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Falls Risk and Vitamin D

Background

Vitamin D is a fat soluble vitamin that is converted in the liver to 25(OH)D (circulating form) and then in the kidney to 1,25-dihydroxyvitamin D (active form). Elderly people do not convert Vitamin D effectively from the sun and instead will need to receive it from their diet or supplementations. It has been recommended to have a minimum level of 25(OH)D concentrations of 30 ng/ml to minimize risk of falls and fractures.[6] When Vitamin D levels dip to <10 or <20 ng/ml in older adults, this is seen with muscle weakness.[2] This is when supplementation is necessary. Most supplements come in two forms of Vitamin D: ergocalciferol (D2) and cholecalciferol (D3). Some studies have suggested that D3 increases serum 25(OH)D more effectively than D2, so currently recommend supplementation with D3. They also do not recommend taking pure calcitriol due to hypercalcemia and/or hypercalciuria. The safe upper limit for Vitamin D is 4000 IU/day. Side effects of too much Vitamin D supplementation include: hypercalcemia, hypercalciuria, kidney stones, and it may increase risk of cancers, mortality, and falls.[7] One out of three people aged 65 years or older fall each year, and many falls are associated with serious injury.[5] About 20% of falls lead to injury requiring medical attention. Low serum 25(OH)D levels are associated with increased bone loss and risk of fractures as well as increased fall rates.[9] Falls happen more consistently when 25(OH)D levels are <20 ng/ml.[1]

Since it has been established that Vitamin D supplementation is important, the question then becomes how much and how often. In a study done by Zheng, et al, high dose, intermittent Vitamin D supplementation was ineffective in preventing mortality, and no benefit was seen in fracture and fall prevention. The negative effects from high doses may arise due to failure to maintain serum Vitamin D concentrations over time.[10] Some meta-analyses conclude that 700-800 IU of Vitamin D daily reduces fracture risk by 13-26%, while other studies show that it's ineffective. In a study performed by Sanders, et al, participants receiving annual high-dose oral cholecalciferol experienced 15% more falls and 26% more fractures than the placebo group, and the increased likelihood of falls was exacerbated in a 3-month period immediately after annual dose. They did see an 11-19% reduction of fall risk with supplementation of Vitamin D of 700-1000 IU daily.[8] In a study by Girgis, et al, they saw that compared with placebo, higher doses of Vitamin D (700-1000 IU) reduced falls risk by 19%, but lower doses had no effect.[3] A study by Uusi-Rasi et al also showed that high 25(OH)D levels have increased risk of falls and fractures, suggesting negative influences on balance and mobility.[9]

Since there seem to be discrepancies on what levels are helpful and the frequency of supplementation, the American Geriatrics Society created some guidelines for Vitamin D usage and fall prevention. Clinicians should recommend Vitamin D supplementation of at least 1000 IU as well as Ca supplementation to community-dwelling older adults (≥65 years old) to reduce the risk of fractures and falls. Serum 25(OH)D concentration of 30 ng/ml should be a minimum goal for older adults, particularly for frail adults, who are at higher risk for falls, injuries, and fractures. Clinicians should not recommend large bolus

doses of Vitamin D2 or D3 ≥300,000 IU. Annual doses of Vitamin D2 or D3 in autumn or winter are not recommended.[4]

Our study is aimed at conducting a retrospective chart review of patients with a diagnosis of falls. Then we will look at the characteristics of the population, specifically Vitamin D levels, supplementation, referrals to therapy and frequency of falls. Our secondary objective is to determine if supplementation with Vitamin D increases or decreases risk of falls, and at what dosage and frequency.

Objectives

The primary objective of the study is to conduct a retrospective chart review of patients with a diagnosis of falls, and to determine characteristics of the population, specifically, Vitamin D levels, supplementation, and referrals to therapy.

Also to determine if supplementation with Vitamin D increases or decreases risk of falls.

Setting of the Human Research

This study is a combination of retrospective for part 1, survey implementation for part 2, and retrospective again for part 3, and all data will be reviewed and conducted using the electronic health records of The Guthrie Clinic.

Study Design

a. *Recruitment Methods:*

In part 1 of the study, a retrospective chart review was performed to see how providers handled fallers. A list of patients was selected whose providers had used a variant of the ICD-10 code for fall for their GC visit of FM or IM providers, from the period of January 8, 2016 to November 29, 2017. The patients were stratified according to demographics, BMI, Vitamin D and Ca levels, polypharmacy (defined as more than 4 medications), treatment chosen (supplementation and/or referral to therapy), and cause of fall. The data was then analyzed looking for trends.

In part 2 of the study, an anonymous paper survey was administered to GC providers from IM and FM to evaluate any barriers to Vitamin D supplementation and other treatment options including therapy. Providers who complete the survey will be provided a $10 gift card for their time involved to complete the survey. A grant application has been approved by the Donald Guthrie Foundation to cover the cost of the gift cards. The survey is administered pre and post education. The post education survey is a shorter version than the pre survey.

In part 3 of the study, new guidelines were established for GC. The IM and FM providers were educated on the new guidelines. After a period of 12 months, another review was performed of patients with ICD-10 codes related to fall to see if referrals and Vitamin D usage had changed.

b. Inclusion and Exclusion Criteria

Patients 65 years and older with a history of falls

c. Study Timelines

See above.

d. Procedures involved in the Human Research

Data will be collected from the electronic medical record. Data will include: Name, Medical Record number, Gender, Age, BMI, Encounter Date, Visit Provider, Visit Location; Diagnosis code related to falls and encounter diagnosis name.

Survey risks: anonymous, optional survey will be given to all providers.

Risks to participants

By design, there is a minimal risk to the participants in this study. However, there is always a small chance of data becoming unsecured. To minimize this possibility, all protected health information will be de-identified before results are shared. Any identifiable data will be accessed using only Guthrie computers, which are secured by the Guthrie network.

Potential benefits to participants

Analyzing data of patients with a history of falls will help increase the knowledge of how to prevent falls in high risk patients.

Provisions to maintain the confidentiality of the data

Any confidential information regarding patients will only be accessed on Guthrie computers, which are backed up through the Guthrie network. All data collection, storage, and analysis will also take place on Guthrie computers. A username and password is required to use EPIC, the software used to access patient health records. Furthermore, before any results are shared, any information that could potentially identify a patient (name, MRN, etc.) will be removed from the data.

Surveys will be completed in a de-identified manner.

Consent process/Process to document consent

A waiver of consent is being requested from the IRB for the review of medical records.

Implied consent will be obtained for the survey.

References:

1. Annweiler, C., & Beauchet, O. (2015). Questioning vitamin D status of elderly fallers and nonfallers: a meta-analysis to address a 'forgotten step'. *Journal of Internal Medicine*, *277*, 16-44. doi:10.1111/joim.12250

2. Bouillon, R., MD, PhD, FRCP. (2017, October 02). Vitamin D and extraskeletal health. Retrieved November 21, 2017, from https://www.uptodate.com/contents/vitamin-d-and-extraskeletal-health?source=search_result&search=vitamin%20d&selectedTitle=5~150

3. Girgis, C. M., Clifton-Bligh, R. J., Turner, N., Lau, S. L., & Gunton, J. E. (2014). Effects of vitamin D in skeletal muscle: falls, strength, athletic performance and insulin sensitivity. *Clinical Endocrinology*, *80*, 169-181. doi:10.1111/cen.12368

4. Judge, J., MD, Birge, S., MD, Gloth, F. M., III, MD, Heaney, R. P., MD, Hollis, B. W., PhD, Kenny, A., MD, . . . Vieth, R., PhD. (2014, January). Recommendations Abstracted from the American Geriatrics Society Consensus Statement on Vitamin D for Prevention of Falls and Their Consequences. *Journal of American Geriatrics Society*, *62*(1), 147-152. doi:10.1111/jgs.12631

5. Larocque, S. C., MS, RD, Kerstetter, J. E., PhD, RD, Cauley, J. A., DrPH, Insogna, K. L., MD, Ensrud, K., MD, Lui, L., MA, MS, & Allore, H. G., PhD. (2015). Dietary Protein and Vitamin D Intake and Risk of Falls: A Secondary Analysis of Postmenopausal Women from the Study of Osteoporotic Fractures. *Journal of Nutrition in Gerontology and Geriatrics*, *34*(3), 305-318. doi:10.1080/21551197.2015.1054574

6. Pazirandeh, S., MD, & Burns, D. L., MD. (2016, January 15). Overview of vitamin D. Retrieved November 21, 2017, from https://www.uptodate.com/contents/overview-of-vitamin-d?source=search_result&search=vitamin%20d&selectedTitle=2~150

7. Rosen, H. N., MD. (2016, December 09). Calcium and vitamin D supplementation in osteoporosis. Retrieved November 21, 2017, from https://www.uptodate.com/contents/calcium-and-vitamin-d-supplementation-in-osteoporosis?source=search_result&search=vitamin%20d&selectedTitle=6~150

8. Sanders, K. M., PhD, Stuart, A. L., BappSc, Williamson, E. J., MA, PhD, Simpson, J. A., PhD, Kotowicz, M. A., MBBS, FRACP, Young, D., MD, MBBS, FRACGP, & Nicholson, G. C., PhD, FRACP. (2010, May 12). Annual High-Dose Oral Vitamin D and Falls and Fractures in Older Women. *Journal of American Medical Association*, *303*(18), 1815-1822.

9. Uusi-Rasi, K., PhD, Patil, R., MSc, Karinkanta, S., PhD, Kannus, P., MD, PhD, Tokola, K., MSc, Lamberg-Allardt, C., PhD, & Sievanen, H., DSc. (2015). Exercise and Vitamin D in Fall Prevention Among Older Women: A Randomized Clinical Trial. *Journal of American Medical Association Internal Medicine*, *175*(5), 703-711. doi:10.1001/jamainternmed.2015.0225

10. Zheng, Y., Cui, Q., Hong, Y., & Yao, W. (2015, January 20). A Meta-Analysis of High Dose, Intermittent Vitamin D Supplementation among Older Adults. *PLoS One*, 1-11. doi:10.1371/journal.pone.0115850