Clinical outcomes and patient satisfaction following initiation of the TOBI Podhaler in Cystic Fibrosis adults

C. Brown, E.F. Nash, V. Carrolan, R. Rashid, J.L. Whitehouse.
West Midlands Adult CF Centre, Heart of England NHS Foundation Trust, Birmingham, United Kingdom.

Background:
TOBI inhalation powder (TIP) is a dry powder formulation of TOBI, delivered by the Podhaler device, which has recently been introduced into clinical practice for the treatment of chronic airway infection in patients with cystic fibrosis (CF). In the clinical trial setting, TIP has been shown to be non-inferior to nebulised Tobramycin Inhalation Solution (TIS) in CF subjects in terms of effectiveness on lung function, with increased adverse events but overall superior patient satisfaction. However, there is currently little "real world" evidence of tolerance and effectiveness of TIP.

Aim:
To assess the experience of CF adults receiving TIP at our large regional UK adult CF centre.

Methods:
We report the preliminary results of a prospective observational study to evaluate changes in lung function, tolerability and antibiotic requirements of 73 CF adults that have received at least one dose of TIP at our centre between December 2011 and June 2012. Patients also completed a visual analogue scale (VAS) score of tolerance, convenience, satisfaction and likelihood to continue (1 = very satisfied/not at all likely) at all satisfaction very satisfied/norm (at all likely) at their 28-day review.

The 73 patients were commenced on TIP for one of 4 reasons. The outcomes of these patients) or at completion (2 patients) of 28 days treatment. See Table 1

Results:

- **Adverse events (AEs)** were common following the test dose. The most commonly reported AE was 'dry cough' (24/73, 32.9%). See Figure 4.
- **At 28 day review:**
  - Median change in FEV1 % predicted was -1.7% (IQR -6.1 to 2.4%).
  - Median changes in FEV1 % predicted in each subgroup are shown in Figure 3. 12/27 patients (44.4%) reported AEs at their 28-day review; most commonly 'dry cough' (10 patients, 37.0%). See Figure 4.
  - AEs were reported more frequently in the 'Intolerant' subgroup (43.5%).
  - No AEs were reported in the 'Treatment burden' subgroup.
  - 12/27 patients (44.4%) were commenced on oral or IV antibiotics for pulmonary exacerbation.
  - Median VAS scores for overall satisfaction, ease of administration, and likelihood to continue were all 1/10.

- **12/2 patients to date have discontinued TIP before completion (10 patients) or at completion (2 patients) of 28 days treatment. See Table 1**
  - 8 of the 12 (66.7%) who discontinued were in the 'Intolerant' subgroup.
  - The most common reason for discontinuation was 'dry cough' (8/12 patients, 75.0%), with median VAS score for severity of all AEs 7/10.

- **Conclusion:**
Despite experiencing a high incidence of adverse events, CF adults commencing TOBI Podhaler report high levels of treatment satisfaction. TIP offers an alternative treatment option to CF patients, including those that have previously failed to tolerate any other nebulised anti-Pseudomonal antibiotic treatments.

References:

Table 1: Baseline demographics and outcome at 28 day review

Table 2: Adverse events reported at 28 day review

Figure 1: Reported and observed adverse events at trial

Figure 2: Median change in FEV1 % predicted at baseline post trial

Figure 3: Median change in FEV1 % predicted from baseline to 28 day review

Figure 4: Adverse events reported at 28 day review

Figure 5: Clinical outcomes and patient satisfaction following initiation of the TOBI Podhaler in Cystic Fibrosis adults