Non pigmented mucosal fixed drug eruption due to tadalafil: A report of two cases

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ABSTRACT

Various ‘sex-stimulant’ medicines with fancy names and attractive packaging are available over the counter. Most contain phosphodiesterase 5 inhibitors in various strengths, often with herbal additions. These drugs are used erratically by the lay public, driven by folklore that such usage leads to increase in the length, girth or firmness of the penis. Such indiscriminate use by an otherwise healthy population leads to undue side effects.

Key words: Fixed drug eruption, sexual stimulant, tadalafil

INTRODUCTION

Various ‘sex-stimulant’ medicines with fancy names are available over the counter. Most contain tadalafil or sildenafil in various strengths, often with herbal additions. These also come in attractive packages to lure potential clientele. These drugs are used erratically by the lay public, driven by folklore that such usage leads to increase in the length and girth of the penis, the firmness of the penis and so on. Such indiscriminate use by an otherwise healthy population leads to undue side effects. Herein, we report two cases of mucosal fixed drug rash due to tadalafil, which we believe to be the second and third reports respectively.

CASE REPORTS

Case 1

A 36-year-old married male presented to our clinic with complaints of few confluent and mildly itchy blisters on the glans penis for one day. The blisters had appeared a day after having protected sexual intercourse with his wife. There was mild fever along with the specified symptoms. On further questioning the patient recalled that he had three similar episodes at the same site about one, two and four months ago. For these he did not seek medical attention since they healed spontaneously without any sequela. On further query, the patient correlated all four episodes of penile blistering with prior intake of an oral sex stimulant medication that he had procured over the counter (OTC).

On examination, skin colored blisters of different sizes were noted on the glans penis [Figure 1] covering an area of 3 cm × 2 cm. The blisters stood on a slightly erythematous base and few of the blisters had coalesced to form larger ones. On palpation the lesion was non-indurated but mildly tender. Rest of the mucocutaneous examination was normal. There was no local or generalized lymphadenopathy. Systemic examination was non-contributory and tests for VDRL, herpes simplex (1 and 2) and human immunodeficiency virus (1 and 2) were negative. We advised a biopsy of the area which the patient declined. Based on the history and clinical findings, we made a diagnosis of fixed drug reaction. The patient furnished a sample of the suspected medicine and also brought his wife for history taking and examination. We prescribed a low potent topical steroid and told him to avoid using the medicine in future.

After one week, the lesions had healed without any residual pigmentation. We found that the medicine contained 10 mg of tadalafil along with herbal ingredients. Patch test over the healed area with the medicine (containing both the tadalafil as well as the herbal ingredients) was negative. The patient declined an oral challenge...
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Figure 1: Several skin colored blisters of different sizes on the glans penis. Few of the blisters had coalesced to form larger ones

test. The Naranjo adverse drug reaction probability score[1] indicated a probable association between medicine intake and the penile lesions.

Case 2
A 17-year-old young Bengali male presented with complaints of a mildly painful ulcer over the tip of the tongue [Figure 2]. The current episode was the fifth, the first episode having occurred six weeks ago. The patient stated that he used to have some medicine before having protected intercourse with his steady girlfriend, as he considered his penis to be too small. He discovered these ulcerations occurred at exactly the same place, each time after intake of medicine and resolved on its own. On further inquiry, he stated that he used to buy these medicines over the counter from a local drug store on the advice of a neighbor. He denied having ever having oro-genital intercourse.

Examination revealed an erosion on the tip and right border of the tongue, 2 cm × 2 cm with a well defined erythematous border and central white slough on the floor. On palpation, the border was slightly tender, but not indurated. The examination of the rest of the skin, mucous membranes and systemic examination including the lymph nodes was normal. Venereal Disease Research Laboratory test, and serology for herpes simplex (1 and 2) and human immunodeficiency virus (1 and 2) was normal. The patient did not consent for a biopsy; history and examination of his girlfriend revealed nothing significant. We diagnosed the condition to be FDE due to tadalafil and instructed him to avoid medicines containing the same.

The Naranjo adverse drug reaction probability score[1] indicated a ‘probable’ association between medicine intake and the oral lesions.

DISCUSSION

Fixed drug eruption (FDE) is considered a form of delayed-type hypersensitivity, mediated by CD8+ T cells. It is characterized by single or multiple, sharply demarcated, pruritic, erythematous, nummular plaques. FDE occurs when patients become sensitized to a particular drug or its metabolites. Intermittent drug administration is more likely to cause sensitization than continuous administration.[2] FDE can develop from 30 minutes to 8 to 16 hours after ingestion of the medication.[3] More than 100 drugs have been implicated in causing FDEs.[3] A challenge or provocation test with the suspected drug may be useful in establishing the diagnosis. Patch testing at the site of a previous lesion yields a positive response in up to 43 percent of patients.[3]

Both tadalafil and sildenafil are phosphodiesterase 5 (PDE5) inhibitors, which help men with erectile dysfunction (ED) obtain and sustain an erection. However, these drugs have adverse effects.[4] Unfortunately, in this country, both of tadalafil and sildenafil have become available widely as OTC medicine and are being randomly used by unsuspecting clients to fulfill varied sexual expectations. We were able to find only one report of fixed drug eruption due to use of tadalafil in the literature.[4] We therefore present these two cases of FDE as the second and third of the same. We re-emphasize here the importance of regulation of sale of these drugs on only prescription basis.

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