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Benchmark Project Cryotherapy to Prevent Chemo Induced Peripheral Neuropathy

Stephanie Davis
sdavis47@patriots.uttyler.edu

Cryotherapy to Reduce Peripheral Neuropathy

Stephanie Davis

The University of Texas at Tyler

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Dr. Coleen Marzilli

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Contents

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Executive Summary

As a nurse working in chemotherapy infusion, I have a direct role in symptom management. For patients receiving Taxanes, the most common adverse effect reported by patients is peripheral neuropathy. According to one meta-analysis, Taxane-induced peripheral neuropathy (TIPN) has very high incidence ranging from 11 to 87% and severely impairs patients' quality of life (Jia et al., 2021). Patients may experience pain, weakness, loss of sensation, decrease in ability to perform ADLs, increased falls among many other impairments as a result. We understand the importance of performance status in oncology patients. This can lead to dose reductions or held treatments depending on the severity of this. With cancer treatment, the prognosis can be affected by delays in treatment.

As a result of this knowledge, patients implement interventions they have researched online to prevent chemo-induced peripheral neuropathy. The most common intervention seen is the application of frozen mittens and socks. Patients implementing this intervention stake claim to

the efficacy and are persistent in doing it every treatment. I investigated this practice to see if there was reliable evidence on cryotherapy usage to prevent chemotherapy induced peripheral neuropathy (CIPN). Upon further investigation, I found use of cryotherapy to the hands and feet while receiving Taxol-based chemotherapy shows promising results in preventing the development of peripheral neuropathy. My proposal is to educate patients on this intervention during their treatment review so they could implement this based off patient preference. This would be an effective and inexpensive way to combat this debilitating side effect of chemotherapy and would help sustain quality of life in patients.

Rationale

Taxanes are the first line agents in many different types of cancer and is one of the most common agents given in the infusion center. With such a high incidence of taxane induced peripheral neuropathy reported, there should be an intervention available to help ameliorate this. There are no interventions or education offered at this time to prevent peripheral neuropathy from treatment. There is however, education being offered on how to reduce side effects such as nausea, vomiting, diarrhea, stomatitis, skin changes, fatigue, taste changes and any other side effect you can think of. While working with a new patient recently, she mentioned she had purchased frozen gloves and socks as recommended by her friend who had gone through the same treatment and did not develop peripheral neuropathy. She was asking about when she should apply the gloves during her treatment. She expressed the desire to have been educated on this at her treatment review as this was the main concern she had, but nothing about this particular side affect was mentioned. Cryotherapy is being used to reduce the incidence of chemo induced mucositis, alopecia and cutaneous toxicity at our cancer center. With high levels of

evidence supporting cryotherapy to prevent CIPN, this intervention should be offered in the appropriate populations. My proposal is to include this information in the treatment review along with all the other patient education so patients can implement this.

Literature to Support Project

A search was performed in Pub Med and twelve articles were reviewed over cryotherapy and chemo induced peripheral neuropathy. Five studies involved participants receiving Taxane agents using cryotherapy to reduce peripheral neuropathy. There were four randomized controlled trials and one metanalysis.

Participants in all of the studies except one were undergoing treatment for breast cancer (Kanbayashi et al. 2020), (Shigematsu et al. 2020), (Akiko Hanai et al., 2018), (Ruddy KJ, Le-Rademacher J, Lacouture ME, et al 2019) and the other was undergoing treatment for gynecological cancer (Sato et al. 2016). The neurotoxic chemotherapies received by the subjects were Taxol, Albumin bound paclitaxel and Taxotere. Cryotherapy was used in all studies by way of using either a frozen gloves or mittens and frozen socks applied to the hands and feet starting 15-30 minutes prior to starting chemotherapy infusion and left on for up to 60 minutes after completion. The Common Terminology Criteria for Adverse Events (CTCAE) was used in four of the five articles to test the outcome (Sato et al. 2016) (Kanbayashi et al. 2020) (Shigematsu et al. 2020), along with other methods including: Patient Neurotoxicity Questionnaire (PNQ), Functional Assessment of Cancer Therapy-Neurotoxicity (FACT-T),Thermography, Nam equivalence test (Kanbayashi et al. 2020) FACT-NTX, PNQ,CTCAE,FACT-Taxane (Shigematsu et al. 2020), monofilament test, thermal stimulator, C 128-Hz tuning fork, grooved pegboard test, patient-reported questionnaire on neuropathy and activities of daily living (Akiko

Hanai et al., 2018), European Organisation for Research and Treatment of Cancer (EORTC QLQ-CIPN2), (Ruddy KJ, Le-Rademacher J, Lacouture ME, et al 2019). Four out of five studies demonstrated statistical significance to the benefit of cryotherapy in reducing the severity of chemo induced peripheral neuropathy.

Project Stakeholders

In order to have sustainability in a change, the interest of the practice stakeholders is critical. It is important to align the vision of the practice with the change proposed. In the case of my benchmark project of using cryotherapy to prevent peripheral neuropathy, the stakeholders will include the doctors, nurses and most importantly the patients. The stakeholders in this project would be the doctors prescribing treatments and the nurse practitioners teaching treatment reviews who would educate patients on this intervention. The practice administrator and the nursing manager both of whom serve as a gatekeeper for the practice and clinical areas would grant permission for the benchmark project. The nurse assistant manager is a change champion who would support efforts to implement by gaining nursing staff buy in and development of teaching materials for patients. The practice administrator would obtain permission from the doctors and support me by allowing pharmacy ice packs to be used by patients. Lastly patients receiving the intervention would serve as a stakeholder by proving feedback on the efficacy of this intervention and on quality improvement.

Proposed Outcomes

The outcome to be measured in this benchmark is a reduction in the development of Taxane induced peripheral neuropathy as a result of having used cryotherapy during treatment. With data

showing significant reduction in the development of peripheral neuropathy with use of cryotherapy, this could be a beneficial intervention our practice could educate patients about to help reduce adverse effects from chemo treatments.

Evaluation Design

Evaluating the outcome of my benchmark project will involve assessing the intervention itself and the response from nursing staff. To evaluate the staff's response to the ease of implementation, the project change lead could attend the chemo nurse meetings on Mondays and ask for feedback. This multisource feedback will determine understanding of where things stand and give a clear direction of travel in terms of improving behaviors, attitudes and skills.

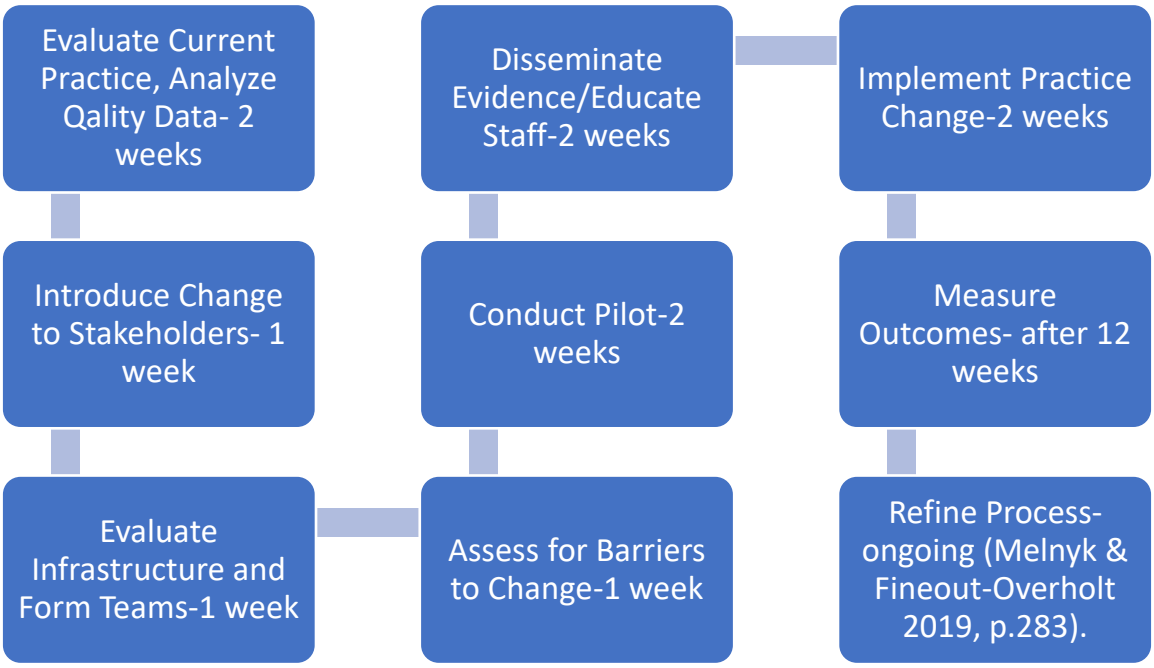
To evaluate the effects of cryotherapy in preventing chemotherapy induced peripheral neuropathy the nursing staff in the chemo dept would assess the level of peripheral neuropathy when patient's come for weekly treatments and document it in the patient's EMR. The PNQ (patient neurotoxicity questionnaire) could be given to patients to fill out at baseline, 6 weeks which would be halfway through a 12-week regimen and at 12 weeks. When patient's come back for a scan after completion of chemo the level of peripheral neuropathy could be checked again.

Timetable/Flowchart

This change project will be held within Tx Oncology clinic and infusion room.

Data needed before initiating the project include the incidence rates of peripheral neuropathy, chemotherapy dose reductions due to peripheral neuropathy, and an estimated loss of billable

units due to dose reductions and held treatments from peripheral neuropathy. This data will help in gaining stakeholder buy in. An assessment of the current educational materials distributed during treatment reviews will be done and new education on the use of cryotherapy can be added. The next step is to present all of this information to the stakeholders with the practice administrator's support and gain permission to move forward. After gaining permission from the doctors to move forward, an evaluation of the infrastructure is needed and teams could be formed. The teams will consist of a change champion which will be myself for the nursing staff and the assistant manager for the nurse practitioners. We will assess for barriers to change from gaining feedback from the nurse practitioners and nurses during the Monday nurse meetings. Next a clinical tool will be developed to help with implementation of the project and decision making. After the development of a clinical tool, a pilot of the change can be launched. Nurse practitioners can begin educating patients on cryotherapy during the treatment review process and patients who decide to implement this intervention can begin doing so during infusion. After having done a pilot of the intervention for two weeks, dissemination of the process can be gained through feedback from infusion nurses, patients and nurse practitioners. Changes to the process can be made based on this feed-back. Further implementation can be planned and after 12 weeks the benefits can be measured through patient feedback and surveys and the process can be refined on an on-ongoing basis.



Data Collection Methods

In order to collect data to determine the success of the benchmark the The PNQ (patient neurotoxicity questionnaire) could be given to patients to fill out at baseline, 6 weeks which would be halfway through a 12-week regimen and at 12 weeks. The PNQ represents a simple self-administered assessment tool created by BioNumerik Pharmaceuticals, Inc. containing data from the FDA. It involves specific questions that aim to draw quantifiable and important diagnostic information directly from CIPN patients that regard both the severity and incidence of subjective CIPN symptoms (Tsoleridis et al., 2021). This tool is a reliable data collection method and was used in most of the randomized controlled trials which studied the effects of cryotherapy. Other data collection methods will be obtaining direct feedback from nursing staff at huddles and from patients at their treatments weekly which can be documented in the patients EMR.

Discussion of Evaluation

This benchmark has not been evaluated. The assistant nurse manager has acknowledged this to be a great intervention worth implementing and is pulling education materials together to begin the process of adding this to the treatment reviews. Patients who I have discussed this with are in agreement this would have been something they would be interested in doing had they been aware prior to starting treatment. Nurses in the infusion department agree to supporting this intervention.

Cost/Benefits

Since this is a benchmark project, I did not have access to patients' personal financial information however, the amount of money lost from treatments being held or dose reduced would be determined by assessing the average amount of money insurance pays for each cycle of Taxol. When a treatment is held due to the development of peripheral neuropathy there are no charges for that cycle. This would include admix charges as well as pre-medications in addition to the actual chemo Taxol. When a dose is reduced, less vials of medication are charged out which is a loss of billable units. I would look at how many treatments were held or dose reduced for a year due to peripheral neuropathy and multiply this by the average amount of money insurance pays for the Taxol infusion to determine the amount of money lost annually. The cost of educating a patient on the intervention of cryotherapy is free. The cost of providing ice packs from the pharmacy is also free and we currently already do this for patients receiving Doxil infusions so this would be no different. Patients can keep these ice packs and re-use or purchase frozen gloves on their own. This simple solution could prevent the development of peripheral neuropathy for patients and save the practice thousands of dollars from treatments being held or dose reduced.

Conclusion/Recommendations

In conclusion, the use of cryotherapy to the hands and feet while receiving taxol-based chemotherapy shows promising results in preventing the development of peripheral neuropathy. This intervention would be an effective and inexpensive way to combat this debilitating side effect of chemotherapy and would help sustain quality of life in patients. I recommend our practice begin to educate patients on this intervention and support patients who choose to implement it by providing ice packs from the pharmacy if they need them and do not already have their own. This could be an easy and inexpensive method to provide the best evidenced based care to our patients.

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Appendix

Patient Neurotoxicity Questionnaire (PNQ)©

Taxanes, Cisplatin and Carboplatin

Item 1.

☐ **A**	☐ **B**	☐ **C**	☐ **D***	☐ **E***
I have no numbness, pain or tingling in my hands or feet.	I have mild tingling, pain or numbness in my hands or feet. This does not interfere with my activities of daily living.	I have moderate tingling, pain or numbness in my hands or feet. This does not interfere with my activities of daily living.	I have moderate to severe tingling, pain or numbness in my hands or feet. This interferes with my activities of daily living.	I have severe tingling, pain or numbness in my hands or feet. It completely prevents me from doing most activities of daily living.

Item 2.

☐ **A**	☐ **B**	☐ **C**	☐ **D***	☐ **E***
I have no weakness in my arms or legs	I have a mild weakness in my arms or legs. This does not interfere with my activities of daily living.	I have moderate weakness in my arms or legs. This does not interfere of my activities of daily living.	I have moderate to severe weakness in my arms or legs. This interferes with my activities of daily living.	I have severe weakness in my arms or legs. It completely prevents me from doing most activities of daily living.

* Please indicate by placing an X in the box or writing in the space provided which activity or activities have been interfered with as a result of therapy.

My ability to:

☐ Button clothes	☐ Open doors	☐ Fasten buckles	☐ Write	☐ Sew
☐ Use a knife	☐ Put in or remove contact lenses	☐ Sleep	☐ Walk	☐ Work
☐ Use a fork	☐ Dial or use telephone	☐ Climb stairs	☐ Put on jewelry	☐ Tie shoes
☐ Use a spoon	☐ Operate a remote control	☐ Type on a keyboard	☐ Knit	☐ Drive
	☐ Other eating utensils, etc	☐ Perform activities of importance to me, specify:		

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