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Case Report

Effect of Enhanced Lung Cleansing on Observed Changes in Performance of Endurance Athletes with Breathing Limitations: An Exploratory Case Series

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Abstract:

This exploratory case series describes changes in athletic performance, respiratory measures (peak flow), and heart rate variability (HRV) in four endurance athletes with reported breathing limitations (e.g., diagnosed Exercise Induced Asthma or self-reported limitations) following four weeks of utilization of an inhaled lung cleansing agent. Athletes completed a one-week baseline period with physiological parameters monitored daily, and routine training efforts were monitored prior to initiation of the lung cleansing agent with four weeks of monitoring of physiological parameters and continued training. Athletic performance assessments were conducted at baseline, Week 2, and Week 4. Athletic performance was measured using a fixed distance time-trial and physiological parameters measured included peak expiratory flow, nightly HRV, and participant-reported perceptions of exercise effort and breathing performance. Time-trial performance improved by 5.75% ± 8.42%, with three of four athletes recording faster times. Peak expiratory flow increased by 11.25% ± 32.68%, with mixed individual responses. HRV increased during the first two weeks (+2.75% ± 22.78%) and then stabilized. Individual HRV increases of 10–13 ms were observed. These findings support a potential benefit of an over-the-counter lung hygiene product in athletes with a history of asthma or reported respiratory limitation and further support the feasibility of essentially a longitudinal monitoring field study in athletes with breathing limitations.

Key words: inhaled lung cleansing agent; athletic performance; heart rate variability

Introduction

Breathing efficiency plays an important role in endurance performance. Athletes with asthma or exercise-related breathing limitations often report symptoms that affect training tolerance, recovery, and perceived effort, even when clinical measures appear stable [1]. While spirometry and symptom reporting are commonly used measures to identify factors that influence performance, they may not fully capture how breathing limitations relate to day-to-day performance and recovery [2]. Frequently, inhaled pollutants, pollen, and other particulates create conditions that impair athletic performance due to these inhaled agents causing mucus to thicken and become dehydrated with the impaired mucociliary clearance [3]. Impaired mucociliary cleansing allows for inflammation and other adverse conditions to exist that can hinder athletic performance. In recent years, heart rate variability (HRV) has become a widely used parameter in athletic settings to track recovery and physiological stress., Emerging data describe how HRV changes when measured alongside performance and respiratory measurements in athletes who experience breathing limitations can be used as a surrogate for recovery. Notably, fine particulate matter ($PM_{2.5}$) has been associated with significant reductions in HRV [4]. This case series study was conducted to determine if an agent previously show to enhance mucociliary clearance would affect athletic performance, respiratory measures, overnight HRV, and participant-

reported experience over four weeks in endurance athletes with breathing limitations.

Cases Presented

Participants

Four U.S.-based endurance athletes that were following a scheduled training program participated. Athletes were training for cycling, running or triathlon. Each athlete reported recurring breathing-related limitations during moderate-to-high intensity training, and some had a diagnosis of asthma or exercise-induced asthma. Baseline characteristics were collected via an intake survey.

Participation consisted of five weeks of performing assessments and reporting, beginning with a one-week baseline period where training and monitoring was completed with no intervention followed by four weeks of training and monitoring while using the L Max lung cleansing agent. Athletic performance was completed at baseline prior to starting L Max and at two and four weeks after twice daily use of L Max.

Intervention

All participants self-administered a 27 mg capsule dose of L Max powder that was delivered using a Plastiape RS-01 high-resistance capsule-based dry powder inhaler twice daily. One dose was administered 15-30 min prior to exercise. If an athlete trained in the evening, then a second dose was administered within an hour of waking in the morning. For athletes that trained in the morning, a second dose was administered within an hour of bedtime. The L Max product is a powder that has been demonstrated to accelerate the mucociliary clearance process in cell-based assays and in an ovine model of mucus clearance [5].

Procedures and Measures

Athletes were instructed to maintain their scheduled training plans provided by an individual coach while adding time trials at the end of the baseline period and after two and four weeks. For each participant, time trials consisted of either a 5 km run or a 5- or 10-mile cycling session at race pace. In order to reduce course, temperature or time of day variations on the measured athletic performance results, the time trials were conducted on the same course and at the same time of day, whenever possible. Subjects were allowed to perform the time trial ±1 day from the schedule to ensure that the weather was similar to prior test efforts. Time trials were chosen as they represent a reliable method to assess athletic performance [6]. Daily respiratory function assessments were performed using a peak expiratory flow (PEF) meter from Nascool with two efforts each morning and 1Xaiogy 5 min after administering L Max. Peak flow was measured according to the device manufacturers directions and was utilized to determine if the L Max product had measurable effects on respiratory function using a device that is easily accessible to consumers. These devices have been well characterized for use [7]. Physiological measurements of health including overnight sleep duration, blood oxygenation, heart rate, temperature difference from mean, and HRV were monitored using an Oura ring [8]. Participants also completed subjective surveys related to breathing comfort, recovery, training tolerance and other observations. Athletes with a diagnosis of exercise induced asthma and prescribed a short acting bronchodilator were allowed to use medication as needed and not limited. Use of bronchodilators was recorded by participants when used.

Ethics

All participants provided voluntary consent to participate in the study and for use of the data for research purposes.

Comparative Outcomes

A total of four athletes were included in preliminary testing to identify if the mucociliary clearance enhancement provided by L Max, resulting in enhanced clearance of particulate matter from the lungs. Participant demographics and athletic characteristics are shown in Table 1.

Table 1: Participant Characteristics

Participant	Sex	Time Trial Activity	Medical Diagnosis
1	M	Running	Exercise Induced Asthma (EIA)
2	M	Cycling	EIA, Asthma
3	F	Cycling	EIA, Asthma
4	M	Running	None

Athletic Performance

Time trial results from each athlete were measured for a running or cycling time trial at race pace. Time trial results for each athlete are shown in Table 2. Most athletes showed improvement from baseline at 2 and 4 weeks with mean time-trial performance improving by **5.75% ± 8.42%**. Three of four athletes recorded faster completion times compared with baseline. One athlete showed no improvement.

Table 2: Athletic performance results

Participant	Baseline	2 Week	4 Week	2 Week Time Differential Absolute (%) [a]	4 Week Time Differential Absolute (%) [b]
1 - Running 10k	44:02	43:11	43:10	0:51 (1.9%)	0:52 (2.0%)
2 - Cycling 5mi	9:38	9:11	9:13	0:27 (4.7%)	0:25 (4.3%)
3 - Cycling 5mi	20:01	16:38	16:22	3:23 (16.9%)	3:39 (18.2%)
4 - Running 5k	18:23	18:25	18:32	-0:02 (-0.2%)	-0:09 (-0.8%)

[a] Difference between baseline and 2-week time trial completion times
[b] Difference between baseline and 4-week time trial completion times

Table 3: Peak Flow Measurements 15 Minutes After L Max Administration

Participant	Baseline Average (± stdev)	PEF Average on L Max (± stdev)	2 Week Differential Absolute (%)	Paired T-test P value (Baseline to PEF average)
1	348 ± 72 L/min	554 ± 62 L/min	+206 L/min (59.2%)	<0.0001
2	485 ± 25 L/min	497 ± 26 L/min	+12 L/min (2.5%)	0.3207

3	403 ± 19 L/min	398 ± 23 L/min	-5 L/min (-1.2%)	0.5997
4	613 ± 13 L/min	523 ± 59 L/min	-90 L/min (-14.7%)	0.0004

Respiratory Measures

To determine if any changes, either positive or negative, in lung function, peak flow was used as a surrogate for respiratory function. While not diagnostic, the induction of bronchospasm by L Max would be expected to reduce peak flow. Overall, peak expiratory flow increased by 11.25% ± 32.68% across the study period. Two athletes demonstrated improved peak flow relative to baseline, while two showed little change or minimal decline. However, no substantial declines in PEF were noted that would indicate bronchospasm had occurred and no participants utilized rescue inhalers due to shortness of breath that they associated with bronchospasm.

Nightly average heartrate and low heart rate, blood oxygen levels, average HRV, and other measures monitored by the Oura ring were recorded each day and analyzed for change from baseline established during the week prior to L Max use. Of the parameters recorded by the Oura ring, HRV was the only parameter that showed a notable change that followed a two-phase pattern. During the first two weeks, mean nightly HRV increased by 2.75% ± 22.78%, with three of four athletes showing higher values compared with baseline. During the latter part of the study, HRV stabilized rather than continuing to increase, corresponding to a mean absolute change of +0.03 ± 0.13 ms from baseline to the final two weeks as shown in Table 4.

Biometric Analysis

Table 4: Overnight HRV Measurements Prior to and During L Max Administration

Participant	Baseline	2 Week	4 Week	2 Week Differential Absolute (%)	4 Week Differential Absolute (%)
1	39 ms	43 ms	41 ms	+4 (10.3%)	+2 (5.1%)
2	41 ms	48 ms	46 ms	+7 (17.1%)	+5 (12.2%)
3	48 ms	33 ms	40 ms	-15 (-31.3%)	-8 (-16.7%)
4	71 ms	83 ms	79 ms	+12 (16.9%)	+8 (11.3%)

At the individual level, HRV responses varied with most gains being recorded at 2 weeks. Athlete 4 showed an increase of 12 ms with 2 weeks of L Max use, while athlete 2 showed an increase of 7 ms and athlete 1 experienced a 4 ms change with athlete 3 showing a decrease of 15 ms at 2 weeks. Absolute increases of 10–13 ms are commonly considered meaningful in endurance training and recovery monitoring [9].

Discussion

In this case series, most athletes demonstrated improved time-trial performance during their benchmark studies. Respiratory assessment by PEF as well as HRV responses varied between individuals during the study period.

While it was anticipated that improved airway clearance could improve many parameters, analysis of physiological outcomes from those captured by the wearable ring, in these subjects no consistent changes in sleep duration, heart rate, or other parameters were observed, with the exception of HRV. For HRV a clear pattern among the physiological parameters evaluated was demonstrated with modest individual HRV increases of 4–12 ms were observed in multiple athletes. Magnitudes greater than 8 ms are commonly viewed as meaningful in applied endurance settings as signals of increased recovery [9]. The pattern of early increase followed by stabilization is consistent with an initial adaptation rather than continuous linear change. This is consistent with cleansing of particulate matter from the lung given that inhalation of $PM_{2.5}$ has been associated with decreased HRV [4]. Changes in HRV did not consistently mirror performance outcomes and dissociation between HRV and athletic performance is common and reflects the influence of multiple factors on performance beyond physiological recovery alone [10].

The majority of subjects in this study demonstrated positive outcomes in athletic performance and improved overnight HRV. The small sample size that prevents conclusion that the use of the lung cleansing agent is responsible for improved performance, but served the purpose of demonstrating that it is possible to collect athletic performance and physiological parameters in a randomized placebo-controlled study for a more in depth study.

Conclusions

In four endurance athletes with breathing limitations, twice daily utilization of a lung cleansing agent resulted in improved time-trial performance in three participants over four weeks, while respiratory responses were mixed. HRV increased early with individual improvements of up to 12 ms by 2 weeks and then stabilized for the final two weeks of L Max use. These findings support the use of HRV as a sensitive physiological marker in this population and demonstrate the feasibility of multimodal longitudinal monitoring.

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