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Research Article

Rexoflus® As Novel Potential Therapeutic Option for The Treatment of Gastroesophageal and Laryngopharyngeal Reflux Disease

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Abstract

Background: Gastroesophageal reflux disease (GERD) and laryngopharyngeal reflux disease (LPRD) are two common pathologies with a high diffusion in the world population. Symptoms reduction in GERD and LRPD can be effectively achieved by combining pharmacological treatment with non-pharmacological ones and dietary improvements. REXOFLUS® is a medical device composed of a patented blend of polysaccharides combined with antacid components. It is indicated for the treatment of gastroesophageal and laryngopharyngeal reflux reducing associated symptoms. This study aimed to evaluate the effect of the medical device REXOFLUS® on GERD and LPRD.

Aim and Methods: The present observational clinical survey was designed to evaluate the effects of the medical device REXOFLUS® on 51 patients, both as a standalone treatment for GERD and LPRD episodes or in combination with PPI therapy, over the entire duration of treatment, investigating its effectiveness and safety.

Results: Rexoflus® treatment after one month reduced the main parameter of reflux diseases according to two different questionnaire used RSI and GIS score. Moreover, the association of Rexoflus® with PPIs showed an improved reduction in the GIS score without showing any side effect.

Conclusions: These results represent an optimum starting point and, after a more complete clinical investigation, if the data will be confirmed, it could be possible to consider Rexoflus® as novel therapeutic tool for GERD and LPRD.

Kew Words: gastroesophageal reflux disease (GERD), laryngopharyngeal reflux disease (LPRD), polysaccharides, antacid

Introduction

The gastroesophageal reflux disease (GERD) is considered as one of the most prevalent diseases of the intestinal tract. In particular, this pathology is associated to abnormal presence of the gastric contents into the oesophagus. In recent decades, approximately 18,1% to 27,8% of the population has experienced symptoms of GERD [1].

The primary symptom related to GERD is the heartburn which occurs in 20% to 40% of patients. The other characteristic symptoms are dysphagia and chest pain. In some cases, patients can also be also affected by excessive salivation, odynophagia and nausea [1].

Many of these symptoms are triggered by an unbalanced diet, unhealthy lifestyle habits, the presence of comorbid conditions such as obesity and the use of drugs such as anticholinergics, antidepressants and inhaled bronchodilators [2].

Reflux-related damages can range from mild cases of esophagitis to the development of oesophageal adenocarcinoma. Esophagitis occurs in excessive reflux of gastric acid and pepsin leads to necrosis of the superficial layers of the oesophageal mucosa, resulting in mucosal

erosions and ulcerations. If not appropriately managed, this condition may progress to oesophageal adenocarcinoma [1].

Another common form of reflux is laryngopharyngeal reflux disease (LPRD) and this condition arises when acidic stomach contents reach the throat, specifically the laryngopharynx, due to dysfunction of the normal ciliated respiratory epithelium of the posterior larynx [3].

Due to absence of specific symptoms, it is difficult to diagnose LRPD in patients. Anyway, this pathological condition is often associated to no-specific manifestations such as sore throat, chronic throat clearing and dysphonia [4].

If LRPD is untreated, this condition can lead to different complications such as laryngeal granulomas and vocal cord polyps. Unlike GERD which commonly happens in supine position at night with impaired esophageal peristalsis and excessive gastric acid content, LRPD occurs when the patient is upright and [3-4].

Symptoms reduction in GERD and LRPD can be effectively achieved by combining pharmacological treatment with dietary improvements [5].

The pharmacological treatment of these pathologies is based on the use of drugs able to inhibit gastric acid secretion. It has been well established that the reduction of gastric acidity can lead to a significant decrease of reflux symptoms in order to preserve the integrity of intestinal mucosa [5].

Two different classes of drugs are used for this purpose like proton pump inhibitors (PPIs) and histamine H2- receptor antagonists (H2RAs) [5].

The PPIs class which includes omeprazole, pantoprazole, esomeprazole, lansoprazole and rabeprazole, act through the inhibition of proton pump H^+/K^+-ATPase, in order to limiting the production of hydrochloric acid [5-6].

Instead, the H2RAs are able to reduce the acid secretion because they block histamine H2 receptors located on gastric parietal cells, thus targeting an earlier step in the acid synthesis pathway [5-7].

Nevertheless, a massive use of PPI by a long-term therapy useful for the treatment of GERD and LRPD which can lead to different adverse effects. In particular, this pharmacological treatment could provoke headache, dizziness and other gastrointestinal diseases like diarrhea and constipation [3].

Additionally, it has been observed that up to 40% of patients with GERD do not show an adequate response to PPI treatment, thus developing a specific pathological condition named refractory-GERD (r-GERD) [8].

In these cases, non-pharmacological treatments and dietary improvements can help to alleviate the GERD and LRPD symptoms through the use of food supplements and medical devices combined with the pharmacological treatments reducing side effects and improving the therapeutic efficacy [9].

REXOFLUS® is a medical device composed of a patented blend of polysaccharides combined with antacid components. It is indicated for the treatment of gastroesophageal and laryngopharyngeal reflux reducing associated symptoms such as reflux esophagitis, acid regurgitation, difficulty swallowing (dysphagia), painful swallowing (odynophagia), and heartburn.

Thanks to the mechanical action of its components, it prevents the backflow of acids and gastric contents into the oesophagus, raises gastric pH, and protects the mucosal membranes from the corrosive effects associated with reflux episodes.

For this purpose, the present retrospective observational survey was designed to evaluate the effects of the medical device REXOFLUS®, both as a standalone treatment for GERD and LPRD episodes and in combination with PPI therapy, over the entire duration of treatment, investigating its effectiveness and safety.

Materials and methods

Settings

The clinical survey has been conducted by three Italian medical specialists and is based on their clinical experience in patients taking REXOFLUS®. The retrospective observational survey was conducted in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. Data were retrospectively collected in the period February 2024 – September 2024 by the medical specialists. Ethical approval was not necessary according to National Code on Clinical Trials declaration because this data derives from a real-life retrospective study [10].

The aim of the present study was to evaluate the effect of REXOFLUS® administration alone or in combination with PPIs in patient with GERD and LPRD at T0 and after one month of treatment.

Study Population, treatment and evaluated parameters

Participants were selected according to defined inclusion criteria that were related to symptomatology typical of gastroesophageal and laryngopharyngeal reflux such as pirosis, esophagitis, cough, pharyngitis, dysphonia. A total of 51 patients met these criteria and were enrolled in the study.

At the first medical examination (T0), the doctor reported for each patient its age, gender, illness and use of PPIs. Then, the patient's clinical condition was assessed through two different standardized questionnaires: Reflux Symptom Index (RSI) and GERD Impact Scale (GIS) [11-12]. The RSI questionnaire, mainly used for laryngopharyngeal reflux, consists of 9 items covering some symptoms: hoarseness or a problem with your voice, clearing your throat, excess throat mucus or postnasal drip, difficulty swallowing, coughing after you eat or after lying down, breathing difficulties or choking episodes, troublesome or annoying cough, sensation of something sticking in your throat or a lump in your throat, heartburn, chest pain, or stomach acid coming up [11]. These ones were rated on a scale from 0 (no symptom) to 5 (severe symptom).

The GIS questionnaire, mainly used for gastro-esophageal reflux, consists of different questions as reported in table 1 with a scale for the evaluation from 1 (never) to 4 (every day) [12].

1. How often have you had the following symptoms :
a. Pain in your chest or behind the breastbone ?
b. Burning sensation in your chest or behind the breastbone ?
c. Regurgitation or acid taste in your mouth ?
d. Pain or burning in your upper stomach ?
e. Sore throat or hoarseness that is related to your heartburn or acid reflux ?
2. How often have you had difficulty getting a good night's sleep because of your symptoms ?
3. How often have your symptoms prevented you from eating or drinking any of the foods you like ?
4. How frequently have your symptoms kept you from being fully productive in your job or daily activities ?
5. How often do you take additional medication other than what the physician told you to take?

Table 1: Questions of the GERD Impact Scale (GIS).

Then, each participant administered Rexoflus® according to the method of use and posology indicated on the package leaflet (from 1 to 3 times a day) and to re-show for a follow-up visit after 1 month (T1). Some patients took only Rexoflus® as therapy (36 patients- group A), others, with higher scores at T0, took Rexoflus® in association with PPIs therapy (15 patients – group B).

At the T1 visit, the patients were again assessed by the doctor monitoring their symptomatology using for group A both RSI and GIS questionnaire as main aim of this study, and for group B only GIS questionnaire.

Results

As reported in figure 1, considering RSI questionnaire all the treated patients only with Rexoflus® showed a very interesting lowering in the symptomatology of laryngopharyngeal reflux. In fact, after only 1 month of treatment the symptomatology was controlled with a mean reduction in the RSI score of more than 50%.All the considered parameters such as hoarseness, clearing your throat, excess throat mucus or postnasal drip, difficulty swallowing, coughing after you eat or after lying down, breathing difficulties or choking episodes, troublesome or annoying cough, sensation of something sticking in your throat or a lump in your throat, heartburn, chest pain, or stomach acid coming up were all improved.

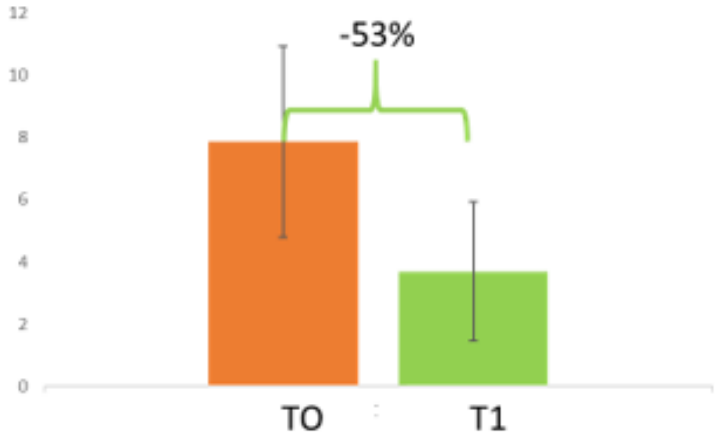

Figure 1: RSI score at T0 (orange) and after one month of treatment with only Rexoflus® (green), number of patients_ n=36. Data are expressed as mean ± standard deviation.

The efficacy and safety of the treatment only with Rexoflus® was evaluated also using a different Questionnaire the GIS scale that is conventionally used for GERD. As reported in figure 2, considering the main symptoms of gastro-oesophageal reflux diseases such as chest or breastbone pain, acid taste in the mount, burning in the upper stomach and sore throat or hoarseness related to acid reflux there was a sensible reduction after one month for every parameter with a mean reduction, considering all five parameters, of more than 30% with respect to T0.

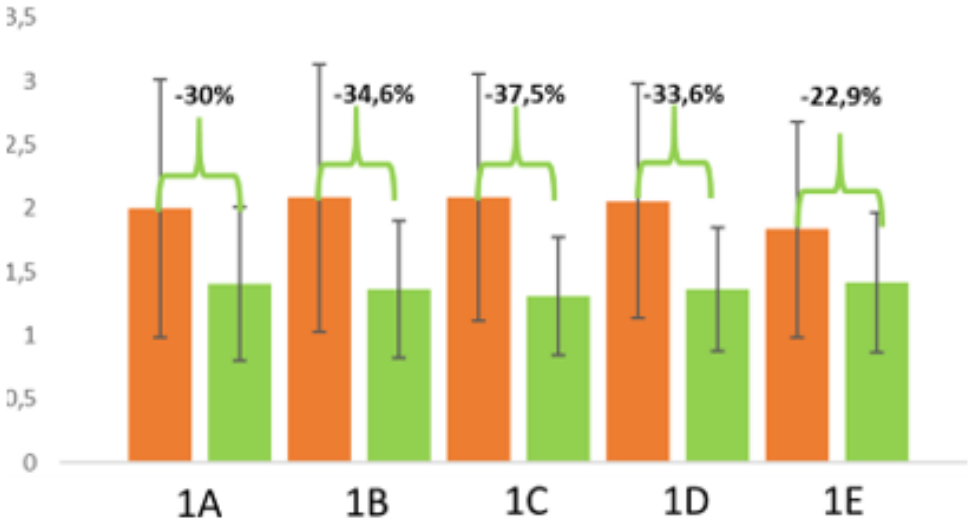

Figure 2: GIS score at T0 (orange) and after one month of treatment only with Rexoflus (green), number of patients_n=36 where 1A, 1B, 1C, 1D and 1E correspond to the questions reported in table 1. Data are expressed as mean ± standard deviation.

As secondary output, the combination of Rexoflus® with standard PPIs treatment was evaluated in terms of reduction of GERD symptomatology in patients with more severe symptoms.

Interestingly, the association of Rexoflus® with the standard therapy with PPIs, improved the reduction of GIS score for all the recorded parameters with a mean reduction of about 42% (figure 3).

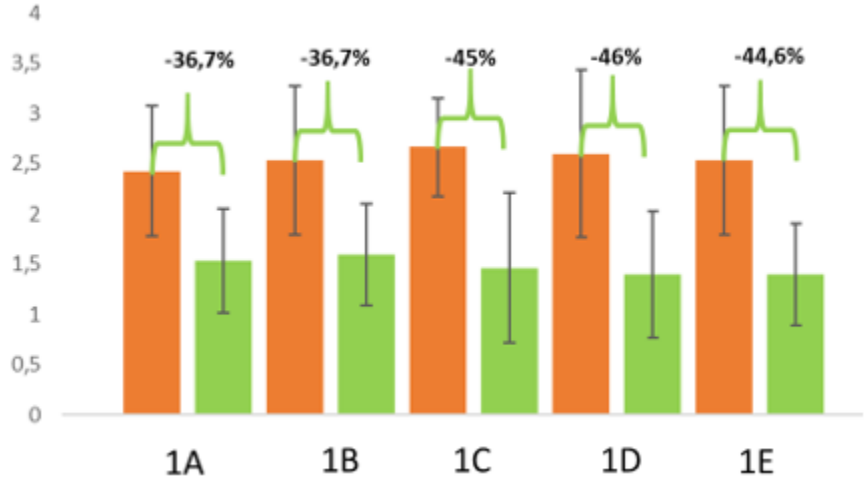

Figure 3: GIS score at T0 (orange) and after one month of treatment with the association of standard PPIs Therapy and Rexoflus (Green), number of patients_ n=15 where 1A, 1B, 1C, 1D and 1E correspond to the questions reported in table 1. Data are expressed as mean ± standard deviation.

Discussion

The management of GERD in both adults and children is still challenging, in fact many combined pharmacological approaches have been adopted because no single drugs class are able to control all the clinical manifestations of reflux disease [13]. For these reasons, as for others therapeutic areas, there is a specific need to develop novel therapeutic tools with a combination of ingredients such as in medical device or food supplements [14-15-16].

Rexoflus® is a medical device with a patented formulation developed to ensure a multi-target approach for a complete treatment of GERD and LPRD without any side effect. The present observational survey was obtained from real life data with a total of 51 patients with GERD and LPRD using only Rexoflus® or a combination of Rexoflus® with standard PPIs treatment.

As reported in the results section, Rexoflus® was able to counteract the symptomatology related to the LPRD after one month of treatment, probably, the polysaccharide patented component (TAMIXAM®) of Rexoflus® thanks to its mucoadhesive properties is able to create a physical barrier on the mucosa reducing the laryngopharyngeal irritation and improving its physiologic hydration with consequent resolution of the classic symptomatology [17]. In addition, thanks to its antacid component combined to the polysaccharide one, Rexoflus® contributed to reduce the typical symptomatology related to GERD such as stomach acidity, burning, acid taste and the typical chest pain. It's interesting to point out that in the present survey patients took the combination of Rexoflus® and PPIs every day for 1 month with the recommended posology without using the medical device therapy or the pharmacological one as "add-on". When an "add-on" approach is applied in could be a limit from a scientific point of view in order to understand the effective contribution to the symptom's resolution.

These data confirmed the optimum compatibility of Rexoflus® with standard treatments prescribed from guidelines and in addiction the high patient compliance and safety without registering any side effects of

patients drop out from the therapy. The present study presents some limitations such as the absence of a placebo group, the absence of data on plasmatic biomarkers and the number of treated patients for each group. So, more complex and organized clinical trials could be useful to effectively confirm the potential role of Rexoflus® for the management of GERD and LPRD.

Conclusion

Rexoflus® treatment after one month reduced the main parameter of reflux diseases according to two different questionnaire used RSI and GIS score. Moreover, the association of Rexoflus® with PPIs showed an improved reduction in the GIS score without showing any side effect. The obtained data demonstrated the efficacy, safety and good usability of Rexoflus® medical device in people with both gastro-oesophageal and laryngopharyngeal reflux alone or in combination with standard pharmacological therapy.

Conflicts of interest

We declare that Umberto Di Maio is a Shedir Pharma Group S.p.A. member, Antonino Bagnulo, Maria Potenza and Andrea Cerciello are Neilos S.rl. members.

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Authors' contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

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