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73 Real world evidence on inhaled tobramycin use in CF patients: analysis of the RAMQ data (Canada)

J. Lachaine[1], M.-È. Lapierre[2], C. Beauchemin[2], G. Angyalosi[3], M.-M. Balp[3], F. Calado[3], L. Debonnett[4], J. Desforges[5], A. Sagkriotis[3]. [1]*University of Montreal, Faculty of Pharmacy, Montreal, Canada;* [2]*University of Montreal, Montreal, Canada;* [3]*Novartis Pharma AG, Basel, Switzerland;* [4]*Novartis Pharmaceuticals Corporation, New York City, United States;* [5]*Novartis Pharmaceuticals Canada Inc., Dorval, Canada*

Objectives: The aim was to describe treatment patterns and measure real-world outcomes with tobramycin powder for inhalation (TIP™), tobramycin inhalation solution (TIS), and other tobramycin formulations (OTF), using Québec's provincial public drug reimbursement program database (RAMQ).
Methods: CF patients covered by the RAMQ who had a prescription either of TIP, TIS, or OTF on at least one occasion during the period from 01.01.2011 to 30.06.2012 were selected. Patient's characteristics, drug utilization patterns and resource utilization were analyzed.
Results: Data were available for a sample of 244 eligible patients: 95 on TIP, 130 on TIS and 149 on OTF. The average age of the sample was 24.3 years (SD=12.5), 56.1% were male. Treatment adherence as measured by medication possession ratio (MPR) and treatment persistence at 6 months were estimated. Higher medication costs on the TIP group were partially offset by lower healthcare resource utilization costs associated (Table 1). Annual rate of exacerbations was 0.5 for patients on TIP and 0.7 for patients on TIS and OTF.

Table 1.

Characteristics	Patients on TIP	Patients on TIS	Patients on OTF
Average MPR [% (SD)]	52.8 (34.5)	41.4 (29.9)	39.7 (33.8)
Proportion of patients (%) treatment persistent at 6 months	78.4	62.8	56.5
Medication costs [mean (SD)]	$4,772 ($3,178)	$3,710 ($2,724)	$3,406 ($4,245)
Health care resource utilization costs [mean (SD)]	$831 ($2,195)	$1,214 ($2,245)	$905 ($1,628)

Conclusions: In a real life setting, TIP was associated with a high level of treatment adherence (as demonstrated by a high MPR and persistence at 6 months) and low utilization of additional healthcare resources (such as hospitalisation due to exacerbations).

74 An evaluation of treatment burden following initiation of TOBI® Podhaler® in patients with CF

D. Bilton[1], E.F. Nash[2], D. Peckham[3], C.S. Haworth[4], M. Carroll[5], G. Connett[5], R.M. Uden[6], L. Oswald[6], F. De Iorio[7], G. Oliver[7]. [1]*Royal Brompton & Harefield NHS Foundation Trust, London, United Kingdom;* [2]*Heart of England NHS Foundation Trust, Birmingham, United Kingdom;* [3]*Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom;* [4]*Papworth Hospital NHS Foundation Trust, Cambridge, United Kingdom;* [5]*University Hospital Southampton, Southampton, United Kingdom;* [6]*PH Associates, Marlow, United Kingdom;* [7]*Novartis Pharmaceuticals UK Limited, Frimley, United Kingdom*

Objectives: Patients with cystic fibrosis (CF) have to maintain a significant daily treatment load and the burden of nebulised therapies remains high. This combined retrospective and prospective observational study describes the change in patients' perception of treatment burden, global satisfaction and convenience following initiation of the TOBI® Podhaler®.
Methods: Patients aged ⩾14 y with chronic *Pseudomonas* infection were screened and those completing 1 cycle of TOBI® Podhaler® treatment were recruited to the study. Patients completed the CFQ-R, Treatment Satisfaction Questionnaire for Medication (TSQM) and modified TSQM, at baseline and on completion of cycle 1 and 3 of treatment (at 1 and 5 months). The primary endpoint of the study was the change in the Treatment Burden domain score of the CFQ-R at 1 and 5 months.
Results: 115 patients were screened from 5 UK CF centres, April 2012 to May 2013, 87 who completed at least 1 cycle of treatment were included in the study (mean age 29.4 y (SD 8.4), 48 (55%) male). 68/87 (78%) patients completed 3 cycles. At baseline, 54/87 (62%) were taking ⩾2 nebulised therapies. Results of CFQ-R and TSQMs are shown in Table 1.
Conclusion: TOBI® Podhaler® was associated with significant improvements in perceived treatment burden, global satisfaction and convenience at 1 month. Quality of life improvements were sustained for up to 5 months.

Table 1.

Patient-reported outcome measure and domain	Mean change in score*	
	After 1 cycle of treatment (1 month)	After 3 cycles of treatment (5 months)
CFQ-R Treatment burden	+7.9 (n = 84) (p < 0.01)	+6.5 (n = 55) (p = 0.089)
TSQM Global satisfaction	+12.9 (n = 83) (p < 0.001)	+19.9 (n = 57) (p < 0.001)
TSQM Convenience	+25.6 (n = 83) (p < 0.001)	+29.7 (n = 57) (p < 0.001)
TSQM Modified (convenience of storage, assembly and care)	+24.2 (n = 80) (p < 0.001)	+27.0 (n = 55) (p < 0.001)

Student t test – against a minimum clinically significant difference of 1 standard error
*All scores are out of 100, increased scores are indicative of improvement.

75 Efficacy of inhaled antibiotics in CF patients with *Pseudomonas aeruginosa* (Pa) infection: a network meta-analysis (NMA)

K. Higashi[1], K. Janssen[1], J. Jansen[1], G. Angyalosi[2], M.-M. Balp[2], F. Calado[2], L. Debonnett[3], A. Sagkriotis[2], G. Döring[4], J.S. Elborn[5]. [1]*Mapi HEOR, AX Houten, Netherlands;* [2]*Novartis Pharma AG, Basel, Switzerland;* [3]*Novartis Pharmaceuticals Corporation, New Jersey, United States;* [4]*Tübingen University, Tübingen, Germany;* [5]*School of Medicine, Dentistry and Biomedical Sciences Queen's University, Belfast, Ireland*

Objectives: The aim of the study was to compare the efficacy of tobramycin powder for inhalation (TIP™) relative to tobramycin inhalation solution 300 mg/5 ml (TIS-T) and 300 mg/4 ml (TIS-B), aztreonam lysine inhalation solution (AZLI), colistimethate sodium (colistin) and colistin inhalation powder (colistin-P) for the treatment of CF patients with chronic Pa lung infection.
Methods: A systematic literature review was conducted for 2010–2012 to update a previously conducted NMA (Littlewood 2012). Individual study results were indirectly compared with a Bayesian NMA. The analysis was performed for change from baseline in FEV_1% predicted at week 4. As some trials included naïve and previously exposed patients in different arms, these were considered separate treatment-by-population groups in the analysis.
Results: Three new randomized controlled trials (Assael 2012, Galeva 2012, Schuster 2012) were identified in addition to the previous NMA (11 studies). Table 1 shows the difference between TIP and comparators for FEV_1% predicted at week 4 for naïve and exposed populations (95% Credible Interval) and the probability (P) that TIP is better than the comparator. Positive differences in FEV_1% predicted and P > 50% favour TIP.
Conclusion: TIP is highly likely to be favourable in comparison to colistin-P and results in similar improvements in changes in FEV_1% predicted as other licensed options for CF patients with chronic Pa infection.

Table 1

	Change in FEV1% predicted at 4 weeks						
	TIS-T		TIS-B		AZLI	Colistin-P	Colistin
	Naïve	Exposed	Naïve	Exposed	Naïve	Naïve	Exposed
TIP	−1.97 (−11.84, 8.03)	−0.78 (−7.65, 5.99)	−2.38 (−12.71, 7.98)	0.01 (−10.42, 10.46)	1.53 (−7.04, 10.00)	11.36 (−1.75, 24.31)	−5.75 (−21.23, 9.89)
P	33%	39%	32%	50%	65%	96%	21%

76 Aerosolized antibiotic therapy in cystic fibrosis with *Pseudomonas aeruginosa* airway infection in children

S. Sciuca[1], R. Eremciuc[1], O. Dimitrova[1], A. Cotoman[1]. [1]*State University of Medicine and Pharmacy "Nicolae Testemitanu", Department of Pediatrics, Chisinau, Moldova, Republic of*

Background: In children with cystic fibrosis (CF) lung damage secondary to chronic infection is associated with poorer growth, increased need for antibiotics and hospitalization, and premature mortality.
Objectives: To determine the efficacy of the inhalation therapy with Colistin in *P. aeruginosa* lung infection in children with CF.
Methods: The study includes 14 children with the average age 4.19±1.7 years (1–3 years – 5 children; 3–6 years – 9 children) with CF who received Colistin treatment for 6 months. The diagnosis was established according to typical clinical signs of CF, positive sweat test, genetic testing with determining the CFTR mutations. In our case, 8 patients were heterozygous and 4 homozygous for F508del. All the children suffered from *P. aeruginosa* pulmonary infection.
Results: During inhaled Colistin therapy, a positive dynamic of respiratory syndrome's evolution was observed: decreased cough intensity and frequency, diminishing of the quantity of sputum. Before undergoing Colistin treatment, the colonisation rate with *P. aeruginosa* was 10^8–10^3. As a result of the inhaled therapy course, after multiple sputum examination, in 3 children no modifications of the concentration of *P. aeruginosa* in sputum were noticed, in 8 cases it decreased with 1–3 titres, and in 3 children *P. aeruginosa* was eradicated. A positive dynamic of the nutrition status and increasing of BMI from 14.52±2.52 to 15.35±2.76 was also observed in these children.
Conclusion: Inhaled Colistin therapy allows to accomplish the eradication of *P. aeruginosa* infection in infants with CF, to control it in preschool children and influences positive the nutrition status of these children.