

The Effectiveness of Viagra on Erectile Dysfunction  
in Males with Chronic Low Back Pain

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## Abstract

### Background

Chronic low back pain greatly affects quality of life. Erectile dysfunction is a problem with increased incidence in males with chronic low back pain. Sildenafil citrate (Viagra) works in diabetics, vascular disease, nerve-sparing radical prostatectomy and some improvement in spinal cord injury (7). There is no clinical studies researching the incidence of erectile dysfunction and Chronic Low Back Pain (LBP) or the effectiveness of Sildenafil citrate in patients that have erectile dysfunction and LBP. The objective of this study was to determine the effectiveness of Sildenafil citrate on erectile dysfunction in patients with Chronic LBP.

### Method

Nineteen male subjects with chronic low back pain were enrolled in an 4-week single-center study. Patients were given nine 50mg tablets and instructed to try 50mg and 100mg tablets and to keep a diary of their success in reaching erection, penetration, and orgasm. Subjects were also surveyed on their use of narcotics and antidepressants.

### Results

Seventeen subjects were on a narcotic and thirteen were on an antidepressant. Fifteen subjects completed the study. Twelve of the subjects were able to reach orgasm with either 50 mg or 100mg of Sildenafil citrate. Only two subjects experienced mild side effects

### Conclusion

Sildenafil citrate is an effective treatment for this problem in this population.

The goal of medicine is to improve, reestablish or maintain quality of life. Multiple factors go into what we call quality and each patient determines this. Most can agree that contributors to this quality include mobility, minimal daily pain, restful sleep, sexual functions, growth and development, mental well-being and emotional relationships. In our effort to treat pain and improve quality, we must continue to treat the whole person. Sexual problems are widespread in the United States. Ten to fifty-two percent of American men experience sexual dysfunction. There is a strong association between erectile dysfunction and decreased quality of life. There is no change on quality of life noted in patients experiencing premature ejaculation. Those who do experience emotional or stress-related problems are more likely to experience sexual dysfunction. Erectile problems increase in incidence with increasing age, along with a decrease in desire for sex (1). Thirty percent of men ages 40 to 70 years of age experience some form of erectile dysfunction. Seventy percent of these men experience erectile dysfunction because of an organic cause (2).

A complete history and physical should be performed before any treatment is begun. Causes of erectile dysfunction fall into four categories, psychogenic, neurogenic, vascular and endocrine. Psychogenic testing begins by testing for nocturnal erections. A Rigiscan can be performed at home. The Rigiscan measures firmness throughout the night. It is a simple test for erections during sleep. Erections occur during sleep normally. If erections continue to occur while asleep, but the patient cannot achieve an erection while awake, he is experiencing psychogenic impotence. Further evaluation would be necessary by a mental health professional. Neurogenic causes are tested by electromyography of the corpus cavernosum. Endocrine testing includes serum testosterone, serum prolactin and serum luteinizing hormone. However, these levels are rarely low in erectile dysfunction and are usually not the cause. This is the reason

insurance companies do not want to pay for lab testing for erectile dysfunction. Evaluation for vascular problems is done by history and injection of a vasoactive drug. A vascular cause is rare and usually occurs with trauma. The most diagnostic screen is to evaluate the response to intracavernous injections of vasoactive drug. An inadequate response indicates a vascular impotence. It is not necessary to perform all tests. Many physicians feel that after the history and physical, an initial trial of Sildenafil citrate is adequate preliminary testing. If the patient is unresponsive to Sildenafil citrate, further testing is warranted (3).

Treatment options include penile prosthesis, vacuum erection devices, sex therapy, injection and intraurethral therapy, surgery, hormone therapy for low levels and oral medications. Oral medication is indicated for organic and psychogenic erectile dysfunction. An older, less effective treatment is Yohimbine (4). Viagra (sildenafil citrate) was introduced to the general public March, 1998 (5). In clinical trial currently are Uprima (apomorphine hydrochloride) and Vasomax (phentolamine). Uprima is a sublingual central dopamine stimulant (6). Vasomax is an alpha-adrenergic blocker, similar to the action of Yohimbine, but hopefully more effective (4). Other drugs in development include Vardenafil and Cialis. Both increase blood flow. Cialis is made by Lilly and is supposed to work faster (10-15 minutes) and lasts 24 hours. Alprox-TD is in trial. It can be injected or used in suppository form (6).

Within the first eight months of the introduction of Sildenafil citrate to the United States, six million prescriptions were written. This is an indication of the demand for treatment of sexual dysfunction. Sixty-five percent of users of Sildenafil citrate were overall satisfied with the drug. Men with severe erectile dysfunction were satisfied 41 percent. People who attempted intercourse were successful 69 percent of the time. Sildenafil citrate works in men with psychogenic erectile dysfunction and erectile dysfunction caused by organic reasons. Sildenafil



citrate works in diabetics, vascular disease, nerve-sparing radical prostatectomy and some improvement in spinal cord injury (7).

Those who do experience emotional or stress-related problems are more likely to experience sexual dysfunction (1). Chronic Pain Syndrome is a combination of symptoms including pain, fatigue, insomnia, depression and anxiety. Any of these problems alone can cause emotional or stress-related problems that can lead to sexual dysfunction. Chronic back pain is a type of pain that leads to the Chronic Pain Syndrome. There is no clinical studies researching the incidence of erectile dysfunction and Chronic Low Back Pain (LBP) or the effectiveness of Sildenafil citrate in-patients that have erectile dysfunction and LBP. The objective of this study was to determine the effectiveness of Sildenafil citrate on erectile dysfunction in patients with Chronic LBP.

## Methods

### Design

A quasi-experimental design was used. The study was open-labeled. The trial was conducted in a single-center with flexible dosing. There was a four-week screening and four-week trial period. Subjects received treatment on an outpatient basis. For the two required in-clinic visits, subjects reported to the clinic. Visit one occurred during a visit to the clinic for another reason. Subjects were instructed to complete treatments in four weeks and the final visit was scheduled at visit one for four weeks later.

### Sample

A convenience sample of 19 subjects was recruited from subjects visiting the clinic for treatment of chronic low back pain. Male patients, at least 18 years or older, with the clinical diagnosis of chronic back pain were screened for the study. Male outpatients were given the Sexual Health Inventory for Men, (SHEM) (8) and a questionnaire regarding their history of sexual health and pain and pain treatments. Chronic low back pain is considered anyone with low back pain for duration of six months or longer. The average age of the subjects was 49 years with an average of 12.4 years of pain. Seventeen subjects were on a chronic narcotic. Five subjects were on a fentanyl patch, seven were using a morphine compound, four were on Oxycontin or Lortab and 2 were on another narcotic. Thirteen were on an antidepressant. Four were on Wellbutrin. Four were on an SSRI and seven were on another antidepressant.

### Inclusion Criteria

A subject was eligible for inclusion in the study if all of the following criteria were present:

1. Patient is diagnosed with chronic low back pain
2. Patient is male and over the age of 18.
3. Patient experiences erectile dysfunction (scores 21 or less on SHEM).

### Exclusion Criteria

A subject was excluded from participation in the study if any of the following were present:

1. Patient takes medication containing nitrites.
2. Significant cardiovascular event in the previous six months.
3. Uncontrolled hypotension (SBP less than 100 and/or DBP less than 50)
4. Uncontrolled hypertension (SBP greater than 190 and/or DBP greater than 100).

### Treatment

All subjects were given nine Sildenafil citrate 50mg tablets. Tablets were provided open-label sample cards from the sponsor, Pfizer.

Subjects were instructed to use one 50mg tablet 30 minutes up to four hours prior to desired sexual activity. They were also instructed that consumption of a high-fat meal might extend the time of onset. Subjects were instructed that sexual stimulation is required for erection.

If the 50mg tablet was effective to cause erection (stage 1), penetration (stage2), and orgasm (stage 3) the subject was instructed to continue with 50mg tablets for four more attempts for a total of five attempts.

If stage 3 was not reached, the subjects were instructed to increase to two 50mg tablets for four more attempts. The subjects recorded the results of each attempt on the sexual diary.

The study consisted of two required visits to Oliver Headache & Pain Clinic. Visit two occurred four weeks after enrollment and drug dispersal. Subjects returned their diary on visit two. The results were reviewed and patients were given prescriptions if they wished to continue the Sildenafil citrate.

#### Data Collection

Information was collected by subject interview, subject questionnaire and physical examination and entered on a data sheet for visit one and two. Subjects collected ongoing data on the sexual diary with each treatment. An individual registered nurse working for the clinic monitored data collection.

#### Results

Nineteen subjects were enrolled in the four-week enrollment period. Fifteen subjects returned for visit two and four were lost to follow-up. Of the fifteen subjects who completed the study, twelve reached stage 3. Ten reached it with Sildenafil citrate 50mg. Two more reached it with Sildenafil citrate 100mg. Three did not reach stage 3 at all.

Overall there were 34 attempts at sex with 50mg tablets. Of the 34 attempts, 20 were successful. There were 31 attempts at 100mg with 24 successful at reaching stage 3.

Two subjects experienced side effects. One experienced transient color-blindness and sensitivity to light. The other experienced facial flushing and a hot sensation of his entire head.



### Discussion

The study conclusions are limited due to the small sample. In order to generalize to a large population, it is recommended that a larger, multi-site study be conducted.

In a single-center, single-physician pain practice, nineteen men with chronic low back pain and erectile dysfunction were discovered in one month's time. Chronic pain syndrome affects many aspects of life, including sexual function. It is important to treat all of the problems, as well as the pain. Eighty percent of the subjects were able to reach orgasm with Sildenafil citrate. There is no way to determine an absolute cause of erectile dysfunction in this population, whether it was chronic pain, chronic narcotic use, antidepressant use or a non-organic reason. However, this population did find success.

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