A Usability Pilot to Improve Peripheral Arterial Disease Detection in the Hemodialysis Population

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Table of Contents

Abstract

The hemodialysis population have higher incidence and prevalence rates of peripheral arterial disease than those without chronic kidney disease. The increase burden of PAD in this population has prompted providers to seek early identification and treatment. This project seeks to explore the usability of a simplified foot screening tool in a hemodialysis unit of a large urban teaching hospital. The tool focuses on the collection of physical assessment findings, followed by risk stratifying the findings into an action plan. Overall goal of this project will be to assess whether nursing staff find the tool usable in practice and can implement the action plans identified.

Keywords: Peripheral Arterial Disease, Hemodialysis, Screening, Usability

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Problem Description

Aging and population growth globally have led to a higher prevalence of peripheral arterial disease (PAD). Globally there are some 200 million people with PAD, highlighting a significant burden of atherosclerotic disease and risk of cardiovascular disease. Death and disability attributed to PAD have been estimated to have increased by more than 30% between 2005 and 2015 as per the Global Burden of Disease Study (Hamburg and Creager, 2017; Vos et al., 2016). The prevalence of PAD in America is estimated to be at least 8.5 million with total annual associated hospital costs more than $21 billion and projected to rise as the population ages (Kullo and Rooke, 2016). PAD increases with age and non-Caucasian ethnicities and have a negative impact on outcomes.

Population

Patients with chronic kidney disease (CKD), have higher incidence and prevalence rates of PAD due to the aggregation of traditional atherosclerosis risk factors (Garimella and Hirsch, 2014). Lin et al. (2015) found the PAD risk in the hemodialysis population to be significantly higher than those who are on other forms of renal replacement therapy. The high PAD burden in patients with end-stage kidney disease, especially those on hemodialysis has prompted providers to identify these patients early in the disease course and provide appropriate management and follow-up (Garimella and Hirsch, 2014).

Traditional risk factors for PAD include older age, cigarette smoking, physical inactivity, hypertension, diabetes, and dyslipidemia. In the hemodialysis population, the traditional risk factors do not entirely explain the excess risk of PAD. Research by Chen et al. (2016) identified

novel risk factors, including biomarkers of inflammation, pro-thrombotic state, oxidative stress, insulin resistance and cystatin C, were associated with increased prevalence of

PAD in patients with CKD. Time on hemodialysis demonstrates an adverse outcome with increased development of peripheral arterial occlusive disease (Lin et al., 2015). The presence of traditional and novel risk factors in the hemodialysis population is exponentially high leading to increased disease and disability among the population. In particular, CKD increases the risk of morbidity, mortality, and limb loss after revascularization (Matsuzawa, Aoyama, and Yoshida, 2015).

Epidemiology of Peripheral Arterial Disease

Peripheral arterial disease is referred to as an atherosclerotic occlusive disease of the lower extremities of one or more peripheral arteries (Criqui and Aboyans, 2015). PAD continues to rise worldwide with an estimate of more than 200 million people worldwide leading to morbidity that is only second to that of coronary artery disease and stroke (Fowkes et al., 2013). Patients with PAD may be completely asymptomatic or have leg symptoms that are manifested by exercise and tissue loss. Although patients may be asymptomatic, they often have reduced exercise capacity, impacting functional capacity and overall quality of life (Lin et al., 2015).

Registry data from the United States and Canada demonstrate that CKD is on the rise. According to the United States, Renal Data System (2017) the unadjusted end-stage renal disease (ESRD) incidence rate increased steadily from 1980 through 2006, with rates per million population rising from 77 to 378, demonstrating an average increase of 8.5 percent per year. In Canada, the (Canadian Institute for Health Information, 2017) organ replacement registry reports similar findings with incident rates increasing from 2007 to 2016 with rates per million population rising from 177 to 200, demonstrating an average 2.35 percent increase per year.

The impact of PAD in the hemodialysis population is known to be significantly higher than in the general population with increased cardiovascular mortality, morbidity, and hospitalization. Lin et al. (2015) conducted a retrospective cohort study at the National Health Research Institutes in Taiwan from 2000 to 2010 collecting demographic, diagnosis and treatment data to determine incidences of PAD in the dialysis population. Authors reported PAD incidence was 18.1% higher in the hemodialysis cohort and 8.10% in the PD cohort and 8.10% compared to the control cohort. Okamoto, Iida, and Mano (2017) findings suggest that PAD in the hemodialysis population is estimated at 15%-23% when defined by assessment of symptoms and history. Overall, PAD has a significant burden and is progressive within the hemodialysis population.

Literature Review

A literature review was performed using CINAHL and PubMed databases for articles determined to be within the scope of practice of this paper. The key MeSH search terms included dialysis, hemodialysis, wounds and prevention, amputation, end-stage renal disease, risk factors for amputation and foot screening. Inclusion criteria incorporated peer-reviewed articles available in English, from 2013 to the present, and involving human subjects.

Articles reviewed were inclusive of observational, longitudinal and randomized control trials along with guideline and quality improvement-based methods. The search process yielded over 710 articles; further narrowing with the use of boolean operations resulted in 45 articles of interest.

A further review of the 45 articles identified four predominant focus areas of focus in the identification of peripheral arterial disease. The current issues focused on the global challenge of increasing prevalence of chronic conditions such as PAD, risk factors for PAD, the disparity of

screening methods used to detect PAD and finally the complications of PAD in the hemodialysis population.

Risk Factors for Peripheral Arterial Disease

Research has identified risk factors of PAD in patients on hemodialysis, including advanced age, hypertension, diabetes mellitus, coronary artery disease, cerebrovascular disease, dyslipidemia, malnutrition, physical inactivity and smoking (Hsu et al., 2013). Risk factors such as cigarette smoking, physical inactivity, and malnutrition, are ones that can be addressed with lifestyle change or by improving socio-economic status. While some of these risk factors are modifiable, a number are not and require prevention and treatment strategies to prevent PAD in the hemodialysis population.

Risk factors among patients with PAD and cardiovascular disease are similar; however, patients with CKD have some unique risk factors. Patients with albuminuria, reduced glomerular filtration rate (GFR), inflammation, oxidative stress, endothelial dysfunction, and abnormal calcium-phosphate metabolism amplify the risk (Bosevski, 2017). Hsu et al. (2013) identified elevated creatinine and triglyceride levels as influential atherosclerotic risk factors among CKD patients. The Chronic Renal Insufficiency Cohort (CRIC) study further identified hsCRP, white blood cell count, fibrinogen, myeloperoxidase, HbA1c, HOMA-insulin resistance and alkaline phosphatase with incident PAD (Chen et al., 2016).

Overall, PAD risk factors are many among the hemodialysis population and continue to evolve with research. In particular, inflammatory biomarkers continue to be identified as risks for PAD and its progression.

Screening for Peripheral Arterial Disease

Guidelines for PAD screening have been developed nationally (American Heart Association, 2016) and internationally (European Society of Cardiology, 2017) and recommend

various tests and tools to detect PAD, divided into either invasive or non-invasive methods (Aboyans et al., 2018; Gerhard-Herman et al., 2017).

Non-invasive tools.

Ankle-brachial pressures indices (ABPI) have been the mainstay of non-invasive diagnostics for clinicians as it is easily performed at the bedside. Wilkes et al. (2015) identified some challenges with the use of ABPI including lack of standardization in methodology in measuring arterial pressures of any one of three arteries in the ankle and the brachial artery. Besides, some environmental factors such as body position can affect peripheral vasomotor tone, causing hydrostatic pressure differences and variances in results. Patients with extensive vascular calcification, such as those with CKD who are on hemodialysis may also present unreliable findings. Finally, a lack of consensus on the normal ranges for ABPI ratios constitutes challenges in referral thresholds among guidelines published by the National Institute for Health and Care Excellence (2018).

Physical exam and screening questionnaires

Lower limb examination and screening questionnaires have been utilized to detect PAD with varying sensitivity, specificity, and positive predictive value. Sensitivity among physical examination remains variable ranging between 10% and 77% with specificity demonstrating better outcomes ranging between 86% and 99%; however, the positive predictive value remains low (0.305 - 0.479) except for the absent pedal pulses (0.912) (Hull and Kishman, 2008).

A number of screening questionnaires have been developed and implemented in clinical practice, including the Edinburgh Claudication Questionnaire , Inlow's 60-second foot screen, and Sibbald's 60 second foot screen demonstrates positivity in diagnosis; however, the tool relies heavily upon the clinician's assessment with the risk of subjectivity and perhaps overestimating

the true values (Leng & Fowkes, 1992; Sibbald et al., 2012; Woodbury, Sibbald, Ostrow, Persaud, & Lowe, 2015).

Gaps

The clinical benefits and harms of screening for PAD with a physical examination have not been well evaluated, although such screening is often performed. Physical examination has low sensitivity in detecting mild PAD in asymptomatic individuals (Guirguis-Blake, Evans, Redmond, & Lin, 2018). Further large population-based randomized screening versus no screening are needed to determine whether screening for PAD using physical examination, questionnaire-based methods and atherosclerotic risk factors improves clinical detection outcomes.

Peripheral Arterial Disease and the Hemodialysis Population

The hemodialysis population is an at-risk population that requires vigilant screening and intervention to identify vascular complications. The increased prevalence of vascular complications necessitates the use of lower limb screening tools at regularly scheduled intervals for early assessment, diagnosis and intervention to prevent limb loss and mortality.

The purpose of this project was to implement and evaluate the effectiveness of a lower limb screening tool to improve early identification of PAD in the hemodialysis population. The focus population was the in-center hemodialysis patients at a large academic teaching hospital in Vancouver, British Columbia.

In clinical practice, hemodialysis nurses are faced with time challenges and access to language translation resources to conduct lower limb screening. A simplified screening tool was adapted from Inlows 60 second screening tool based on feedback from the hemodialysis nurses. Feedback from hemodialysis nurses identified limitations of Inlows 60 second screening tool, fostering the development of a simplified screening tool. The simplified foot screen tool

incorporates established nursing assessment knowledge of circulation and skin integrity to identify risk factors and physical assessment findings, assigning a score to assessment findings and an action plan based on the findings. The simplified screening tool was developed to facilitate detection of PAD without a need for significant verbal response from patients. Usability of the screening tool in detecting PAD was assessed by RNs in the hemodialysis unit and is in keeping with the standard of care for PAD assessment.

Design and Methods

Setting

The hemodialysis program at Providence Health Care is situated in an academic teaching environment in a large urban center. The hemodialysis program is comprised of an in-center hospital-based unit and seven community dialysis units that provide life-sustaining treatment to some 400 hemodialysis patients. The in-center hospital-based unit cares for approximately 250 patients and is the focus of this proposal.

The hemodialysis unit census is comprised of 46 stations, where patients undergo hemodialysis treatments thrice weekly for 4 hours each treatment except for nocturnal patients who dialyze 7-8 hours per treatment. The unit is divided into six pods where registered nurses (RN) provide direct care and supervision. The nurse to patient ratio varies within the unit ranging from 1 to 4 for those patients who can carry out self-care activities and 1 to 2 for those patients who require more intensive management due to medical acuity.

The hemodialysis program is known for its excellence in providing compassionate, patient-centered care as evidenced by the numerous awards and positive feedback from patients and families it has received over the years. Prior to the implementation of the project, the program has made a leadership change, engaging an experienced nephrology nurse to take on the role of manager and leadership of the in-center hemodialysis program. I anticipated that the availability

of staff resources may be a barrier, however, the leadership team is committed to facilitating research and knowledge translation in the practice environment to maintain clinical excellence.

Participants/Population

Inclusion criteria for the project included RNs who actively worked in the in-center hemodialysis unit at St. Paul's hospital regardless of nephrology nursing experience. Patient inclusion criteria included outpatients who were receiving chronic hemodialysis patients who are dialyzing in the in-center unit. Exclusion criteria consisted of student nurses, clinical nurse leaders and clinical educators as they provide limited direct patient care in the unit and would not be the end user of the tool. Additional exclusion criteria included patients who had acute kidney injury and required acute hemodialysis either in the outpatient or inpatient environment.

The unit has approximately 70 RNs who work full-time, part-time or on-call. A convenience sample was utilized as nursing staff work varying schedules on a rotational basis. The unit has approximately 230 chronic hemodialysis outpatients who were eligible to receive foot screening.

The personal identity of nurses providing feedback on the usability of the screening tool was not collected. An explanation and description of the assessment process and feedback format was provided to hemodialysis nurses in the in-center hemodialysis unit.

Project Intervention

The simplified hemodialysis foot assessment was performed twice, 5 weeks apart by RNs on willing chronic hemodialysis patients for two consecutive months (Appendix A). RNs were provided with instruction on how to carry out the foot assessment. Education was provided in the form of a power point presentation and reverse demonstration 2 weeks prior to initiating foot screen assessments. Education sessions were conducted within the hemodialysis unit nursing pods to facilitate access to the education and application of the tool. Patients were educated about

the simplified assessment tool and its purpose through the media board in the waiting area and during weekly rounds 2 weeks prior to intervention.

The simplified hemodialysis foot screening tool required assessment of skin integrity, skin discoloration, temperature and pedal pulses. The paper-based forms were placed in the patient's hemodialysis chart for RNs to access. Placement of the screening tool within the chart was done as per unit standard. RNs recorded patient findings on the paper-based screening form and assigned a score based of aggregate findings. The higher the number of abnormal findings the higher the risk score. RNs actioned on the results as per the action plan in the screening tool. RN's conducted foot screening over a 1week period and then placed them in designated folders in each of the nursing pods. Completed screening forms were collected by the project leader. Each chronic hemodialysis patient had the opportunity to have one assessment during each screening week. Forms were reviewed for completion accuracy by the project leader.

Measures

The simplified hemodialysis foot screening tool was evaluated to establish its usability in clinical practice. The following parameters were recorded and evaluated using a provider satisfaction survey:

- how long it took to administer the screening tool?
- how easy it is was to score the finds?
- how easy can participants interpret findings?
- how easy was it to action on the findings?
- did the RN refer any patients to the MD/NP for further assessment?

The satisfaction survey utilized a likert scale, dichotomous scale and comment box for open ended feedback regarding the use of the screening tool (Appendix B). Survey Monkey was be utilized to construct the satisfaction survey with and was distributed to RNs electronically via

email at the close of foot screening week. Email reminders to RNs were sent one and two weeks after completion of the screening intervention. Surveys were distributed to nursing staff after each foot screen week at week 5 and week 10 to gather feedback.

Usability testing allows the clinician to evaluate the screening tool, explore participants ability to administer the screening tool, and identify problems qualitatively and quantitively to determine the participant's satisfaction with the screening tool (Affairs, 2013). For the purposes of this project quantitative feedback was collected using a satisfaction survey and qualitative feedback through thematic analysis of comments submitted in the text box of the survey.

Analysis

Usability evaluation includes a number of metrics to analyze a user's experience when interacting with the screening tool. Usability elements included, ease of learning, the efficiency of use, error frequency in use of the tool, and overall subjective satisfaction. Quantitative data was gathered and focused on application and use of the screening tool within the clinical environment, while qualitative data explored participants perceptions and recommendations for improvement of the screening tool. Retrospective review of the completed screening tools focused on identifying any anomalies in scoring clinical findings and referral to the hemodialysis nurse practitioner or nephrologist. Results of the satisfaction survey and completion accuracy were reported to the hemodialysis leadership team for discussion and to seek opportunities for improvement in the use of the simplified foot screen tool.

Ethical Considerations

A formal ethics application was submitted to Providence Health Care and Oregon Health & Sciences University as part of conducting human subject research. RN participant identification was not collected. Participant identity was protected by anonymizing responses in the survey. Participants were advised of the process and activities involved in the use and

collection of data for the simplified hemodialysis foot screening tool. Participation in the study was open to all who met the inclusion-exclusion criteria.

Costs

Resources for the project include, paper, personnel for distribution and collection of the foot screen tool. The above resources were absorbed within the operational capacity of the hemodialysis program without any additional cost. The DNP student was responsible for educating RN staff on the purpose and application of the tool. The DNP student was not remunerated for this activity.

Project Implementation and Evolution

The project commenced with engagement of RNs and hemodialysis leadership team, presenting the project plan and proposed dates to carry out implementation and data collection of the foot screening tool. Education of the RN staff occurred over a two week period prior to implementation of the foot screening tool. Prior to the second foot screen there was a need to change the screening date, advancing it forward by one week to accommodate another initiative. Feedback from nursing staff necessitated a change to the way the survey was distributed to accommodate a technical issue with the website browser within the health care facility. Survey reminders were once again sent out to encourage participation with a one week extension to participate in the survey after the first screening interval.

Data Details

As I reviewed the foot screening forms, I discovered various missing elements. The name of the RN conducting the assessment was missing in eight screening forms, while sixteen of the screening forms had a signature on the form but the name was not legible. Lastly, there were 4 foot screens conducted without any affixed patient label to the form, requiring the RN to review the form and ascertain if they could determine who the foot screen belonged to.

Findings

The results of the quality improvement initiative were reviewed and analyzed using descriptive statistics. The quality improvement project sample included 54 RNs from the in-center hemodialysis unit, who completed 406 screens over a ten week period. The average number of completed foot screens per RN was 7, with a range between 1 and 18 and a median number of 6 completed foot screens. Registered nurses referred 36 patients to either the nurse practitioner or nephrologist as findings demonstrated a need for advanced assessment, intervention and referral to specialist services.

Results from the survey exploring the usability of the screening tool had 33 RNs participate who reported an average of 5 minutes to complete to the survey. The mean number of years of practice as a registered nurse for the survey group was 16 with a median of 14 years and a range between 4 and 43 years. The survey sample further delineated respondents having an average of 10 years of hemodialysis experience or a median of 7 years with a range between 1 and 30 years. Overall, the survey provided a range of participants with the majority having been in practice as a registered nurse or hemodialysis nurse for a considerable amount of time.

The usability metrics of the survey in table 1 below identify that the screening tool was easy to use when screening patients for peripheral arterial disease however, the respondents represent approximately 51 percent of the total number of hemodialysis RNs in the unit.

Table 1

Ease of Use of the Simplified Foot Screen Tool

Answer Choices	Responses	
Very easy	39%	13
Easy	55%	18
Neither easy nor difficult	6%	2
Difficult	0%	0
Very difficult	0%	0
Total		33

Interpretation of the finding from the foot screen tool was described as very easy or easy by RNs in table 2. The findings indicate the tool's application and interpretation in the clinical environment to be supportive in screening for PAD.

Table 2

Ease of Interpretation of Simplified Foot Screen Tool Findings

Answer Choices	Responses	
Very easy	27%	9
Easy	61%	20
Neither easy nor difficult	12%	4
Difficult	0	0
Very difficult	0	0
Total		33

Qualitative feedback from RNs indicated the foot screening tool was easy to follow and would like to see the tool implemented for ongoing PAD screening. RNs also noted that the tool was helpful in assessing the patient's foot condition especially for diabetic patients and was much easier and less time consuming than the previous foot screening tool. One of the respondents indicated the they wanted to perform more foot screens but could not find the forms. The RN also indicated that she was confused by the follow-up steps required if a high score was identified. This response is likely a result of the participants lack of orientation to the screening tool.

Outcomes

The findings of this quality improvement initiative highlight the importance of foot screening in the hemodialysis population with early identification of foot problems using a simple screening tool (Pernat et al., 2016). The implementation of a screening tool that promotes its usability for clinicians is one that has the potential to reduce lower limb amputation rates among the hemodialysis population. The observed results of this initiative are congruent with the

expected results as identified by clinician responses. Overall, the simplified foot screen was identified as a relatively easy to use tool in practice and one that detected abnormal findings as evidenced by the 36 referrals.

The impact of this project has the potential to reduce health care costs with the implementation of a simplified foot screen tool. The integration of this tool into the electronic health record could trigger foot screening notification to clinicians, requesting them to conduct the screen and then initiate a referral if finding warranted to the provider. The implementation of a scheduled frequency allows for a coordinated and systematic effort.

As a result of this initiative the in-center hemodialysis program has begun work on establishing a PAD clinic as a subset population of the vascular access clinic. The hemodialysis program is looking to develop an order set of labs, diagnostics and referrals that could be easily accessed by providers and the vascular access team. The workflows for the PAD clinic and order sets are in the process of development and validation with the team and once approved will be built within our electronic health record. The hemodialysis program has also engaged the organizations clinical nurse specialist in wound and skin care to provide education and clinical support to the vascular access team for ongoing assessment and case management.

Limitations of this project include its application to the community dialysis environment where patients are distanced from the acute hospital setting and differentiated among nephrologists and nephrology nurses who may not endorse this initiative. This initiative has the potential to influence the provincial renal community to endorse foot screening for the hemodialysis population and other chronic kidney disease groups given its ease of use in the clinical environment.

Conclusion

Improvement outcomes through the implementation of quality improvement processes such as lower limb foot screening aim to identify and resolve key gaps in current models of care. The pilot of a simplified lower limb screening tool for PAD detection in the hemodialysis population sought to understand usability of the tool in practice by RNs. The utility of the simplified foot screen tool proved to be useful to clinicians in the detection of PAD. The simplified foot screening tools ease of use as represented by the completion rates demonstrated its sustainability in practice. In addition, findings from the project informed clinicians and researchers of the potential of this tool to improve PAD outcomes through early detection and referral. Next steps include presentation of these findings to the provincial hemodialysis committee for implementation in hemodialysis units across the province as well as poster presentation at British Columbia Kidney Days to highlight the impact of PAD screening utilizing a simplified tool. Validation of the simplified screen tool is another aspect of consideration for the hemodialysis and chronic kidney disease community.

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Appendix A

Hemodialysis Simplified Foot Screen Tool

Patient risk Factors: **□ Prior lower limb amputation** **□ Diabetes**

Date										
Foot	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**
Skin integrity										
Skin Discolouration										
Temperature										
Pedal Pulse										
Other associated findings (below)										
Total Score										
Action Taken										
MD/NP notified (name)										
Education Provided*										
Next assessment (Date)										

Reference Number Point:

Foot	**0 point**	**1 Point**	**2 Points**	**3 Points**
Skin integrity	Intact and healthy skin	Calluses, cracking, evidence of fungal infection	Open ulceration or wound	Purulent discharge from wound
Discolouration (skin)	None	Erythema or dependent rubor	Dusky colour, no change from baseline	New onset dusky or black discoloration
Temperature of foot	Normal, warm	Hot or Cold (bilateral)	Cold (asymmetric)	
Pedal Pulse (DP or PT)	Present		Absent	
Other associated findings		Thickened, discolored, poorly kempt toenails†		Fever **or** new acute onset severe pain of one limb

Action Plan:
0-1 Points → Reassess in 6 weeks
2 points → Contact NP/MD to assess foot – if nocturnal or evening patient, place on NP/MD clipboard
≥3 points → Contact NP/MD **immediately** for further orders – Blood C+S if febrile, Wound C+S if discharge present (see HD Admission PPO)

*****Provide patient foot care pamphlet
†If severe toenail changes present and patient does not have a podiatrist, place issue on NP/MD clipboard to prompt podiatry referral (non-urgent)

Glossary of Terms:

- DP – Dorsalis Pedis
- PT – Posterior Tibialis
- Dependent Rubor - Dusky red to bright red discoloration seen when the limb is in dependent position but not when the foot is elevated due to peripheral vascular disease.

Appendix B

Simplified Foot Screen Survey

This survey is being utilized to collect feedback from registered nurses who have conducted foot screens utilizing the Simplified Foot Screen Questionnaire. Your participation in this survey is voluntary and will have no negative impact on your employment. Your confidentiality will be maintained at all times. The survey will not be collecting any personal identifying metrics (ie. you name).

1. How many years have you practiced as a registered nurse?

2. How many years have you practiced in hemodialysis?

3. On average how long (in minutes) did it take you to complete the simplified foot screen?

4. How easy is the simplified foot screening tool to use?

- Very easy
- Easy
- Neither easy nor difficult
- Difficult
- Very difficult

5. How easy was it to interpret your findings and apply them to the simplified screen tool scoring system?

- Very easy
- Easy
- Neither easy nor difficult
- Difficult
- Very difficult

6. How easy was it for you to act on your findings from the simplified screening tool?

- Very easy
- Easy
- Neither easy nor difficult
- Difficult
- Very difficult

7. Did you refer any patients to the Nurse Practitioner or Nephrologist for further assessment?

8. Do you have any other comments, questions, or concerns?