

Diabetes and Covid-19 Pandemic-A T1 Patient Perspective

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ABSTRACT

How might we successfully treat diabetes patients who become seriously ill and hospitalised suffering from Coronavirus and requiring ventilator breathing assistance?

Coronavirus, Covid-19 is the most feared pandemic ever experienced on a global scale with dramatic morbidity and is challenging to treat and overcome. Media reports suggest that 25% of patients who die from Coronavirus are elderly and have an underlying health condition, often diabetes.

Could inhaled therapy drug treatment delivered to Critical Care Patients with the Multisonic®Infracontrol Nebuliser lead to improved recovery and reduced morbidity?

Keywords: Coronavirus; Covid-19; Patients; Blood glucose; Hypoglycaemia; Insulin; Temporary Mental Impairment

PROFESSIONAL BIOGRAPHY

Derek Beatty gained his BSc in Biological Science & Business Studies, Edinburgh University, 1972, and his Diploma in Marketing, Slough College, 1977. He is a Director of Aston Clinton Scientific Ltd since 1997 supplying respiratory nebulisers and specialising in diabetes. He is a Healthcare Consultant.

He recently founded Mobile MedTech Ltd to offer a Mobile Diabetes Service in Scotland involving NHS Scotland with experience in the team launching Europe's First Mobile MRI Service in 1990. He has had T1D for 42 years and overcome diabetic retinopathy.

Published featured articles include 'Shared Mobile Services' Medical Focus 1990; 'Sharing in Caring' The Health Service Journal, 1990; 'Shared Mobile Services Save Money for Providers', European Congress of Radiology, Vienna 1991; 'Mobile MRI, Safety and Operational Guidelines' 1992; 'A Listening Ear' 2017; www. DRI-FT.co.uk Diabetes Research Information-Facts for Treatment.

INTRODUCTION

Coronavirus, Covid-19 is the most feared pandemic ever experienced on a global scale with dramatic morbidity and is challenging to treat and overcome. Media reports suggest that

25% of patients who die from Coronavirus are elderly and have an underlying health condition, often diabetes[1].

Many respiratory disorders and lung infections have been treated and managed successfully over generations such as asthma, COPD, PAH Pulmonary Arterial Hypertension, Cystic Fibrosis, and many more treated and managed with varying degrees of success depending on availability of healthcare provision and patient compliance. Prevention is always better than cure and lockdown with social distancing offers a sensible and statistical approach to reduce and prevent further spread of Coronavirus. It is hoped that one day in the near future a vaccine cure and a vaccine prevention inoculation will be discovered by eminent researchers. In the meantime hospital critical care departments receive many serious and critically ill patients every day. Breathing assistance by ventilator assists many patients but sadly many die [2,3].

A key to possible successful treatment may be very small particle sized drug droplets (3-6 micron) delivered by inhaled nebuliser therapy deep into the lung and vascular system. Recent success with inhaled insulin therapy has led to good blood glucose BG levels being achieved in patients using the therapy to manage Type 1 diabetes patients in the USA and at least one patient in the UK [4].

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The question now arises as to whether a similar approach might lead to improved recovery in patients with severe Covid-19 Coronavirus?

Inhaled Therapy Delivery

The Multisonic Infracontrol is a powerful ultrasonic inhalation medical device for preventative and therapeutic deep inhalation. The Infracontrol demonstrated medical device clinical excellence when Schill GmbH was founded in 1991 in Probstzella, Germany, and later to win a Thuringen award. The device was not designed for life saving emergency treatment at the time however if used with a ventilator and appropriate inhaled drug therapy may offer hope and treatment success for patients.

The Multisonic Infracontrol can be used at home, whilst travelling, and in clinics thanks to its universal voltage supply options, mains or rechargeable battery or car adaptor. The multisonic infracontrol effectively combines aerosol therapy with safe environmentally friendly inhalation. Its innovative design prevents the release of medicines into the environment. The comfort of patients was one of the main considerations in the design of the Multisonic Infracontrol to provide:

- Universal usage
- Optimal penetration of tissues
- High nebuliser performance and short inhalation times
- Warming of aerosol
- Low wastage of medicines and ease of setting doses
- Simple and safe to use
- Easy to clean
- Noisless in operation
- Modern design
- Small, easy to handle and transport
- Suitable for the inhalation of all common inhalation solutions

The Instructions for use must be carefully read and understood to ensure correct use [5,6].

DESCRIPTION Inhalation therapy with the Multisonic®-Infracontrol

Progress in medicine demands improvements in medicine delivery technology and treatments. The Multisonic® Infracontrol is a silent operating drug delivery device and was developed to reduce medicine consumption and wastage. The infrared control in the device makes the operation easier for patients and offers reliable performance. The Multisonic® Infracontrol provides good lung drug deposition, economical drug use, easy patient use and compact and reliable device technology [7,8].

42 years T1D insulin treatment and personal hypoglycaemia experience following wrong insulin care 1987-94 led the author to research published reports. The first hypoglycaemic event was described by Banting, Best and Macleod at the time of insulin discovery as a treatment for diabetes in 1921/22. This review includes observations from 'Forensic Aspects of Hypoglycaemia' by Prof Vincent Marks, 629 case references, February 2019 and other published papers over many years.

Complications affecting stable Blood Glucose levels include Otitis Externa, Osteomyelitis, Neuropathy pain, infection treatment by IV antibiotic delivery, periodontal dental link with gum disease, inflammation, chemical change reducing insulin effectiveness, calcium stones in the saliva duct, sodium, calcium, magnesium electrolyte imbalance, Omega 3 deficiency, night saliva duct cortisol secretion, depression.

Use of insulin and C Peptide assay is beneficial in forensic investigations following unexplained death or insulin use as a weapon in alleged criminal matters.

Society can learn from this research to provide improved diabetes care for patients to achieve good health and long life despite the daily burden of managing a condition with no cure.

A duty of care exists by a witness, partner, friend or colleague to a person in a state of hypoglycaemia to assist and if severe summons paramedic helps when the person is unable to help themselves because of temporary mental hypoglycaemia impairment.

Inhaled Therapy

The effectiveness of inhalation therapy depends on the active substance reaching the required destination in the lungs. An important factor is the droplet distribution and particle size generated by the nebuliser. The smaller the droplets, the more deeply the medication can penetrate into the lungs. The bigger the droplets, the more inhalation solution remains in the area of the upper breath-ways. Effective treatment of many diseases requires that the alveoli and deep lung areas should be targeted and reached in delivery of the prescribed medication. The Multisonic® Infracontrol generates an extraordinarily fine aerosol. 65% of the particles are smaller than 5µm. The aerosol penetrates into deep lung areas, a prerequisite for the effectiveness of many treatment therapies [9-12].

Most nebulisers operate continuously or on press button operation. The first technique leads to high medicine consumption, because aerosol is always delivered even if the patient pauses during inhalation. This is a critical point particularly with expensive inhalation medications. The second technique requires that the patient co-ordinates breathing respiration and medication delivery from the nebuliser. This often leads to difficulties and poor patient compliance.

The infrared control of the device solves both problems in a simple way and is therefore a real improvement in inhalation therapy. The aerosol is generated only if the patient breathes with the appliance. The patient sucks exactly the required aerosol volume out of the nebuliser through his inspiratory flow. The infrared beam crosses the nebuliser chamber and a sensor recognises the aerosol production. This activates the piezoelectric crystal which generates the ultrasound-waves. The aerosol is generated and made available for inhalation. If the patient stops the inhalation the chamber fills itself with dense aerosol medication. This is recognized by the infrared control and the aerosol production is stopped. It then starts anew if the patient inhales again or if the fog-density decreases through condensation in the nebuliser chamber [13].

The Multisonic® Infracontrol requires no patient co-ordination. The patient can simply inhale or exhale with their own breath rhythm with mouthpiece or mask and no press button activation is necessary. When on a ventilator the Infracontrol can be linked to the ventilator system for efficient drug delivery.

Two control lights in the device allow checkup of correct appliance function. The green light signals that the power supply is in order. The second light can show yellow or red. A yellow light means that the appliance works and is generating aerosol. A red light shows the inhalation solution is used up leaving the residual volume or that the device function is interrupted. A visual inspection of the device leads to improved therapy [14].

SAFETY FEATURES

When the unit reaches the residual volume or responds to the temperature protection feature the device switches itself off. When this happens unplug the device and allow the unit to cool for 5 minutes before plugging in and switching on again.

The device must be cleaned daily with single patient use, or after each patient if set up for multiple use, and consumables and filters replaced at the intervals recommended in the Instructions for Use Guide.

The Instructions for Use Guide provides instructions and information for the patient, nursing staff and carers regarding how to use the device, get the best efficiency from the device, and how to recognise potential error conditions and trouble shooting.

In the event of an error or other problem the patient or clinical staff in the first instance should refer to the Trouble Shooting section of the Instructions for Use Guide. If the problem cannot be resolved the hospital or clinic responsible for the patient's welfare should be involved to correct the issue.

INFRACONTROL-VENTILATION

The Multisonic InfraControl 83000 (clinic) / 83001 (home) is highly specialized and specially tailored to the **needs of respiratory patients** and to the needs of **medical professionals**. It is compatible with ventilators, home ventilators and CPAP systems®.



Figure 1: Multisonic InfraControl.

The **nebulizer** does not generate device-related airflow that could affect connected ventilators. This is why the device is particularly cost-effective in drug recycling and can remain in the ventilation circuit even after switching off [15-17].

In addition, the Multisonic InfraControl 83000 / 83001 can be used as a **handheld device for spontaneous inhalations** and is therefore very suitable for **tracheostoma patients**® [18,19].

OPTIONAL USE OF FILTER

The device can be optionally fitted with an exhalation filter which prevents active ingredients present in the exhaled air from entering the surrounding environment. This minimises skin and eye irritation to the patient and potential side effects (eg headache) to the patient's carer or nurse who may be exposed to exhaled active ingredients during treatment. An optional inhalation filter can also be placed on the dome of the device.

Protocol for use

The protocol procedure requires the patient or carer to understand and prepare the dose of the medication to be inhaled under the guidance of the clinician responsible for the patient's welfare.

Continuing in home use

Patients can be instructed on how to use the home use infracontrol device in the home and inhale the recommended dose of medication at the intervals recommended by the prescribing physician who is also responsible for suggesting regular interval patient consultations during treatment.

Indications for use

The Multisonic Infracontrol nebuliser is intended for home use, hospital use, clinic use, and when travelling by patients with respiratory disorders including:

- Bronchial asthma
- Chronic obstructive bronchitis
- Bronchiectasis
- Mucoviscidosis
- Pulmonary hypertension
- Acute recurring infections
- Chronic diseases of the airways with pulmonary emphysema
- Cystic fibrosis

Note: Patients under 10 years of age should be evaluated by their physician for their capacity to perform the necessary tasks associated with the use of the infracontrol nebuliser.

Recommendation

Only medicines that have been prescribed or recommended by a physician should be used with the infracontrol nebuliser. If a patient accidentally inhales medication not suitable for inhalation or for the patient's therapy then the patient's physician should be notified straight away.

Warning: The infracontrol is not designed for emergency life saving measures but may warrant use with a ventilator to treat certain patients when under clinical physician care.

Use of the infracontrol nebuliser in a defined target treatment population is intended to assist the physician responsible for the patient's disorder and treatment therapy in making appropriate treatment adjustments which may include changes in dose and timing of treatment.

Physician involvement

The patient's use of the Multisonic Infracontrol nebuliser will actually involve the participation of those medical professionals and nurses responsible for the patient's welfare, who will also be responsible for prescribing medication to be inhaled with the device. Physicians should ensure that patients are following the continuing hospital, clinic or inhome treatment and dose protocol prescribed. Physicians should also ensure that the device is cleaned on a daily basis and consumables are replaced at the intervals stated in the Instructions for Use guide, especially:

- Daily-replace exhalation filter
- Monthly-replace filter holder, nebuliser head, baffle plate, mouthpiece, valves, sealing rings

Physicians or hospital staff requiring details of particle size distribution or technical data should refer to the Instructions for Use guide or product brochure. Details of treatment protocols can be provided with published information on request.

Further information

Physicians may contact the customer service department of Flores Medical (Germany); Schill Medical (UK) to obtain further information on the Multisonic Infracontrol. Copies of Physician Guide, Instructions for Use Guide and Product Information are available on request.

- Multisonic®Infracontrol is a registered trademark of Flores Medical GmbH & Co.KG
- Multisonic®Infracontrol carries registered CE approval.

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