clinical nurse leader (CNL). The nursing role most suited for improvement project is that of a CNL. A CNL may serve as a point-of-care clinician, outcomes manager, risk anticipator, and as an educator just to name a few of the roles. An evidenced based change-in-practice project such as decreasing the incidence of peripheral phlebitis related to amiodarone infusion, is the type of improvement project for which the CNL role was created. The nursing implications for an
evidence-based project like this is that it can be replicated by any telemetry nursing unit looking to improve patient outcomes related to amiodarone infusion, and can ultimately contribute to improved quality of care, greater patient satisfaction, and decreased healthcare costs.

As nurses are on the frontline in healthcare delivery, it can be argued that they make the biggest impact in patient care. Improvement projects such as addressing phlebitis incidence in collaboration with a CNL and other multi-disciplinary team is providing quality nursing care. The current healthcare climate is driven by quality measures and since payments are increasingly tied to performance, providing quality care has become the focus of every healthcare organization. Quality care and EBP have now become synonymous, and therefore, the utilization of CNL skills will likely expand in the future. The roles specific for CNL are aligned with the goals and direction of the healthcare industry in general.

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The author did not receive any funding or financial support for the improvement project from any organization or individuals. The educational poster for nursing staff was created at the author’s own expense.
References


Appendix A

Types of Phlebitis

Figure A1. Adapted from Infusion Nurses Society. (2016) Infusion therapy standards of practice. *Journal of Infusion Nursing, 39*, (1S), 95-10. Copyright 2016 by Infusion Nurses Society.
Appendix B

CAUSES OF AMIODARONE-RELATED PERIPHERAL PHLEBITIS

Figure B1. Ishikawa Diagram: Factors contributing to the development of high incidence of amiodarone-related peripheral phlebitis in a cardiac-focused.
Appendix C
The Cardiac Microsystem Profile

Appendix D

The PDSA Cycle

Figure D1. Quality improvement method used for a change-in practice project related to amiodarone infusion causing high incidence of phlebitis in a cardiac-driven unit.
## Appendix E

### Gantt Chart

<table>
<thead>
<tr>
<th>Planning</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
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<tr>
<td>Microsystem Reassessment, Discussed planned project with preceptor, day shift staff. Team building: met with charge nurses all 3 shifts, IV nurse, and pharmacist. Reviewed guideline and policy.</td>
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<td>Literature review, revised SDD, discussed project with day/ pm/noc shift staff. Baseline survey of staff’s knowledge of amiodarone.</td>
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<td>Evaluation/Data Analysis: Meet with team members. Reassessed knowledge of staff. Distribute the same survey questions collected for baseline knowledge. Compare current knowledge to baseline data. Compare incidence rate of phlebitis pre and post guideline implementation. Discuss trends with team member, staff and preceptor.</td>
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<td>Present Poster at USF</td>
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</table>

*Figure E1.* Change in practice project timeline to decrease the incidence of peripheral amiodarone-related phlebitis in a cardiac-driven unit.
Appendix F

Guideline for Peripheral Amiodarone Infusion

1. USE DEDICATED LINE
   a. No other medication is injected or infusing with amiodarone
   b. Always have two lines. One for amiodarone and one for other medications the patient may need

2. ASSESS THE IV PRIOR TO INFUSION
   a. Assess for pain, redness, and assure an adequate flush with 10ml of NS
   b. If any issues, document infiltration and phlebitis scale
   c. Use the smallest catheter possible in the largest vein
   d. Never use an area of joint flexion
   e. Use a catheter stabilization device, such as Statlock

3. USE A SEPARATE FILTER FOR AMIODARONE BOLUS AND INFUSION

4. CHECK THE SITE AFTER BOLUS, AND REMOVE THE IV FOR PAIN

5. INSTRUCT PATIENT TO IMMEDIATELY NOTIFY RN FOR ANY PAIN, REDNESS, OR OTHER CHANGES
   a. Remove the IV at FIRST sign of pain (does NOT have to be red to begin vein irritation)
   b. Continue the infusion through a different IV catheter

6. INCLUDE THE IV SITE INSPECTION (not just the drip) DURING CHANGE OF SHIFT REPORT

7. AT FIRST SIGN OF PAIN, REDNESS, INFILTRATION OR PHLEBITIS, ASPIRATE AS MUCH MEDICATION FROM THE CATHETER AS POSSIBLE, THEN DISCONTINUE IV
   a. Clean area with CHG
   b. Apply ice pack
   c. Elevate the affected arm.
   d. Document using Infusion Nurses Society approved phlebitis scale

Note. Adapted with permission from Mary Spiering MN, RN, CNS, Professional Practice Program Manager. Magnet Program Director Nursing Administration, Kaiser Westside Medical Center, Hillsboro, Oregon. The study was completed at Providence Saint Vincent Medical Center, where she was previously employed.
Survey Questions Used in Assessment of Nursing Staff knowledge

NURSING STAFF KNOWLEDGE ASSESSMENT RELATED TO AMIODARONE INFUSION:

**SCALE:**
1 = Poor  
2 = Below Average  
3 = Average  
4 = Above Average  
5 = Outstanding

Please rate your knowledge on a scale of 1 to 5 as above:

**A.**

1. What is your knowledge regarding the drug Amiodarone?

2. How familiar are you with the possible side effects of peripheral amiodarone infusion?

3. What is your knowledge of the rate, dosing, and set up of intravenous amiodarone infusion?

4. Your knowledge of Infusion Nurses Society phlebitis scale?

5. Your knowledge of different causes/types of phlebitis?

6. What is your knowledge on how to treat phlebitis?

7. What is your understanding of the length of time it takes for phlebitis to appear?

**B. WHICH IV SITE DO YOU PREFER TO INFUSE THE AMIODARONE DRIP? (circle one answer)**

a. 18 gauge, large vein  
b. 18 gauge, small vein  
c. 22 gauge, small vein  
d. 22 gauge, large vein

Appendix H
Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion (Before Educational Program)

*Figure H1.* Breakdown results of nursing staff baseline knowledge assessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion
(Before Educational Program)

Figure H2. Breakdown results of nursing staff baseline knowledge assessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion (Before Educational Program)

3. What is your knowledge of the rate, dosing, and set up of IV amiodarone infusion?

*Figure H3.* Breakdown results of nursing staff baseline knowledge assessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion
(Before Educational Program)

*Figure H4.* Breakdown results of nursing staff baseline knowledge assessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion (Before Educational Program)

Figure H5. Breakdown results of nursing staff baseline knowledge assessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion
(Before Educational Program)

Figure H6. Breakdown results of nursing staff baseline knowledge assessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion
(Before Educational Program)

Figure H7. Breakdown results of nursing staff baseline knowledge assessment related to
amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are:
1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix H

Results of Baseline Nursing Staff Knowledge Assessment Related to Amiodarone Infusion (Before Educational Program)

![Bar chart showing IV site preferences](chart.png)

*Figure H8.* Breakdown result of nursing staff baseline assessment of their preferred intravenous (IV) gauge size, and site when infusing amiodarone.
Appendix I

Results of Nursing Staff Knowledge Reassessment Post- Educational Program Related to Amiodarone Infusion

1. What is your knowledge regarding the drug amiodarone?

![Pie chart showing knowledge levels for amiodarone]

Figure II. Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix I

Results of Nursing Staff Knowledge Reassessment Post-Educational Program Related to Amiodarone Infusion

2. How familiar are you with the possible side effects of peripheral amiodarone infusion?

Figure I2. Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question above. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix I

Results of Nursing Staff Knowledge Reassessment Post- Educational Program Related to Amiodarone Infusion

3. What is your knowledge of the rate, dosing and set of IV amiodarone?

![Pie chart showing knowledge distribution](image)

*Figure I3. Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question above. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.*
Appendix I

Results of Nursing Staff Knowledge Reassessment Post-Educational Program Related to Amiodarone Infusion

4. What is your knowledge of the Nurses' Society phlebitis scale?

*Figure I4.* Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question above. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix I
Results of Nursing Staff Knowledge Reassessment Post- Educational Program Related to Amiodarone Infusion

5. What is your knowledge of the different causes/types of phlebitis?

![Pie chart showing the distribution of knowledge levels.]

Figure I5. Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question above. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix I
Results of Nursing Staff Knowledge Reassessment Post- Educational Program Related to Amiodarone Infusion

6. What is your knowledge of how to treat phlebitis?

Figure 16. Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question above. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix I

Results of Nursing Staff Knowledge Reassessment Post-Educational Program Related to Amiodarone Infusion

7. What is your understanding of the length of time it takes for phlebitis to appear?

Figure 17. Breakdown results of nursing staff knowledge reassessment related to amiodarone infusion based on the designated question above. Scale rating of knowledge equivalent are: 1=poor, 2=below average, 3=average, 4=above average, 5=outstanding.
Appendix I

Results of Nursing Staff Knowledge Reassessment Post- Educational Program Related to Amiodarone Infusion

![Bar Chart]

**Figure I8.** Breakdown result of nursing staff reassessment of their preferred intravenous (IV) gauge size, and site when infusing amiodarone.