

'Real world' tolerability, ease of use, patient satisfaction and reported adherence in CF adults commencing Colobreathe®

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BACKGROUND

- Colobreathe® dry powder inhaler (CSDPI) is a new inhaled formulation of colistimethate sodium, recently introduced for CF patients infected with *P. aeruginosa*.
- In the clinical trial setting, CSDPI has been found to be non-inferior to nebulised TOBI (as measured by change in FEV₁) and rated as easier to use by patients¹.
- However, there is currently little 'real world' evidence to support these clinical trial findings.
- We therefore conducted this study to assess our initial clinical experience with CSDPI at a large regional UK adult CF centre.

METHODS AND MATERIALS

- This was a prospective observational cohort study.
- We identified patients for a month trial of CSDPI who were clinically intolerant of or demonstrated poor adherence to nebulised colistimethate sodium (NCS).
- At test dose of CSDPI, the following were recorded:
 - Demographics
 - Spirometry
 - Reason for switching to CSDPI
- At 1 month review, the following were documented:
 - Spirometry
 - Side effects
- Patients were asked to compare the following parameters with regards to use of NCS and CSDPI:
 - Ease of use
 - Time taken to perform one dose (including preparation, administration and care of nebuliser equipment or inhaler device)
 - Satisfaction
 - Estimated adherence
- Patients were also asked to rate their:
 - Likelihood of continuing with CSDPI
 - Treatment preference

RESULTS

- 23 patients (10 male) with median age 31 yrs and FEV₁ 58.5% predicted were recruited.
- 10 patients trialled CSDPI due to intolerance of NCS (INTOL group) and 13 patients due to poor adherence to NCS (ADH group).

Lung function

- Combining both groups, FEV₁ did not change from baseline to 1 month visits in patients who completed a full month of CSDPI. FEV₁ pre-test dose of CSDPI was 59% predicted (IQR 42-85%) and at 1 month review was also 59% predicted (IQR 43-81%) (p=0.04).

Tolerance

- At 1 month review:
 - 7/10 patients in the INTOL group and 12/13 patients in the ADH group successfully tolerated a full month of CSDPI and planned to continue.
 - 4/23 patients discontinued CSDPI before or at 1 month review due to the intolerable side effects of bronchospasm (4/4) and cough (1/4).
 - Of the 19 patients continuing with CSDPI, 7/19 reported tolerable side effects of cough (5/7), bronchospasm (1/7), sore throat (1/7).

Adherence

- At 1 month review:
 - In the ADH group, reported adherence was higher with CSDPI (median 100% of doses) compared with NCS (50% of doses) (p=0.002).

RESULTS (continued)

Other outcomes

- CSDPI was reported to be easier to use than NCS and less time consuming.
- All patients who tolerated a full month of CSDPI, expressed a preference for this rather than NCS and planned to continue long-term, despite some initial reports of device functioning issues.

Data in the following tables reflects patients who had used NCS for at least 1 month consistently in the preceding 12 months and who were continuing with CSDPI at 1 month review.

Preparation and administration

Parameter	NCS	CSDPI
Median ease of preparation (VAS 1-10, 1 = very easy)	5 (IQR 3-8)	1 (IQR 1-2)
Median ease of administration (VAS 1-10, 1 = very easy)	4 (IQR 3-7)	2 (IQR 1-3)
Median time required for one dose (minutes)	25 (IQR 20-30)	3 (IQR 2-4)

Satisfaction

Parameter	NCS	CSDPI
Median time required for one dose (VAS 1-10, 1 = very satisfied)	8 (IQR 7-9)	1 (IQR 1-2)
Median degree of interference with QOL (VAS 1-10, 1 = no interference)	6 (IQR 5-8)	2 (IQR 1-2)
Median overall satisfaction with therapy (VAS 1-10, 1 = very satisfied)	6 (IQR 5-7)	2 (IQR 2-3)
Median satisfaction with Colobreathe® device (VAS 1-10, 1 = very satisfied)		3 (IQR 2-5)
Median likelihood to continue long-term with Colobreathe® (VAS 1-10, 1 = very likely)		1 (IQR 1-2)

Patient comments regarding Colobreathe®

- "It's a very good product. I can't believe how much of a difference it has made to me in terms of convenience and time."
- "It's easy to use. I can take it in my handbag and use it on the move."
- "It saves time and it's easier to organise within my treatment plan. I'm excited about when the manufacturers get the inhaler design right."
- "I tolerated Promixin® better but the ease of doing Colobreathe® outweighs the chest tightness I get with it."
- "I've sometimes breathed in bits of capsule and I'm concerned that they might be going onto my lungs."
- "I'm very disappointed with the design of the device and the way the capsules fracture. When this happens there can be a large influx of powder all at once which causes coughing – I then feel I'm losing the powder that I've breathed in."
- "I'm worried that I may not always be getting a full dose. Sometimes when the capsules crack, powder is left in the inhaler or it gets stuck behind the pieces of broken capsule and I have to try and shake/open the capsule to free the trapped powder."
- "Powder starts to build up on the inside of the inhaler. This stops the capsules from spinning properly and sometimes I get a 'gush' of powder and sometimes very little. A supply of two inhalers rather than one a month would be better."
- "Sometimes bits of the capsule get stuck in the inhaler and I have to use a pencil to get them out."

CONCLUSIONS

- Despite reporting significant difficulties with the Colobreathe®, all patients who tolerated a full month of Colobreathe® expressed a preference for this rather than nebulised colistimethate sodium and planned to continue long-term.
- Early real world evidence suggests that Colobreathe® is well tolerated, easier to use, less inconvenient and associated with improved adherence compared to nebulised colistimethate sodium.
- Longer-term outcomes are needed to assess whether these benefits are maintained and are associated with improved clinical outcomes.

References: 1. Schuster et al. Thorax 2013; 68:344-350.

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