Implementation of a Smoking Cessation Program Prior to Surgical Cases, a Pilot Study Proposal.

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Abstract

Smoking has long been well established as a world-wide, public health epidemic that is directly linked to poor healthcare outcomes for surgical patients (WHO, 2013; Dai et al., 2022; Janssen et al., 2020). This epidemic is cause for alarm because the preceding decades of research have provided thousands of studies with evidence to establish solid causative relationships between tobacco smoking and its detriment to nearly every body system, organ, and tissue in the human body, yet the Centers for Disease Control and Prevention (CDC) reports that in 2019, 14% of the population of the United States were current smokers. The negative effects of smoking on overall health status as well as on surgical outcomes is more than well-documented. Historically, documentation of smoking status and cessation education were at the behest of primary care physicians. As a United States Preventive Services Task Force Grade A recommendation, all clinicians are recommended to screen patients for tobacco use, advise those who do smoke to stop use, and offer assistance with quitting. Implementing an evidence-based smoking cessation program in a small pilot study, the orthopaedic RN who works with elective surgical candidates indicated for total hip arthroplasty could improve postoperative patient outcomes, reduce postoperative complications, and reduce the need for reoperation, and readmissions. When surgical patients who smoke participate in a preoperative smoking cessation program, will there be improved postoperative healing and less postoperative complications at 30 and 60-day follow up appointments, as evidenced by decreased complications of infection, non- or malunion of bone, return to operating room, or readmission.

Keywords: Smoking, tobacco, surgery, complications, surgical patients.

Implementation of a Smoking Cessation Program Prior to Surgical Cases, a Pilot Study Proposal

Smoking is a known public health crisis and is well established to be one of the most significant modifiable health risk factors facing health care providers today. The detrimental effects of smoking on the body have been established for decades. The United States Surgeon General, Luther Terry, in 1964 issued the first definitive report directly linking smoking to lung cancer and increased mortality (1964, p.33-37). Since the Terry report, smoking and tobacco use in general, though declined, has been and remains a major risk to public health, costing billions annually for smoking related illnesses, lost productivity (CDC, 2021). Modifiable lifestyle risk factors, specifically smoking, play a role in postoperative outcomes and infection rates (Elmallah et al., 2021; Kay-Rivest et al., 2019; Sahota et al., 2017). Despite decades of research and data presented that clearly shows the correlation of smoking to health detriment from direct links to cancer to the microscopic effects of tissue and the vascular system, tobacco use persists at a rate of approximately 14% of the U.S. population (CDC, 2019), and continues to plague the medical community.

Problem Statement

People who smoke increase health risks in general overall health as well as postoperative complications which results in poor patient outcomes and increased health care costs.

Significance

According to the Centers for Disease Control and Prevention (CDC), smoking is a major modifiable, and significant risk factor in cardiovascular, vascular, and overall health detriment (1984), resulting in poor outcomes in smokers undergoing surgery. Bedard et al. report that Epidemiologic studies estimate that in the year 2030, upward of 96,000 revision

THA procedures will be performed (2018). Almost 12 million elective procedures are performed annually (AHRQ, 2021). As of 2019, 14% of the population of the United States are smokers (CDC, 2021), and the estimated number of smokers having elective surgery was 30%, or approximately ten million surgeries on smokers each year (Kim & Patel, 2016). Implementation of smoking cessation protocols prior to elective surgeries can impact not only post-operative complications and mortality but improve patients' overall health and wellness, as Smoking has negative effects on wound healing, is associated with infections, post-operative readmission, the need for reoperation, as well as numerous medical complications post-operatively (Borad & Merchant, 2017; Elmallah et al., 2021; Kay-Rivest et al., 2020).

Purpose Statement

The purpose of this paper is to develop a pilot study to explore implementation of an identified smoking cessation intervention pre-operatively for a specific procedure, with measurable outcomes compared at 30 and 60days postoperatively, to those outcomes of non-smokers who had the same procedure. Though it is limited, research is beginning to focus on preoperative smoking cessation interventions and the effect on postoperative outcomes. As smoking is a major modifiable risk factor, a smoking cessation program initiated for smokers prior to elective surgeries may result in improved surgical outcomes and an overall improvement in their health. These findings could lead to further recommendations for development and implementation of smoking cessation programs in orthopaedic perioperative clinics and with individual providers performing elective surgical cases.

Pilot Study

PICOT: “Can a smoking cessation program initiated at least 14 days prior to Veterans indicated for elective hip surgeries result in improved post-operative outcomes as evidenced by decreased complications of wound infection, non-/malunion of bone, return to operating room, and readmission, measured 30 and 60-days post-operatively?”

Theoretical Framework

To aid the in implementation of this pilot study recommendation, which focuses on smokers undergoing elective surgical procedures, starting an evidence-based smoking cessation program prior to surgery to reduce the risk for complications, infections, readmissions and resurgery, the framework chosen to guide this pilot study is the American Nurses Association’s (ANA) Precautionary Principle (2001). This principle posits that when there is any uncertainty, erring on the side of caution is an appropriate course of action for policy making and effecting change. The ANA contend that the Precautionary Principle challenges nurses to protect those who are most vulnerable, those who are least powerful and those who are the earth’s future generations (ANA, 2003). It is embedded in us as nurses to facilitate prevention, early detection, monitoring and reduction of stressors on people. Nurses also understand the need to act and advocate for preventative measures, when possible, as well as the need to identify and reduce risks to patients.

Literature Review

For an extensive review of the literature, a search was initiated using CINAHL, PubMed and Google Scholar using keywords: Smoking, tobacco, surgery, complications, surgical patients, and included articles published in English from 2012-2022. 352 articles were returned on the initial search and screened for duplicate articles between the databases. Additional screening to include articles directly related to smoking and the effect on postoperative

complications led to five studies that met criteria and most clearly provided evidence that smoking has detrimental effects on surgical outcomes, with findings indicating significance for reduction of post-op complications for those interventions for some surgical procedures but did not demonstrate significance for others (Borad & Merchant, 2017; Elmallah et al., 2021; Kay-Rivest et al., 2020). Three studies from the previous research, "*What is the effect of smoking on postoperative outcomes?; A Preliminary Critique of the Literature."* (Hawkins, 2022), were selected to support the recommendation. Selection was based on the wide array of postoperative complications mentioned in the literature. Using these three studies, the complications to measure for this pilot study recommendation were narrowed down to the most common found in all the literature, wound infection, readmission, return to operating room (revision surgery). Non- or malunion of bone was included due to the specific orthopaedic nature of the surgery selected for this recommendation. While there is no single evidenced-based smoking cessation intervention recommended to reduce the risk of complications in post-operative patients who smoke, the evidence in RCTs point to implementation of a smoking cessation intervention prior to surgery as significantly reducing poor outcomes in smokers. Additional review of literature using CINAHL, PubMed and Google Scholar using keywords: Smoking cessation, preoperative, and abstinence was conducted from years 2012-2022, to identify evidence-based practice smoking cessation programs to model the pilot study program after. 17 articles were produced from the search accounting for duplicates in the various databases. After a follow up search through the references of the initial articles produced, several RCTs that explore the use of Varenilcine and additionally, the use of supportive follow-up contacts for the smoking cessation intervention, and then measure success of the program for abstinence (Wong et al., 2012; Wong et al., 2017; Leone et al., 2020). Leone et al., established "An Official American

Thoracic Society Clinical Practice Guideline" in 2020 with strong recommendations to initiate smoking cessation with Varenicline, giving further strength to the recommendation. Leone et al. provide an evidence-based guideline that addresses several pharmacotherapy-initiation questions that routinely confront treatment teams. These guidelines which include seven recommendations, was prepared in a collaborative effort by a 30 clinician, *ad hoc* subcommittee of the American Thoracic Society Assembly on Clinical Problems, using 185 references.

Supporting Evidence

A summary literature matrix is depicted to compare the results of the studies that corresponded with the inclusion criteria for this evidenced-based review, that serve as the basis for the pilot study recommendation. Overall, the three retrospective cohort studies included revealed the negative impact of smoking on post-operative outcomes, increased rates of infection, increased rates of post-operative readmission, and increased rates of resurgery. The literature also revealed that smokers have poorer outcomes after surgery compared to nonsmokers undergoing the same surgery. Current smokers have a significant increase of superficial or deep wound infection, and wound dehiscence compared to nonsmokers. The studies further reveal that return to the operating room and 30-day readmission were increased in smokers compared to nonsmokers, and that smokers were at overall increased risk of a myriad of other complications, from pneumonia, deep vein thrombosis, pulmonary embolism, mal- or nonunion of bone, however this recommendation will look to observe for improvement in postoperative infections,

Pilot Study Project Proposal

With the well-known detrimental effects of smoking on the human body, APRNs working in the surgical setting can help to start to change the tide of poor outcomes for patients undergoing elective surgical cases. Because smoking has been identified and is well accepted as the most important modifiable risk factor for health, implementation of protocols for smoking cessation prior to elective procedures may improve post-operative outcomes, while at the same time benefitting overall health.

Pilot Study

Implement an identified evidence-based smoking cessation strategy with Chantix combined with Orthopaedic NP led counseling and support at least 14 days prior to day of surgery. The smoking cessation program will include data and integrate multiple strategies to increase the success of the implemented program (Wong et al., 2017). Though this pilot study recommendation does provide for implementation of both an evidence-based pharmacotherapeutic program and evidence-based counseling prior to surgery, which may increase the overall success of preoperative smoking cessation a secondary unintended for this pilot study outcome may be sustained abstinence postoperatively. The pilot study will focus on the narrow intent of observing postoperative outcomes in smokers who started and maintained a smoking cessation program for a full 14 days prior to surgery.

Included patients will be presented with information regarding:

- The risks and effect of smoking related to orthopaedic surgery
- Photographic and graphical data, visual evidence of poor outcomes in smokers vs non-smokers in Primary Total Hip Arthroplasty cases
- The benefits of sustained smoking cessation on overall health

And be provided with:

- Evidenced-based smoking cessation counseling
- Assistance with smoking cessation in the form of providing a proven evidence-based smoking cessation medication, Chantix beginning at fourteen days prior to surgery.
- Motivational support to encourage and maintain smoking cessation via active Orthopaedic NP involvement
- Orthopaedic NP engagement at ten, seven, and three days preoperatively via phone, secure video call (doximity), or text message, providing positive reinforcement and support for sustained smoking cessation
- Orthopaedic NP follow-up at no less than 30 and 60 days postoperatively to observe for any complications

Goals

- Implement a low cost, effective evidence-based smoking cessation program to provide:
  - Evidence-based smoking cessation counseling
  - Pharmacotherapy with Chantix or placebo based on randomized selection process
  - Supportive communication, positive reinforcement, encouragement via chosen communication medium

    To observe for:
  - Decreased post-operative complications of wound infection, non-/malunion of bone, return to operating room, and readmissions

Participation Criteria

Inclusion criteria will begin with smokers indicated for total hip arthroplasty being screened for eligibility, over age 21, smoked a minimum of 10 cigarettes per day in the year prior to surgery, no previous cessation longer than 30 days in the year leading up to surgery, surgical date no less than 14 days prior to induction of program. Exclusion criteria will be based on Wong

et al.'s, 2012 and 2017 RCT exclusions, those who are less than 30days post op, pregnant or breastfeeding, any psych disorder that increases risk for suicide, use of Nicotine Replacement Therapy or Wellbutrin use within 90 days prior, history of drugs or ETOH use/abuse, marijuana or other than cigarette tobacco use less than 30days prior to surgery, actively participating in other smoking related studies, those with language barriers, cognitive disorder, prediabetes or Diabetes Mellitus diagnoses, or those that fail to maintain abstinence after induction and prior to surgery will be excluded.

Methods

Sampling:

Will be conducted from all adults (21yo) indicated for total hip arthroplasty, who are current smokers and exhibit the willingness and readiness to quit, it will be convenience sampling from one orthopedic clinic office, participants will be approached during discharge from an appointment where surgery has been indicated and surgery is at least 30 days out, patients will randomly be placed in either placebo or experimental group based on arrival order to preop —controlling for selection bias.

Preoperative Process:

Pilot Study, conducted over six-month time frame, three months for sample/participant collection and intervention initiation, two months for data collection (30 and 60days postoperatively), and one month for data analysis. The study will be conducted at Department of Veterans Affairs Orthopaedic Specialty Clinic, within preoperative, intraoperative, postoperative interactions. The smoking cessation program will be initiated at the preoperative appointment, 14 days prior to day of surgery, where all participants will receive evidence-based smoking cessation counseling and Chantix or placebo will be issued, based on a predetermined

randomized basis. The orthopaedic NP will conduct outreach at 10, 7, and 3 days pre-operatively, relaying positive reinforcement and support for sustained cessation with participant choice of communication, via either: Phone, Secure video app (doximity), or text message. On the day of surgery Serum Cotinine level will be confirmed with serum blood analysis to confirm abstinence. To strengthen the validity of the smoking cessation program, the orthopaedic NP will attend a five-day smoking cessation certification program from a Council for Tobacco Treatment Training Programs (CTTTP) accredited training provider. All accredited programs provide an evidence-based approach to counseling in an intensive program based on the Council's Core Competencies for the Evidence-based Treatment of Tobacco Dependence (CTTTP, 2022).

Postoperative Process:

Monitoring for complications will be done by the Orthopaedic NP during follow up appointments 30 and 60-days post operatively and recording any complications experienced by any study participant, to include: Non-or Malunion of bone, wound infection, readmission, or return to operating room. The data collected at the 30 and 60day postoperative follow up appointment with the orthopaedic NP will note when the complications occurred within the timeline prior to the appointments. This data will include what the complication was, how long after surgery the complication occurred and the severity of complication. Since there is only one orthopaedic NP position within the local VA, the data collected can remain consistant. Data returned will be analyzed to answer the PICOT question posed, "Can a smoking cessation program initiated at least 14 days prior to Veterans indicated for elective hip surgeries result in improved post-operative outcomes as evidenced by decreased complications of wound infection, non-/malunion of bone, return to operating room, and readmission, measured 30 and 60-days post-operatively?"

Risks and Barriers of Smoking Cessation

The risks of quitting smoking may manifest in physical symptoms including headaches, nausea, uncontrollable cravings, increased irritability, weight gain, anxiety, trouble sleeping, loss of concentration and restlessness. Barriers to quitting smoking largely center around the individual's willingness and readiness to quit. Other barriers to quitting smoking can be lack of compliance, loss of stress management technique, lack of support to quit, simple enjoyment of the act of smoking, nicotine addiction, and inability to afford medication.

Benefit Potential

The program is a rather simple, low risk, and cost-effective option to implement. Cost breakdown: Smoking cessation counseling training $1,100, Varenicline prescription is covered by insurance with little to no copay, Orthopaedic NP engagement for counseling, follow up call/texts are within the salary of the NP, while counseling literature/handout run approximately $140 per 250 units. The program is expected to have the potential to reduce postoperative complications, postoperative readmission and surgery, reduce comorbid medical complications, while having an increase of overall health benefits, and overall patient satisfaction.

Limitations

This pilot study is a very small, single institution study that focuses on a single surgical procedure. As with any study, attrition is always a consideration for internal validity threat. When individuals drop out of a study, the effect of that attrition is a threat to the validity of the results. After the attrition the remaining participants likely no longer accurately are reflective of the beginning sample. Due to the lack of final participant reflection of the original sample, the will not be able to be generalized to a larger population. This is true for the likely small sample size that will be experienced, though the selected institution indicated almost 170 total hip

arthroplasties in the past year. Using a three-month period to recruit for participants would generate approximately 43 cases, using the population of 14% of the US population being smokers, may generate approximately six smokers to screen for inclusion, with exclusion criteria, this will severely limit the sample size. The results of this small pilot study will not produce a valid generalizable outcome but will pave the way for future larger scale studies that will be needed to corroborate the results of this pilot study. Another limitation is the relatively short project timeframe of six months. This time frame may not be conducive to appropriate sampling or even generate enough cases to screen, thus future recommendations would call for a longer study both preoperatively and postoperatively when crafting at study intervention timeframe. Though allowing for consistency, another limitation is that there is only a single orthopaedic NP provider within the local VA orthopaedics department. Larger orthopaedic departments both in the VA and in the community would prove to have a likely better and more robust program with better more generalizable outcomes.

Conclusion

APRNs have a unique opportunity to help effect change in predominantly physician led clinics. Orthopaedic NPs are poised to potentially improve poor outcomes for orthopaedic patients. With APRNs on the front lines having the position to typically spend more time with patients, and with smoking cessation being a USPSTF Grade A recommendation, the orthopaedic NP is positioned make a potential impact on not only orthopaedic surgical, but overall health outcomes. Kurtz et al., in 2014, estimated that by 2020, 511,837 primary total hip arthroplasties (THA) will be performed annually and will only continue to rise. APRNs working in the orthopaedic setting have a unique opportunity to directly affect post-operative outcomes for smokers. This small pilot study may prove to positively benefit a single surgical procedure, but if

successful, additional research on a larger scale will be necessary to expand the results and improve generalizability beyond this single small study and unequivocally begin to improve not only post-operative outcomes but also the overall health on a larger scale, with hopes to affect worldwide outcomes. All APRN's can affect change in smokers that have long been resistant to the change of quitting smoking. When implementing future smoking cessation programs, APRN's can deliver personalized information to the smoker that is relevant to their indicated surgical procedure and educate with evidence-based data and processes to improve their success and ultimately their surgical outcomes. Though the effects of smoking are generally understood, smoking continues to remain the most important modifiable risk factor affecting all aspects of health care, and APRN's are in a place to help reduce the effects of this behavior.

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