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RESEARCH ARTICLE

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A Real-World Clinical Study of First-Time User of OC-01 (Varenicline Nasal Spray- Tyrvaya) For Dry Eye Disease-The Compliance and Acceptability

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Abstract

Purpose: To investigate the compliance and acceptance of first time using nasal spray OC-01 (Tyrvaya) for dry eye in order to study the potential strategy to improve the usage.

Method: Twenty patients with DED either having resistance to eye drops therapy or having difficulty applying eye drops were included from January 2023 to July 4, 2023.

A sample of one bottle of Varenicline was given to patients to spray both nasal cavities two times a day for two weeks. Detailed instructions and possible side effects were given according to the pharmaceutical pamphlets.

The second bottle was given to those patients who stopped for the first bottle for the second chance to try.

Questionnaire consisted of the following questions:

1) In two weeks did you stop the treatment? If you did stop and cannot continue, what was the reason?

2) were your dry eye symptoms being less and you can accept this treatment and continue?

3) How did the second bottle work?

Result: Out of 20 patients, 18 responded (90%). 56% had good response with either mild side effect or can tolerate well and experience improvement in dry eye. 44% had poor response with sneezing, cough, nasal irritation resulting in abandoning the nasal spray. The second bottle improved the discontinue rate to 17%and good response rate to 83%. There was 1.1% lost follow up.

Conclusion: The first-time successful rate of using nasal spray of Tyrvaya is about 56%. The discontinuation rate was about 44%. Second bottle with further education had better successful rate. The discontinuation rate improved to 17% and the successful rate to 83%. Education and reinforcement may increase the acceptance and compliance for patients who are indicated for the medication.

Introduction

Dry Eye Disease (DED) is a multi-factorial disease [1]. As population's ages increasing complicated by computer usage, systemic disease and medications, more and more people have DED with or without symptoms. DED symptoms such as blurred vision, tearing, sandy feelings and itchiness can be bothersome [2-4].

Varenicline 0.03mg nasal spray (Tyrvaya) is believed to bind nicotine acetylcholine receptors in the nasal cavity of terminal branches of trigeminal nerves to stimulate endogenous tear *via* efferent parasympathetic inner action [5].

The studies published by Oyster pharmaceutical in 2021 and were approved by FDA [6].

Various treatment options are available but mostly need to use eye drops and ointment. Some may be expensive and may not be effective. Many patients cannot apply eye medication due to hand disability. Moreover, patients who have severe superficial cornea disease are due to multiple eyes drops that have preservatives for glaucoma. Therefore, a nasal spray to treat dry eye disease was developed to eliminate or reduce eye medication to further irritate superficial cornea.

It was reported to have fast effectiveness and can stimulate your own tear of all three layers such as mucus, aqueous, and lipid.

FDA has approved the Tyrvaya nasal spray based on clinical trials that have demonstrated efficacy and safety [7-9]. However, many first -time patients had difficulty applying the spray for various reasons. This study intended to survey the percentage and the reasons for

rejection. After analyzing the reasons for the rejections, suggestions were developed to reduce the resistance of the spray for those patients who are indicated to use the medication to treat DED.

Method

Twenty patents with DED either having resistance to eye drops therapy or having difficulty applying eye drops were included from January 2023 to July 4, 2023.

A sample of one bottle of Varenicline was given to patients to spray both nasal cavities two times a day for two weeks. Detailed instructions and possible side effects were given according to the pharmaceutical pamphlets.

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Questionnaire consisted of the following questions:

1) In two weeks did you stop the treatment? If you did stop and cannot continue, what was the reason?

2) were your dry eye symptoms being less and you can accept this treatment and continue?

3) How did the second bottle work?

Demographic: There were six male and fourteen female subjects, and the age were between 39 to 88 years old. All of them were Asian.

Results

Out of 20 patients, 18 responded (90%). 56% had good response with either mild side effect or can tolerate well and experience improvement in dry eye. 44% had poor response with sneezing, cough, nasal irritation resulting in abandoning the nasal spray. The second bottle improved the discontinue rate to 17% and the successful rate improved to 83%. There was 1.1% lost follow up (Figure 1).

Discussion

The studies published by Oyster pharmaceutical in 2021 and were approved by FDA [6]. According to the studies, 82% of patients reported at least one sneeze during the trial. However, 98% reported it as mild and 65% of sneezing resolved within one minute. 16% had coughed, 13% had throat irritation and 8% had nasal irritation. The discontinuation rate was 2%.

In our real time clinical study as the first-time user, the adverse reactions were higher, and the discontinuation rate was much higher. There were several reasons why the rejection of this nasal spray.

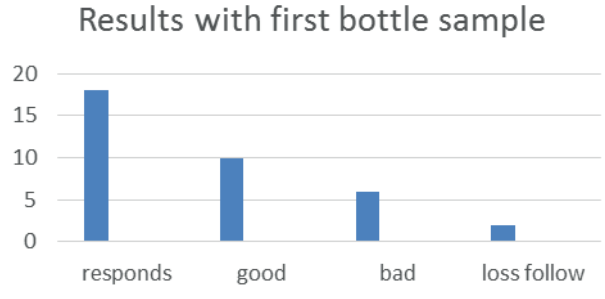

Figure 1: Results with first bottle sample.

Due to this is a brand new and the first time using the spray for eye, many patients did not know how to use properly and experiencing there was no spray came out. Detailed education with on-site demonstration and instruction of avoiding shake bottle and need to prompt 7 times of spray and perform a heavy push at last spray. Secondly many patients did not like and cannot tolerate the sneezing. Perhaps to exclude patients who have nasal diseases.

Those who experienced burning in nose, we proposed placing nasal spray in refrigerator.

The cost is also a big issue, coupons and pre-authorization from insurance companies can reduce the burden.

After further education with the second bottle the discontinuation rate decreased by 16%. Patients having nasal allergies and poor understanding may have more difficulties. Carefully select patients with detailed education and longer repeat trials may improve acceptability. Perhaps treating underlying nasal disease first may also help.

Those patients may be indicated for this nasal spray is patients with hand arthritis, handicaps who have difficulty in still eye drops to eyes. Patients with blepharospasm can also benefit from the nasal spray. If eye drops for dry eye did not help enough to relieve the symptoms and signs of superficial cornea diseases such as glaucoma and diabetics patients who are on multiple eye drops.

Further study may find better compliance and usage if education emphasizes the benefits of this special pathway.

Conclusion

The first-time successful rate of using nasal spray of Tyrvaya is about 56%. Second bottle with further education had better successful rate. Education and reinforcement may increase the acceptance and compliance for patients who are indicated for the medication.

The sample bottles of Tyrvaya were provided by Oyster pharmaceutical.

I have no financial interest to disclose.

Institutional ethics committee clearance was not done.

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