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Journal of the Association of Chartered Physiotherapists in Respiratory Care

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Editorial

Editorial

Elizabeth King, Owen Gustafson

Journal of the Association of Chartered Physiotherapists in Respiratory Care

We are delighted to share our spring issue of The ACPRC Journal for 2024. We welcome Liz King as co-editor to the journal who brings a breadth of quality improvement and qualitative research experience to the journal. This edition is the first to have been reviewed and prepared through the new peer review and production platform Scholastica. We thank authors and reviewers for their engagement with this, and as co-editors have found it valuable to have had more time to spend supporting authors in their manuscript preparation. Moving forward, as we optimise our use of this system, we hope to dedicate more time to developing the journal and to supporting new authors and reviewers.

This edition includes five articles that encompasses a range of manuscript styles including: a literature review, an observational study, two service evaluations and a commentary article.

This edition opens with an article by Hubbard et al which is a literature review of five studies concluding that the use of MI-E is safe to use in acutely invasively ventilated critically ill patients on the background of only two studies reporting transient and non-clinically significant adverse events such as oxygen desaturations or blood pressure changes). Goodard et al undertook a service evaluation exploring staff opinions of how pulmonary rehabilitation provision has changed due to COVID-19 identing some valuable themes to contribute to future service delivery. Gale et al reported their observational study assessing within-day reliability and concurrent validity of the 2MWT and 10MWT in healthy individuals wearing a surgical mask which were both considered to be excellent. Henry et al undertook a service evaluation exploring the demographics, characteristics and healthcare utilisation of people with asthma referred to an ambulatory respiratory hub with a reduction in healthcare utilisation and recognition of the need to assess common asthma co-morbidities. The final article is by Harris et al which is a commentary of a systematic review regarding the use of video games as a supplement component to pulmonary rehabilitation.

The content of this edition highlights the breadth and depth of respiratory care delivered to our patients, and education and support we provide to students and staff. Overall, we hope you will agree this is a refreshing read and consider how best to share it with your local teams and how it might impact your clinical practice.

We are very keen to support members in developing their academic writing for publication. We hope you will feel welcome in contacting us at journal@acprc.org.uk if you would like support or guidance on writing your manuscript or developing potential ideas for articles.

Liz King and Owen Gustafson

Hubbard D, Witts C, Wong K, Stent L, Swingwood E. Adverse effects of Mechanical Insufflation-Exsufflation in Mechanically Ventilated Patients in the Adult Intensive Care Unit - A Literature Review. *ACPRC Journal*.:2-11. doi:10.56792/NIOE5015

Critical care

Adverse effects of Mechanical Insufflation-Exsufflation in Mechanically Ventilated Patients in the Adult Intensive Care Unit - A Literature Review.

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Keywords: Physiotherapy, Mechanical ventilation, Critical care, Cough Assist, Airway Clearance

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Abstract

Introduction

Mechanical ventilation via an artificial airway can impede cough, predisposing the critically ill patient to retained secretions and an increased risk of respiratory complications. Physiotherapeutic techniques aimed at mobilising secretions and optimising airway clearance are often relied upon in this cohort. Mechanical Insufflation-Exsufflation (MI-E) is a cough augmentation device that utilises positive pressure, followed by a rapid switch to negative pressure, to simulate a cough and aid sputum clearance from proximal airways. To date, MI-E has been widely researched in the neuromuscular population, with emerging use in the critically ill. However, adverse effects associated with MI-E in intubated populations remains unknown. The aim of this review was to report on the incidence of adverse events associated with MI-E in acutely invasively ventilated critically ill patients.

Methods

An electronic search of online databases was conducted using AMED, CINAHL, Cochrane Library, EMBASE, MEDLINE, SPORTDiscuss and Web of Science. Additionally, the reference lists of relevant articles were hand searched for eligible studies. Studies including adult subjects (>18 years) who were invasively ventilated and receiving MI-E were deemed eligible for inclusion. The outcome of interest was adverse events. Studies were excluded if they were in a paediatric population, not written in English language and were editorials or conference papers. Quality was assessed using the Critical Skills Appraisal Programme tool.

Results

A total 77 citations were identified, five of which met the inclusion criteria: three randomised crossover studies, one randomised parallel-group open label trial and one case series (278 participants in total). All studies applied MI-E followed by endotracheal or tracheal suction. Insufflation and exsufflation pressures ranged from +30 to +50cmH_2O and -30 to -50cmH_2O across studies. Only two studies pre-defined an adverse event. Common reported measures included heart rate, systolic and diastolic blood pressure, and oxygen saturations. Two studies reported the occurrence of an adverse event (oxygen saturations, blood pressure and heart rate changes) but noted that changes were transient and not clinically significant. Overall, all studies concluded that MI-E was a safe intervention in this patient cohort.

Conclusion

Overall, the use of MI-E in the acutely intubated patient does not result in adverse events that are clinically significant. However, limitations to the evidence base should be acknowledged and include a lack of definition and variation in outcome measures used and small sample sizes across studies. Larger clinical trials are needed, to further evaluate the safety of MI-E on clinically important parameters that are more clearly defined.

INTRODUCTION

Mechanical ventilation (MV) is a lifesaving invasive treatment strategy for critically ill patients but is associated with an increased risk of respiratory complications. The presence of an endotracheal tube limits cough effectiveness due to the glottis being held in abduction, preventing the generation of adequate intrathoracic pressures for effective cough and airway clearance.[1] The use of sedatives diminishes the cough reflex and contributes to intensive care acquired weakness due to prolonged offloading of the respiratory muscles.[1,2] Additionally, exposure to dry gases used during MV are thought to cause airway mucosal dysfunction and consequently increased sputum load and viscosity.[3] This, along with an ineffective cough can lead to sputum retention, increasing the risk of complications such as atelectasis, ventilator-acquired pneumonia, and ultimately respiratory failure.[4,5]

Many patients who are mechanically ventilated rely on physiotherapeutic techniques to mobilise secretions and optimise airway clearance. These include strategies such as suction, manual or ventilator hyperinflation and manual assisted cough. More recently cough augmentation devices such as mechanical insufflation-exsufflation (MI-E) have also been used in the ICU setting.[6] Mechanical insufflation-exsufflation is a non-invasive technique that utilises positive and negative pressure to augment expiratory airflow that facilitates sputum mobilisation.[7] Over the past two decades there has been a growing trend for the use of MI-E in ICU and an increasing evidence base for its efficacy.[8] A substantial body of evidence exists supporting the use of MI-E in patients with neuromuscular disease[7] and emerging evidence for its use in other populations.[9] To date, studies have demonstrated improvements in sputum clearance, pulmonary mechanics (airway resistance and lung compliance) and promising results in the reduction of re-intubation rates.[4,10,11]

Despite this, MI-E is often underutilised[12-14] with several barriers described including concerns regarding safety and the risk of adverse events, particularly associated to the use of high levels of positive pressure in patients who are critically ill.[12] The physiological effects of positive pressure such as altered cardiopulmonary dynamics are recognised and well documented.[15] Targeted recruitment techniques may cause undesirable effects associated with volutrauma and barotrauma, increasing the risk of a pneumothorax.[16] Other possible complications of positive pressure may include chest and abdominal pain, haemoptysis, gastroesophageal reflux, and abdominal distention.[17] Adverse effects associated with negative pressure such as lung unit de-recruitment have also been recognised in the literature[18] but not specifically with the use of MI-E. Notwithstanding this, evidence regarding the safety of using MI-E in intubated critically ill patients is sparse.[8,14] The aim of this Literature Review is to report on the occurrence of adverse events associated with MI-E in invasively ventilated critically ill patients.

METHODS

SEARCH STRATEGY

An electronic search was performed using the following databases: AMED, CINAHL, Cochrane Library, EMBASE, MEDLINE, SPORTDiscuss and Web of Science, from database inception to January 2023, using the search terms listed in Appendix 1. Additionally, reference lists of relevant articles were hand searched for eligible studies.

SELECTION CRITERIA

Inclusion criteria included (1) primary research, (2) adult subjects (18> years) who were invasively ventilated, (3) MI-E applied in isolation or in conjunction with other treatment interventions, (4) adverse effects of MI-E as an outcome. Studies were excluded if they were in a paediatric population, not written in English language and were editorials, opinion pieces or conference papers (not original data).

STUDY SELECTION

Study selection was carried out by all five reviewers. Three were rotational band 5 physiotherapists (CW, KW and LS). One a Consultant Physiotherapist and Clinical Doctoral Research Fellow (ES) and one a Senior Lecturer in Cardiorespiratory Physiotherapy (DH). Four reviewers (CW, KW, LS and ES) independently screened study titles and abstracts of the studies retrieved from the search. Any uncertainties were reviewed in full text. All reviewers screened all remaining full text studies and assessed for eligibility. This process was repeated by the lead author (DH) to ensure accuracy.

DATA EXTRACTION

Information regarding study characteristics including participants, interventions, outcomes, and results was extracted into a table by four authors and cross checked by one author (ES) (Table 1).

QUALITY ASSESSMENT

The Critical Appraisal Skills Programme (CASP) tool was utilised by four independent reviewers to assess study quality.[19] The included studies were assessed against each question using the corresponding checklist. Results were compared and any discrepancies resolved by discussion.

DATA ANALYSIS

Descriptive statistics were used to summarise quantitative data accompanied by a narrative synthesis of findings.

RESULTS

STUDY SELECTION

The study selection process is presented in Figure 1. A total 77 studies were identified through the electronic search.

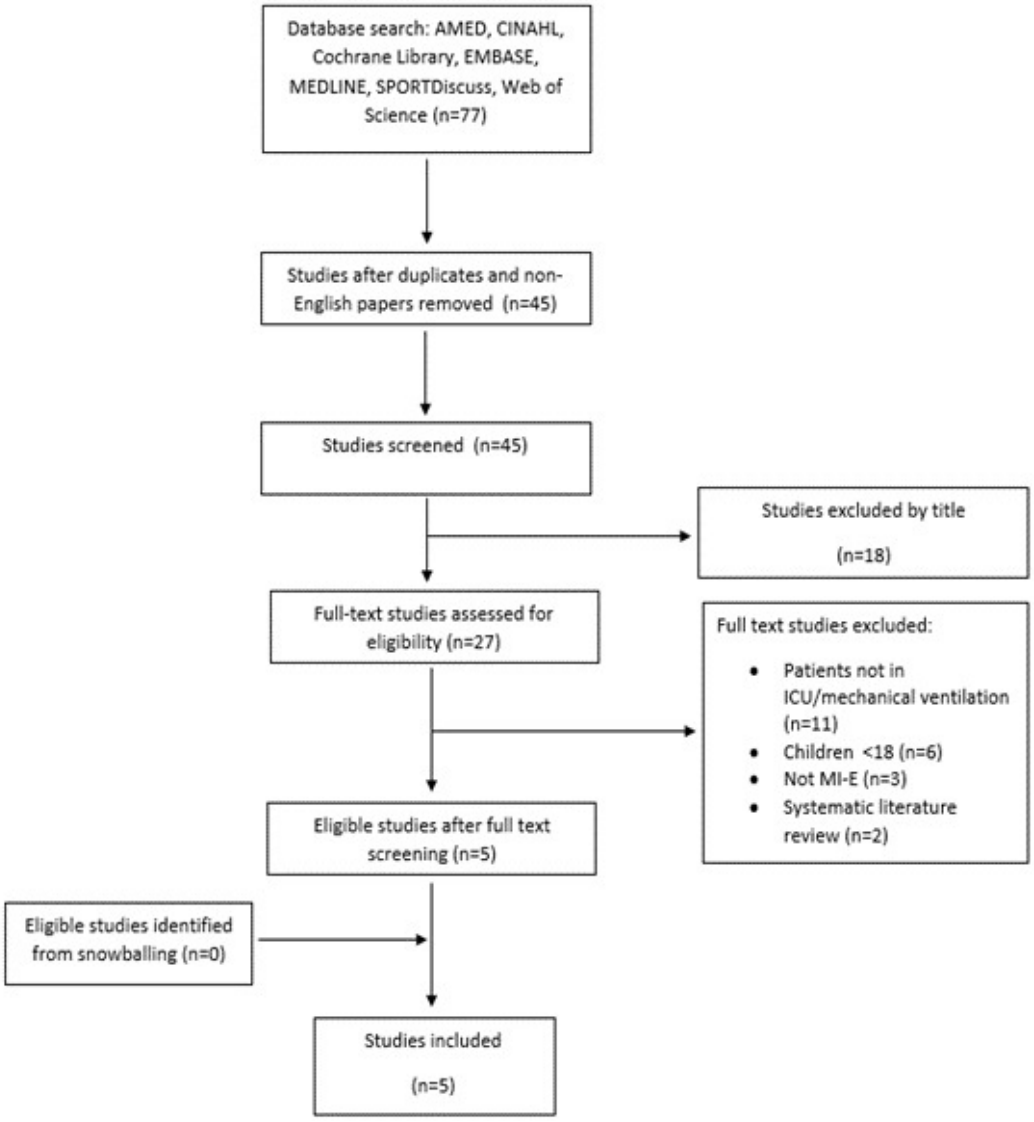

Figure 1. Flow diagram for study selection

After removal of duplicates (44) and studies not written in English (1), 45 titles were screened. A total of five studies were selected for inclusion. No further studies were identified via hand searching reference lists.

STUDY DESIGN

Of the included studies, three studies were randomised crossover studies. There was one randomised parallel-group open label trial and one case series. Studies were conducted in Brazil (n=3), France (n=1) and Spain (n=1).

STUDY CHARACTERISTICS

A summary of the included studies is shown in Table 1.

PARTICIPANTS

All studies included participants who were mechanically ventilated for more than 24 or 48 hours. Three of the five studies included participants ventilated via an ETT[10,11,20] and one study included participants with ETT and tracheostomies.[21] Participant mean age ranged from 51.4 to 75.7 years. The reason for ICU admission and diagnosis varied across studies and included surgical, medical, trauma and neurological conditions. Sample sizes ranged across studies from 13-180.

MI-E INTERVENTION

A variety of MI-E protocols were presented across included studies. All studies applied MI-E followed by ETT or tracheostomy suction. One study applied MI-E in conjunction with Expiratory Rib Cage Compressions (ERCC).[10] Coutinho et al.[22] and Sánchez-García et al.[21] provided supplementary oxygen prior to and during MI-E. One study utilised MI-E with inbuilt oscillations.[21] Mechanical insufflation-exsufflation protocols varied across studies with some lack of detail reporting. Insufflation-exsufflation pressures ranged from ±30 to ±50 cmH_2O. Insufflation and exsufflation times ranged from 2 to 3s and 1.5 to 4s respectively. Treatments

Table 1. Study characteristics.

Author	Year	Location	Study design	Study aims	Population	n	Intervention/Protocol	Outcome measures	Result
Nunes	2019	Brazil	Randomised crossover study	To evaluate effects of MI-E on respiratory mechanics haemodynamic and clearance of bronchial secretions.	Adults (>18 years) On MV > 24hrs via OTT Mixed diagnosis	16	Three protocols, 3-hr application interval: 1.MI-E (+30/-30) plus endotracheal suctioning; 2.MI-E (+50/-50) plus endotracheal suctioning; and 3.isolated endotracheal suctioning MI-E set up: Auto mode. Ti 2.5s and Te 1.5s, 0.5s pause. 4 sequences of 4 respiratory cycles and a 20 sec interval between each sequence Treatment applied by a physiotherapist.	Parameters evaluated: -5 min before -Immediately after -10 min after HR SBP DBP S_PO_2	No significant difference in HR across protocols (p=0.2) SBP and DBP significantly increased immediately after MI-E (+30/-30cmH_2O) and execution of isolated endotracheal suctioning (p=0.0006*) SpO_2 significantly reduced immediately after both the use of I/E pressures of +30/-30cmH_2O and the execution of isolated endotracheal suctioning (p=0.0001*) The execution of I/E with pressures +50/-50 cmH_2O did not result in significant changes in SBP, DBP or SpO_2.
Coutinho	2018	Brazil	Randomised crossover study	To compare the effects of MI-E verses isolated conventional tracheal suctioning on respiratory mechanics, haemodynamic stability, and aspirated secretion volume	Adults (>18 years) On MV > 48hrs Mixed diagnosis	43	Two protocols (intervention v control) Intervention: MI-E (+40/-40) 5 times in 4 cough cycles Automatic mode Ti/Te 3s, without pause. with tracheal suctioning Control - Conventional tracheal suctioning	Parameters evaluated: Before 1 min after 15 min after 30 min after HR SBP DBP MAP RR SpO_2	No significant difference over time or between groups in HR, MAP, RR and SpO_2.
Ferreira de Camillis	2018	Brazil	Randomised parallel-group, open label trail	To evaluate effectiveness of MI-E with respiratory physiotherapy v respiratory physiotherapy alone based on the weight of aspirated airway secretions	Adults (>18 years) On MV> 24hrs via ETT Medical and surgical cohort (haemodynamically stable)	180	Intervention v control Intervention: MI-E (+40/-40) 3 sets of 10 cycles Ti2s and Te3s, 2s pause, followed by orotracheal suction. Control – bilateral compression and manual vibration followed by manual hyperinflation and orotracheal suction Treatment applied by a physiotherapist	Parameters evaluated: 5 min before 5 min after WOB Ventilator adverse event 'decrease in SaO_2 by 3%' Haemodynamic adverse event 'SBP <90mmHg'	No difference in WOB between two groups No haemodynamic or ventilatory adverse events were observed
Martínez-Alejos	2021	France	Prospective single-blind randomised crossover trial	To evaluate the efficacy and safety of MI-E combined with expiratory. rib cage compressions	Adults (>18 years) On MV > 48hrs via ETT Mixed diagnosis	26	Two protocols, 4-hr washout interval: Control: ERCC followed by endotracheal suction Intervention: ERCC plus MI-E Pressures (+40/-40) 4 series of 5 I-E cycles, with a 1	Parameters evaluated: Before During After HR SBP	HR significantly increased in both treatment arms. SaO_2 significantly increased after 1hour in the ERCC+MI-E group (p=0.03*) PaO_2 significantly increased after the ERCC+MI-E intervention (p=0.003*) A total of 21 episodes of brief

Author	Year	Location	Study design	Study aims	Population	n	Intervention/Protocol	Outcome measures	Result
							min pause between series. Medium inspiratory flow I-E time 3s and 2s, 1s pause. Automatic mode Followed by endotracheal suction Treatment applied by an experienced respiratory physiotherapist.	DBP PaO_2 $PaCO_2$ SaO_2	desaturations or haemodynamic variations were documented: 10 during ERCC+MI-E 11 during ERCC (no significant difference between interventions)
Sánchez-García	2018	Spain	Case series	To evaluate the safety of MI-E use in the intubated patient population	Adults (>18 years) On MV via ETT/ tracheostomy Mixed diagnosis (Post operative, Medical Trauma)	13	MI-E with I/E pressures of +50/-45 cmH_2O, with oscillations at 16Hz Cycles of 10-12 I-E time – 3s and 4s followed by endotracheal/ tracheal suction	Parameters evaluated: At baseline Immediately before 5 min after 60 min after HR MAP SaO_2 PaO_2 $PaCO_2$ RR	No statistically significant difference in HR, MAP, $PaCO_2$ and RR between time points SaO_2 and PaO_2 significantly increased from baseline (p=0.04* and p=0.031* respectively) One episode of raised ICP (from 17cmH_2O to 28cmH_2O)

Abbreviations: **cmH_20** – centimeters of water; **DBP** – Diastolic Blood Pressure; **ERCC** – Expiratory Rib Cage Compressions; **ETT** – Endotracheal Tube; **HR** – Heart Rate; **Hrs** – Hours; **Hz** – hertz; **ICP** – Intracranial Pressure; **I/E** - Insufflation/Exsufflation; **MAP** – Mean Arterial Pressure; **MI-E** – Mechanical Insufflation-Exsufflation; **min** – minute; **MV** – Mechanical Ventilation; **OTT** – Orotracheal Tube; **$PaCO_2$** – Partial Pressure of Carbon Dioxide; **PaO_2** – Partial Pressure of Oxygen; **RR** – Respiratory Rate; **s** – second; **SaO_2** – Oxygen Saturation Level; **SBP** – Systolic Blood Pressure; **SpO_2** – Oxygen Saturation; **Ti** – Inspiratory Time; **Te** – Expiratory Time; **WOB** – Work of Breathing; * statistically significant finding

were applied by physiotherapists in three studies.[10,11,20] However, Coutinho et al.[22] and Sánchez-García et al.[21] did not detail who applied the treatment. Detail regarding clinician level of experience was not included across included studies.

OUTCOMES

Ten different outcomes across the five included studies were identified relating to safety and/or adverse events (respiratory and haemodynamic). Only two studies examined adverse events as a primary outcome.[21,22] One study provided further definition for a ventilatory and haemodynamic adverse event.[11]

OCCURRENCE OF ADVERSE EVENTS

No haemodynamic or ventilatory adverse events were observed in two of the five studies.[11,22] Of the studies that observed adverse events only transient changes were described.[10,20,21] No study reported clinically significant adverse events that required cessation of MI-E treatment or medical intervention.

DISCUSSION

The aim of this review was to report on the occurrence of adverse events associated with MI-E use in invasively ventilated critically ill patients. The findings suggest that the use of MI-E in this patient group does not result in adverse events that are clinically significant. Despite all studies concluding that MI-E is safe in this population, limitations to the evidence base should be acknowledged when interpreting the results.

There was large variation in MI-E protocols across studies and a lack of detail regarding device set up, which limits the ability to draw firm conclusions regarding the link between MI-E and adverse events. Although varied, the use of insufflation and exsufflation pressures of +40/-40cmH_2O is consistent with findings from a recent scoping review by Swingwood et al.[8] It is well documented pressures of at least +40/-40cmH_2O are required to generate higher expiratory flows.[23] However, emerging evidence suggests even higher pressures may be required in those with an artificial airway, to overcome resistance to flow.[24,25] Only one study in this review applied higher insufflation and exsufflation pressures (+50/-50 cmH_2O), which did not result in significant changes in respiratory or haemodynamic parameters.[20] This is consistent with the findings of Hyun, Lee, and Shin[25] and Martí et al.[26] where no adverse events were observed when pressures of +50/-50 cmH_2O and +40 to -70cmH_2O (respectively) were utilised. It is worth noting that Martí et al.[26] utilised pig models, therefore findings from this study cannot be extrapolated directly to a patient population. Whilst reassuring, studies investigating adverse events with higher pressures are limited.

To allow for more accurate representation of adverse events with different pressures perhaps standardisation of MI-E protocols would be preferable. Although this approach is thought to improve clinician confidence, arguably, one set protocol is unlikely to be effective and does not take into consideration individual risk factors that may predispose patients to adverse events occurring. Previously in the literature an individualised approach to MI-E set up has been advocated.[7] Progressively building up pressure until efficiency is achieved allows for careful monitoring of adverse effects and is potentially safer.

There was also a wide variation in the outcomes reported across studies including heart rate, blood pressure, oxygen saturation, respiratory rate, work of breathing and arterial blood gas measurement, which again limits comparisons. Differences in the definition of an adverse event used within studies may have caused conflicting results on their prevalence. Whilst Martínez-Alejos et al.[10] suggested a threshold for MI-E cessation (when arterial oxygen saturation falls below 85% or blood pressure changes of over 20% from baseline), only Ferreira de Camillis et al.[11] provided a clear definition for a ventilatory and haemodynamic adverse event (a decrease in oxygen saturation of 3% or drop in systolic blood pressure below 90mmHg). The remaining studies did not state at which point they determined changes in respiratory or haemodynamic parameters to be indicative of an adverse event. Therefore, the occurrence of adverse events in those studies may be under-reported. Additionally, the timepoints at which measurements were taken also varies across studies. It is worth noting that adverse events were reported as secondary outcomes in three of the five studies,[10,11,20] which again may result in the under-estimation of adverse events in this population.

Methodological quality of the included studies was assessed using the CASP tool. Overall, issues were identified relating to completeness of reporting, blinding, and a lack of pre-defined measurements. All included studies were based outside of the United Kingdom (UK) and varied in study design. Differences in ICU practices have been highlighted, in particular disparities in the management of patients who are mechanically ventilated.[27,28] Consequently, little is known about the impact of confounding factors of standard ICU care protocols. Standardisation of usual care and transparency of adjunctive interventions would mitigate potential confounders in future trials. Heterogeneity in study design limits the ability to draw comparisons across studies and make firm conclusions regarding the occurrence of adverse events with MI-E.

STRENGTHS AND LIMITATIONS OF THIS REVIEW

This review outlines the current available evidence regarding the safety of MI-E in mechanically ventilated adults. Clear inclusion and exclusion criteria were developed, and robust methodology applied. Multiple reviewers were used which was a further strength of the study methods. However, the findings of this review were limited by the paucity of studies on this topic. This review highlights that overall, there is a lack of published studies investigating the relationship between MI-E and the occurrence of adverse events, suggesting it is an under researched area. The lack of available evidence has been identified as a barrier to MI-E implementation in practice, which may be contributing

to the underutilisation of the device in this population.[13,14] The absence of robust large-scale studies is not surprising given the complexity of researching patients who are critically ill, and the ethical implications of withholding vital treatment interventions.[29] Further publication of observational studies could strengthen conclusions regarding the safety of MI-E and increase clinician confidence in the device.

CONCLUSION

There are limited studies specifically investigating whether the use of MI-E results in adverse events in critically ill patients who are mechanically ventilated. In the five studies included, MI-E was reported to be safe, and its use did not result in adverse events that are clinically significant. Variations is study design, protocols and outcome measures limit direct comparisons between studies. Therefore, further research is needed with emphasis on standardisation of protocols and usual care. Larger clinical trials are needed to further evaluate the safety of MI-E on clinically important parameters that are more clearly defined. Additionally, to improve clinician confidence in practice, further research exploring the occurrence of adverse events across a range of pressures is warranted.

Key points

- The use of MI-E in the acutely intubated patient does not result in adverse events that are clinically significant.
- There were variations in study design, MI-E protocols and outcome measures used.
- Standardisation of protocols and usual care is needed, as well as a consensus on clinically important parameters that are clearly defined.

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REFERENCES

1. McGarvey L, Rubin BK, Ebihara S, et al. Global Physiology and Pathophysiology of Cough. *Chest*. 2021;160(4):1413-1423. doi:10.1016/j.chest.2021.04.039

2. Jonkman AH, Jansen D, Heunks LMA. Novel insights in ICU-acquired respiratory muscle dysfunction: Implications for clinical care. *Crit Care*. 2017;21(1). doi:10.1186/s13054-017-1642-0

3. Lellouche F. Humidification during invasive mechanical ventilation: Hygrometric performances and cost of Humidification Systems. *Humidification in the Intensive Care Unit*. Published online September 23, 2011:137-155. doi:10.1007/978-3-642-02974-5_17

4. Gonçalves MR, Honrado T, Winck J, Paiva J. Effects of mechanical insufflation-exsufflation in preventing respiratory failure after extubation: A randomized controlled trial. *Critical Care*. 2012;16(2):R48. doi:10.1186/cc11249

5. Fernández-Carmona A, Olivencia-Peña L, Yuste-Ossorio ME, Peñas-Maldonado L. Ineffective cough and mechanical mucociliary clearance techniques. *Medicina Intensiva (Engl Ed)*. 2018;42(1):50-59. doi:10.1016/j.medin.2017.05.003

6. Tronstad O, Martí JD, Ntoumenopoulos G, Gosselink R. An update on cardiorespiratory physiotherapy during mechanical ventilation. *Semin Respir Crit Care Med*. 2022;43(03):390-404. doi:10.1055/s-0042-1744307

7. Chatwin M, Toussaint M, Gonçalves MR, et al. Airway clearance techniques in neuromuscular disorders: A state of the art review. *Respiratory Medicine*. 2018;136:98-110. doi:10.1016/j.rmed.2018.01.012

8. Swingwood EL, Stilma W, Tume LN, et al. The use of mechanical insufflation-exsufflation in invasively ventilated critically ill adults. *Respir Care*. 2022;67(8):1043-1057. doi:10.4187/respcare.09704

9. Chatwin M, Wakeman RH. Mechanical insufflation-exsufflation: Considerations for improving clinical practice. *Journal of Clinical Medicine*. 2023;12(7):2626. doi:10.3390/jcm12072626

10. Martínez-Alejos R, Martí JD, Li Bassi G, et al. Effects of mechanical insufflation-exsufflation on sputum volume in mechanically ventilated critically ill subjects. *Respir Care*. 2021;66(9):1371-1379. doi:10.4187/respcare.08641

11. Ferreira de Camillis ML, Savi A, Goulart Rosa R, et al. Effects of mechanical insufflation-exsufflation on airway mucus clearance among mechanically ventilated ICU subjects. *Respir Care*. 2018;63(12):1471-1477. doi:10.4187/respcare.06253

12. Stilma W, van der Hoeven SM, Scholte op Reimer WJM, Schultz MJ, Rose L, Paulus F. Airway care interventions for invasively ventilated critically ill adults—a Dutch National Survey. *Journal of Clinical Medicine*. 2021;10(15):3381. doi:10.3390/jcm10153381

13. Swingwood E, Stilma W, Tume L, et al. The use of mechanical insufflation-exsufflation in invasively ventilated critically ill adults: A scoping review protocol. *Syst Rev*. 2020;9(1). doi:10.1186/s13643-020-01547-8

14. Rose L, Adhikari NK, Poon J, Leasa D, McKim DA. Cough augmentation techniques in the critically ill: A Canadian national survey. *Respir Care*. 2016;61(10):1360-1368. doi:10.4187/respcare.04775

15. Mahmood SS, Pinsky MR. Heart-lung interactions during mechanical ventilation: The basics. *Ann Transl Med*. 2018;6(18):349-349. doi:10.21037/atm.2018.04.29

16. Soni N, Williams P. Positive pressure ventilation: What is the real cost? *British Journal of Anaesthesia*. 2008;101(4):446-457. doi:10.1093/bja/aen240

17. Auger C, Hernando V, Galmiche H. Use of mechanical insufflation-exsufflation devices for airway clearance in subjects with neuromuscular disease. *Respir Care*. 2017;62(2):236-245. doi:10.4187/respcare.04877

18. Park HY, Ha SY, Lee SH, et al. Repeated derecruitments accentuate lung injury during mechanical ventilation*. *Critical Care Medicine*. 2013;41(12):e423-e430. doi:10.1097/ccm.0b013e3182986268

19. CASP checklists - critical appraisal skills programme. Published 2021. https://casp-uk.net/casp-tools-checklists/

20. Nunes L de C, Rizzetti DA, Neves D, et al. Mechanical insufflation/exsufflation improves respiratory mechanics in critical care: Randomized crossover trial. *Respiratory Physiology & Neurobiology*. 2019;266:115-120. doi:10.1016/j.resp.2019.05.008

21. Sánchez-García M, Santos P, Rodríguez-Trigo G, et al. Preliminary experience on the safety and tolerability of mechanical "insufflation-exsufflation" in subjects with artificial airway. *Intensive Care Medicine Experimental*. 2018;6(1). doi:10.1186/s40635-018-0173-6

22. Coutinho WM, Vieira PJC, Kutchak FM, Dias AS, Rieder MM. Comparison of mechanical insufflation–exsufflation and endotracheal suctioning in mechanically ventilated patients: Effects on respiratory mechanics, hemodynamics, and volume of Secretions. *Indian Journal of Critical Care Medicine*. 2018;22(7):485-490. doi:10.4103/ijccm.ijccm_164_18

23. Volpe MS, Guimarães FS, Morais CC. Airway clearance techniques for mechanically ventilated patients: Insights for optimization. *Respir Care*. 2020;65(8):1174-1188. doi:10.4187/respcare.07904

24. Guérin C, Bourdin G, Leray V, et al. Performance of the coughassist insufflation-exsufflation device in the presence of an endotracheal tube or tracheostomy tube: A bench study. *Respir Care*. 2011;56(8):1108-1114. doi:10.4187/respcare.01121

25. Hyun SE, Lee SM, Shin HI. Peak expiratory flow during mechanical insufflation-exsufflation: Endotracheal Tube Versus Face Mask. *Respir Care*. 2021;66(12):1815-1823. doi:10.4187/respcare.09150

26. Martí JD, Martínez-Alejos R, Pilar-Diaz X, et al. Effects of mechanical insufflation-exsufflation with different pressure settings on respiratory mucus displacement during invasive ventilation. *Respir Care*. 2022;67(12):1508-1516. doi:10.4187/respcare.10173

27. Burns KEA, Rizvi L, Cook DJ, et al. Ventilator weaning and discontinuation practices for critically ill patients. *JAMA*. 2021;325(12):1173. doi:10.1001/jama.2021.2384

28. Russotto V, Myatra SN, Laffey JG, et al. Intubation practices and adverse peri-intubation events in critically ill patients from 29 countries. *Journal of American Medical Association (JAMA)*. 2021;325(12):1164. doi:10.1001/jama.2021.1727

29. Freitas dos Santos S, Almeida MP, Winck JC. Effects of mechanical insufflator-exsufflator in people with Spinal Cord Injury: A systematic review. *Physical Therapy Reviews*. 2022;28(1):18-29. doi:10.1080/10833196.2022.2141527

Appendix 1. Search terms

Search 1	"ICU" OR "intensive care unit" OR “critical care” OR “critical*” OR "intubat*" OR "mechanical* ventilat*" OR "artificial airway*" OR "ITU" OR "invasive* ventilat*"
Search 2	"Cough Assist" OR "NIPPY clearway" OR "MI-E" OR "MI:E" OR "mechanical insufflation-exsufflation" OR "CoughAssist E70" OR "CoughAssist T70" OR "mechanically assisted cough"
Search 3	"safe*" OR "impact*" OR "Adverse event*" OR "Adverse effect*" OR "Haemodynamic instability" OR "pneumothorax" OR "Hypotension" OR "Cardiovascular instability" OR "Harm*" OR "Negative effect*" OR "Negative event*" OR "Gastrointestinal reflux" OR "stomach distention" OR "abdomen distention" OR “work of breathing” OR “arrhythmia” OR “haemoptysis” OR “nausea” OR “bradycardia” OR “ tachycardia” OR “barotrauma” OR “dyspnoea” OR “dyspnea”

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Sparkes EL, Fitzgerald E, Koppa J, O'Rourke O, Perry E, Goddard S. Practitioner experiences of pulmonary rehabilitation service delivery during COVID-19 and impact on future service delivery. *ACPRC Journal*.:13-19. doi:10.56792/FQFI5623

Long term conditions

Practitioner experiences of pulmonary rehabilitation service delivery during COVID-19 and impact on future service delivery.

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Keywords: Pulmonary rehabilitation, Telerehabilitation, COVID-19

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Journal of the Association of Chartered Physiotherapists in Respiratory Care

Abstract

Introduction

During COVID-19, pulmonary rehabilitation as we know it ceased to exist. The service needed to adapt rapidly to the requirements of the patient group, while complying with government isolation guidelines. Most groups moved online, but with little time to evaluate the service. What can we learn from this roll out to ensure practitioners continue to deliver a safe and effective pulmonary rehabilitation service.

Aim

To explore the opinions of physiotherapist and respiratory nursing specialists' on how pulmonary rehabilitation has changed due to COVID-19 and the impact on future service delivery.

Methods

A qualitative design was used to gain in-depth understanding of lived experiences. Forty nine participants completed the online survey of 14 open ended questions, and a four-stage thematic analysis used to identify emergent themes.

Findings

Three main themes were identified- a need for best practice, a need for patient centred care, and acknowledging the emotional stressors of COVID-19 on vulnerable patients.

Conclusion

Patients should be offered both online and face-to-face options for pulmonary rehabilitation, to promote patient centred care; providing options to participate in effective rehabilitation without physical or emotional restriction; and to increase staff training to enable practitioners to provide the increasingly complex and holistic service required.

INTRODUCTION

Prior to COVID-19, the majority of pulmonary rehabilitation classes were held in community or church halls (29%), or local leisure centres or gyms (24%).[1] To protect vulnerable people shielding, these face-to-face meetings typically adapted during the pandemic to a home-based telerehabilitation service.[2] The CSP defines telerehabilitation also widely known as telehealth, virtual or remote monitoring as "the use of electronic communications and virtual technology to deliver healthcare beyond traditional healthcare settings including the use of video or telephone communication and mobile apps ".[3]

Telerehabilitation is not a pandemic novelty; roll out began many years prior, with evidence suggesting that providing a home-based telerehabilitation service is equally effective, safe and well tolerated compared to face-to-face delivery as part of a randomised controlled trial.[4] However, while several studies demonstrate similar improvements in exercise capacity and quality of life measures when undertaking telerehabilitation, these studies also included thorough face-to-face pre- and post- assessments; limiting the applicability of findings to patients shielding from COVID-19 due to the restrictions faced by services at this time.[5]

Research by Burge, Holland[6] highlighted telerehabilitation to be on average $4497 cheaper than face-to-face pulmonary rehabilitation. Although statistically insignificant, and analysing the USA health system, these savings may be clinically relevant in the UK.

It takes on average 17 years to integrate research into clinical practice.[7] The rapid advancement of COVID-19 and need to expedite changes to service delivery has instead

provided a unique situation where clinical needs have leapfrogged research in an unprecedented way and as such, data on the effectiveness of these changes are limited. Research to date has focused on the effectiveness of a telerehabilitation programme, but little exists on how this change in delivery has affected service users, service providers, or what can be learned from this rapid and unplanned change to a core NHS service. Our research aimed to explore the opinions of physiotherapist and respiratory nursing specialists' on how pulmonary rehabilitation has changed due to COVID-19 and the impact on future service delivery.

METHODS

ETHICS

This study was approved by the University of Plymouth School of Health Professions Undergraduate Research Ethics Committee (3299).

STUDY DESIGN

To ensure breadth of opinions from across the whole of the UK and ensuring anonymity of participants, an online survey was developed by the research team, and uploaded[8] for voluntary completion by eligible participants.

The survey consisted of 14 open ended questions, producing richer and more complex data about participant experiences, providing a depth of understanding and opinions on changes to future service delivery.[9]

In line with the conclusions in the review paper by Foy, Eccles,[10] the questions were piloted by a healthcare professional specialising in pulmonary rehabilitation prior to data collection for respondent understanding, difficultly, timing and answer variation; while two researchers, blinded to the survey creation, tested the survey for flow, timing, layout, broken links and spelling errors.

PARTICIPANTS

Participants were recruited using purposive sampling via advertisement on respiratory physiotherapy and nursing social media accounts. Eligible participants were required to be either a respiratory specialist physiotherapist or nurse working in the UK. They must have led, or assisted with, pulmonary rehabilitation and experienced a change in delivery because of the COVID-19 pandemic.

DATA ANALYSIS

The online survey was open for six weeks from October 17th to November 25th, 2022, with 49 individual surveys submitted.

All identifying information was redacted from the transcripts. Data were analysed using a four-stage framework[11] manually assigning codes to key thoughts and ideas. Each researcher read all responses a minimum of three times to ensure data immersion before developing more detailed codes from a subgroup of questions. To increase reliability, codes and categories were defined by the five researchers independently, and then refined as a group until themes were identified and consensus was reached.[12] Each question was analysed by a different researcher pairing to ensure the coding framework was applied consistently and avoid researcher bias.

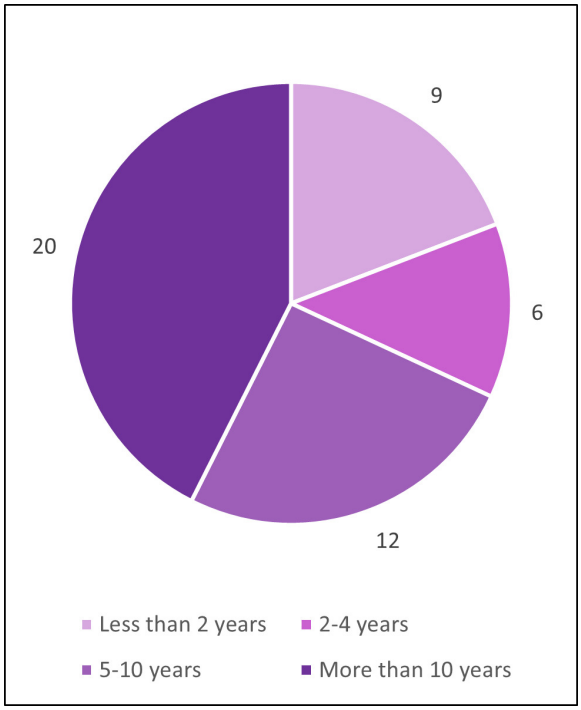

Figure 1. Number of years participants have been qualified.

FINDINGS

The majority (37/49) of respondents have been qualified for over 10 years (Figure 1) and delivering pulmonary rehabilitation services for over 10 years (Figure 2).

Thematic analysis of the data identified three themes-

1. A need for best practice
2. A need for patient centred care
3. Acknowledging the emotional stressors of COVID-19 on vulnerable patients

"WE MAY NOT BE DELIVERING GOLD STANDARD TREATMENT."- A NEED FOR BEST PRACTICE

Over half of participants (27/49) expressed need for more training and research into telerehabilitation delivery.

> PR is traditionally run as a F2F intervention and is therefore widely researched and established in this format. Delivering PR in any other medium means we are unsure of the effectiveness... we may not be delivering gold standard treatment... [Participant 8]

Participants also expressed a need for training in wider areas,

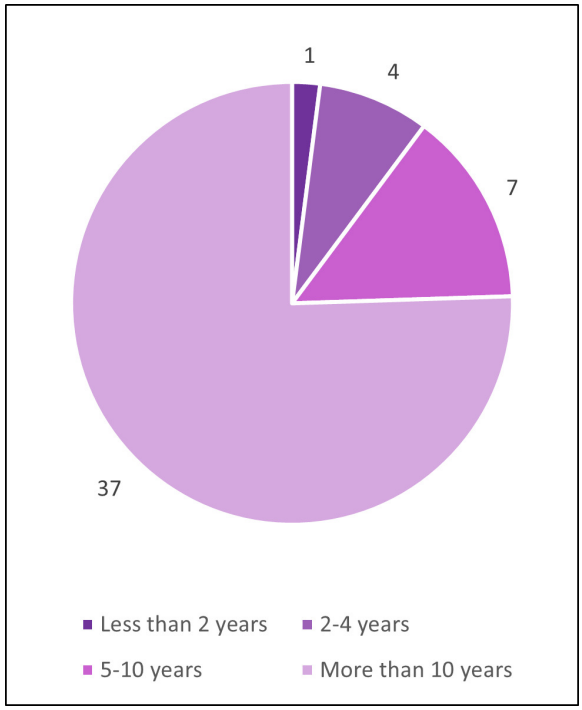

Figure 2. Number of years participants have been delivering pulmonary rehabilitation.

> We need a level of cardiac and general training as the patients are getting more complex with multiple patients requiring a cardiac/pulmonary rehab approach [Participant 46].

The British Thoracic Society (BTS) pulmonary rehabilitation guidelines, developed in 2013, suggest a minimum of twelve in-person sessions including education and physical activity for effective pulmonary rehabilitation. There are minimal references to integration of telerehabilitation as research in this area was in its infancy.[13] The NHS pulmonary rehabilitation service guidance also recommends minimum staffing ratios of 1:8 in exercise classes with a minimum of two supervisors per group, and greater staffing for oxygen users or complex patients.[14]

In 2018, Taskforce for Lung Health, reported 40% of hospitals had at least one respiratory clinician vacancy, and highlighted a need for more experienced respiratory specialists. An additional 600 physiotherapists over the next five years were recommended to keep up with current demand for pulmonary rehabilitation services.[15] This was echoed by one participant.

> I do feel in general though that putting the pandemic aside we have a general issue in the quality of PR delivery, with the workforce having been so diluted and recruitment issues. In my experience there are fewer actual specialists out there than there were 8-10 years ago, and the workforce is generally more junior/ inexperienced than it was [Participant 27]

With staff shortages, expanding in-person services is unlikely at present, however, many existing locations were unable to facilitate in-person programmes whilst complying with government social distancing guidelines "...halls were too small to accommodate infection prevention and control..." [Participant 43] so in-person services were unable to continue.

Recognising the workforce's need for standardisation of delivery and to ensure best practice across the UK, the Pulmonary Rehabilitation Services Accreditation Scheme (PRSAS) was launched in 2018, based on the BTS guidelines.[16] To date, only seven services in the UK are accredited to the scheme. As guidelines have not been reviewed since before most departments began integrating telerehabilitation, and therefore accreditation still requires teams to deliver rehab in person; many may not currently meet accreditation standards.

Some participants also reported poorer patient outcomes "...an audit of our outcomes from the socially distanced classes were not as good as the circuit class from before the pandemic... [Participant 36]". However, it is unclear whether the same outcome measures were used in both cohorts, it also fails to consider patients were self-isolating and likely to be less active during the pandemic, contributing to lower baselines. This was acknowledged by another participant.

> Although patients are more willing to engage with other technology, they are often very deconditioned and finding exercise hard. Some are motivated to get fitter and engage because of this, some groups of patients are resigned to being more unfit and have lost motivation by feeling very low in mood [Participant 25]

Zhang, Maitinuer[17] monitored 174 COPD patients over an 8-week telerehabilitation programme. Patients reported significant improvement in dyspnoea symptoms and reduction in 6MWT distances. Lack of a control group, and follow up at only 12 weeks limits long-term evaluation, however findings were substantiated by Cox, McDonald[18] who used a multicentre RCT with assessor blinding to investigate whether telerehabilitation was equivalent to face-to-face. The 142 participants had equivalent 6MWT distances in the telerehabilitation and in-person groups at 6 months. The 84% completion rate reported for the telerehabilitation programme in a rural location exceeded that typically seen in face-to-face programmes. Telerehabilitation may also provide an alternative, clinically equivalent, delivery method by removing barriers to attendance in under resourced locations where in person attendance is prohibitive.

"WE CAN'T FORCE PATIENTS TO DO FACE TO FACE"- PATIENT CENTRED CARE

Participants reported patient benefits with online or hybrid service delivery.

> I think a menu of options for participation re PR is a good thing. The evidence is stronger re face to face but we can't force pts to do face to face if they don't want to travel or are house bound. We have staffing issues too so offering a virtual based PR programme will help us increase the scope to deliver in localities where the

> travel/ staff/ accommodation might have prevented delivery of a face to face programme [Participant 31]

This study focused on the changes in service delivery from the practitioner's perspective, it is prudent to be conservative with generalisations and drawing conclusions of patient's experiences using only practitioner's experiences. Although our study was focused on practitioner perspective, it is notable how many responses directly referenced patient experience, highlighting a promotion of patient-centred therapy services.

Participants acknowledge benefits to telerehabilitation with caution.

> Virtual delivery offers something to patients that cannot attend in person, however they are missing out on an individualised approach and peer support that is only possible in face to face groups [Participant 43]

Skibdal, Emme[19] reported similar patient benefits, using surveys and semi structured interviews to explore attitudes towards telerehabilitation in patients with severe COPD who declined face-to-face classes. They discovered 28% of patients were interested in participating in telerehabilitation, 70% felt safe and willing to initiate the home programme, with 42% perceiving telerehabilitation to be equally beneficial to face-to-face services. As participants had not undertaken pulmonary rehabilitation, caution must be taken before linking perception to clinical benefit. It is important to note these patients had declined face-to-face contact, but were likely to engage in telerehabilitation, this may present an opportunity to rehabilitate and monitor these patients who may otherwise disengage, but further research is required to quantify this benefit.

Several participants highlighted transport to pulmonary rehabilitation centres as a major barrier for patients with reduced mobility, offering telerehabilitation as a potential benefit to these patient groups,

> Those who do not want to come face to face with people yet, or unable to travel out of home. Or even those who can't afford the rising costs of living and high petrol prices [Participant 14]

Another participant acknowledged that telerehabilitation was patients preferred delivery method.

> Many patients preferred this style of PR and subsequent results in outcomes match results of those who would complete a F2F programme. Many more patients able to access a distance PR if they have other commitments such as work or carer commitments [Participant 40]

Graves, Sandrey[20] found similar results, reporting patients living over 25 minutes from pulmonary rehabilitation classes were less likely to attend or adhere to programmes. By targeting patients who were more likely to adhere, they were able to reduce 'wasted' appointments and increase graduation rates. However, by only offering face-to-face appointments, those unable to attend often missed out on the benefits of regular contact with healthcare professionals.

"STAY AT HOME OTHERWISE COVID-19 WILL KILL YOU"- ACKNOWLEDGING EMOTIONAL STRESSORS

During COVID-19 lockdowns, government guidance to people with chronic conditions was to isolate at home and face-to-face services were not an option. Participants reported increased anxiety in patient groups.

"... patients found it difficult to let go of the advice given to them at the start of the Pandemic which was stay home at all costs otherwise COVID-19 will kill you. Even now anxiety about leaving the house combined with significant deconditioning prevent many patients from attending PR... [Participant 43]". There was also reluctance to participate in services:

"We surveyed our patients at the beginning of the pandemic and 90% could not or did not want to engage with virtual PR... [Participant 26]".

Mousing and Sørensen[21] used semi structured interviews to understand the experiences of 13 COPD patients during COVID-19 lockdowns. Their patients' experiences agreed with our findings, feeling compelled to self-isolate because they have lived experiences of respiratory distress contributing to a fear of dying from COVID-19. Feelings of anxiety and social isolation were reportedly heightened, as patients feared being forgotten about by medical services, concluding telerehabilitation could be beneficial to this population enabling regular contact without breaking social isolation.[21]

CONCLUSION

The study aimed to contribute to a broader understanding of respiratory practitioners' opinions on pulmonary rehabilitation changes and how these may impact plans for future service delivery.

Based on our findings, clinicians' feel that future pulmonary rehabilitation delivery should offer patients choices to participate in effective rehabilitation without physical or emotional restriction, through the offering of both online and face-to-face pulmonary rehabilitation programmes. Clinicians also highlighted a need for increased staff training to enable practitioners to provide the increasingly complex and holistic service required.

Although the survey was advertised equally to both populations, the response rate from respiratory nurses was significantly lower. Whether there are fewer nurses in pulmonary rehabilitation, or we failed to target this population effectively is unclear. Due to the constraints of university ethics policy, we were unable to directly target pulmonary rehabilitation workers within the NHS system, relying solely on social media to advertise our study. As such, we were predominantly limited to respondents who were active on social media, following relevant organisations. This may elicit selection bias, as participants are more likely to be utilising online technologies already, and more comfortable with integrating these into their practice. Future studies would gain NHS ethics to target distribution and ensure

all eligible staff were offered opportunity to contribute; and would extend to face-to-face interviews in an attempt to capture the entire workforce.

Further research will aim to connect practitioners and patients to ensure both viewpoints are considered equally in service development and provide weight to accreditation and guidelines supporting the inclusion of telerehabilitation alongside face-to-face programmes.

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DECLARATION OF INTEREST

None

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REFERENCES

1. Physicians RC. National COPD Audit Programme. Pulmonary Rehabilitation: An exercise in improvement. Published online 2018. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiNvZe_iPaEAxXrX0EAHXn_BoUQFnoECA0QAQ&url=https%3A%2F%2Fwww.rcplondon.ac.uk%2Ffile%2F9479%2Fdownload&usg=AOvVaw0mb08v6rQHlt8Q_-sEYz0_&opi=89978449

2. Houchen-Wolloff L, Steiner MC. Pulmonary rehabilitation at a time of social distancing: prime time for tele-rehabilitation? *Thorax*. 2020;75(6):446-447. doi:10.1136/thoraxjnl-2020-214788

3. Chartered Society of Physiotherapists. *Telehealth*. Published online 2020. https://www.csp.org.uk/professional-clinical/digital-physiotherapy/telehealth

4. Bourne S, DeVos R, North M, et al. Online versus face-to-face pulmonary rehabilitation for patients with chronic obstructive pulmonary disease: randomised controlled trial. *BMJ Open*. 2017;7(7):e014580. doi:10.1136/bmjopen-2016-014580

5. British Thoracic Society. COVID-19: information for the respiratory community. Published online 2020. https://www.brit-thoracic.org.uk/covid-19/covid-19-information-for-the-respiratory-community/

6. Burge AT, Holland AE, McDonald CF, et al. Home-based pulmonary rehabilitation for COPD using minimal resources: An economic analysis. *Respirology*. 2019;25(2):183-190. doi:10.1111/resp.13667

7. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *J R Soc Med*. 2011;104(12):510-520. doi:10.1258/jrsm.2011.110180

8. Jisc. Online Survey. Published online 2022. https://www.onlinesurveys.ac.uk

9. Braun V, Clarke V. *Successful Qualitative Research: A Practical Guide for Beginners*. SAGE; 2013.

10. Foy R, Eccles M, Jamtvedt G, Young J, Grimshaw J, Baker R. What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review. *BMC Health Serv Res*. 2005;5(1):1-7. doi:10.1186/1472-6963-5-50

11. Green J, Willis K, Hughes E, et al. Generating best evidence from qualitative research: the role of data analysis. *Australian and New Zealand Journal of Public Health*. 2007;31(6):545-550. doi:10.1111/j.1753-6405.2007.00141.x

12. Bengtsson M. How to plan and perform a qualitative study using content analysis. *NursingPlus Open*. 2016;2:8-14. doi:10.1016/j.npls.2016.01.001

13. Bolton CE, Bevan-Smith EF, Blakey JD, et al. British Thoracic Society guideline on pulmonary rehabilitation in adults: accredited by NICE. *Thorax*. 2013;68(Suppl 2):ii1-ii30. doi:10.1136/thoraxjnl-2013-203808

14. England NHS. Pulmonary rehabilitation service guidance. Published online 2020. https://www.england.nhs.uk/wp-content/uploads/2020/03/pulmonary-rehabilitation-service-guidance.pdf

15. Health TFL. A national five year plan for lung health. Published online 2018. https://cdn.shopify.com/s/files/1/0221/4446/files/PC1802_Taskforce_Report_MASTER_v8.pdf?30&_ga=2.212669789.819391140.1682668234-383192421.1682668234

16. Physicians RC. Pulmonary Rehabilitation Services Accrediation Scheme. Published online 2023. https://www.prsas.org/RegisteredUnits.aspx

17. Zhang L, Maitinuer A, Lian Z, et al. Home based pulmonary tele-rehabilitation under telemedicine system for COPD: a cohort study. *BMC Pulm Med*. 2022;22(1). doi:10.1186/s12890-022-02077-w

18. Cox NS, McDonald CF, Mahal A, et al. Telerehabilitation for chronic respiratory disease: a randomised controlled equivalence trial. *Thorax*. 2021;77(7):643-651. doi:10.1136/thoraxjnl-2021-216934

19. Skibdal KM, Emme C, Hansen H. Listen to Me! – A Mixed-Methods Study of Thoughts and Attitudes Towards Participation in Pulmonary Telerehabilitation Among People with Severe and Very Severe COPD Who Declined Participation in Pulmonary Rehabilitation. *PPA*. 2022;Volume 16:2781-2798. doi:10.2147/ppa.s380832

20. Graves J, Sandrey V, Graves T, Smith D. Effectiveness of a group opt-in session on uptake and graduation rates for pulmonary rehabilitation. *Chron Respir Dis*. 2010;7(3):159-164. doi:10.1177/1479972310379537

21. Mousing CA, Sørensen D. Living with the risk of being infected: COPD patients' experiences during the coronavirus pandemic. *Journal of Clinical Nursing*. 2021;30(11-12):1719-1729. doi:10.1111/jocn.15727

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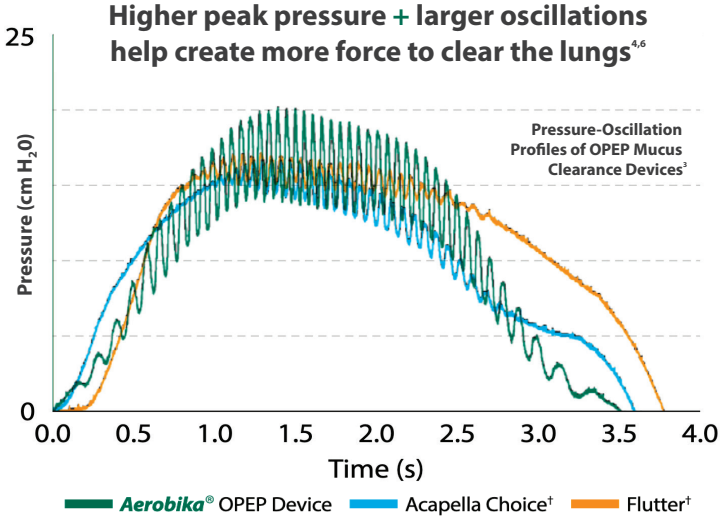

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1 GpRx Primary Care Data [Feb 2024]. **2** GOLD 2023 Report. **3** Hill AT *et al.*, British Thoracic Society Guideline for bronchiectasis. **4** Van Fleet H, *et al.* Respiratory Care 2017;62(4):451-458. **5** Suggett, J. *et al.* CHEST 2017.**6** Coppolo, *et al.* Pulmonary Therapy (2021)..

Wang L, Wan L, Qin Y, Gale N. An observational study to evaluate the within-day reliability and concurrent validity of 2-minute walk test (2MWT) and 10-metere walk test (10MWT) in healthy individuals while wearing a mask. *ACPRC Journal*.:21-28.
doi:10.56792/SFKK8730

Long term conditions

An observational study to evaluate the within-day reliability and concurrent validity of 2-minute walk test (2MWT) and 10-metere walk test (10MWT) in healthy individuals while wearing a mask.

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Keywords: within-day reliability, concurrent validity, wearing a surgical mask, 2-minute walk test, 10-meter walk test

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Journal of the Association of Chartered Physiotherapists in Respiratory Care

Abstract

Background

Exercise tests are widely used to prescribe exercises for patients with cardiorespiratory conditions and assess impact of treatments. The 2-minute walk test (2MWT) and 10-metre walk test (10MWT) are common assessments of functional exercise capacity. The COVID-19 pandemic resulted in people wearing masks (commonly surgical masks) to reduce infection. However, the validity and reliability of 2MWT and 10MWT wearing a mask is unknown and further research is required.

Aim

To assess the within-day reliability and concurrent validity of the 2MWT and 10MWT in healthy individuals wearing a surgical mask.

Design and Setting

Observational study, in a university setting

Methods

All participants completed three tests of 2MWT and 10MWT wearing a surgical mask (on one day) and one test without a mask (on a separate day) within one week. Oxygen saturation and heart rate were measured using pulse oximetry and the Borg scale assessed dyspnoea. Statistical analyses included: intraclass correlation coefficients (ICC) for within-day reliability of mask-wearing during three tests and Pearson's coefficient for concurrent validity correlated tests with a surgical mask and without a mask (the gold standard).

Results

15 people, mean (standard deviation) age 26 (2) years were included. The 2MWT and 10MWT (with mask) had excellent within-day reliability (ICC =0.823, 0.920 respectively). Both the 2MWT and 10MWT with and without a mask were highly correlated (r = 0.815, 0.943 respectively, p<0.01).

Conclusions

The results showed excellent within-day reliability and concurrent validity of 2MWT and 10MWT with a surgical mask in healthy individuals. Further research in clinical populations is needed.

INTRODUCTION

Exercise tests are widely used to prescribe exercises for patients with cardiorespiratory conditions such as chronic obstructive pulmonary disease (COPD) and assess impact of treatments. The cardiopulmonary exercise test (CPET) is the gold standard for maximal exercise testing but is difficult and expensive to administer.[1] Consequently, sub-maximal exercise tests, such as walking tests, are useful due to their ease and limited cost. The 6-minute walk test (6MWT), 2-minute walk test (2MWT) and 10-metre walk test (10MWT) are now widely used in clinical practice.[2] Although the validity and generalisability of the 6MWT have been well established, some patients have insufficient en-

durance or are unable to walk for 6 minutes. Therefore, 2MWT and 10MWT are efficient alternatives in clinical practice, where time and equipment are often limited. The 2MWT has been measured with intragroup retest reliability of 0.82,[3] and Leung et al.[4] also demonstrated high retest reliability for the 2MWT ($r = 0.999$; $p < 0.05$). In addition, Chan and Pin[5] found strong reliability (ICC = 0.95 - 0.99) and validity (r = 0.89 - 0.92) for the 10MWT in frail older adults, while Marques et al.[6] demonstrated high intra-rater reliability for the 10MWT in older patients with COPD (ICC = 0.903). Previously a high correlation was found between 2MWT and 6MWT (r = 0.937),[4] and a moderate correlation between 10MWT and 6MWT (r=0.449) ($p<0.05$).[7] This shows that the 2MWT and 10MWT are reliable and valid tests for assessing exercise capacity.

Most studies of exercise capacity are performed without wearing a mask. However, since 2020, the highly contagious nature of the COVID-19 pandemic resulted in the common use of masks to reduce infection risk. Surgical masks were widely used due to their low cost and availability. A rapid review has shown that wearing surgical masks reduced community transmission from COVID-19 because the face-mask could prevent the spread of coarse droplets and fine aerosols.[8] However, wearing surgical masks while walking on a treadmill has shown increased respiratory and heart rate, which may affect walking speed and endurance.[9] Additionally, mask-wearing may enhance resistance to inspiration and breathing and increase respiratory work.[10]

Shaw et al.[11] showed that wearing a surgical mask did not affect exercise performance in healthy subjects. Salles-Rojas et al.[12] found a strong correlation between 6MWT results with and without wearing a mask in healthy individuals ($r = 0.91$, $p < 0.001$). Several studies have shown no significant difference between the results of 6MWT with and without facemasks.[13,14] However as reliability and validity are different concepts concerning consistency and accuracy of the measurement, these must be established before use during exercise testing.[15] There have been no studies investigating the reliability and validity of the 2MWT and 10MWT wearing surgical masks. This study included healthy individuals to avoid any potential risks to patients, which is necessary before testing in people with cardiorespiratory conditions. The aim was to assess the impact of mask-wearing on within-day reliability and concurrent validity on healthy individuals.

OBJECTIVES

The objective of this study was to assess the within-day reliability of the 10MWT and 2MWT wearing a surgical mask (a cut-off of ICC>0.75 was used to indicate excellent reliability),[16] and the concurrent validity of the 10MWT and 2MWT with a surgical mask (correlation coefficient >0.70 was used to indicate good validity ($p<0.05$)).[17]

METHOD

STUDY DESIGN

In this observational study, all participants completed three tests of 2MWT and 10MWT wearing a surgical mask (on one day) and one test without a mask (on a separate day) within one week.

SETTING AND SAMPLE SIZE

Healthy individuals from Cardiff University were recruited from September to November 2022.

Sample size was based on the reliability analysis: to achieve good reliability, based on an ICC of 0.75, $\alpha = 0.05$, power set to 80% and R0 set to zero were used according to guidance.[18] According to guidance, a minimum of 11 participants were required. However, the calculation values were derived from a minimum sample size and there was a risk of data loss and participants dropping out midway, needed to consider recruiting an additional 20% of participants.[18] Therefore, 15 participants were recruited for this study.

The recruitment advertisements were shared on WhatsApp and Twitter and included inclusion/exclusion criteria, participants' requirement and contact details of the researcher. Interested participants emailed researchers, who responded by sending a participant information sheet.

INCLUSION AND EXCLUSION CRITERIA

For the safety of the participants and to ensure research completion, inclusion and exclusion were devised (Table 1). To ensure that potential risks were reduced, the Physical Activity Readiness Questionnaire (PAR-Q) was completed by each participant.[19] All subjects provided informed consent. This study was approved by the School of Healthcare Sciences Cardiff University Research Ethical Committee (No. REC904).

ASSESSMENTS

Baseline data included age, gender, height (SECA Leicester portable NS2030), weight (SECA Scales ETEKCITY 817915023259), and BMI (Kgm^2). A finger probe oximeter (ChoiceMMed MD300-D) recorded heart rate, and peripheral oxygen saturation before and after the tests, the modified Borg scale assessed dyspnoea, (Borg CR10 scale).[20] These are in line with previous work, to ensure the safety and recovery of the participants.

THE 2MWT PROTOCOL

Participants were asked to walk back and forth as far as possible on a flat 10m route for 2-minutes, in line with technical standards.[3] A 10-metre track was acceptable according to Beekman et al.[21] The researcher asked the participants to do their best during the 2MWT. The total distance walked by the 2MWT was recorded for each test.

Table 1. Inclusion and exclusion criteria

The inclusion criteria:	The exclusion criteria:
• Healthy adults aged 18-60 years from Cardiff University • Able to speak English. • Able to walk on the flat for 2 minutes. • Adults who agree to wear a surgical mask for whole test process	• Have current lower limb musculoskeletal disorders e.g., knee orthopaedical problems that limit the ability to walk. • Neurological conditions that affect walking, e.g., spinal cord injury affecting lower limb function • History of cardiopulmonary disease and cardiopulmonary symptoms that potentially affect the walking test, e.g., heart attack within the past month, severe uncontrolled hypertension, dizziness. • Adults who are exempt from wearing a surgical mask due to underlying conditions e.g., allergic to medical masks or had severe breathing difficulties when wearing a mask. • Have symptoms of covid-19 within two weeks. • Screened by PAR-Q questionnaire with "Yes" to one or more questions.

Table 2. 2MWT and 10MWT protocols

	2MWT and 10MWT	Day 1	Rest days	Day 7
Reliability (with mask)	Test 1	X		
	Test 2	X		
	Test 3	X		
Validity test (no mask)	Test			x

THE 10MWT PROTOCOL

The participants walked on a flat 10m route using standardised instructions.[22] The assessor recorded the time to complete the test using a stopwatch. Walking speed was calculated as distance/time, with walking speed used for analysis as it is a valid, reliable, and sensitive assessment of motor function.[23]

Participants performed three tests of the 2MWT and 10MWT, wearing a 3-layer surgical mask (Wecolor B0875S5TWF) to assess within-day reliability. Each test was separated by a 30-minute rest period to avoid participant fatigue as recommended by Eiser et al.[24] to ensure participants are recovered. Within one week, the 2MWT and 10MWT were completed without a mask (Table 2). This result was used as the gold standard to assess concurrent validity by comparing it with data from previous mask-wearing.

STATISTICAL ANALYSIS

Data entered was analysed using version 27.0 of the Statistical Package for Social Sciences (SPSS). Descriptive analysis of demographic data was reported as mean, standard deviation (SD), and range. The Shapiro-Wilks tested normality, $p > 0.05$, indicating that the 10MWT and 2MWT data followed a normal distribution.[25]

Within-day reliability was analysed for the three mask-wearing tests (test 1, test 2, test 3), using a two-way mixed intraclass correlation coefficient (ICC), ICC > 0.75 indicating excellent reliability.[16]

To assess validity, data from the third test of the reliability study wearing a mask were correlated to results without a mask (gold standard) for both 2MWT and 10MWT. The third test of the reliability assessments was used to ensure participants were familiar with the procedures and to reduce errors. A scatter plot was generated, and the correlation coefficient (r) was calculated using Pearson's coefficient[26,27] $r > 0.7$, indicating a strong correlation.[17] Bland-Altman plots (B&A) with 95% limits of agreement (LOA) were employed to illustrate absolute differences and identify systematic bias and outliers.[28]

RESULTS

A total of 15 subjects (53% males and 47% females) were included. Mean (SD) age was 26.0 (1.7) years, and BMI was 22.7 (2.5) Kg/m^2 (Table 3). Baseline heart rate, SPO_2, and Borg scores before and after the participants' 10MWT and 2MWT were all in the normal range.

WALKING DISTANCE (METRES) AND WALKING SPEED(M/S)

Table 4 shows descriptive statistics of walking speed and duration in the 10MWT and 2MWT with and without wearing masks.

For the reliability data: the mean walking speed for 10MWT results were similar, ranging from 1.3 (0.13) to 1.5 (0.2) m/s and the 2MWT range was 179.3 (16.2) to 183.7 (18.2) m. For the validity study, the 10MWT reliability Test 3 (with mask) and no mask were similar both 1.45 (0.2) m/s and 2MWT reliability Test 3 (with mask) was 183.7 (18.2), similar to no mask 187.1 (16.5) m.

RELIABILITY OF WEARING A MASK 10MWT AND 2MWT

The within-day reliability analysis for 10MWT was ICC 0.92, and for 2WMT was 0.823. This indicated that the 2MWT and

Table 3. Demographic descriptive data at baseline

Sample size=15	Mean	Std. Deviation	Range
Age (years)	26.7	1.7	6
Height (m)	1.67	0.06	0.24
Weight (kg)	63.3	9.1	34.6
BMI (kg/m²)	22.7	2.5	9.9
HR (bpm)	81	10	41
Borg	0.13	0.23	0.5
O2 (%)	98.0	1.0	3.0

Kg = kilogram, m = meter, BMI = body mass index number, SD = standard deviation.
bpm = beat per minute, HR= Heart rate, O_2= oxygen saturations

Table 4. The descriptive data of walking test with and without a mask

Sample size=15	Mask test 1 mean (SD)	Mask test 2 mean (SD)	Mask test 3 mean (SD)	No Mask test1 mean (SD)
10MWT m/s	1.3 (0.1)	1.4 (0.2)	1.5 (0.2)	1.5 (0.2)

m/s = meter/second, SD = standard deviation, m= meter, s= second.

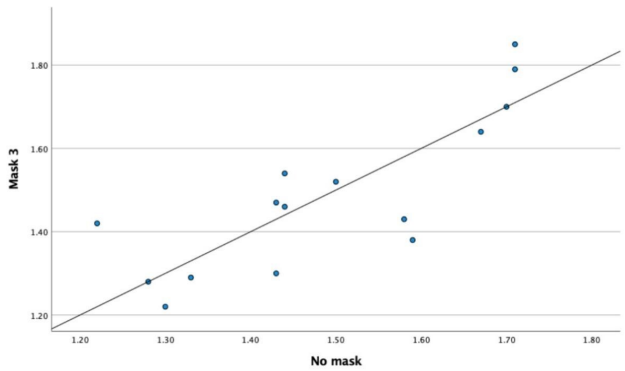

Figure 1. Scatter plot for 10MWT (Mask 3 and No mask)

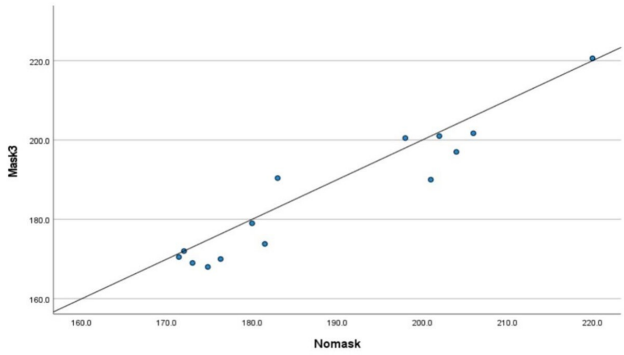

Figure 2. Scatter plot for 2MWT (Mask 3 and No mask)

10MWT had excellent reliability (ICC > 0.75) across 3 tests wearing a mask.[29]

VALIDITY OF WEARING A MASK 10MWT AND 2MWT

The scatter plots for 10MWT (Figure 1) show most of the data for mask and no mask were evenly distributed around the line of best fit. The number of points above, and below the reference line were almost equally distributed, demonstrating a positive linear relationship and a correlation between the two tests.

The scatter plots for 2MWT (Figure 2) show the data points were relatively evenly distributed on both sides of the reference line on the right and middle side of the line, demonstrating a positive linear relationship and a correlation between the two tests.

CORRELATION ANALYSIS

10MWT: For the 10MWT, the Pearson correlation coefficient r value for Test 3 (with mask) and no mask was 0.815 ($p < 0.001$), indicating an excellent and significant correlation as $r>0.75$.[22]

2MWT: For the 2MWT, Pearson's correlation coefficient of the Test 3 (with mask) and no mask was r=0.943 (p<0.01), indicating excellent correlation.[18]

BLAND-ALTMAN PLOTS FOR 10MWT AND 2MWT

The Bland-Altman plots for 10MWT validity (Figure 3) show a small difference of -0.03m/s between the mean of Test 3 (mask) and no mask suggesting good agreement, while the LOA (95% CI) ranged from -0.25 to 0.19m/s. One outlier in the plot exceeds the upper limit (0.19m/s), indicating a bias between the two tests.

The Bland-Altman plots for 2MWT validity (Figure 4) for Test 3 (mask) and no mask showed a mean difference between the two is -3.87 m, which indicated a small difference, and their LOA (95% CI) ranged from -16.17m to 8.45m, a relatively wide range. Most of the data points were scattered within this interval, while one outlier lies below the LOA, indicating some bias between the two tests.

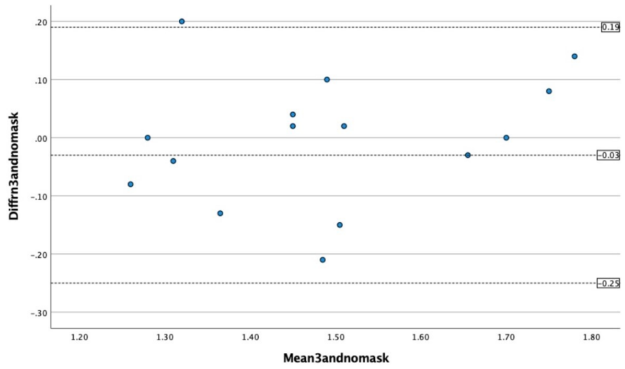

Figure 3. Bland-Altman plots for 10MWT (Mask 3 and No mask)

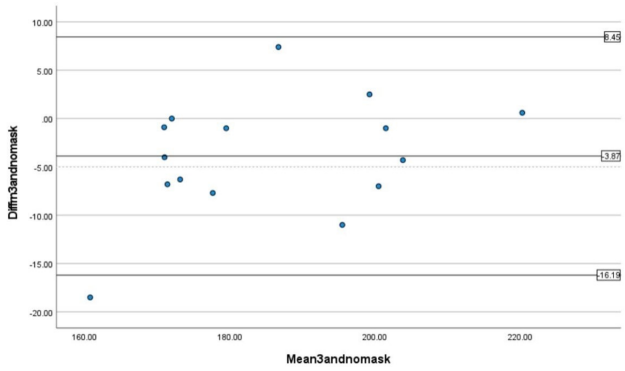

Figure 4. Bland-Altman plots for 2MWT (Mask 3 and No mask)

DISCUSSION

The aim of this study was to evaluate the within-day reliability and concurrent validity of the 10MWT and 2MWT wearing a surgical mask. The results showed the 2MWT with a surgical mask had excellent within-day reliability (ICC=0.92) and concurrent validity (Pearson's r value =0.943). The 10MWT with a mask also indicated excellent within-day reliability (ICC=0.823) and concurrent validity compared to those without a mask (Pearson's r-value = 0.815). In addition, the Bland-Altman plots for 10MWT and 2MWT validity showed good agreement, although some values were more dispersed, which may be attributed to the small sample size.[30]

To date there have been no published studies of the reliability and validity of 10MWT and 2MWT wearing a face mask, thus this study was compared to other research investigating mask-wearing with 6MWT and the reliability and validity of the 10MWT and 2MWT without a mask. Salles-Rojas et al.[12] found during the 6MWT, distances walked with or without a mask were significantly related in healthy people (r=0.91 (P< 0.001)). In 84% of participants, the difference in walking meters was within ±30m, and there was no difference in the degree of dyspnoea. These findings are consistent with the present study and the studies of Bohannon et al.[3] and Swiatek et al.[13] who found there was no difference in distance walked with mask or without mask. Leung et al.'s[4] study in COPD showed that 2MWT was highly correlated with 6MWT (r=0.937) and their ICC for reliability was (r=0.99, p<0. 005). This was similar to our ICC for 2MWT. Chan and Pin[5] also showed that the 10MWT without a mask had strong reliability (ICC = 0.95 - 0.99) and strong validity (r = 0.89 to 0.92) in frail older adults, which was consistent with our findings ICC 0.823 and r= 0.815. Despite differences in methodology, sample size and participants of the aforementioned studies, all studies concurred that the 10MWT and 2MWT without a mask were a reliable and viable instrument.

From a physiological perspective, Kyung et al.[31] argued that mask-wearing can influence airflow resistance and gas exchange. This is in contrast to Samannan et al.[32] who found that gas exchange was not significantly affected by the use of surgical masks. In a recent systematic review, Shaw et al.[12] examined the effects of wearing a mask on exercise and found that wearing a surgical mask or N95 mask did not affect exercise performance in healthy subjects. Dacha et al.[14] and Swiatek et al.[11] also showed that wearing a mask had no effect on functional ability (6MWT) but dyspnea was increased in healthy people. This suggests mask wearing may affect dyspnoea in the 6MWT. The 10MWT outcome is walking speed, whereas the 2MWT and 6MWT are more focused on assessing endurance.[33] The 2MWT and 10MWT are shorter than the 6MWT, which may account for the limited impact of wearing a mask. Wearing the mask for less time may have less impact than wearing it for 2 minutes, which explains the 10MWT had better reliability than 2MWT.

The overall findings suggested that wearing a mask for the 2MWT and 10MWT appears to be a valid and reliable exercise test in healthy people, which may reduce the risk of COVID-19 infections. However, the current study was limited to healthy young subjects (23-29 years), which may not be representative of a wider age group and different conditions. The increased airway resistance may have a greater physiological impact when using a face mask in patients with COPD or older people.[34] Therefore, further research is needed in other age groups and populations. The sample size was small but justified according to Bujang and Baharum,[18] however, this could limit generalisability.

CONCLUSION

The results of this study showed that wearing a mask during the 2MWT and 10MWT had excellent within-day reliability and concurrent validity. This suggests that mask-wearing does not impact 2MWT and 10MWT in healthy people. The results help to alleviate concerns about the use of surgical masks for walking tests and may increase the wider acceptance and use of masks. The results of the current study should be interpreted with caution as they are based on healthy adults, and the wearing of masks cannot be recommended for all exercise tests or populations. Before wearing a mask during the 2MWT and 10MWT, a larger and more diverse sample can be recommended, including cardiorespiratory conditions.

Key points

- Wearing a surgical mask for 2MWT and 10MWT had excellent within-day reliability.
- Wearing a surgical mask for 2MWT and 10MWT had excellent concurrent validity.
- The results help to alleviate concerns about the use of surgical masks for walking tests and may increase the wider acceptance and use of masks.

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ETHICAL APPROVAL

This study was approved by the Ethical Research Committee of the School of Health Research at Cardiff University (No. REC904). The authors declare that they have no known competing financial interests or personal relationships that would appear to influence the work reported in this article.

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REFERENCES

1. Zhang G, Li M, Zheng M, et al. Effect of Surgical Masks on Cardiopulmonary Function in Healthy Young Subjects: A Crossover Study. *Front Physiol*. 2021;12:710573. doi:10.3389/fphys.2021.710573

2. Radtke KL, Porcari JP, Foster C, Miller M, Helget A. Evaluation of six-minute walk test (6MWT) performance with and without a facemask. *Int J Appl Exerc Physiol*. 2021;16(2):67-80.

3. Bohannon RW, Wang YC, Gershon RC. Two-minute walk test performance by adults 18 to 85 years: normative values, reliability, and responsiveness. *Archives of Physical Medicine and Rehabilitation*. 2015;96(3):472-477. doi:10.1016/j.apmr.2014.10.006

4. Leung ASY, Chan KK, Sykes K, Chan KS. Reliability, validity, and responsiveness of a 2-min walk test to assess exercise capacity of COPD patients. *Chest*. 2006;130(1):119-125. doi:10.1378/chest.130.1.119

5. Chan WLS, Pin TW. Reliability, validity and minimal detectable change of 2-min walk test and 10-m walk test in frail older adults receiving day care and residential care. *Aging Clin Exp Res*. 2020;32(4):597-604. doi:10.1007/s40520-019-01255-x

6. Marques A, Cruz J, Quina S, Regêncio M, Jácome C. Reliability, agreement and minimal detectable change of the timed up & go and the 10-meter walk tests in older patients with COPD. *COPD: Journal of Chronic Obstructive Pulmonary Disease*. 2016;13(3):279-287. doi:10.3109/15412555.2015.1079816

7. Pehlivan E, Balci A, Kilic L, Yazar E. Is it Possible to Use the Timed Performance Tests in Lung Transplantation Candidates to Determine the Exercise Capacity? *Turk Thorac J*. 2020;21(5):329-333. doi:10.5152/turkthoracj.2019.19046

8. Abboah-Offei M, Salifu Y, Adewale B, Bayuo J, Ofosu-Poku R, Opare-Lokko EBA. A rapid review of the use of face mask in preventing the spread of COVID-19. *International Journal of Nursing Studies Advances*. 2021;3:100013. doi:10.1016/j.ijnsa.2020.100013

9. Roberge RJ, Kim JH, Benson SM. Absence of consequential changes in physiological, thermal and subjective responses from wearing a surgical mask. *Respiratory Physiology & Neurobiology*. 2012;181(1):29-35. doi:10.1016/j.resp.2012.01.010

10. Shaw K, Butcher S, Ko J, Zello GA, Chilibeck PD. Wearing of cloth or disposable surgical face masks has no effect on vigorous exercise performance in healthy individuals. *International Journal of Environmental Research and Public Health*. 2020;17(21):8110. doi:10.3390/ijerph17218110

11. Shaw KA, Zello GA, Butcher SJ, Ko JB, Bertrand L, Chilibeck PD. The impact of face masks on performance and physiological outcomes during exercise: a systematic review and meta-analysis. *Appl Physiol Nutr Metab*. 2021;46(7):693-703. doi:10.1139/apnm-2021-0143

12. Salles-Rojas A, Guzmán-Valderrábano C, Madrid WA, et al. Masking the 6-Minute Walking Test in the COVID-19 Era. *Ann Am Thorac Soc*. 2021;18(6):1070-1074. doi:10.1513/annalsats.202009-1088rl

13. Swiatek KM, Lester C, Ng N, Golia S, Pinson J, Grinnan D. Impact of face masks on 6-minute walk test in healthy volunteers. *Pulm Circ*. 2021;11(1):2045894020988437. doi:10.1177/2045894020988437

14. Dacha S, Chuatrakoon B, Sornkaew K, Sutthakhun K, Weeranorapanich P. Effects of wearing different facial masks on respiratory symptoms, oxygen saturation, and functional capacity during six-minute walk test in healthy subjects. *Can J Respir Ther*. 2022;58(85):85-90. doi:10.29390/cjrt-2022-014

15. Atkinson G, Nevill AM. Statistical methods for assessing measurement error (reliability) in variables relevant to sports medicine. *Sports Med*. 1998;26(4):217-238. doi:10.2165/00007256-199826040-00002

16. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *Journal of Chiropractic Medicine*. 2016;15(2):155-163. doi:10.1016/j.jcm.2016.02.012

17. Benesty J, Chen J, Huang Y, Cohen I. Pearson correlation coefficient. *Noise reduction in speech processing*. 2009;2009:1-4. doi:10.1007/978-3-642-00296-0_5

18. Bujang MA, Baharum N. A simplified guide to determination of sample size requirements for estimating the value of intraclass correlation coefficient: a review. *Archives of Orofacial Science*. 2017;12(1).

19. Warburton DE, Jamnik VK, Bredin SS, McKenzie DC, Stone J, Shephard RJ, et al. *Evidence-Based Risk Assessment and Recommendations for Physical Activity Clearance: An Introduction*. NRC Research Press; 2011:S1-S2.

20. Williams N. The Borg Rating of Perceived Exertion (RPE) scale. *Occupational Medicine*. 2017;67(5):404-405. doi:10.1093/occmed/kqx063

21. Beekman E, Mesters I, Gosselink R, et al. The first reference equations for the 6-minute walk distance over a 10 m course. *Thorax*. 2014;69(9):867-868. doi:10.1136/thoraxjnl-2014-205228

22. Roush J, Heick J, Hawk T, Eurek D, Wallis A, Kiflu D. Agreement in Walking Speed Measured Using Four Different Outcome Measures: 6-Meter Walk Test, 10-Meter Walk Test, 2-Minute Walk Test, and 6-Minute Walk Test. *Internet Journal of Allied Health Sciences and Practice*. 2021;19(2). doi:10.46743/1540-580x/2021.1971

23. Middleton A, Fritz SL, Lusardi M. Walking speed: the functional vital sign. *Journal of aging and physical activity*. 2015;23(2):314-322. doi:10.1123/japa.2013-0236

24. Eiser N, Willsher D, Dore CJ. Reliability, repeatability and sensitivity to change of externally and self-paced walking tests in COPD patients. *Respiratory Medicine*. 2003;97(4):407-414. doi:10.1053/rmed.2002.1462

25. Le Boedec K. Sensitivity and specificity of normality tests and consequences on reference interval accuracy at small sample size: a computer-simulation study. *Veterinary Clinical Pathol*. 2016;45(4):648-656. doi:10.1111/vcp.12390

26. Field MJ, Lo B. Conflict of interest in medical research, education, and practice. Published online 2009.

27. Hicks CM. *Research Methods for Clinical Therapists: Applied Project Design and Analysis*. Elsevier Health Sciences; 2009.

28. Lexell JE, Downham DY. How to assess the reliability of measurements in rehabilitation. *American Journal of Physical Medicine & Rehabilitation*. 2005;84(9):719-723. doi:10.1097/01.phm.0000176452.17771.20

29. Cain KL, Geremia CM, Conway TL, et al. Development and reliability of a streetscape observation instrument for international use: MAPS-global. *Int J Behav Nutr Phys Act*. 2018;15(1):1-11. doi:10.1186/s12966-018-0650-z

30. Cooperstein R, Young M. The reliability of lumbar motion palpation using continuous analysis and confidence ratings: choosing a relevant index of agreement. *The Journal of the Canadian Chiropractic Association*. 2016;60(2):146.

31. Kyung SY, Kim Y, Hwang H, Park JW, Jeong SH. Risks of N95 face mask use in subjects with COPD. *Respir Care*. 2020;65(5):658-664. doi:10.4187/respcare.06713

32. Samannan R, Holt G, Calderon-Candelario R, Mirsaeidi M, Campos M. Effect of face masks on gas exchange in healthy persons and patients with chronic obstructive pulmonary disease. *Annals of the American Thoracic Society*. 2021;18(3):541-544. doi:10.1513/annalsats.202007-812rl

33. Gupta A, Prakash NB, Honavar PR. Gait training with robotic exoskeleton assisted rehabilitation system in patients with incomplete traumatic and non-traumatic spinal cord injury: A pilot study and review of literature. *Ann Indian Acad Neurol*. 2023;26(7):26. doi:10.4103/aian.aian_1075_21

34. Fikenzer S, Uhe T, Lavall D, et al. Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity. *Clin Res Cardiol*. 2020;109(12):1522-1530. doi:10.1007/s00392-020-01704-y

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Long term conditions

An Evaluation of the Demographics, Characteristics and Healthcare Utilisation of People with Asthma Referred to an Ambulatory Respiratory Hub.

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Keywords: Asthma exacerbation, Comorbidities, Ambulatory care, Healthcare utilisation, T2-biomarkers

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Abstract

Background

Asthma is the most treated condition in the Ulster Hospital Ambulatory Respiratory Hub (ARH). This multidisciplinary rapid assessment and treatment centre reviews respiratory patients to prevent hospital admission. This service evaluation (SE) may identify improvements for the service and better outcomes for asthma patients.

Aims

The demographics, clinical characteristics including biomarker profile and co-morbidities, alongside subsequent healthcare utilisation of patients with asthma were explored.

Method

Retrospective review of electronic healthcare records identified 151 patients with asthma attending the ARH between 1st July 2019 and 31st Dec 2019. Baseline demographics, clinical characteristics, comorbidities and asthma biomarkers were extracted. Patients were characterised according to their T2-biomarker expression and comparisons made. Healthcare utilisation was assessed by collecting data regarding hospital admissions, emergency department attendances and GP out of hours visits 6 months before and after attending the service.

Results

Most patients with asthma were female (73.5%), T2- biomarker low (74.2%) and had a high prevalence of obesity (49%). Prevalent comorbidities included rhinosinusitis, gastro-oesophageal reflux disease, depression and anxiety. Investigations included spirometry, chest x-ray and asthma biomarkers (fraction of exhaled nitric oxide and blood eosinophil count). Hospital admissions were reduced by 93%, ED attendances by 83.4% and GP OOH visits by 71.4% during the 6-month period following attendance.

Conclusions

The identification and management of common asthma comorbidities is important and should be routinely assessed. The ARH reduces healthcare utilisation for patients attending with asthma. It could provide additional support to the regional service enabling quicker access to biologic therapies.

INTRODUCTION

Asthma is typically a lifelong chronic respiratory disease, affecting around 5.4 million people in the UK and approximately 180, 000 people in Northern Ireland.[1] It is the cause of considerable worldwide morbidity, mortality and substantial healthcare costs.[2]

Exacerbations occur where people experience worsening of their normal day to day symptoms, often requiring increased treatment (e.g. oral corticosteroids, antibiotics, nebulised medication) and unscheduled healthcare utilisation. The latter may include attending a GP surgery, hospital emergency department (ED), Ambulatory Care hub or hospital admission. The primary aim of the Ambulatory Respiratory Hub within the Ulster Hospital (Belfast) is to provide rapid assessment, diagnostics and treatment in an ambulatory setting preventing overnight admission for pa-

Table 1. Service Evaluation Objectives

	Service Evaluation Objectives
1.	Describe the population of patients with asthma referred to the Ambulatory Respiratory Hub in terms of their demographics, clinical characteristics and comorbidity.
2.	Compare demographics, clinical characteristics and co-morbidities between T2 biomarker high and T2 biomarker low patients.
3.	Identify the prevalence of patients attending the Respiratory Hub with Difficult Asthma, their disease expression and subsequently how many of these attend the Regional Difficult Asthma Clinic.
4.	Determine the number of patients who attended with asthma and were given an alternative diagnosis following assessment and map their subsequent management pathway.
5.	Assess the impact on healthcare utilisation (hospital admission, GP OOH visits, ED attendances) for this asthma population 6 months pre and post attendance at the respiratory hub

tients with respiratory conditions (Appendix 1-Summary of Hub Service).

Morbidity, mortality and health care costs are particularly high amongst patients with difficult asthma[2] and it has been suggested by Chung and Wenzel[3] that difficult asthma accounts for approximately 5-10% of the total asthma population. A previous study[4] by Antonicelli *et al.* suggested that this small percentage of the total asthma population accounts for a disproportionately large fraction of the total asthma disease cost. Patients diagnosed with difficult asthma often require specialist out-patient care involving inhaler adherence monitoring and optimisation of oral corticosteroid use, more frequent or continuous courses of oral steroids which can increase the risk of adverse effects related to steroids and progression to expensive biologic immuno- modulatory therapies.

Type 2 (T2) cytokine-driven eosinophilic airway inflammation is the predominant phenotype in difficult asthma. For these patients, T2- biomarkers such as fraction of exhaled nitric oxide (FeNO) and blood eosinophil count (BEC) can be useful as markers for exacerbation risk and predictors of treatment response to corticosteroids.[5] Phenotyping the asthma population attending the ambulatory respiratory hub would allow comparison with other population's in recent studies and provide guidance on the best treatment options.

An important consideration in the management of patients with asthma, is the impact of comorbid diseases on exacerbations. Asthma often occurs with other conditions such as gastro-oesophageal reflux disease (GORD), vocal cord dysfunction (VCD), chronic rhinosinusitis, anxiety and depression which can exacerbate, complicate or simulate asthma symptoms and potentially lead to poor symptom control and increased hospital attendance.[6]

AIM

The primary aim of this service evaluation (SE) was to explore the demographics, clinical characteristics and co-morbidities of patients with asthma who attended the Ambulatory Respiratory Hub Service. It was also to assess the effectiveness of the service at reducing healthcare utilisation. Specific service evaluation objectives are detailed in Table 1.

Table 2. Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Adults ≥18 years old	Patients with Asthma/ Chronic Obstructive Pulmonary Disease (COPD) overlap
Primary reason for referral of acute exacerbation of asthma or poorly controlled asthma	

METHODS

STUDY DESIGN

Retrospective review of electronic records and quantitative evaluation of data from patients with asthma referred to the Ambulatory Respiratory Hub in the Ulster Hospital, South Eastern Health and Social Care Trust (SEHSCT) over a 6-month period between the 1st July 2019 and 31st Dec 2019. The criteria for patient's data to be included or excluded from the study are described in Table 2.

DATA COLLECTION PROCEDURES

A bespoke excel data base was prepared enabling existing anonymised data to be collated and summarised relating to the aims and objectives of this service evaluation (SE). Outcome measures recorded in this excel database are summarised in Appendix 1. Patients with a diagnosis of asthma following hub assessment were identified using the trust scheduler IT data collection system. The Northern Ireland Electronic Care Record (NIECR) was then used to obtain baseline demographics, clinical characteristics and information regarding the prevalence of 11 common asthma co-morbidities previously reported by Porsbjerg and Menzies-Gow[7] with the addition of diabetes (Appendix 2). NIECR was also used to identify patients who met the BTS /SIGN Asthma Guideline[8] definition of difficult asthma.

BIOMARKER PROFILE

Blood eosinophil count (BEC) was recorded at initial assessment as well as the highest historic BEC available on NIECR. FeNO was only recorded at initial assessment. In the absence of any international consensus for validated

biomarker thresholds, T2 biomarker high patients were defined as having a FeNO level ⩾30ppb and BEC ⩾300cells/μL. These thresholds for biomarker positivity are similar to those used by Busby *et al*.[9] and Denton *et al*.[10] T2 low group for comparison was defined if one of these biomarkers were below these thresholds.

ALTERNATIVE DIAGNOSIS

The Trust's scheduler IT system was used to identify patients diagnosed with dysfunctional breathing or vocal cord dysfunction. Clinical records including the respiratory hub email were then reviewed to determine if they had been referred with asthma but given this alternative diagnosis.

IMPACT ON HEALTHCARE UTILISATION

NIECR was accessed for information relating to healthcare utilisation 6 months before and after assessment at the respiratory hub. This included data on ED attendances, hospital admissions and GP (OOH) attendances (Appendix 2).

DATA ANALYSIS

Descriptive statistics were used to summarise baseline demographics, characteristics, prevalence of difficult asthma, alternative diagnosis, healthcare utilisation and co-morbidity. Results were then tabulated to facilitate comparisons of co-morbidities and clinical characteristics within this asthma population and its subgroups. Categorical variables were summarised using counts and percentages and continuous variables summarised using mean (SD) and/or median (IQR). To determine if healthcare use was affected by the introduction of the hub, we calculated the total number of hospital admissions, A+E attendances, and GP attendances, at each time point (before vs after), presenting any % change. We compared the demographics and clinical characteristics between the independent groups, T2- high vs T2- low patients; for categorical variables we used cross tabs and odds ratios (OR) with 95% confidence intervals (95% CIs), and for the numerical variables (T2- biomarker outcomes (FeNO/BEC)) we used Independent –Samples Mann-Whitney U tests. A Statistical Package for the Social Sciences (SPSS ®) version 28 was used to perform all analyses and statistical significance denoted with a P-value of <0.05.

ETHICAL APPROVAL

Ethical approval was granted by the INHR Filter/Ethics Committee, Ulster University (Reference number FCNUR-21-094). Informed consent was not required as this was a retrospective, anonymised service evaluation and patients will have received normal routine care. Approval was obtained from the physiotherapy professional lead (SEHSCT).

RESULTS

This SE included n=151 patients who attended the Ambulatory Respiratory Hub with a clinical diagnosis of asthma between July 2019 and December 2019. The demographic and clinical characteristics including co-morbidities are summarised in Table 3 below. Within the study population asthma was more prevalent in females (73.5%) than males (26.5%) with the most prevalent age ranges being 36-45years (19.2%) and 46-55 years (19.2%) (Figure 1, Appendix 3). Many patients never smoked (46.4%), while 27.8% were ex-smokers and 25.8% current smokers. Nearly half (49%) of the population were obese (BMI⩾30) with an increased prevalence of obesity among females (71.6%). The most frequently reported comorbidities in the study population were rhinosinusitis (49.7%), obesity (49%), GORD (46.4%), depression (35.8%), anxiety (23.2%). N=14 patients (9.3%) were classified as having difficult asthma according to the BTS /SIGN Asthma Guideline (2019) definition.[8] Three patients required onward referral to the regional difficult asthma service as they required maintenance oral steroids in addition to maximal inhaled therapy to manage their asthma symptoms.

BIOMARKER PROFILE

The median highest recorded BEC was 0.48 (IRQ 0.48) cells/10^9L. This was notably higher than the median BEC at initial assessment 0.15 (IQR 0.43) cells/10^9L which was below the T2-high –biomarker threshold. Similarly, the median FeNO level at initial assessment of 20 (IRQ 30) ppb was below the T2-biomarker positive cut point (Table 3).

COMPARISON OF T2 HIGH VERSUS T2 LOW PATIENTS

Criteria for T2-low asthma were met by 112 (74.2%) patients with 23 (15.2%) classified as T2- high. Compared with the T2-high group, T2-low patients were more likely to be female (75.9% vs 65.2%; OR 1.7; 95% CI 0.6 to 4.4, p=0.29), older (67% ⩽ 55years vs 86.8%; OR 3.2 ; 95% CI 0.9 to 11.7, p=0.06), have anxiety (23.2% vs 4.3%;OR 7.7; 95%CI 0.99 to 59.6, p=0.05) and depression (35.8% vs13% OR 4.2; 95% CI 1.2 to 14.8; p=0.03). The T2-low patients were also more likely to have GORD (47.3% vs30.4%; OR 2.1; 95% CI 0.78 to 5.4, p=.14) (Appendix 4).

Median FeNO values were significantly higher at initial hub assessment in the T2-high group 51: IQR 37.5 ppb vs T2- low group 13: IQR 17.5 ppb with p<0.001).

Similarly, the median BEC at initial assessment was significantly higher in the T2-high group versus T2-low group (0.57: IQR 0.435 vs 0.09: IQR 0.168) with p<0.001. (Figure 2).

It's worth noting that some patients categorised as T2-biomarker low had BEC or FeNO levels above the agreed thresholds. This is due to the thresholds used to categorise the T2-biomarker groups and the fact that if one biomarker was below these thresholds then they were defined as T2-low. There was no statistically significant difference (P>0.05) in the prevalence of co-morbidities, gender, age

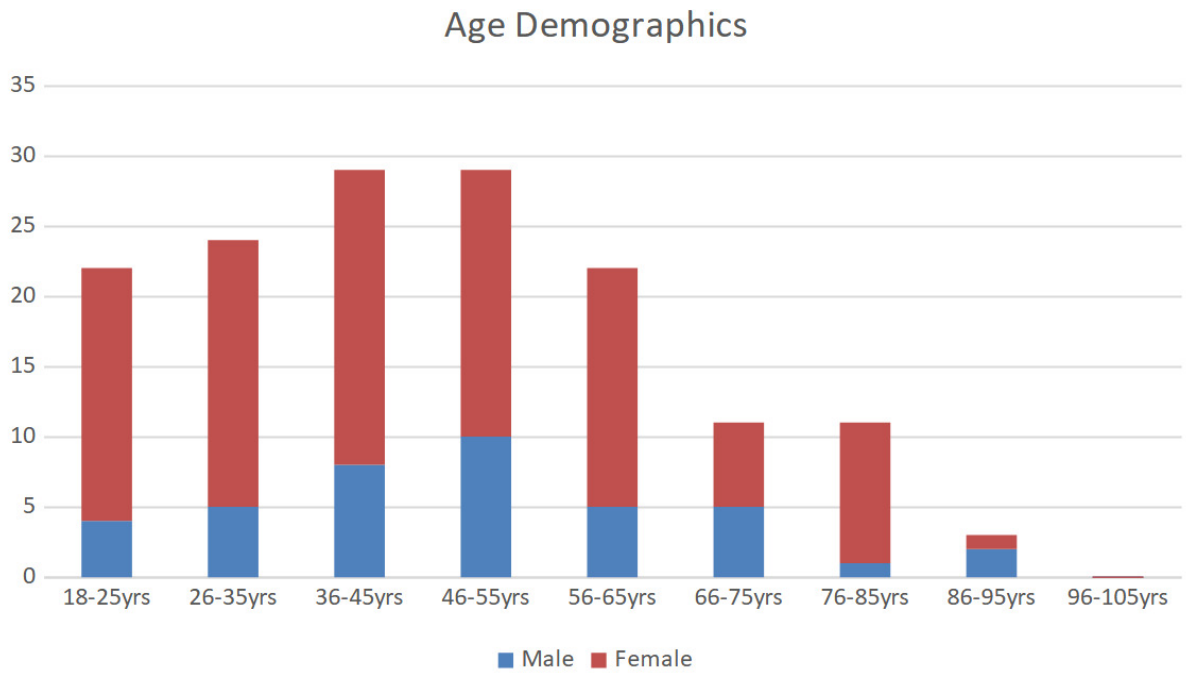

Figure 1. Age ranges and prevalence within the study population (N=151)

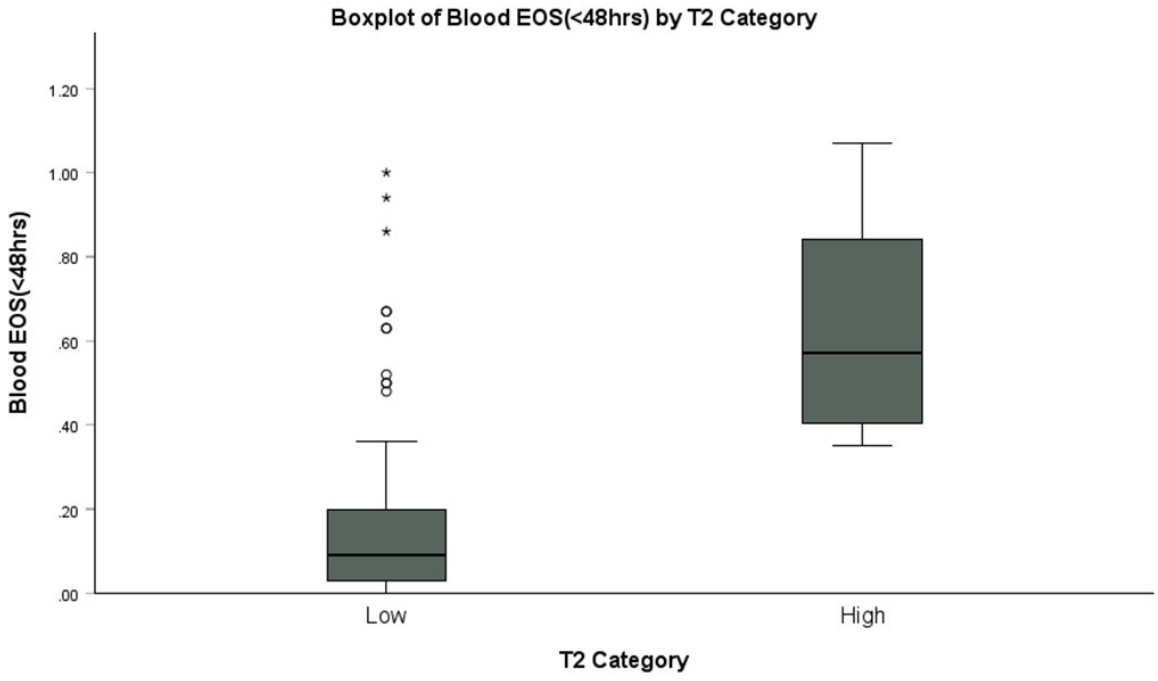

Figure 2. Comparison of Blood EOS between T2 groups at initial assessment

or smoking status between the T2 biomarker high and low groups.

DIFFICULT ASTHMA

Only 14 patients (9.3%) met the criteria for difficult asthma. The median BEC for this group was 0.14 (IRQ: 0.42) N/10^9L and median FeNO 21 (IRQ: 33) ppb, both of which fall short of the T2- biomarker high thresholds.

ALTERNATIVE DIAGNOSIS

Only five patient's referred to the respiratory hub with asthma were given an alternative diagnosis. These patients were subsequently referred to either the SEHSCT Dysfunctional Breathing Clinic or Ear Nose and Throat (ENT) services for follow-up.

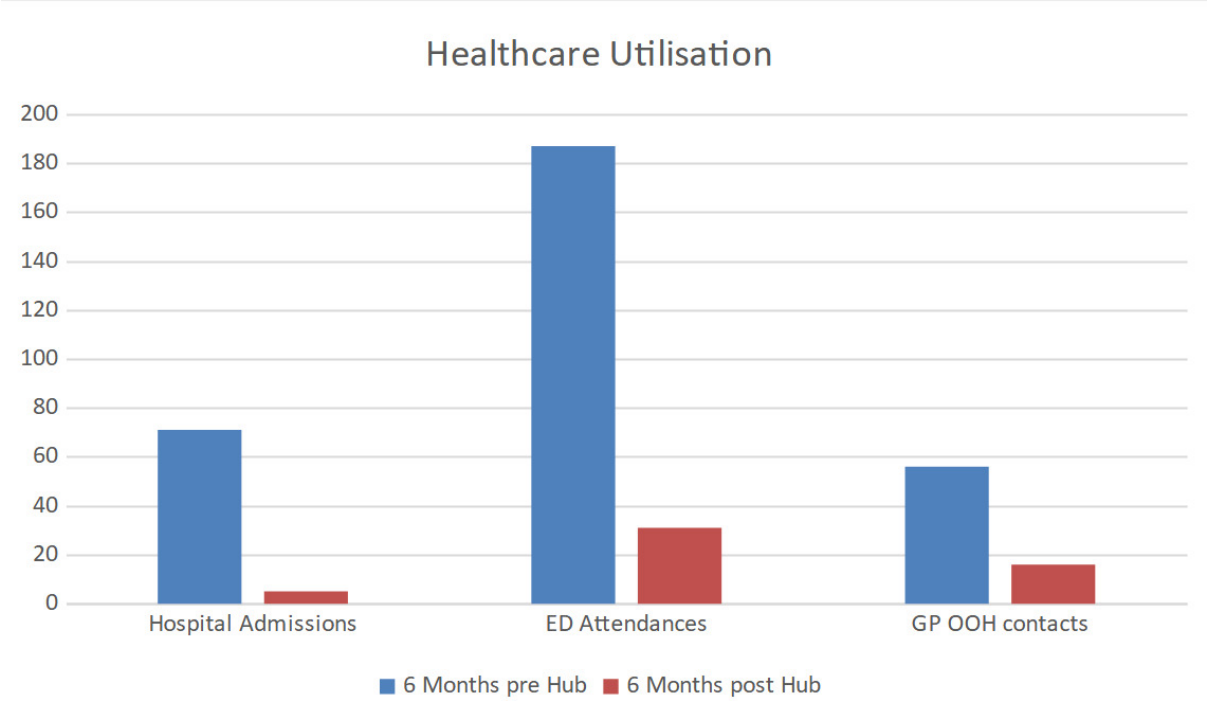

Figure 3. Healthcare Utilisation (contacts) 6 months pre vs post hub attendance.

ED= emergency department, GP OOH= General Practitioner Out of hours

HEALTHCARE UTILISATION

Hospital admissions were significantly reduced ($p<0.001$) by 93%, ED attendances by 83.4% and GP OOH visits by 71.4% (Figure 3). Total combined medical contacts were therefore significantly reduced by 83.4% ($p<0.001$) during the 6-month period after respiratory hub assessment (Figure 2).

DISCUSSION

The majority of the 151 asthma patients in this SE were female , T2- biomarker low and had a high prevalence of obesity . This biomarker low, obese, female phenotype with poor symptom control is similar to that previously highlighted in a UK multicentre randomised controlled trial by Heaney *et al.*[11]

Asthma often co-exists with other conditions[12] and these comorbidities contribute to poor symptom control, perceived exacerbations, reduced quality of life and increased healthcare utilisation.[13] The most prevalent comorbidities reported were rhinosinusitis , GORD , depression and anxiety . This is similar to the findings of a small cohort study assessing adherence and psychological morbidity in 103 asthma patients which found that 30% had a psychiatric disorder (asthma/depression), particularly patients with poor asthma control and adherence.[14] If clinicians including physiotherapists were better able to identify these common comorbidities, then adherence with medication and asthma control may be improved without the need for escalating asthma treatment.

Using the reference criteria, the vast majority of patients in this study (74.2%) met the biomarker definition of T2-low asthma at the point of data collection. However, review of their historic highest BEC revealed a median count fulfilling the T2- high biomarker definition which is similar to findings in a multicentre trial by Jackson *et al.*[15] One possible explanation could be that some patients had already started high dose oral corticosteroids for a potential exacerbation by the time they were assessed in the Respiratory Hub, thus already supressing T2 inflammation. Alternatively, they could have been repeat hub attenders with better inhaled corticosteroid management. It is important that T2-biomarker low patients with poor symptom control can be accurately identified as they are not as steroid responsive and may not benefit from increased ICS or oral corticosteroid treatment to manage exacerbations. Rapid access to an ambulatory respiratory hub or difficult asthma clinic during exacerbation enables these T2 biomarkers such as FeNO and BEC to be checked prior to commencing oral corticosteroids.

This evaluation suggests that healthcare utilisation can be significantly reduced for patients with asthma who attend an ambulatory respiratory hub. Although this evaluation only provides a short window into the service, it suggests that ambulatory care should be considered as an alternative to hospital admission for patients with asthma during exacerbation. It has the potential to reduce the burden on the hospital's ED, primary care services and provide a satellite service to the regional difficult asthma clinic therefore reducing waiting times and more timely access to biologic therapies for difficult asthma patients.

One limitation of this evaluation was that it was retrospective rather than prospective, and as such relied upon accurate data entry, accurate data coding of comorbidities by GPs and other health care professionals (HCPs), there-

fore reducing the validity if there were any inaccuracies in the clinical coding. Furthermore, the improvements in healthcare utilisation may have been influenced by input and treatment from other healthcare professionals during the 6 month follow-up period. This evaluation also lacked objective data on lung function, asthma symptom control and medications to enable classification and comparison of disease severity with T2 phenotype. A future prospective study could provide this data as well as more detailed information on asthma comorbidities. This would help to address any unmet need particularly for patients with severe asthma who may benefit from biologic therapy targeting T2 inflammation.

In conclusion, this study highlights the potential value of an Ambulatory Respiratory Hub to significantly reduce healthcare utilisation for patients who attended with asthma. The majority of patients with asthma attending the respiratory hub were T2-biomarker low. Future research is required to establish what is driving poor control (e.g. poor inhaler technique and/or adherence) and exacerbations for these patients in the absence of steroid responsive T2- inflammation.

Although not measured in this evaluation, there is potential for future impact in terms of reduced ED re-attendance rates, improved hospital patient flow and cost effectiveness due to bed days saved; this should be a focus for any further study.

Key Points

- The SEHSCT Ambulatory Respiratory Hub significantly reduces healthcare utilisation for patients attending with poorly controlled asthma.
- Commonly reported co-morbidities included rhinosinusitis, GORD, depression and anxiety. Physiotherapists and clinicians should routinely screen and treat these to improve asthma control and reduce exacerbation risk.
- The T2- biomarker low obese female, with poor symptom control was the most common phenotype identified in this evaluation.

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DECLARATION OF INTEREST

There are no conflicts of interest to declare.

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REFERENCES

1. Asthma UK. Understanding asthma. Published 2020. Accessed July 10, 2022. https://www.asthma.org.uk/advice/understanding-asthma/what-is-asthma/

2. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Published 2020. Accessed June 19, 2022. http://www.ginasthma.org

3. Chung KF, Wenzel SE, Brozel JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *European Respiratory Journal*. 2014;43:343-373. doi:10.1183/09031936.00202013

4. Antonicelli L, Bucca C, Neri M, et al. Asthma severity and medical resource utilisation. *European Respiratory Journal*. 2004;23(5):723-729. doi:10.1183/09031936.00202013

5. McDowell PJ, Busby J, Hanratty CE, et al. Exacerbation profile and risk factors in a T2-low severe asthma population. *American Journal of Respiratory and Critical Care Medicine*. Published online 2022. doi:10.1164/rccm.202201-0129OC

6. Prosser R, Carleton B, Smith A. The comorbidity burden of the treated asthma patient population in British Columbia. *Chronic Diseases in Canada*. 2010;30(2):46-55. doi:10.24095/hpcdp.30.2.03

7. Porsbjerg C, Menzies-Gow A. Co-morbidities in severe asthma: Clinical impact and management. *Respirology*. 2017;22:651-661. doi:10.1111/resp.13026

8. British Thoracic Society / Scottish Intercollegiate Guidelines Network (BTS/SIGN). *British Guideline on the Management of Asthma*. SIGN 141; 2019. https://www.brit-thoracic.org.uk/quality-improvement/guidelines/asthma/

9. Busby J, Mathews JG, Chaudhuri R, et al. Factors affecting adherence with treatment advice in a clinical trial of patients with severe asthma. *European Respiratory Journal*. 2021;59(9):2100768. doi:10.1183/13993003.00768-2021

10. Denton E, Price DB, Tran TN, et al. Cluster analysis of inflammatory biomarker expression in the international severe asthma registry. *Journal of Allergy and Clinical Immunology: In Practice*. 2021;9:2680-2688. doi:10.1016/j.jaip.2021.02.059

11. Heaney LG, Busby J, Hanratty CE, et al. Composite type-2 biomarker strategy versus a symptom risk-based algorithm to adjust corticosteroid dose in patients with severe asthma: a multicentre, single blind, parallel group, randomised controlled trial. *Lancet Respiratory Medicine*. 2020;9:57-68. doi:10.1016/S2213-2600(20)30397-0

12. Robinson DS, Campbell DA, Durham SR, Pfeffer J, Barnes PJ, Chung KF. Systematic assessment of difficult to treat asthma. *European Respiratory Journal*. 2003;12:1209-1283. doi:10.1183/09031936.03.00017003

13. Gherson AS, Wang C, Guan J, Wang C, Victor JC. Burden of Co-Morbidity in individuals with asthma. *Thorax*. 2010;65(7):612-618. doi:10.1371/journal.pone0034967

14. Cluley S, Cochrane GM. Psychological disorder in asthma is associated with poor control and poor adherence to inhaled steroids. *Respiratory Medicine*. 2001;95:37-39. doi:10.1053/rmed.2000.0968

15. Jackson DJ, Busby J, Pfeffer PE, et al. Characterisation of patients with severe asthma in the UK Severe Asthma Registry in the biologic era. *Thorax*. 2020;76:220-227. doi:10.1136/thoraxjnl-2020-215168

SUPPLEMENTARY MATERIALS

Appendices

Download: https://acprcjournal.scholasticahq.com/article/117468-an-evaluation-of-the-demographics-characteristics-and-healthcare-utilisation-of-people-with-asthma-referred-to-an-ambulatory-respiratory-hub/attachment/226843.docx?auth_token=wIR-T8ShWQPAKhLtqmD-

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Harris C, Banks J, Edwards C, Hurst S, Hill JE. Active video games as an adjunct to pulmonary rehabilitation of patients with Chronic Obstructive Pulmonary Disease: a commentary on a systematic review. *ACPRC Journal*.:39-42. doi:10.56792/WABG1646

Long term conditions

Active video games as an adjunct to pulmonary rehabilitation of patients with Chronic Obstructive Pulmonary Disease: a commentary on a systematic review

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Abstract

Pulmonary rehabilitation is a key evidence-based intervention to improve the outcomes of people living with Chronic Obstructive Pulmonary Disease (COPD). However, there are challenges in delivering pulmonary rehabilitation including reduced referral rates and suboptimal uptake and completion rates. Active video game interventions, when used as an adjunct, may increase the adoption of and access to pulmonary rehabilitation. This commentary summarises and critically appraises a systematic review which investigated the effectiveness of active video games as a supplementary component in the pulmonary rehabilitation of individuals suffering from chronic obstructive pulmonary disease.

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a common progressive lung condition causing persistent breathing difficulties in patients.[1] Many patients with COPD experience a significant burden of symptoms and exacerbations in their condition which impacts on their quality of life and results in increased use of healthcare resources.[2]

Pulmonary rehabilitation is a key evidence-based intervention to improve the outcomes of people living with COPD, improve their quality of life and reduce healthcare utilisation.[3] Current challenges in delivering pulmonary rehabilitation include reduced referral rates,[4] and suboptimal uptake and completion rates.[5]

The NHS Long Term Plan supports providers of pulmonary rehabilitation to develop new models of care to increase accessibility and to promote self-management and personalised care.[6] The expansion of digital healthcare options through the COVID-19 pandemic also encourages the exploration of digital solutions to complement the traditional face-to-face model of pulmonary rehabilitation.[7] One such digital solution which may have the potential to enhance access to, and boost the adoption of, rehabilitation is the use of active video games.[8] In a prior systematic review conducted by Wang et al. in 2020,[8] they investigated the effectiveness of active video games as a supplementary component in the pulmonary rehabilitation of individuals suffering from COPD.

AIM OF COMMENTARY

This commentary aims to critically appraise the methods used within the review by Wang et al., 2020,[8] and expand upon the findings in the context of clinical practice.

METHODS OF WANG ET AL., (2020)

A comprehensive search of seven databases was carried out to 3 April 2019. Randomised controlled trials (RCTs) and quasi-experimental studies of active video gaming as an intervention for the pulmonary rehabilitation of patients with an objective diagnosis of COPD were included in the review. Robust screening, data extraction and quality assessment processes were undertaken by two reviewers independently. Quality assessment was conducted using the Cochrane Risk of Bias tool for RCTs, and the Methodological Index for Nonrandomized Studies (MINORS) for quasi-experimental studies. A meta-analysis was conducted using a random effects model for the outcome of exercise capacity (measured by the 6-min walk distance test). The outcomes of dyspnoea, quality of life, enjoyment, adherence, and adverse events were synthesised through a descriptive analysis.

RESULTS OF WANG ET AL., (2020)

Seven papers were included in the review: three RCTs and four quasi-experimental studies. For the three RCTs there were risk of bias concerns around blinding of participants and personnel, blinding of outcome assessment, and allocation concealment. For the four quasi-experimental studies there were risk of bias concerns around insufficient in-

formation on the outcome assessments in all four studies, lack of sample size calculations in three of the studies, and lack of an appropriate follow-up period in two of the studies. The review found that active video games as an adjunct to pulmonary rehabilitation, compared to pulmonary rehabilitation alone, produced a clinically and statistically significant increase in exercise capacity, with an average increase of 30.9 metres in the 6MWD test (95% Confidence Interval 10.63 to 51.16, P = 0.003) based on the results of the three RCTs. No heterogeneity was found in the outcome of the 6MWD test. However, the I^2 test was not statistically significant.

In the descriptive analysis, none of the four studies reporting on level of dyspnoea found a statistically significant difference in the dyspnoea score in the active video game intervention groups. A significant improvement in quality of life after active video game interventions was found in four studies, and four studies reporting on enjoyment identified indications that patients found the active videogames to be enjoyable.

Two studies reported on adherence with the active videogame interventions. In one study adherence was self-recorded so the accuracy of the data could not be verified; another study determined adherence based on an attendance rate above 50% (76% in the study). Two studies reported on adverse events, with one reporting no adverse events occurring during the study, and the other reporting adverse events in six patients (the need to use nitroglycerin spray in one patient and temporary decrease in SpO_2 below 85% in five patients) but did not report whether these occurred in the intervention or in the control groups.

COMMENTARY

Using the AMSTAR2 tool[9] to assess the quality of the review, 11 out of the 16 criteria were judged to be satisfactory. The criteria that were judged not to be satisfactory included no explicit statement that there was a review methods protocol prior to conducting the review, which introduces the possibility of reporting bias since it is not possible to compare the results of the review with what was originally intended.[10] Secondly, although the review authors did assess the risk of bias in the included studies, they did not interpret the potential impact of this on the certainty of the findings. Additionally, they did not investigate potential publication bias which is important to consider since missing studies can potentially skew the estimate of effects.[11] Finally, the sources of funding for each study were not reported. Due to the critical nature of these quality domains the results of the review should be interpreted with caution.

The main outcome analysed in the review was exercise capacity, as measured by the 6-minute walk distance test (6MWT). For patients with COPD the minimum difference in the 6MWT considered to be clinically important is 54m.[12] The results of the meta-analysis estimated an increase in the 6MWT much lower than this with an average of 30.9m, and with a difference of only 10.63m at the lowest point of the estimate. Therefore, although the evidence shows a positive effect, it is not significant enough to recommend a change to clinical practice. Additionally, the review found no evidence of statistically significant changes in the symptom of dyspnoea when comparing interventions incorporating active video games to conventional therapies alone, and therefore no conclusions can be drawn as to which is better to improve this symptom. This is reflected in other recent systematic reviews of video gaming interventions for other related conditions, such as general respiratory conditions[13] and cardiovascular disease,[14] which have similarly found no clear difference in effect on exercise capacity or dyspnoea outcomes when comparing video game-based interventions with traditional rehabilitation.

However, studies included in this review indicated that participants found the active video game interventions to be enjoyable; an aspect which may encourage patient adherence to rehabilitation and engage patients to be more physically active. Guidelines recommend that patients with COPD should be encouraged to exercise as part of pulmonary rehabilitation[12,15] and enjoyment has been identified as a key factor which may increase adherence to physical exercise in patients with chronic diseases.[16] Studies included in the review did not report any significant adverse events in participants using active video games suggesting that they are relatively safe to use (although clinical and patient safety was not the main aim of the included studies and future research should assess this further). Therefore, clinicians could consider suggesting active video games as a supplementary component to traditional pulmonary rehabilitation to encourage physical activity in patients, where they are readily accessible, and patients have an interest in using them. Active video games should only be used as an adjunct and not as a replacement for traditional pulmonary rehabilitation.

Another key aim of pulmonary rehabilitation is to maximise patients' self-management of their condition and long-term adherence to positive health behaviours.[15] Although the review did report on adherence to the interventions it found that this was not robustly measured or reported by the included studies. Therefore, future research should further investigate patient levels of activation and compliance with rehabilitative strategies that incorporate active video games and should evaluate these outcomes over an extended follow-up period to assess maintenance over the longer term.

Four of the studies included in the review reported exercise intensity (as assessed by the Borg Dyspnea scale, with the scores ranging from 3 to 6); but three did not. Exercise intensity delivered by active video games is likely to vary depending on the system used, type of game, and on individual patient factors.[17] This may make it more challenging for clinicians to manage the intensity of exercise required at different levels when using active video games as an adjunct. Therefore, more detailed reporting of exercise intensity in research studies would be beneficial to support optimal and safe exercise prescription of these interventions.

The findings of this review are limited by the small number of studies being included (seven) with small sample sizes (10-60 participants). It would therefore be beneficial to conduct larger randomised controlled trials of active

video game interventions for pulmonary rehabilitation to strengthen the evidence in this area. It is also notable that the severity of participant COPD in the included studies was moderate to very severe. Further research on the effectiveness of active video games in the mild COPD population would be valuable as active video game interventions may have the potential to increase the accessibility to rehabilitation for this group.

Key Points

- Evidence from this review suggests that active video game interventions, when used as an adjunct to rehabilitation, have a positive but small effect on increasing exercise capacity for people with moderate to severe COPD.
- Clinicians could consider suggesting active video games as a supplementary component to rehabilitation to encourage patients to be more physically active where they are readily accessible, and patients have an interest in using them.
- Active video games should only be used as an adjunct and not as a replacement for traditional pulmonary rehabilitation.
- When suggesting the use of active video games as an adjunct to rehabilitation, consideration should be given to individual patients' levels of activation and digital literacy.

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REFERENCES

1. Agarwal AK, Raja A, Brown BD. Chronic Obstructive Pulmonary Disease. 2023 Aug 7. In: *StatPearls [Internet]*. StatPearls Publishing; 2024.

2. Sansbury LB, Lipson DA, Bains C, Anley GA, Rothnie KJ, Ismaila AS. Disease Burden and Healthcare Utilization Among Patients with Chronic Obstructive Pulmonary Disease (COPD) in England. *Int J Chron Obstruct Pulmon Dis*. 2022;17:415-426. doi:10.2147/copd.s336158

3. McCarthy B, Casey D, Devane D, Murphy K, Murphy E, Lacasse Y. Pulmonary rehabilitation for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2015;2015(2):CD003793. doi:10.1002/14651858.cd003793.pub3

4. Milner SC, Boruff JT, Beaurepaire C, Ahmed S, Janaudis-Ferreira T. Rate of, and barriers and enablers to, pulmonary rehabilitation referral in COPD: A systematic scoping review. *Respir Med*. 2018;137:103-114. doi:10.1016/j.rmed.2018.02.021

5. Lahham A, Holland AE. The Need for Expanding Pulmonary Rehabilitation Services. *Life (Basel)*. 2021;11(11):1236. doi:10.3390/life11111236

6. NHS. The NHS long term plan. Published 2019. Accessed October 18, 2023. https://www.longtermplan.nhs.uk/

7. Pimenta S, Hansen H, Demeyer H, Slevin P, Cruz J. Role of digital health in pulmonary rehabilitation and beyond: shaping the future. *ERJ Open Res*. 2023;9(2):00212-02022. doi:10.1183/23120541.00212-2022

8. Wang YQ, Liu X, Ma RC, et al. Active Video Games as an Adjunct to Pulmonary Rehabilitation of Patients With Chronic Obstructive Pulmonary Disease: A Systematic Review and Meta-Analysis. *Am J Phys Med Rehabil*. 2020;99(5):372-380. doi:10.1097/phm.0000000000001341

9. Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*. 2017;358:j4008. doi:10.1136/bmj.j4008

10. Stewart L, Moher D, Shekelle P. Why prospective registration of systematic reviews makes sense. *Syst Rev*. 2012;1(1):7. doi:10.1186/2046-4053-1-7

11. Page MJ, Higgins JPT, Sterne JAC. Chapter 13: Assessing risk of bias due to missing results in a synthesis. In: Higgins JPT, Thomas J, Chandler J, et al., eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 6.4 (Updated August 2023)*. Cochrane; 2023. Accessed November 23, 2023. http://www.training.cochrane.org/handbook

12. Bolton CE, Bevan-Smith EF, Blakey JD, et al. British Thoracic Society guideline on pulmonary rehabilitation in adults: accredited by NICE. *Thorax*. 2013;68(Suppl 2):ii1-ii30. doi:10.1136/thoraxjnl-2013-203808

13. Condon C, Lam WT, Mosley C, Gough S. A systematic review and meta-analysis of the effectiveness of virtual reality as an exercise intervention for individuals with a respiratory condition. *Adv Simul (Lond)*. 2020;5(1):33. doi:10.1186/s41077-020-00151-z

14. Blasco-Peris C, Fuertes-Kenneally L, Vetrovsky T, Sarabia JM, Climent-Paya V, Manresa-Rocamora A. Effects of Exergaming in Patients with Cardiovascular Disease Compared to Conventional Cardiac Rehabilitation: A Systematic Review and Meta-Analysis. *Int J Environ Res Public Health*. 2022;19(6):3492. doi:10.3390/ijerph19063492

15. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and prevention of Chronic Obstructive Pulmonary Disease. Published 2024. Accessed November 23, 2023. https://goldcopd.org/wp-content/uploads/2023/11/GOLD-2024_v1.0-30Oct23_WMV.pdf

16. Collado-Mateo D, Lavín-Pérez AM, Peñacoba C, et al. Key Factors Associated with Adherence to Physical Exercise in Patients with Chronic Diseases and Older Adults: An Umbrella Review. *Int J Environ Res Public Health*. 2021;18(4):2023. doi:10.3390/ijerph18042023

17. Peng W, Crouse JC, Lin JH. Using active video games for physical activity promotion: a systematic review of the current state of research. *Health Educ Behav*. 2013;40(2):171-192. doi:10.1177/1090198112444956

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