

## PREVENTION OF TADALAFIL INDUCED BACKACHE IN ERECTILE DYSFUNCTION PATIENTS

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### ABSTRACT

Back pain is a known side effect associated with tadalafil use in erectile dysfunction patients. This is a unique and first of kind study that deals with its prevention.

#### AIMS AND OBJECTIVES

To prevent discontinuation of tadalafil in needy patients with erectile dysfunction due to back pain.

#### MATERIALS AND METHODS

Among 956 erectile dysfunction patients started on tadalafil 10 mg daily in an outpatient clinic over 2 yrs., 79 patients discontinued due to back pain. They were restarted with tadalafil 10 mg daily and two add-on drugs (Combination) for initial three days. The observations were noted.

#### RESULTS

This add-on regimen was 96.2% successful in preventing tadalafil induced backache when tadalafil was reintroduced.

#### CONCLUSION

Tadalafil discontinuation due to back pain can be avoided in needy erectile dysfunction patients by following this add-on regimen for just three days.

#### KEYWORDS

Back Pain, Tadalafil, Erectile Dysfunction.

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#### INTRODUCTION

Back pain along with pain radiating to legs/myalgia on taking tadalafil is a known adverse event associated with tadalafil use. In a patient already stressed with erectile dysfunction, this side effect causes severe mental distress. According to research by Adsetel et al., all radiological and biochemical investigation performed during or after the back pain or myalgia were normal. Increased blood supply due to PDE5 (Phosphodiesterase 5) suppression was the postulated mechanism and usual onset was within 24 hrs. of taking tadalafil (12 to 24 hrs.) and back pain or myalgia were relieved within 48 hrs. (24 to 48 hrs.).<sup>[1]</sup> But in a day-to-day practice, some patients could not tolerate this back pain or myalgia and discontinued tadalafil.<sup>[2,3,4]</sup> In these patients successful reintroduction of tadalafil without this distressing back pain or myalgia with the help of two add-on drugs (Combination) was attempted in this study.

#### METHODS

This study was conducted over a two-year period Feb. 2014 to Jan. 2016 in a sexology outpatient clinic. Since back pain is a known side effect of tadalafil, patients with previous history of back pain were excluded from this study.

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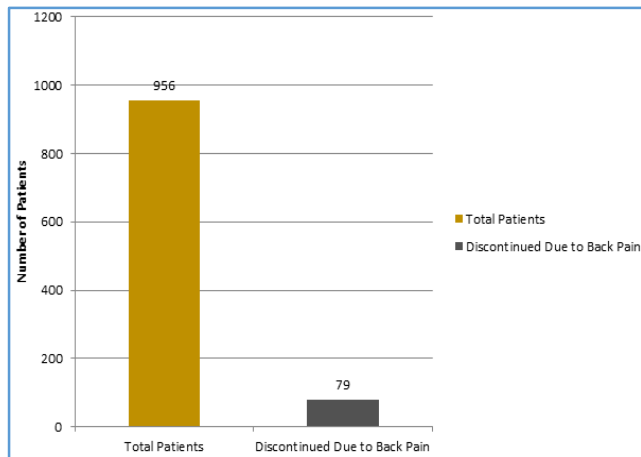
During this period among 956 patients started on tadalafil 10 mg daily for their erectile dysfunction after baseline investigation, those who developed back pain or myalgia with tadalafil and wanted to stop the drug in spite of repeated reassurance that pain is self-limiting were segregated. They were asked to stop the drug. In this two-year period, the total number of patients who stopped taking tadalafil due to this were 79. All these 79 patients did not have any history of back pain before taking tadalafil. In these patients after a drug wash over a period of one week, the back pain or myalgia was completely relieved. Reintroduction of tadalafil 10 mg daily was attempted along with 1. Aceclofenac 100 mg + Chlorzoxazone 250 mg + Paracetamol 325 mg combination and 2. Pantoprazole 40 mg + Domperidone 10 mg combination (In empty stomach) for the initial three days. The results were tabulated. See Table 1 and 2 and Chart 1 and 2.

#### RESULT

Out of 79 patients 55 were married, 12 unmarried, 7 separated and 5 divorced. They were in the age group of 24 to 35 years. Two patients (2.53%) discontinued due to unknown reasons and one patient (1.27%) discontinued due to gastrointestinal irritation probably induced by Aceclofenac. Among the rest 76 patients (96.2%), none of them developed back pain or myalgia again and are on tadalafil still. See Table 3 and Chart 3.

No.	Particulars	Number of Patients
1	Total Number of Patients on Tadalafil 10 mg over a two-year period	956
2	Patients who Discontinued due to back pain	79

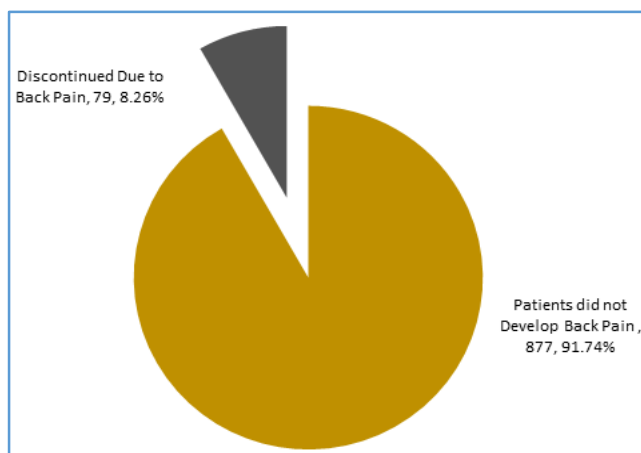
**Table 1: Table showing the Total Patients and the Patients who Discontinued due to Back Pain**



**Chart 1: Chart showing the Total Patients and the Patients who Discontinued due to Back Pain**

No.	Particulars	Number of Patients
1	Patients did not develop back pain	877
2	Discontinued due to back pain	79
	<b>Total</b>	<b>956</b>

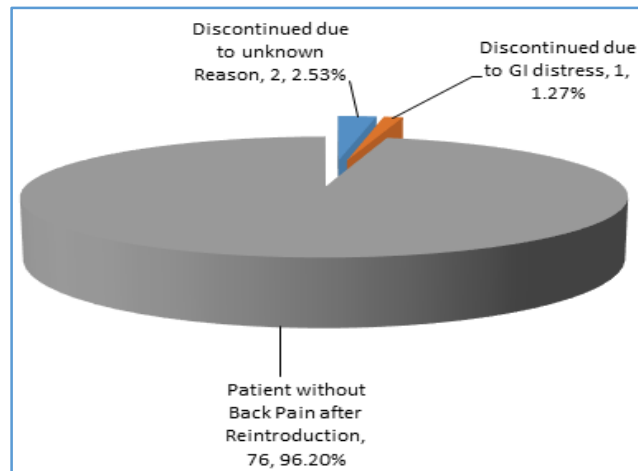
**Table 2: Table showing the Patients who Discontinued due to Back Pain and those who did Not Develop Back Pain**



**Chart 2: Chart showing the Patients who Discontinued due to Back Pain and those who did Not Develop Back Pain**

No.	Particulars	Number of Patients	Percentage
1	Discontinued due to unknown reason	2	2.53
2	Discontinued due to GI distress	1	1.27
3	Patient without back pain after reintroduction	76	96.20
	<b>Total</b>	<b>79</b>	<b>100.0</b>

**Table 3: Table showing Patients who Discontinued and those who Continued after Reintroduction**



**Chart 3: Chart showing those Patients who Discontinued and those who Continued after Reintroduction**

**DISCUSSION**

In a male potency is a synonym for masculinity. Patients who have erectile dysfunction, particularly in Indian setup are further confused by lots of myths and misconceptions about sex. This adds on to their problem. In this scenario when they develop back pain or myalgia with tadalafil, it definitely increase their emotional distress further.<sup>[2,5]</sup> In spite of repeated reassurances and explanation that this pain is self-limiting (Adseftel et al.), their fear is difficult to alleviate.<sup>[1]</sup> So they were allowed to discontinue the drug with an explanation that symptoms are due to increased blood supply (Adseftel et al.) and it will stop once the drug is discontinued.<sup>[6,7,8]</sup>

They were then individually explained the benefits of tadalafil versus side effects and reassured that restarting tadalafil along with the two add-on drugs Aceclofenac 100 mg + Chlorzoxazone 250 mg + Paracetamol 325 mg combination and 2. Pantoprazole 40 mg + Domperidone 10 mg will prevent back pain or myalgia. Research by Samuel et al. put the discontinuation rate due to side effects of tadalafil was between 1 % to 6%.<sup>[5,9]</sup> Research by Carson et al. showed that 11% of patients developed back pain with 10 mg of tadalafil.<sup>[3]</sup> Other research by Carson et al. and Montorsi et al. put discontinuation rate due to total adverse events as 3.2% and 6.4% respectively.<sup>[3,4]</sup>

The relative high affinity of tadalafil for phosphodiesterase 11, an isoform found in skeletal muscle is considered to be related to the higher incidence of back pain or myalgia in patients on tadalafil according to research by Samuel Washington et al.<sup>[5]</sup> Though research say this back pain is self-limiting, Adseftel et al.<sup>[1,8]</sup> Psychiatrists, sexologists and urologists must definitely pay attention to the emotional distress associated with back pain, particularly when it develops in a patient already suffering from erectile dysfunction. This is much more important in an Indian scenario filled with myths and misconceptions about sex, which further complicates the problem.

**CONCLUSION**

This study concludes that discontinuation rates due to back pain associated with tadalafil use in erectile dysfunction is high in Indian population and this causes further distress to the patient. By adding a simple regimen of these two drugs

for only three days, the patient will be able to avoid back pain and also improve his erection, thereby retaining the marital bliss.

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