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Title : Utilization of the electronic medical record to evaluate vaginal atrophy in a geriatric primary care population; measuring impact of screening and treatment on quality of life and patient satisfaction.

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Structured Abstract:

Purpose: Improve screening for postmenopausal vaginal atrophy by utilizing the electronic medical record online chart tool.

Scope: Quality of life in women is negatively impacted by vaginal atrophy. Using the Explorys database to determine vaginal atrophy prevalence at our center, we identified a need for better screening and treatment. For this, we used the electronic medical record online chart tool to screen women in a geriatric primary care outpatient setting.

Methods: A prospective, randomized study of women over age 50. Those who subscribe to MyChart were randomized to vaginal atrophy screening with the UAQ survey or a placebo screening. Women over 50 who were not MyChart subscribers were randomized to either paper instructions or personal assistance with enrollment and completion of questionnaires. All patients had access to standard of care treatments during the study. Data was recorded upon enrollment and again at 6 months..

Results: 454 women were enrolled, including 251 MyChart users and 203 Non-MyChart users. Of those who completed screening, 95% had symptoms of atrophy, but only 19 were diagnosed with the condition. Of those, only 9 were prescribed vaginal estrogen therapy. Mychart users were more likely to complete their questionnaires at baseline (88% vs 51%) and also at 6 months (36% vs 5%), but both groups' 6 month response rate dropped significantly. At 6 months, there were no differences in vaginal atrophy scores or diagnosis of atrophy in any of groups.

Key Words: vaginal atrophy, menopause, genitourinary syndrome, online chart, EMR

Purpose: The purpose of this study was to improve screening for postmenopausal vaginal atrophy and enhance treatment of symptoms by engaging patients through the electronic medical record and health information technology. The intervention aimed to evaluate whether improving access to health information technology via enrolling in MyChart will help to improve diagnosis of vaginal atrophy, treatment adherence, and patient satisfaction with evaluation and treatment.

We will evaluate the utility of the electronic record as a means of communication in the aging population. We will identify differences between those who use the electronic records versus those who use only standard forms of physician communication, and we will demonstrate if utilizing the electronic record improves outcomes.

Scope: Quality of life estimates in the international studies have demonstrated the negative impact that atrophy can have on women. Stenberg et al. noted that 32% of women complaining of vaginal dryness had lost interest in sexual relations. (1) Further, some postmenopausal women experience recurrent episodes of urinary tract infection with severe, disabling symptoms. Despite a general knowledge of the condition, primary care physicians often have too many other problems and concerns to address to make a strong effort at sexual and vaginal health screening in routine visits. There is often a lack of time for menopause discussions during office visits, particularly for PCPs who often must address a number of chronic conditions in a limited time period. The menopause discussion can be awkward for many providers and patients. Some patients may arrive to these discussions with negative preconceptions and fears about hormone therapy. From the Vaginal Health: Insights, Views & Attitudes (VIVA) survey study, half of respondents had experienced vaginal discomfort since they had stopped menstruating, most commonly (88%) vaginal dryness; over half (56%) reported having experienced symptoms for three years or longer. 82% of women felt that vaginal discomfort would have a negative impact on various aspects of their lives, most notably sexual intimacy (72%), 'having a loving relationship with a partner' (39%) and 'overall quality of life' (30%). (2).

In clinical practice, our staff has noted a low rate of diagnosis for postmenopausal vaginal atrophy. The Explorys database was queried to examine the number actual of patients with the diagnosis of vaginal atrophy throughout our medical center. Investigation into the diagnosis rate at our institution confirmed our low rate. In the population of female patients ages 50 and over, 1026 of the >196,000 women have the diagnosis of vaginal atrophy, giving us a diagnosis rate of only 0.5%. While the worldwide prevalence of vaginal atrophy symptoms is often underestimated, ranging from 27-55% of women (1, 3-4), our rate of diagnosis, and thus treatment, is far too low.

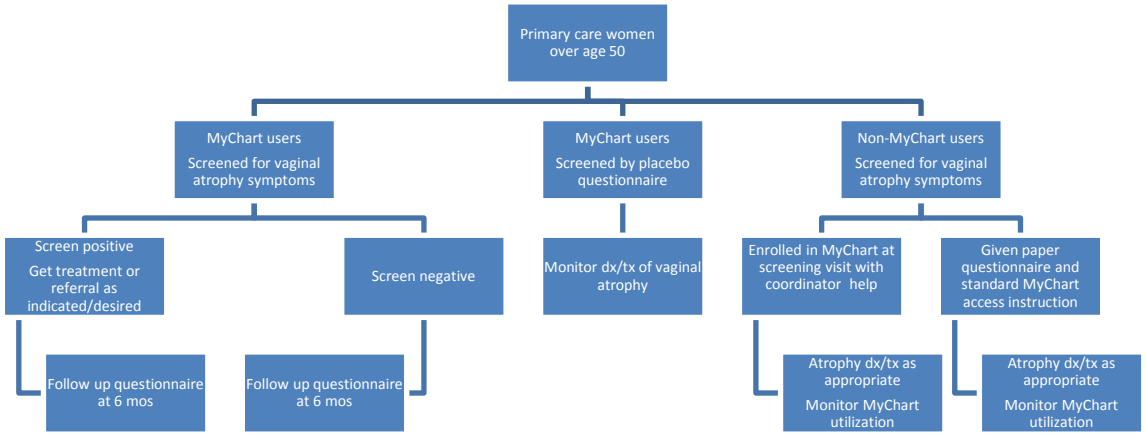
The New England Journal of Medicine study by Cebul et al. from our institution and Center for Healthcare Research and Policy cited a significantly higher achievement of care and better outcome standards in sites that effectively use the electronic health record. (5) Recent advances in the health information technology and electronic medical record capabilities at our institution have prompted us to look for new ways to reach out to patients and improve communication. The MyChart online chart tool

through the EPIC-based electronic medical record and the Internet allows physicians and patients to communicate in a confidential, interactive format. Questions can be answered, results given, and open lines of communication can be established.

Increasing effective physician-patient communication helps to improve outcomes. (6) All patients seen in the outpatient clinics over the last year have been given instructions on accessing and enrolling in the MyChart program on the standard after-visit paperwork. Upon review of EPIC utilization data, our current rate of MyChart enrollment for women over age 50 is 29%. There are 8171 MyChart females ages 50-105 out of the total 28015 MyChart patients. The un-enrolled rate of 71% in the over 50 population is high, despite these older patients having a large burden of medical issues and greater need for interaction with their physicians. In addition to improving outcomes, communication improves the patient experience. One large review study indicates consistent positive associations between patient experience, patient safety and clinical effectiveness for a wide range of disease areas, settings, outcome measures and study designs. (6) There is an ongoing effort at all institutions nationally to improve the patient experience and overall quality of care.

This aimed to enhance the screening process for vaginal atrophy symptoms and improve the diagnosis of post-menopausal vaginal atrophy in the population of women over age 50 at our institution. The intervention also evaluates whether improving access to health information technology and the online chart tool will help to improve diagnosis, treatment adherence, and patient satisfaction.

Methods: This is a prospective, randomized study of vaginal atrophy screening and EMR usage. The intervention is designed to assess multiple aspects of patient care from screening, to treatment, to outcomes, to satisfaction, to compliance and informatics utilization. The patient population is all women in a primary care setting over age 50. Those who subscribe to MyChart EMR access will be randomized to either a vaginal atrophy screening or a placebo screening. Randomization schemes were set up by the consulting statistician prior to study initiation. This randomization and controlled placebo group will allow us to observe whether the act of screening via MyChart increases health discussions and increases the diagnosis of vaginal atrophy, or if directed screening for vaginal atrophy is necessary to increase the diagnosis and treatment rate. A third arm of patients will be those women over 50 who are not MyChart subscribers. Those women will be randomized to either standard hard-copy MyChart enrollment instructions or assisted enrollment in MyChart and completion of electronic questionnaires with direction from research staff. All patients have access to standard of care treatments by their physicians and also access to referrals as indicated and desired. See the flow diagram below. Recruitment for new enrollees will take place for 1 year, and follow up questionnaire data will be collected at 6 months.



Once enrolled in the study, data will be collected regarding patient demographics and baseline EMR utilization. Baseline vaginal atrophy symptoms will be obtained from their questionnaires. Validated questionnaires for scoring will be used. The Urogenital Atrophy Questionnaire, UAQ, will provide the scores for the the primary comparisons. Other validated questionnaires used will be the PFDI and PFIQ which are commonly used in pelvic floor and quality of life research. Those who are screened for vaginal atrophy will be "flagged" in the EMR. EPIC notifications will alert those PCPs to the positive screening status and the potential for vaginal atrophy in that patient. For those in the placebo questionnaire group, their diagnosis and treatments will also be recorded. The diagnosis of vaginal atrophy will be recorded after screening, and any treatments will be recorded to evaluate how this varies when compared to our current practices. The questionnaires administered at 6 months after screening will help to determine if screening improved diagnosis rate, treatment rate, symptoms, and overall perception of satisfaction with the quality of care. 6 Month data will also assess willingness to continue with current treatments and overall impressions of improvement.

Throughout enrollment and until completion of the study data collection period, all data will be stored securely in the RedCAP online data management system. We would hope to see a 25% increase in diagnosis rate, an increase that would make our diagnosis rate more

consistent with the prevalence of the condition of vaginal atrophy. We would expect that there would be some effect of the placebo, so the number needed in each randomized arm to see a difference in proportions between these groups with an 80% power to detect a 15% difference would be 100, with an alpha error of 0.05.

Results: : 454 women were enrolled in the study between July 2013 and August 2014. Access to a computer and email account were requirements for enrollment, and any patient with dementia or inability to read the questionnaires was excluded. 251 MyChart users and 203 Non-MyChart users were enrolled in the study. Demographic data showed that the majority of the population was low income, Caucasian, obese women with government sponsored insurance programs or Medicare. Other demographics such as parity, marital status, and history of pelvic surgery or cancer were collected and did not differ between groups. Of those who completed screening questionnaires, 95% had symptoms of atrophy by screening "positive" with a score of 2 or greater on the Urogenital Atrophy Questionnaire (UAQ), but only 5% were diagnosed with Vaginal Atrophy by a physician. Of those diagnosed with atrophy, only 9 women had been prescribed vaginal estrogen therapy. This number did not change after 6 months at the repeat collection of the data. There was no difference in mean UAQ scores at 0 and 6 months. There was no increase in the diagnosis rate and it remained 5% in the study cohort.

Mychart users were more likely to complete their questionnaires at baseline (88% vs 51%) and also at 6 months (36% vs 5%), but both groups' 6 month response rate dropped significantly. There was no difference in diagnosis or treatment of atrophy with vaginal estrogen between existing Mychart users and new enrollees. There was also no difference or improvement in UAQ scores at 6 months between these groups. There were no differences in vaginal atrophy scores or diagnosis of atrophy or treatment in any of groups. The response and utilization rate of those who had assisted enrollment was significantly greater that those that were given the standard instructions (96% vs 8%). This is a potential area for improvement in the utilization of the electronic medical record and online chart tools if assistance can be readily available, especially to an aging population.

Overall, this was a negative study. The methods were followed, but the expected outcomes were not met. We did not demonstrate an improvement in diagnosis rate despite an improved screening system and increased awareness of the condition of vaginal atrophy and its symptoms. Further education of primary care providers and patients is needed to help correlate the symptoms of vaginal atrophy to the diagnosis and then the treatments. If this can be accomplished, symptom scores could then improve and quality of life could be recovered.

Key Words: vaginal atrophy, menopause, genitourinary syndrome, online chart, EMR

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