Introduction and Objective

Introduction:
Myelodysplastic syndromes (MDS) are a heterogeneous group of clonal disorders characterized by cytopenias and risk of progression to acute leukemia. The majority of MDS patients are anemic at the time of diagnosis, and many become dependent on red blood cell (RBC) transfusions as the disease progresses. RBC transfusions are a non-cure medical treatment aimed at maintaining disease course and improving healthcare-related quality of life (HRQoL).

Fatigue is the most common of the patient reported symptoms in MDS and is improved by treating the underlying anemia. The decision to transfuse a patient with MDS is most often based on a pre-determined hemoglobin threshold (usually between 7g/dL and 9g/dL). However, data to support these threshold values are lacking.

Fatigue is a subjective term that remains more qualitative than quantitative. This provides a hurdle when trying to develop a standard guideline for RBC transfusions. Traditionally, oncology patients are evaluated by performance status (PS) and patient reported outcomes (PROs). This is subject to interobserver variability and leads to inconsistencies in management. PROs are also limited by subjectivity, bias, and poor reporting.

A digital health technology like wearable physical activity monitors (i.e. Fitbit) presents an opportunity to gather objective and quantitative data that may give providers a better insight into PS. Physical activity is a patient health metric that can be measured via steps taken and may correspond to fatigue. Various studies of differing oncology patient populations have shown the acceptability and feasibility of using wearable activity trackers to monitor daily steps count. Furthermore, commercially available active activity trackers have been validated as being a reliable means of measuring steps.

We hypothesize that activity level is a more relevant surrogate marker for symptomatic anemia than hemoglobin level.

Objectives:

Primary:
1. To determine the feasibility of physical activity monitoring via step counting in RBC transfusion dependent patients with MDS.
2. To assess anemia-related symptoms and HRQoL (Fact-An score) in patients with transfusion dependent MDS.

Secondary:
1. To establish change in step count as a surrogate marker for symptomatic anemia.
2. To assess anemia-related symptoms and HRQoL. (Fact-An score) in patients with transfusion dependent MDS.

Methods

Study Design:
Single-arm, prospective, observational study

Assessment Tools and Tests:

- Fitbit wearable activity monitor to track daily steps count and heart rate. These devices will be paired with a centralized data aggregation platform that will be used to automatically collect and store data.
- Anemia-related symptoms and HRQoL data will be assessed using the FACT-An questionnaire, assessed at baseline and at each subsequent provider office visit.
- Hemoglobin/anaemia levels will be monitored by complete blood count (CBC), assessed at baseline and subsequently two times weekly.

Analysis Plans:

- The primary aim of this study is to demonstrate compliance with the wearable device defined as usage of the device for at least 80% of the days under observation.
- The overall study period compliance rate along with a one-sided exact 95% confidence interval will be estimated. The device will be considered to have acceptable levels of compliance if the lower bound of the CI is above 0.6 or, equivalently, if at least 71/22 (80%) of participants are compliant for at least 70% of the days under observation.

Study Schedule:

- Total 21 patients obtain informed consent. Screen potential subjects by inclusion and exclusion criteria, obtain history, document.
- Perform baseline assessments. Obtain baseline quality of life data using FACT-An questionnaire, and provide patient with Fitbit wearable device.
- Reassess quality of life using FACT-An questionnaire at each subsequent outpatient visit with hemoglobin monitoring. Data from the wearable device will be collected and stored in a centralized data platform.

Results

Research protocol is in the process of being finalized. Full protocol to be presented at multi-disciplinary group for approval on February 2019. Protocol will then be submitted for IRB approval.

Timeline of Accountability:

- 1/16/18 Initial protocol presentation for CTR project.
- 5/8/18 Redirected to MDS project. Would allow me opportunity to participate in protocol submission and clinical trial at TJUH.
- 6/8/18 MDS project still pending. With Dr. Lau’s approval, new project and design for Y2 oral presentation and abstract.
- 12/13/18 Project resumed and protocol submission underway. Wrote background information for protocol over winter break.

Conclusions

Potential Impact:

1. Tracking steps via wearable activity trackers may give us the chance to objectively assess MDS patient status and anemia.
2. Provide evidence based medicine (EBM) data to establish RBC transfusion guidelines for patients with MDS.
3. Improve MDS patient HRQoL.
4. Deliver personalized medicine to patients.
5. Modernize healthcare approach by incorporating burgeoning digital health technology into patient management.

Possible Future Studies:

1. A scaled up trial that examines the relationship between physical activity and symptomatic anemia. This would establish greater study power and ability to extrapolate the results. It would also confirm the ability to reproduce the study results.
2. A clinical trial with a control and experimental group. The control group would be current standard of care which is transfusion at a set hemoglobin level. The experimental group would receive RBC transfusion. The groups could then be compared for HRQoL.
3. Trials that look at physical activity and symptomatic anemia in non-MDS RBC transfusion dependent populations.

Limitations of Study:

1. Small sample size can limit the generalizability of the study.
2. MDS is a heterogeneous group of disorders that may make it difficult to draw conclusions that apply to the entire MDS patient population.

Acknowledgements

Thank you to Dr. Adam Dicker, MD, PhD and the Digital Health Scholarly Inquiry Track at Sidney Kimmel Medical College for the guidance and bringing me to this research opportunity.

Thank you to Dr. Lindsay Wilde, MD and Dr. Vincent Yeung, MD for their help in making this research and poster possible.

References

17. Lau’s approval, new project and design for Y2 oral presentation and abstract.