PCCA LoxaSperse®

Chronic Rhinosinusitis

SUMMARY: An adult female suffering from chronic rhinosinusitis was prescribed a compounded medicine post endoscopic sinus surgery. According to the patient's self-reported assessment, the treatment with the compounded medicine contributed to a 100% improvement (full recovery) of the patient's chronic rhinosinusitis symptoms (e.g. nasal congestion, facial pain and headache).

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Introduction:

Chronic rhinosinusitis (also known as chronic sinusitis) is a complex inflammatory disease of the nose and paranasal sinuses characterized by at least 8-12 weeks of recurrent symptoms, such as nasal congestion and discharge (anterior/posterior nasal drip), facial pressure and/or reduction of smell, which commonly co-exists with asthma. Chronic rhinosinusitis is the second most prevalent respiratory disease among adults, women in particular, affecting 12.1% of the U.S. population and approximately 28.5 million patients. The current overall expenditure with chronic rhinosinusitis has been recognized as a socioeconomic burden, considering the number of work days missed, office visits, surgical interventions (e.g. endoscopic sinus surgery) and medicines prescribed [1-3].

The purpose of this case study is to discuss the management of chronic rhinosinusitis using a LoxaSperse compounded medicine. LoxaSperse is a proprietary powder excipient used in compounding for nasal nebulization or nasal and wound irrigation (Figure 1). Multiple active ingredients are often combined with LoxaSperse in the form of capsules or sachets to be mixed with saline or sterile water prior to use [4].

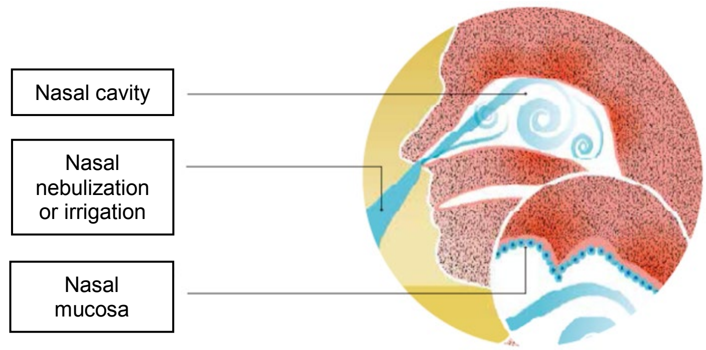

Figure 1. *Schematic representation of the nasal cavity, nasal nebulization or irrigation and the nasal mucosa.*

Levofloxacin hemihydrate USP	12.800 g
Mupirocin USP	10.000 g
Fluticasone propionate USP micronized	0.300 g
LoxaSperse®	22.994 g
Capsules size #0	100 units

Figure 2. *Compounded medicine prescribed post-surgery (PCCA Formula #11657).*

Case Report:

A 59 year-old Caucasian female has been suffering from chronic rhinosinusitis for 20 years and was subjected to 3 endoscopic sinus surgeries in the years of 2001, 2009 and 2013. The patient is asthmatic and her condition deteriorates with the asthma exacerbations. Several commercial medicines (e.g. Claritin-D®) were used throughout this long period without success. Approximately 2 weeks following the third surgery, the patient was prescribed a compounded medicine containing levofloxacin 125 mg, mupirocin 100 mg and fluticasone propionate 3 mg in LoxaSperse (Figure 2) – capsules to be opened prior to dosing, mixed with sterile saline and administered using a NasoNeb® Nasal Nebulizer, an intranasal drug delivery system which delivers aerosols to the nasal and paranasal sinus cavities (Figure 1) [5]. The patient was instructed to administer the compounded medicine 3 times daily, for a period of 8 months (post-surgery). The patient observed that her chronic rhinosinusitis symptoms, such as headache, congestion and posterior nasal drips, improved considerably following treatment with the compounded medicine (Figure 2).

Methodology:

Valid and reliable assessment of outcomes is essential in scientific case studies and, therefore, 2 validated research instruments were selected, as follows:

1. *Numeric Rating Scale (NRS)*: a generic, unidimensional, self-reported questionnaire that consists of a segmented, 11-point intensity scale (from 0 to 10). The raw change and percent change are calculated taking into account the baseline and endpoint scores selected by the patient. The NRS is commonly used to assess pain [7] and it was adapted in this case study to measure the overall severity of the chronic rhinosinusitis symptoms, before and after treatment with the compounded medicine.

2. *Sino Nasal Assessment Questionnaire (SNAQ) 11*: a patient focused, rhinosinusitis specific outcome measure that consists of a multidimensional 11-point assessment.

This self-reported questionnaire covers a list of symptoms and social/emotional consequences often found in chronic rhinosinusitis. Patients are invited to classify their level of problem as follows: no problem (n=0), very mild problem (n=1), mild problem (n=2), moderate problem (n=3), severe problem (n=4) and problem as bad as it can be (n=5). The first three questions (i.e. nasal blockage, congestion and facial pain) are depicted as the most relevant and, therefore, the individual scores are multiplied by 3 or 2. All other questions (e.g. sneezing, cough, headache) have a maximum score of 5. As a result, the SNAQ-11 total score range from 0 (completely asymptomatic) to 80 (worst possible symptoms) [8]. Written permission was obtained to use the SNAQ-11 for scientific purposes, copyright by F.F. Fahmy (United Kingdom). Written informed consent was obtained from the patient to publish this case study.

Results and Discussion:

The patient reported a NRS baseline score of 10, which corresponds to the worst possible chronic rhinosinusitis symptoms (before treatment); and an endpoint score of 0, which corresponds to no chronic rhinosinusitis symptoms (after treatment). The NRS raw change (baseline to endpoint) of 10 points indicates a 100% improvement of the chronic rhinosinusitis symptoms, according to the patient's self-reported assessment. Considering that 30% is the minimum level of change that represents a clinically important outcome [7], this study results demonstrate that the compounding treatment contributed to a significant clinical improvement of the patient's chronic rhinosinusitis symptoms.

The patient completed all questions of the SNAQ-11 questionnaire (adapted), before and after treatment with the compounded medicine, as displayed in Table 1.

Parameters	*Score (n) Before*	*Score (n) After*
Blocked nose	3 (x3)	0
Nasal congestion	5 (x3)	0
Facial pain	5 (x2)	0
Nasal discharge	5	0
Phlegm	5	0
Sneezing	5	0
Cough	5	0
Altered smell	5	0
Headache	5	0
Earache	4	0
Fatigue	4	0
Total	72	0

Table 1. *SNAQ-11 scores, individual and total, before and after treatment with the compounded medicine.*

Before treatment with the compounded medicine, the patient classified her symptoms as 'bad as can be' (n=5) for the majority of the questions, with the exception of blocked nose, earache and fatigue (Table 1). The total score of 72 corresponds to 90% of the maximum score of 80, which indicates a very severe problem, according to the patient's self-reported assessment of her condition.

After treatment with the compounded medicine, the patient classified all her symptoms as 'no problem' (n=0), as displayed in Table 1. The total score decreased from 72 pre-treatment to 0 post-treatment, which corresponds to an improvement of 100% and suggests a full recovery of the chronic rhinosinusitis symptoms, according to the patient's self-reported assessment of her condition.

Conclusions:

A valid and reliable assessment of outcomes is essential in scientific case studies and requires the use of validated research instruments for a meaningful estimate of treatment outcomes. To demonstrate the effectiveness of a compounded medicine in chronic rhinosinusitis, both NRS and SNAQ-11 validated questionnaires were used. According to the patient's self-reported assessment, the treatment with the compounded medicine contributed to a 100% improvement (full recovery) of the patient's chronic rhinosinusitis symptoms.

References:

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