Patient attitudes to nebulised antibiotics in the treatment of bronchiectasis: a mixed-methods study

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Shareable abstract (@ERSpublications)
Patients with bronchiectasis have a significant daily treatment burden. Novel therapies need to be as effective as current therapies, rather than simply more convenient, before being accepted. https://bit.ly/3JIgDfn

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Abstract

Background Regular daily nebulised antibiotics are widely used in managing bronchiectasis. This patient population typically has severe bronchiectasis requiring multiple other medications. Given that little is known about patients' views and preferences for such therapies, this was the focus of our study.

Methods To explore patient lived-experience using nebulised antibiotics, focus groups and semi-structured interviews were conducted with patients and carers; these were audio-recorded and transcribed to enable thematic analysis. QSR NVivo software facilitated data management. The themes developed from the qualitative data analysis were then used to co-design a questionnaire to capture attitudes and preferences towards nebulised therapy. Questionnaires were completed by patients and statistical analysis was performed. Ethical approval was obtained (13/WS/0036).

Results The study's focus groups comprised 13 patients and carers, and 101 patients completed the questionnaire. Patients described nebulised therapy as an imposition on their daily routine, in turn affecting reported rates of adherence. Results demonstrated that 10% of all patients using nebulised antibiotics found these hard/very hard to administer. Further, 53% of participants strongly agreed/agreed that they would prefer an antibiotic delivered by an inhaler over a nebuliser, if it were as effective at preventing exacerbations. Notably, only 10% of participants wished to remain on nebulised therapy.

Conclusions Inhaled antibiotics delivered *via* dry powder devices were deemed quicker and easier to use by patients. Providing they were at least as effective as current nebulised treatments, patients deemed inhaled antibiotics to be a preferable treatment option.

Introduction

Bronchiectasis is a clinical syndrome linking radiological evidence of airway dilatation with recurrent sputum production and infections. Clinically significant bronchiectasis results in recurrent cough, dyspnoea, fatigue and episodic infective exacerbations [1, 2]. Bronchiectasis exacerbations are key events characterised by a worsening cough frequency, increased sputum viscosity, purulence and volume [2–4]. Increasing severity and frequency of exacerbations is associated with a decrease in health-related quality of life, reduced lung function, increased daily symptoms and increased mortality [3, 5–7]. Two or more exacerbations per year occur in ∼50% of patients and up to one third require hospitalisation [3, 7–9]; decreasing the incidence and severity of exacerbations is therefore a key treatment goal [2]. Treatments for bronchiectasis aim to reduce daily symptoms and the severity and frequency of exacerbations, maintain lung function, and prevent progression of the disease [2].

In the UK it is estimated that over 300 000 patients are diagnosed with bronchiectasis [10], with the prevalence increasing worldwide [10–13]. Severe bronchiectasis is associated with a shorter life expectancy compared to the normal population and elevated healthcare costs due to hospitalisation [2]. Recent interest in bronchiectasis has led to various clinical research trials including nebulised and dry powdered inhalers [14–17]. Antibiotics target the bacterial load and potentially reduce airway inflammation. Emerging therapies include inhaled antibiotics that are selectively delivered to the airways, unlike oral regimens [18, 19], allowing higher drug concentrations within the lungs and minimising systemic exposure. This may reduce the risk of systemic side effects and bacterial resistance to the antimicrobial drug [20].

To date there are no licensed inhaled antibiotics for the treatment of bronchiectasis unrelated to cystic fibrosis [1, 2]. Regular, twice daily nebulised antibiotics are unlicensed in bronchiectasis but are recommended in prevailing guidelines, albeit with a limited evidence-base. Patient treatment regimens can include a combination of inhaled drugs, *e.g.* bronchodilators, oral antibiotics and other treatments, including airway clearance techniques to clear bronchial secretions. The rate of adherence to nebulised regimes remains unclear, but it is likely to be poor [21, 22]. In a study of 75 participants, only 53% were adherent to all nebulised antibiotics and low adherence was associated with poorer health outcomes [21, 22]. New inhaled antibiotics delivered by inhalers are also being investigated; however, their efficacy is yet to be proven [15]. Despite the increased interest in emerging pulmonary-targeted antibiotic therapies for bronchiectasis, little is known about the views of patients on these regimens.

Aims and hypotheses

This study aimed to explore patient lived-experiences with using nebulised treatments for bronchiectasis, as well as investigate patients' attitudes towards new inhaled devices, specifically in comparison to nebulised regimens. It was hypothesised that younger patients would be less adherent to nebulised regimens. Additionally, it was hypothesised that patients would prefer inhaled antibiotics over nebulised regimes if these were to become available. Furthermore, it was expected that in the hypothetical case of inhaled antibiotics being less effective than nebulised antibiotics, patients would still be inclined towards the most convenient format.

Methods

Study setting and design

The study commenced in October 2014 and recruitment completed in December 2016. The study was conducted within a large teaching hospital in the North East of England (UK). Ethical approval was obtained from the NHS West of Scotland Ethics Committee (reference: 13/WS/0036) and research governance was granted by the participating NHS organisation.

This mixed-methods study was designed to have two stages, each enabling further understanding of patient lived-experiences and attitudes to nebulised treatments: stage 1 involved qualitative investigation with focus groups and semi-structured interviews; stage 2 used a questionnaire to capture patient attitudes towards nebulised therapy, the results of which were analysed using statistical analysis.

Study recruitment and sampling

The consolidated criteria for reporting qualitative research (COREQ) checklist was followed (supplementary file). To be eligible, participants were ⩾18 years old, had computed tomography-confirmed bronchiectasis, had current or recent (within 1 year) treatment with inhaled antibiotics and were willing and able to participate in focus groups or interview.

Patients were recruited from clinics in the large teaching hospital in accordance with the two stages of the study design: 1) patients and their carers were recruited for the focus groups or interviews and 2) the questionnaire was completed by patients. Recruitment was conducted within the adult bronchiectasis clinic (sample size of ~500 patients) *via* a gatekeeper clinician to introduce the study to eligible participants. All interested participants were given a participant information sheet detailing the purpose and aim of the research. Those who wished to participate gave their written consent and were enrolled. There was no relationship established between the researchers and participants prior to study commencement. Purposive sampling was used to recruit participants from different genders, diverse socioeconomic backgrounds and varying age ranges to ensure inclusion of representative views.

Qualitative data collection and analysis

A semi-structured interview schedule was developed by the authors (JD and RL, section 1 in the supplementary material); this used open and closed questions to elucidate patient responses. The focus

groups and interviews were facilitated by two authors with qualitative research expertise (JD and RL) and were held in private, in a hospital room. During qualitative data collection and analysis, inductive and iterative working led to modification of the interview schedule, a recognised aspect of qualitative methodology. Data sufficiency occurred when no new themes were elicited.

All qualitative data collected were audio-recorded and transcribed verbatim to enable analysis. All data were anonymised during transcription and all transcripts were checked for accuracy (AR-B). Authors (JD and RL) performed reflexive thematic analysis; initial descriptive codes were derived from the data and these were grouped, which enabled the development of analytical themes. The themes were then refined and defined (and reviewed by authors ADS and TR; section 2 in the supplementary material) and used to co-design the questionnaire. NVivo software (QSR International, version 12) was used to facilitate data management.

Questionnaire development based on qualitative findings

The questionnaire was co-designed by authors and research participants, who provided review and comments following their involvement in focus groups or semi-structured interviews (section 3 in the supplementary material). The aim of the questionnaire was to capture the patients' views on treatment burden, adherence, side effects, tolerability and management of nebulised therapy. It also aimed to survey patients on the impact nebulised antibiotics have on their lives and those of significant others. Hypothetical "treatment choice" scenarios comparing nebulised with dry powder therapies were also developed; these compared nebulised to dry powder inhaled therapies with varying degree of effectiveness and treatment burdens between the treatment choices.

Quantitative analysis

Questionnaire responses were scaled using Likert scale methodology, except questions in which answers combined two nominal values (yes/no). Each value of the scale was assigned to a number. Consequently, all responses were coded and stored in a Microsoft Excel file; coding from the original Excel file was completed and reanalysed. Two main groups of participants were distinguished: patients who were currently prescribed nebulised treatment and patients who were not. For the purposes of the study, responses given by patients receiving non-nebulised treatments were only included within the study analysis for those questions that did not address experiences and views on nebulised antibiotics. Data were further divided into subcategories of gender (female and male) and age (⩽65 years and >65 years); this was chosen as the cut-off age because it was the participants' median age, as well as a common retirement age in the UK.

The statistical package SPSS and GraphPad Prism 7.04 were used for statistical analysis and elaborating graphs, respectively. Within each question, the median and frequency for each group and subgroup were reported. Participants' responses were compared as a function of treatment modality, age and gender. Mann–Whitney U-test was used to analyse Likert scale data. Data combined into two nominal categories (yes/no) were analysed using a chi-squared test. Results were considered significant at $p \leqslant 0.05$.

Results

Qualitative focus groups and semi-structured interviews

In total, 13 participants were recruited, with an age range of 37–73 years. Participant characteristics are described in table 1; there were no participant dropouts or repeat interviews. All focus groups and interviews were conducted in person and included participants ranged from "inexperienced" users of nebulised antibiotics (<1 year of treatment) to "long-term" users (>5 years of treatment).

TABLE 1 Participant demographics for focus groups and semi-structured interviews

	Focus group 1	Focus group 2	Paired interview	Interview 1	Interview 2	Interview 3
Participants (n)	4	4	2	1	1	1
Age range (years)	64–73	37–67	63–66	58	72	60
Length of time using inhaled or nebulised antibiotics	Long-term >5 years	Long-term >5 years	Inexperienced <1 year	Long-term >5 years	Long-term >5 years	Long-term >5 years

TABLE 2 Participant demographics questionnaire responders

	Participants using nebulised treatment	Participants using non-nebulised treatment	Total
Participants	76 (75.25)	25 (24.75)	101 (100.00)
Age group			
⩽65 years	38 (50.67)	8 (30.77)	46 (45.54)
>65 years	37 (49.33)	18 (69.23)	55 (54.46)
Reported gender			
Female	48 (63.16)	16 (64.00)	64 (62.75)
Male	28 (36.84)	9 (36.00)	37 (32.25)

Data are presented as n (%).

Questionnaire

As shown in table 2, 101 patients completed the questionnaire survey. The mean±SD age was 65±10.63 years with unequal gender distribution (62.75% female, 32.25% male). 46% (n=46) were ⩽65 years old and 54% (n=55) were older than 65 years. The majority of patients (75%) were either on current nebulised treatment or had been in the last 6 months.

The treatment burden of bronchiectasis

The median treatment burden for all therapies including chest clearance exercises, nebulisers, inhalers and tablets was 30–60 min·day^{-1} (figure 1a, b). 27% of patients on nebulised antibiotics took >1 h to prepare treatments, compared to 0% of participants on non-nebulised antibiotic treatment (p=0.003). As expected, patients within the ⩽65 years cohort showed lower burden times; 47% reported taking <30 min·day^{-1} to prepare their treatments *versus* 27% within the >65 years group. Whereas the majority of >65 years patients (43%) had a burden time of 30–60 min, only 29% within the ⩽65 years cohort reported this.

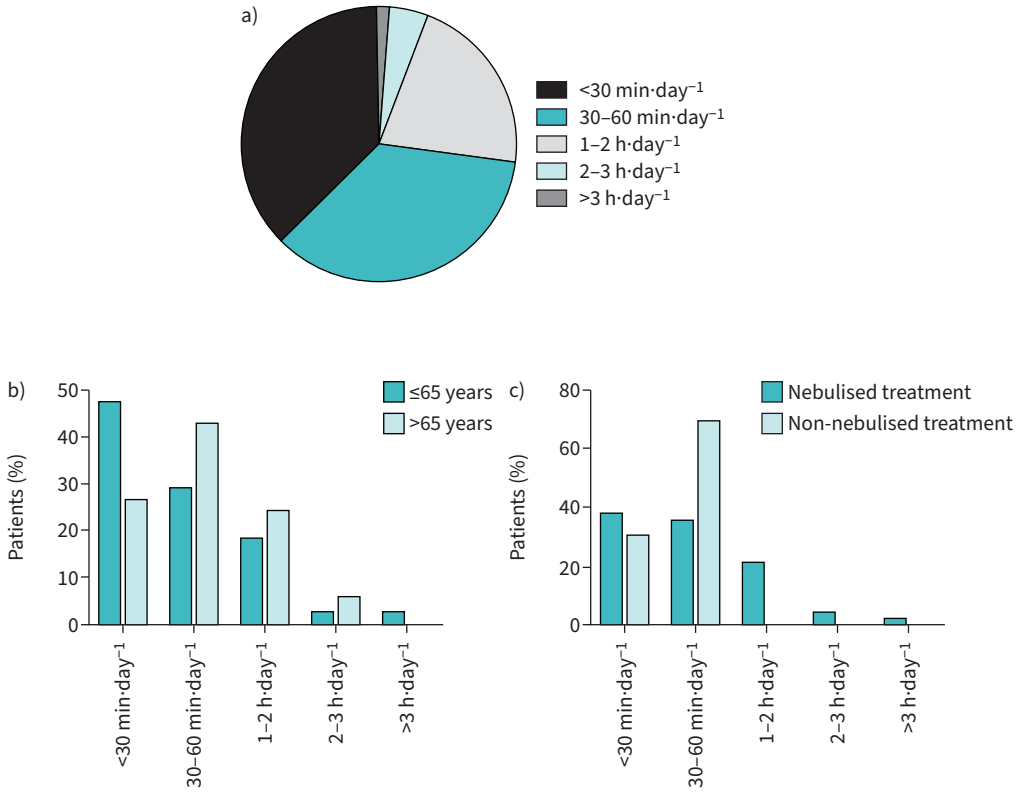

FIGURE 1 a) Treatment burden for all therapies. b) Treatment burden for patients aged ⩽65 years *versus* >65 years who received nebulised therapies. c) Treatment burden of nebulised *versus* non-nebulised therapies.

Medians across the two age groups were, however, the same (30–60 min) with no significant differences (p=0.149). No significant difference was seen across gender groups (p=0.472).

As shown in figure 1c, treatment burden was significantly different between treatment groups (p=0.014). While 30–60 min·day^{-1} was the maximum burden time reported by those patients who were not on nebulised treatment, 21% patients on nebulised therapies reported burden treatments of 1–2 h·day^{-1}, 4% of 2–3 h·day^{-1} and one patient reported over 3 h·day^{-1}.

Side effects

Tolerability to nebulised drugs was the same across age groups (p=0.576). However, significant differences were found between genders (p=0.015) and overall women experienced side effects more frequently (figure 2). 15% of women reported side effects "always" or "frequently", as compared to 7% of men. Notably, 82% of men stated that they never experienced side effects, in contrast to only 55% of women.

Treatment adherence

Reported adherence to nebulised treatment was relatively low; only 72% of patients reported taking their prescribed nebulised treatment "always" (49.3%) or "frequently" (22.7%). 14.7% responded that they "never" (10.7%) or "infrequently" (4%) used their nebuliser twice a day, with 77.7% stating that side effects associated with the nebulised antibiotics were "always" (33.3%) or "frequently" (44.4%) the reason for this. Treatment adherence was not significantly different across age groups (p=0.967) or genders (p=0.472).

88.7% of participants reported having childcare or having to look after others as an uncommon reason for missing nebulised antibiotics doses. There were significant differences between genders (p=0.033). Whereas 100% of men reported childcare/care of others as an "uncommon reason" to miss nebulised antibiotics, 18% of women reported this as a reason for missing their nebulised antibiotics ("common" (10.3%), "very common" (5.1%) or "extremely common" (2.8%)). As expected, a larger number of ⩽65 years patients (19.3%) reported having childcare/care of others commitments as a reason to miss their treatment as compared to 3.3% within the >65 years cohort. However, such differences were nonsignificant (p=0.119).

Treatment importance and new treatments

All 101 patients were asked to rate which treatments they considered the most important within their routines. Inhalers were considered to be the most important treatment, with 31% of participants reporting this. Tablets were the second most important treatment according to patients (23%), followed by nebulised

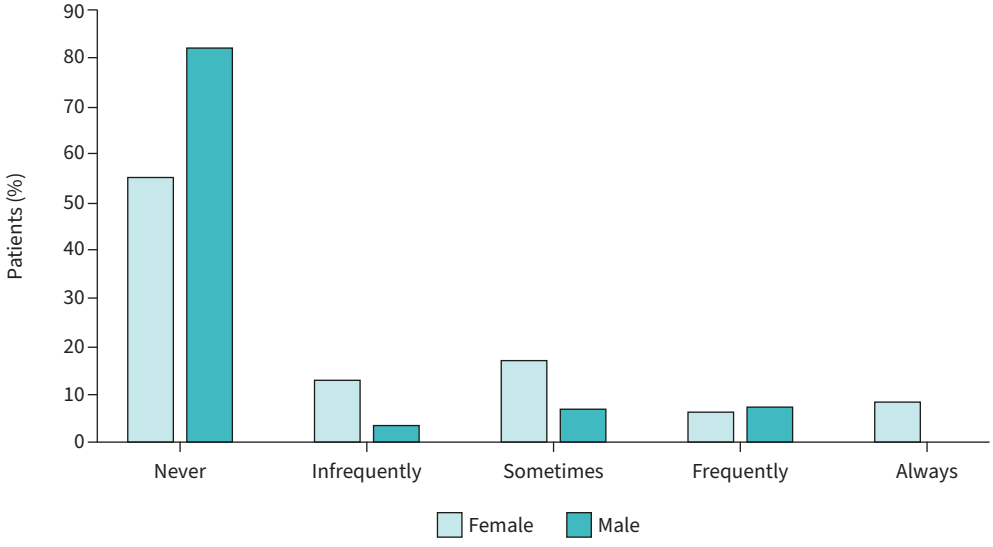

FIGURE 2 Side effects reported with nebulised antibiotic use.

antibiotics (18%) and nebulised salbutamol (18%). Breathing exercises were reported to be the least important treatment (10%).

Patients' attitudes to emerging therapies in relation to inhaled antibiotics were explored. As can be seen in table 3, the majority of patients on nebulised treatment strongly agreed (46.7%) or agreed (25.3%) with the statement "I would prefer an antibiotic in an inhaler to a nebuliser". Of the 12% of patients stating that they "strongly disagree" or "disagree" with this statement, 75% reported a beneficial effect of the wet mist associated with the nebuliser, as compared to the 40% of those who agreed or strongly agreed with a preference for switching to an inhaler. As shown in table 3, patients again showed a preference towards inhalers when asked to consider the statement "I would be more likely to use an antibiotic *via* an inhaler". 64.4% strongly agreed or agreed with this, whereas 12.3% strongly disagreed or disagreed. 23.3% neither agreed nor disagreed.

Overall, patients did not feel that disruption from their previous routine would be a barrier to switching to inhaled antibiotics when considering the statement, "I would prefer the nebulised antibiotic over an inhaled antibiotic because I already have a routine with my nebuliser" (table 4). However, the majority of patients (73%) reported that if a new inhaled antibiotic was to become available, this would have to be as effective as the current nebulised antibiotics.

Patients' views on treatments did not significantly differ across age groups or gender ($p>0.05$). Similar attitudes towards inhalers were shown by patients who were not on nebulised antibiotics; when asked if they would prefer antibiotics in an inhaler to a nebuliser, the median response was also "agree" although this was not statistically significant ($p=0.213$, table 3). The majority of these patients (72%) also believed that they would be more likely to engage with their therapies if the antibiotics were taken *via* an inhaler rather than a nebuliser.

As seen in table 5, patients' attitudes were not significantly influenced by age. In contrast to what was expected, the percentage of patients ⩽65 years who would opt to use inhaled antibiotic in the hypothetical case of these being more effective (78%) or as effective (80.6%) was lower than in the >65 years cohort (84% and 95%, respectively). Additionally, only 14% of participants ⩽65 years would be willing to use inhalers if this meant two extra exacerbations per year, as compared to 27% within the >65 years age group. As shown in table 4, difference across genders and between patients on nebulised and non-nebulised treatments were nonsignificant.

TABLE 3 Level of agreement reported by participants when posed the statements: "I would prefer an antibiotic in an inhaler, instead of a nebuliser" and "I would be more likely to use an antibiotic *via* an inhaler"

	Age		Gender		Treatment	
	⩽65 years	>65 years	Female	Male	Nebulised	Non-nebulised
"I would prefer an antibiotic in an inhaler, instead of a nebuliser"						
Strongly disagree (%)	5.4	8.1	8.3	3.7	6.7	0.0
Disagree (%)	5.4	2.7	4.2	7.4	5.3	4.3
Neither agree or disagree (%)	13.5	16.2	1.04	22.2	14.7	8.7
Agree (%)	18.9	32.4	20.8	33.3	25.3	56.5
Strongly agree (%)	54.1	40.5	54.2	33.3	46.7	30.4
Someone does it for me (%)	2.7	0.0	2.1	0.0	1.3	0.0
Median	Strongly agree	Agree	Strongly agree	Agree	Agree	Agree
p-value	0.245		0.096		0.213	
"I would be more likely to use an antibiotic *via* an inhaler"						
Strongly disagree (%)	11.1	2.8	8.7	3.7	6.8	0.0
	8.3	2.8	6.5	3.7	5.5	9.1
Neither agree or disagree (%)	25.0	22.2	21.7	25.9	23.3	18.2
Agree (%)	13.9	22.2	8.7	37.0	19.2	31.8
Strongly agree (%)	41.7	50.0	54.3	29.6	45.2	40.9
Median	Agree	Agree	Strongly agree	Agree	Agree	Agree
p-value	0.636		0.071		0.912	

TABLE 4 Level of agreement reported by participants when posed the statements "I would prefer my nebuliser over an inhaler because I already have a routine with my nebuliser" and "I would prefer my nebuliser over my inhaler because I like the effect of the wet mist on my lungs"

	Age		Gender		Total
	⩽65 years	>65 years	Female	Male	
"I already have my routine with my nebuliser"					
Strongly disagree (%)	21.6	13.9	20.8	11.5	17.6
Disagree (%)	35.1	44.4	43.8	30.8	39.2
Neither agree or disagree (%)	16.2	16.7	14.6	19.2	16.2
Agree (%)	16.2	13.9	6.3	34.6	16.2
Strongly agree (%)	8.1	11.1	12.5	3.8	9.5
Someone does it for me (%)	2.7	0.0	2.1	0.0	1.4
Median	Disagree	Disagree	Disagree	Neither agree or disagree	
p-value	0.920			0.109	
"I like the effect of the wet mist on my lungs"					
Strongly disagree (%)	18.9	13.9	18.8	11.5	16.2
Disagree (%)	27.0	38.9	35.4	26.9	32.4
Neither agree or disagree (%)	21.6	25.0	25.0	19.2	23.0
Agree (%)	13.5	8.3	6.3	23.1	12.2
Strongly agree (%)	18.9	13.9	14.6	19.2	16.2
Median	Neither agree or disagree	Disagree	Disagree	Neither agree or disagree	
p-value	0.474			0.092	

Discussion

Bronchiectasis is associated with significant symptoms and, in more severe cases, morbidity requiring hospitalisation. Pulmonary-targeted antibiotics are widely used in patients despite limited evidence, perhaps reflecting the dearth of high-quality studies of any effective therapy. British Thoracic Society annual audits suggest 10–20% of patients are prescribed nebulised antibiotics [23]. The subpopulation of patients requiring these often have high rates of comorbidities. Importantly, this study shows there is significant treatment burden in bronchiectasis, with a median treatment burden of 30–60 min per day.

This is one of the largest studies in bronchiectasis investigating patients' beliefs on inhaled therapy in bronchiectasis. Authors have explored the lived-experiences of patients with long-term nebulised regimes and their attitudes towards emerging therapies, particularly new inhaled dry powder antibiotics. It is essential to explore patients' views on emerging, novel therapies, as well existing ones, to understand issues relating to adherence and effectiveness [16]. Extending the understanding of patients' individual needs and concerns may help improve adherence to treatments in the future. Our study adds to the literature demonstrating that a significant treatment burden is reported by our patients as compared to

TABLE 5 Hypothetical treatment choice situations comparing nebulised to dry powder inhaled therapies with varying degree of effectiveness

	Age		Gender		Treatment	
	⩽65 years	>65 years	Female	Male	Nebulised	Non-nebulised
More effective						
Yes (%)	77.8	83.8	83.3	76.9	81.1	81.0
No (%)	22.2	16.2	16.7	23.1	18.9	19.0
p-value	0.515		0.501		0.989	
As effective						
Yes (%)	80.6	94.6	83.3	96.2	87.8	76.2
No (%)	19.4	5.4	16.7	3.8	12.2	23.8
p-value	0.068		0.107		0.184	
Less effective (*e.g.* 2 extra exacerbations per year)						
Yes (%)	13.9	27.0	18.8	23.1	20.3	23.8
No (%)	86.1	73.0	81.3	76.9	79.7	76.2
p-value	0.165		0.658		0.725	
Less effective (*e.g.* 3 extra exacerbations per year)						
Yes (%)	11.1	8.1	8.3	11.5	9.5	5.0
No (%)	88.9	91.9	91.7	88.5	90.5	95.0
p-value	0.663		0.653		0.526	

non-nebulised regimens. Patients not using nebulised drugs reported a maximum treatment burden of 30–60 min per day, while some patients on nebulised regimens spent over 3 h on their treatments daily. Efforts were taken to present these findings simply, with scope for future in-depth analysis.

The existence of an age-related barrier to adherence was hypothesised, with younger patients being less adherent than older participants due to the existence of other commitments such as childcare, work or social activities. Prior data suggest a 10-year increase in age is associated with a three-times increase in odds of being adherent [22]; however, this was not seen in the results of this study but may warrant further investigation in future work.

Prior clinical research trial programmes have focused on the development of inhaled dry powder antibiotics for bronchiectasis management [15, 16]. Such approaches if translated into practice would deliver the antibiotics *via* small, portable devices that offer quicker administration times (<30 s), as well as the possibility of treatment management outside of the home. As was hypothesised, the vast majority of patients expressed their preference towards inhalers because of their convenience and practicality. Notably most but not all participants (64%) reported that they would be more likely to take their antibiotics if these were delivered *via* an inhaler. Effectiveness was essential to patients on nebulised regimens, only 20% of these patients would opt for inhalers if this meant two extra exacerbations per year. The severity of the hypothetical exacerbations in this context, however, was not defined and this is a limitation of the questionnaire. Some studies assessing treatment burden have used time to take treatments and a further limitation of our questionnaire was the lack of a "time trade off" aspect; further work using this or a discrete choice experiment methodology may have worked well for this type of investigation.

Because inhaler devices are portable and quicker to administer, they may be more easily incorporated into busy lifestyles. Because of this, as well as the belief that younger patients have different perceptions of their health, it was hypothesised that the majority of younger patients would still prefer inhalers even if these were less effective. However, younger patients were just as concerned about effectiveness as older patients, expressing that they would only use inhaled antibiotics providing they were as effective as nebulised regimens.

The study has limitations that should be acknowledged. The study was single centre and therefore may not have broader generalisability; this is particularly relevant because reimbursement for different treatments is likely to vary by geography. There are no costs to our patients within the UK National Health Service for equipment purchase, maintenance or drugs; certain healthcare systems may not provide nebulisers or consumables and, thus, our patient response may not apply to these systems. To our knowledge, there is no validated patient-preference questionnaire for use in bronchiectasis; we therefore developed a draft questionnaire based on qualitative findings. The questionnaire developed has not been externally validated nor had internal validity or test–re-test assessment. It is important to note that during the COVID-19 pandemic, patients with bronchiectasis were asked to shield and, consequently, their attitudes to treatment burden may now have changed; this study was conducted immediately prior to the pandemic. The patient population included in this study was typical of bronchiectasis cohorts; however, the questionnaires did not ask for the exact aetiology of bronchiectasis from each respondent to avoid limiting the respondents likely to be identified (for instance, in rare aetiologies). The authors recognise that different additional treatment (*e.g.* in a cohort with wider immunosuppression) may impact upon a person's perception of burden.

Conclusions

Whereas some patients have incorporated the treatment regimen into their routine or find the effects of the nebulisers beneficial, the majority expressed a preference for inhalers, apparently owing to the perceived convenience. These findings show that treatment barriers and motivators vary between individuals.

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