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PILL AVERSION IN HIV-INFECTED PREGNANT WOMEN: THEORY TO PRACTICE

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Abstract

In our perinatal HIV cohort we have observed difficulty swallowing pills as a frequent and significant barrier to adherence to highly active antiretroviral therapy. We refer to this problem as pill aversion and define it as difficulty swallowing pills with no persistent medical or structural cause as well as the anxiety and physical symptoms associated with pill swallowing. By applying cognitive behavioral theory to behavioral patterns within our pregnant HIV-infected population, we seek to better understand the development and reinforcement of pill aversion behavior. Based upon this theory, our experience, and the pediatric pill swallowing literature, we propose a conceptual framework for understanding the multiple causes of pill aversion and applying therapeutic interventions to a perinatal population. In a theoretical discussion we address the roles of classical conditioning and cognitive theory in the development and experience of pill aversion in an HIV-infected pregnant population. We propose future steps for characterizing these behaviors and testing theories and interventions.

Keywords

pill aversion; pill swallowing; pill burden; HIV; HAART; adherence; classical conditioning; cognitive theory

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INTRODUCTION

Effective management of HIV requires adherence to a highly active antiretroviral therapy (HAART) medication regimen (1, 2, 3, 4). Among HIV-infected pregnant women, sustained excellent HAART adherence is particularly crucial to reach the combined goals of improving or maintaining maternal health and preventing mother-to-child transmission (MTCT) of HIV (5). Yet, many HIV-infected women face significant psychosocial barriers to HAART adherence. In our perinatal HIV clinic, difficulty with pill swallowing, or pill aversion is a frequently identified barrier to sustained undetectable HIV viral load. Our working definition of pill aversion is the physical or mechanical difficulties with swallowing pills with no persisting medical cause, as well as anxiety and physical symptoms associated with pill swallowing. While pill swallowing has been studied among children, little is known or published about pill aversion in adult HIV-infected patients and specifically in HIV-infected pregnant women. Herein, we describe this heterogeneous problem among pregnant and reproductive-aged women and apply cognitive and behavioral theory to characterize and treat pill aversion. Based upon this theoretical understanding, we will propose treatment interventions to address the varying contributing factors.

HAART use decreases HIV-related mortality (6) and has resulted in increased lifespans for individuals with HIV (7). However, HAART is ineffective unless taken with consistency. Virologic failure results in worsening disease, viral resistance (8), and, often, increased pill burden. Thus, those who experience pill aversion chronically are at risk for increasingly challenging problems with this behavioral issue over time.

During pregnancy, strict adherence of HAART is essential for promotion of the health of the mother and fetus as recommended by the perinatal guidelines (5). Prevention of MTCT is the primary goal of perinatal antiretroviral therapy; failure to achieve a suppressed maternal viral load is the highest predictor of vertical transmission (9). Without therapy, MTCT rates are as high as 25% (10), but the rate of vertical transmission decreases to less than 2% with intensive antepartum HAART treatment, intrapartum zidovudine (AZT), and neonatal AZT (11, 5). However, pregnancy introduces further complications that can lead to pill aversion at a time when adherence is of the utmost importance.

BEHAVIORAL INTERVENTIONS FOR PILL SWALLOWING

Dysphagia, or difficulty swallowing, occurs for an estimated 16–22% of people over age 50 (12) but most evidence suggests lower prevalence among younger adults. In most cases, a cause is identified and treatment includes medication, surgery, or speech therapy. However, younger women typically do not have such comorbidities. In our observations of pill aversion in HIV-infected women, the dysphagia experienced involves only HAART and/or other large tablets or capsules, suggesting that psychological factors, not structural or neurological dysfunction, are the primary etiology. Scant literature exists on pill aversion and its role in medication adherence in HIV-infected adults.

In the pediatric HIV literature, however, pill-swallowing dysphagia is identified although it largely addresses new learning for pill swallowing in children (13). Sallows (14)

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demonstrated success in a case study with a child learning pill swallowing using an in-vivo behavioral graded exposure intervention or systematic desensitization. This intervention required the child to swallow a substitute “pill” (candy), gradually increasing size and number as well as changing shape over several visits. Ultimately the child is transitioned to take the actual pill. Similarly, Garvie, Lensing, and Rai (15) demonstrated success in a pediatric intervention, also using candy to enable taking HAART, often in only one session. These authors found younger children to progress quickly, while older children required more sessions. Of note, the young children were naïve to pill swallowing and did not have previous negative experiences or established aversions; Garvie et al (15) proposed that lifetime experience with illness and medication adds to the complexity of interventions required to treat behaviorally-based pill swallowing difficulties. There are two major limitations to directly adapting these pediatric strategies for a perinatal population. First, most pregnant women with HIV, both chronically-infected and newly-diagnosed, have been exposed to prior pill use and thus may have a history of difficulty swallowing pills. Some have had negative experiences with medication use prior to pregnancy, whereas others encounter new negative experiences related to pregnancy or new HIV diagnoses. Second, pregnancy offers a limited amount of time in which to control maternal viremia. To engage in an intervention that delays the initiation of HAART potentially exposes the fetus to increased risk for MTCT. Thus, successful pediatric interventions are unlikely to be directly applicable to a perinatal population. We hypothesize that applying the principles of other cognitive and behavioral theories and interventions will address the psychological barriers to pill swallowing without increasing the risk of MTCT.

COGNITIVE AND BEHAVIORAL THEORY

Classical conditioning

Classical conditioning was first demonstrated by Ivan Pavlov (16) when he presented a natural stimulus (meat powder) and observed dogs salivating, a natural response; by pairing the meat powder with a ringing bell, ultimately the sound alone resulted in salivation. Such conditioning pathways have been demonstrated in many human settings. For example, chemotherapy patients who experience medication-related nausea commonly associate factors associated with chemotherapy with nausea even in the absence of the medications. Patients may then become conditioned to experience nausea when they hear music that was played during treatments, for example, even if not receiving any nauseating medications.

To treat an unhealthy conditioned response, psychologists rely upon extinction and counterconditioning. Extinction of the conditioned response (nausea) occurs when the conditioned stimulus (music in the treatment room) is presented repeatedly without the presence of the unconditioned stimulus (chemotherapy). In time, the conditioned relationship lessens and eventually extinguishes completely. In order to achieve symptom-free trials, an individual must be able to create a state of calm without conditioned symptoms. Counterconditioning is the replacement of an undesired response with a desired response (17). Counterconditioning is used to enhance extinction and refers to pairing the conditioned stimulus with a calming or pleasing stimulus such as relaxation exercises.

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Cognitive theory and cognitive restructuring

Drawing from cognitive theory (18), cognitive behavioral theory focuses on how thoughts lead to emotions which lead to behavior. Behavior then yields an outcome which either confirms or refutes the initial beliefs and emotions. Maladaptive thoughts and behavior, thus, may be reinforced. Cognitive restructuring is a psychotherapeutic process of learning to identify, question, challenge, and modify recurrent distorted and irrational thoughts (19). Through various therapeutic strategies, one can learn to identify distorted thoughts, understand the relationship between the thoughts and the emotion, and propose realistic alternative thoughts that lead to different emotions and behaviors.

Physiological responses to stress and anxiety

When a person is faced with a physically threatening situation, the body initiates the acute stress response, or the “fight or flight” response (20). This physiological reaction includes the tightening of muscles, increased heart rate, increased blood pressure, and a decrease or slowing of the upper gastrointestinal system, which can lead to acid reflux and nausea (21). Although the response is life-saving in a state of true physical danger, this acute stress response may develop from *perceived threat*, including work stress, interpersonal challenges, or other stressors. Effective interventions for an unnecessary acute stress response allow the individual to calm the body and mind and induce a relaxation response (22). The relaxation response can be achieved through many different exercises including diaphragmatic breathing, progressive muscle relaxation, imagery, visualization, meditation, and autogenic relaxation. These exercises can be used by the individual in any time of stress or anxiety, including at the time of pill taking.

CLINICAL OBSERVATIONS

Patients treated in an urban academic medical center in the Women’s HIV Program from 2009–2014 were evaluated and supported by a health psychologist during pregnancy and the postpartum period, as a supplement to perinatal HIV medical care. During this time period, the health psychologist was introduced to each of the 140 pregnant patients as they enrolled in the program. In this time period, seventeen (12%) presented with or developed symptoms of pill aversion; the health psychologist assessed patients and offered behavioral interventions. Screening for pill aversion (Figure 1) was included as a standard element of the psychological evaluation beginning 2011. Observational data and experience generated patterns in presentation of pill aversion. Table A summarizes the themes explored below.

First Trimester Classical Conditioning

Women in the first trimester frequently experience altered smell and taste, nausea and vomiting linked to temporal and pathologic alterations in pregnancy hormones (23). In the US, many women are also diagnosed with HIV in their first trimester of pregnancy through routine screening; they may be started on HAART during that time, as recommended by the US Department of Health and Human Services guidelines (5). Therefore, many HIV-infected women are learning to take a new oral medication regimen that coincides with the peak of pregnancy-associated first trimester symptoms, thereby creating a classically conditioned association between nausea/vomiting and HAART pills that can persist after pregnancy-

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associated nausea improves. Although it is common to treat nausea and vomiting with medications, antiemetics are not always a cure for the aversive sensations.

Intervention for classical conditioning requires the ability to present the conditioned stimulus in the absence of the unconditioned response. Women must be able to predictably take HAART in the absence of nausea, which is not always possible in early pregnancy. One therapeutic option considers waiting to start HAART until after nausea symptoms cease. Although not ideal for prevention of MTCT, vertical transmission in the first trimester is infrequent. This option could potentially reduce the development of pill aversion. However, providers must balance the benefits of this option with the risks of vertical transmission. While early second trimester initiation of HAART can still lead to successful viral suppression in an adherent patient, later initiation of therapy, as has been shown among women who present late to care, is associated with failure to achieve viral suppression and greater risk of MTCT. Delaying initiation of therapy until cessation of early pregnancy nausea clearly reduces the amount of time available to achieve viral suppression and diminishes the time available for intensive psychotherapy to address pill aversion issues.

A second option is to initiate early HAART as a focus on perinatal HIV treatment. Close monitoring for swallowing difficulties is indicated, and early identification, counseling and training may prevent or extinguish potential conditioning. The risk with this option is that the conditioning can become strong and combine with potential additional challenges related to the trauma of a new diagnosis (see below), making extinction difficult. For those patients with an established history of medication adherence and no difficulty with swallowing, we have observed temporary pill swallowing difficulties during the first trimester that becomes easily extinguished after the symptoms abate. For treatment of conditioning with new diagnoses, teaching relaxation exercises for use in counterconditioning is often beneficial in preventing a conditioned response. With the use of relaxation exercises, the patient learns to calm gastrointestinal symptoms and can learn to pair relaxation with taking pills. In our experience, consistent with the pediatric literature, early detection and early intervention of pill aversion often leads to rapid resolution.

Reflux and anticipatory anxiety

Up to 80% of women in the second and third trimesters of pregnancy experience symptomatic gastroesophageal reflux disease (GERD) (24). In our patient population, we have identified these symptoms to be associated with the development of pill aversion. GERD can be experienced by pregnant or non-pregnant individuals as a feeling of difficulty swallowing (25), heartburn, nausea, or excessive fullness. As with first trimester nausea, these feelings can become conditioned or associated with HAART. Women may begin to interpret the feeling of fullness or difficulty swallowing as an effect of the medication, thus potentially developing a barrier to taking the medication. Our patients have reported emesis after pill administration related to the feeling of fullness, as well as difficulty swallowing HAART pills in the setting of reflux. For many women, GERD resolves after pregnancy, thus eliminating the obstacle to pill swallowing. This observation indicates that either conditioning was not established or that extinction occurred naturally with the removal of the unconditioned response.

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In addition to conditioning, symptoms of reflux, primarily fullness and difficulty swallowing, can lead to anticipatory anxiety about the ability to avoid vomiting or associated sensations. Due to this anxiety, many women begin to construct the “perfect” or “necessary” conditions under which they need to take their pills. These conditions, for example, include eating certain foods at precise times or a precise amount of time between eating and taking pills. When these conditions are disrupted, they experience anxiety and a belief that they cannot successfully swallow and avoid emesis. This anxiety leads to increased muscle tightness and stomach acid, which then reinforces the original belief that they cannot successfully swallow pills in the presence of GERD symptoms.

In this common scenario, early identification and treatment of symptoms are of utmost importance in order to encourage extinction. When the symptoms of GERD are treated or resolve naturally after pregnancy, the patient then has the opportunity to take the pills in the absence of symptoms, thereby extinguishing the conditioned response. As with the conditioned response of first trimester nausea, chronically HIV-infected individuals on HAART antecedent to pregnancy with no pill aversion and a memory of successfully taking HAART tend to experience extinction more readily. Newly diagnosed individuals, on the other hand, have the additional burden of the emotional adjustment to diagnosis. In this instance, the intervention of counterconditioning via relaxation exercises might successfully extinguish the conditioning as well as increase the individual’s confidence in her ability to manage her symptoms. In addition to addressing conditioning, a psychologist may also use cognitive restructuring to address the specific and rigid beliefs that lead to anxiety when certain conditions are not met.

Adjustment to HIV diagnosis and associated trauma

A new HIV diagnosis often elicits emotional and physical distress, and the manner in which patients think about the disease and their anticipated life with HIV affects coping and behaviors. As described above, emotions can influence the physical response. Thus, when a patient looks at her pills and thinks negative and anxious thoughts about her illness, her body responds with stress, which can include the physical changes that lead to difficulty swallowing. This physical response reinforces, or confirms, the belief that pill swallowing is difficult or impossible, leading to fears of taking pills. For example, a patient looks at her pills and thinks about being “unhealthy,” taking pills for a lifetime, and being undesirable to others. Anxiety prompts immediate physical symptoms of nausea or tightness; she then has difficulty taking her pills. These paired thoughts and sensations occur so quickly that the patient may only be aware of the physical sensations when she takes her pills. When she has this experience with some repetition, she begins to believe that she is unable to swallow pills and the anxiety loop continues.

Cognitive restructuring of the thoughts about health and HIV is a reasonable intervention in this clinical situation. The addition of relaxation training further allows the woman to calm her physical anxiety responses, thereby decreasing muscle tension and gastrointestinal upset that might accompany anxious thoughts. Relaxation training also provides the individual with confidence that she may affect change.

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Pill burden beliefs

Medical literature recognizes that increased pill number and frequency is associated with poor medication adherence (26, 27). Indeed, patients' *thoughts* about the number or size of pills can become a barrier to success with pill-taking. The patient might, for example, look at her pills and imagine pills getting stuck in her throat. These thoughts cause fear, which lead to a physical response manifested as muscle tightening or gastrointestinal distress. This physical response reinforces the belief that pill swallowing is difficult or impossible. Cognitive restructuring to address these thought processes may benefit patients by targeting the thoughts about the impossibility of pills fitting down the esophagus. Treatment might incorporate visualization techniques that emphasize a smooth path to the stomach. This visualization decreases the anxiety response, provides distraction from negative thoughts about the pills, and increases self-efficacy.

DISCUSSION

Practice Implications

Based upon our clinical observations, pill aversion is a salient issue among individuals treated for HIV. However, only the most severe cases are presenting themselves because providers are not accustomed to asking patients about concerns they may have taking their pills. By asking the questions prior to substantial adherence issues, we can identify those developing pill aversion and implement interventions to manage this potential future barrier to adherence. For those patients who have developed impaired adherence to HIV medications due to pill aversion, this paper offers preliminary ways to understand the problem as well as to offer intervention. In a pregnant population, adherence to medication prevents mother to child transmission of HIV.

Future Directions

Our experience as interdisciplinary clinical providers for women with HIV during and after pregnancy has afforded an opportunity to explore the many barriers women face during pregnancies complicated by a serious chronic disease associated with stigma. We have found pill aversion to be a common barrier to success. Yet, we propose that pill aversion may be diagnosed and managed using common principles of health psychology, behavioral medicine and more specifically, cognitive and behavioral theories. The proposed interventions are based upon theory and our in-practice applications. However, literature in this field is lacking. Areas of future investigation include developing screening tools, further characterizing this heterogeneous problem, and assessing interventions longitudinally.

Specifically, we propose that development of an assessment tool to capture the nuances of pill aversion will be critical to helping patients. Such a tool would ideally identify, classify, and manage the problem early and in a standardized manner, while allowing exploration of specific issues that underlie each person's difficulty. Finally, pill aversion affects women of all ages, men, and children in addition to the perinatal women's cohort. Future research will assess for the problem of HIV pill aversion in other populations as well as evaluate the impact of the proposed interventions.

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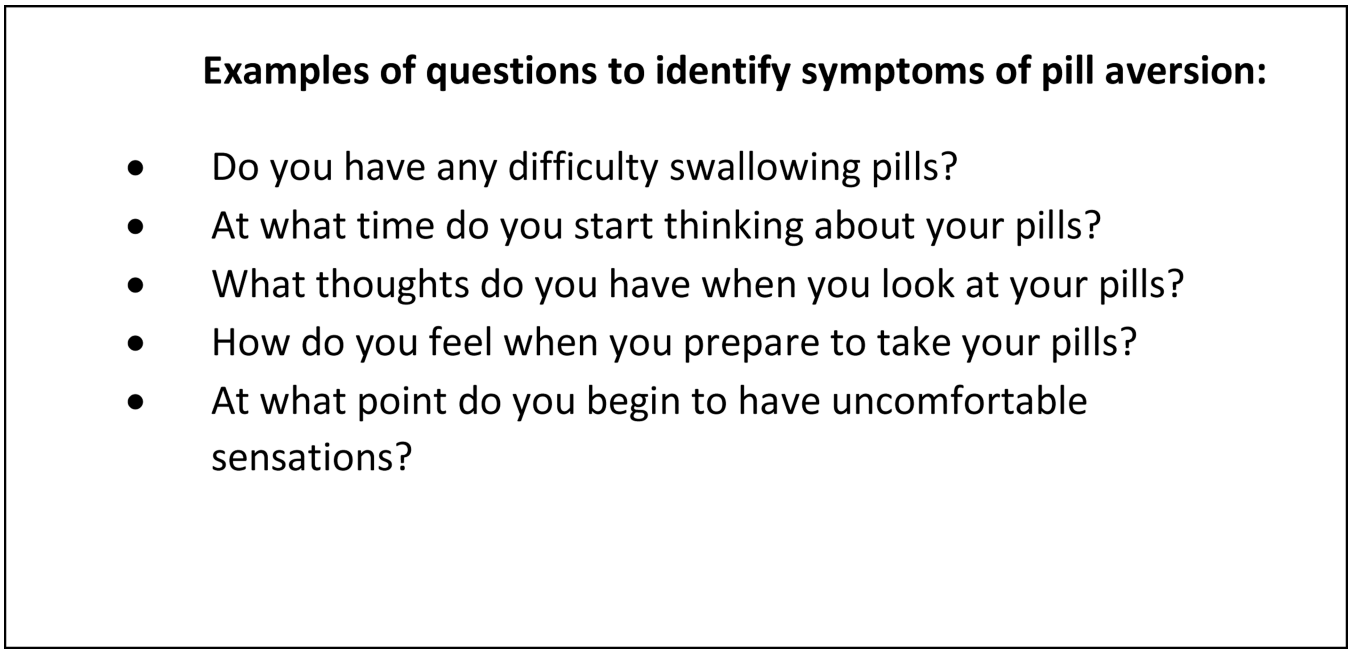

Figure 1.
Screening Questions to Detect Pill Aversion

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Table A

Conceptualization of Pill Aversion for HIV Positive Women

Theme	Type of Patient		Example	Psychological Principle	Treatment/Intervention
	Pregnancy Status	**HIV Diagnosis Status**			
Classical conditioning related to nausea of early pregnancy	Pregnant, first trimester	New diagnosis or existing	• Existing HIV diagnosis • No previous problems with pill swallowing • Nausea during the first trimester • Vomiting after taking pills • Association formed between pills and vomiting • Nausea started when thinking about or looking at pills	Classical conditioning - pills conditioned with nausea	• Counterconditioning with relaxation, diaphragmatic breathing • Address nausea medically • Focus on successful pill swallowing after resolution of nausea (extinction)
Classical conditioning related to ARV associated nausea or HIV associated esophageal diseases	Pregnant or non pregnant	New to HAART or new medication regimen	• Long standing HIV positive status • Many medications for medical comorbidities. • HIV related esophageal disease (Candida sp., Herpes Simplex Virus, Cytomegalovirus, *HIstoplasma capsolatum*) • Nausea when thinking about taking pills • Nausea worse when holding pills and preparing to take them • Has been on many regimens over the years with nausea as a frequent side effect	Classical conditioning - pills conditioned with nausea	• Counterconditioning with relaxation, diaphragmatic breathing • Address nausea medically • Cognitive restructuring for anxious thoughts about medications.
Reflux caused by pregnancy and related physical sensations	Pregnant, second and third trimester	New diagnosis or existing	• Existing HIV diagnosis • No previous problems with swallowing, though adherence was variable • Feeling of “fullness” during pregnancy that often preceded vomiting after taking pills • Taste of pills became bothersome during pregnancy • Began using a certain drink to take pills; that drink began to taste like the pill when the pill was not present	Classical conditioning - pills conditioned with feeling full, acid reflux, or nausea Anticipatory anxiety leads to physical symptoms	• Medical treatment of GERD • Counterconditioning with relaxation, diaphragmatic breathing • Extinction with coiresolution of GERD symptoms
HIV diagnosis adjustment and trauma	Pregnant or non pregnant	New diagnosis or existing; Poor integration of HIV diagnosis,	• HIV diagnosis as an adolescent • At HAART dose time, thinks about being sick and having a hopeless future	Anticipatory anxiety and negative thoughts lead to physical	• Cognitive restructuring to address thoughts about illness

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Theme	Type of Patient		Example	Psychological Principle	Treatment/Intervention
	Pregnancy Status	HIV Diagnosis Status			
		internalized stigma	• Gagging reflex with frequent vomiting within seconds of swallowing pills	symptoms	• Relaxation training to manage GI response
Pill burden beliefs	Pregnant or non pregnant	New diagnosis or existing	• New HIV diagnosis • Looks at pill and thinks about large size of the pills • Evaluates which are too big and will likely get stuck on the way down • Images of the pill getting stuck • Reports feelings of the pills being stuck in her throat	Anticipatory anxiety leads to physical symptoms	• Cognitive restructuring to address thoughts about pills • Imagery to address images of pills getting stuck • Relaxation to calm esophageal muscles • Change medium in which to take pills (ie thick liquid, applesauce, pudding, etc)

HIV, human immunodeficiency virus; ARV, antiretroviral; HAART, highly active antiretroviral therapy; GERD, gastroesophageal reflux disease