Original Research

Augmentation Therapy for Alpha-1 Antitrypsin Deficiency: Patient Experiences with Self-Infusion, Home Providers, and Clinics

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Running Head:

Abbreviations:
AATD= Alpha-1 antitrypsin deficiency
COPD= Chronic obstructive pulmonary disease
AAT = Augmentation Therapy

Keywords: self-infusion; antitrypsin; COPD; alpha-1 antitrypsin deficiency; AATD

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Note: This article has an online data supplement
Abstract

Background:
Currently approved therapies for individuals with alpha-1 antitrypsin deficiency (AATD) are intravenously infused products. The burdens and demographics of infusion practices in the United States are not well characterized.

Research Question:
What is the prevalence of different infusion practices in the United States?

Study Design and Methods:
AlphaNet disease management participants completed a survey that captured current and past infusion practices. Reasons for choosing their current infusion practice, problems with past infusion practices, resources required, and support services utilized were collected from February 8, 2022, through July 1, 2022.

Results:
Among 5266 individuals, infusions happened at home by health care providers (60.2%), at infusion clinics (30.6%), and by self-infusion (8.1%). Self-infusion prevalence increased with time on therapy and was more prevalent in younger individuals (61.2 ± 10.5 years) compared to users of other infusion practices (64.1 ± 11.0 years), (p<0.001). Perceived benefits of self-infusion included freedom and flexibility (77.9%), ability to travel (44.5%), avoidance of infusion clinics (41.8%), time-savings (35.9%), less absence from work (26.6%), less exposure to infections (22.1%), and less cost (16.4%). Self-infusion was done through permanent intravenous catheters in 41.2% and peripheral intravenous catheters by 58.3%. Self-infusers were more satisfied (93.1% very satisfied) than other groups. Among individuals currently infusing with home nurses or in clinics, 21.4% would consider self-infusions in the future.

Interpretation:
Self-infusion of alpha-1 antitrypsin is feasible and associated with high satisfaction scores. Recommendations for catheter care, infusion support, and cost management are informed by survey results.
Introduction

Alpha-1 antitrypsin deficiency (AATD) is a rare genetic disease that is associated with progressive pulmonary emphysema and liver disease. The only licensed and FDA approved therapies for lung disease in AATD are intravenous therapies that have been licensed since 1989. The typical dose of alpha-1 augmentation therapy (AAT) is 60 mg/kilogram given once weekly. Intravenous administration creates significant burdens on the AATD population and has prompted shared efforts to improve the quality of life associated with drug administration.

The administration of these regular intravenous infusions can take place at a medical facility, a dedicated infusion center, at home with a visiting medical professional, or by self-infusion. The location of treatments is often determined by the insurer. Travel to infusion centers by AATD affected individuals is dependent upon distance from an infusion center and access to transportation. As a result, many individuals with AATD have chosen to get their infusions through a home nursing company that provides nurses and scheduled infusions weekly. Specifically, core Medicare benefits do not cover self-infusion, or home nursing services although many non-Medicare insurers cover these services.

In the past several years, there has been increasing interest in and emphasis on the need for at-home administration of augmentation therapy for AATD by medical professionals and also by patients themselves. Self-administration has been embraced by many in the Alpha-1 community because of the known safety profile of augmentation therapies and the short infusion times. There are many details of self-infusion that often are spread by word of mouth and through communication channels in the very connected Alpha-1 community. Therefore, this study was designed to assess patients’ experiences with augmentation therapy for AATD, including demographic characteristics associated with self-infusion and perceived benefits of and barriers to self-infusion in the United States. Since some of these infusions occur through permanently-placed central venous catheters, the survey also captured self-reported catheter complications without discriminating between PICC (peripherally inserted central catheters) and port (subcutaneous central venous catheter access) devices.
The characteristics of AATD patients and their infusion practices have not been a subject of a comprehensive manuscript. Therefore, this paper seeks to characterize the infusion practices of a large AATD population in the United States, as seen through the perspective of the patients who are living this journey. Data was collected by AlphaNet, a not-for-profit organization that provides a telephone-based disease self-management program designed for individuals with AATD-associated lung disease who are prescribed augmentation therapy. AlphaNet follows the majority of individuals in the United States who are prescribed augmentation therapy for lung disease due to AATD. As such, AlphaNet is uniquely well-positioned to examine patients’ experiences with augmentation therapy in a large sample of geographically diverse patients.

Methods
Individuals in the AlphaNet disease management program were invited to participate in a survey regarding their experiences with augmentation therapy. The survey defined self-administration as follows: administration of augmentation therapy by the patient without regular involvement by a paid medical professional (either alone or with help from a spouse, partner, relative, or friend). This definition is consistent with the definition used by Horvath et al. The survey contained one set of questions for individuals who self-infuse and a different set of questions for individuals who do not self-infuse. The key topics among individuals who self-infuse were learning how to self-administer, satisfaction with self-administration, challenges with self-administration, and assistance needs for self-administration. The key topics among individuals who do not self-infuse were reasons for receiving augmentation therapy in the location in which they received therapy (i.e., via a healthcare professional who travels to the patient’s home versus traveling to a facility), reasons why they would or would not consider self-administering augmentation therapy, and prior experiences with self-administration.

Trained coordinators (who also have Alpha-1) administered the survey by telephone and through an invited online portal from February 8, 2022, through July 1, 2022 with responses collected centrally. The dataset was de-identified and analyzed at the Medical University of South Carolina (MUSC) with JMP PRO Version 16, Cary, NC). IRB approval for the analysis of deidentified data was obtained through the Medical University of South Carolina IRB. Statistical analysis was performed with summary statistics reporting demographics of the study population.
Correlative statistics were performed using simple linear regression or logistic fit for categorical and continuous data. T-tests or Chi-square analysis was used to compare continuous and categorical values respectively. P-values of less than 0.05 were considered significant.

**Results**

Among 5925 individuals sent the survey, 628 did not return it; 5 individuals were not on augmentation therapy; and 26 individuals were missing data on the central question regarding whether they self-infuse (and therefore also did not answer the remaining survey questions). Therefore, the study population consisted of 5266 (88.9% of those invited) adult individuals receiving alpha-1 augmentation therapy (Figure 1). Intravenous augmentation therapy was weekly for 93.0% of participants. Infusions occurred with a home health nurse (N= 3169, 60.2%), in an infusion clinic (N=1609, 30.6%), and by self-infusion (N= 424, 8.1%). (Table 1).

Multiple demographic differences are present among the 3 cohorts. Clinic infusing participants were older (likely from Medicare coverage at infusion clinics), less likely to be receiving infusions on a weekly infusion schedule, and the least satisfied with their infusion practice. They were more likely than home nursing infused participants to consider self-infusion. Those who self-infuse were more often male, more commonly used a port or PICC, had the highest number of infusion years of any group, and had the highest percentage of responses in the very satisfied range (93.1%) for infusion choice.

Current self-infusion prevalence increased with time on therapy and yet was more prevalent in younger individuals (61.2 ± 10.5 years) compared to users of other infusion practices (64.1 ± 11.0 years), (p<0.001). The first mention of self-infusion most frequently came from physicians (32.9%), nurses (28.4%), or AlphaNet coordinators (18.7%). Among current self-infusers, 20.6% started within the first month of alpha-1 augmentation therapy, 28.4% started between 1 and 12 months after augmentation had begun, 40.5% began between 1 and 10 years after starting, and 8.8% began after they had infused for more than 10 years. Training was usually by a nurse from a home nursing agency (60.4%), or hospital/office/infusion center (15.9%). Other sources of training included the internet (9.7%), friend or family member (8.1%) or a physician/ advanced care provider (2.7%). Three or fewer training sessions were given to 68.0% of individuals.
Perceived benefits from self-infusers were freedom and flexibility (77.9%), ability to travel (44.5%), avoidance of travel to infusion clinics (41.8%), time-savings (35.9%), less absence from work (26.6%), less exposure to infections (22.1%), and less cost (16.4%). Self-infusion was done through permanent intravenous catheters in 41.2% and peripheral intravenous catheters by 58.3%. Most self-infusing individuals were very satisfied (93.1%) with their decision. Among individuals currently infusing with home nurses or in clinics, 21.4% would consider home infusions in the future and this increased to 34.4% among those not currently “very satisfied” with home nurses or in clinic infusions.

There were individuals who previously self-infused but now use a health care practitioner for infusions (N=152). Past infusion duration was <6 months (33.6%), 6-12 months (8.6%), 1-5 years (24.3%), 5-10 years (18.4%) or >10 years (10.5%). Among reasons for stopping home infusions, most common were lack of insurance coverage (25.0%), difficulty with venous access (14.5%), difficulty with port (13.8%), lack of home support (10.5%), and fear of adverse events (4.6%). Port use was not different for this cohort (40.7%) compared to the larger group that has continued home infusions (45.0%), p=0.63.

Opportunities to improve the self-infusion experience, use of ancillary help with infusions, concerns of patients, and challenges with self-infusion are enumerated in Table 2. In short, the majority of patients felt empowered to self-infuse and appeared to do so safely.

Additional information was obtained from the 1268 individuals who had ever had central venous access lines placed (usually a subcutaneous port) (Figure 2). Self-infusion prevalence was higher among individuals who ever had a port (15.0%) compared to those who never had a port (5.8%) (p<0.001). Among all individuals with current or past port placements, 366 (28.9%) had one or more removed. The most common reasons for removal were lack of blood return (29.2%), infection including endocarditis (28.7%), thrombosis (8.2%), migration (4.4%), and mechanical catheter problems (3.0%). Infection was more common in self-infusers (39.2%) compared to those with nursing administered care (25.7%), p=0.02. In the cohort with port removal, self-infusion rates remained high (17.9%).
Discussion

Individuals who self-infuse report being highly satisfied with self-infusing, and the most frequently reported reasons for self-infusing were flexibility and the belief that self-infusing makes it easier to travel. The optimal candidate for self-infusion has a good support system, good venous access, baseline knowledge that is usually acquired over the first year of infusions, and insurance that allows drug shipment to the home. Although, this survey did not collect actual or estimated costs, the lack of ancillary costs associated with the home nursing agency or infusion clinic necessarily saved money for the healthcare system. Therefore, we were surprised to see that the most frequent reason for stopping self-infusion was from insurance issues, presumably since traditional Medicare only authorizes intravenous infusions in healthcare facilities, despite the cost savings of other methods.

The success and satisfaction of this United States experience is important for other parts of the world where the ability to receive augmentation therapy in the home may be more limited. In Europe, one study that included 15 physicians from 13 European countries found that all of the respondents would consider self-administration for at least some of their patients, if it were available. In addition, 78.6% of respondents believed that three or fewer training sessions would be needed for patients to be able to self-administer independently. The belief of these physicians aligns with the findings of the current study, in which 68.0% of the participants who self-infused had three or fewer training sessions.

While infusion at home by a nurse has been widespread in the United States, this has not been the case in other countries. In Italy, where administration has largely been done in a medical setting, one study examined nurse-administered augmentation therapy in the patient’s home. This study found an improvement in quality of life, specifically with regard to less perception that therapy interferes with life activities.

A study conducted in the United States examined patient perspectives regarding transitioning to self-infusing in a small sample of 22 individuals with AATD. In this study, 40% of participants indicated that they would consider self-infusing if training and education were provided. Among
those who were not willing to consider self-infusing, the most frequently-cited reasons were lack of skills and fear of problems. These findings suggest that more patients might consider self-infusion if a formalized training program were available. Such education could be developed, formalized, refined, and tested for optimal use in AATD community programs.

In addition to training, access to ongoing support is likely to be a key to success with self-infusing. In our study, 25.1% of self-infusers indicated that they had some type of help with all 10 of their most recent infusions. The vast majority of self-infusers (92.5%) indicated that they could get help if needed. Support in the home appears to come from many sources, but many individuals cite family, friends, and telephone support as equally important as help from healthcare providers. In contradistinction, those who choose to use a nursing infusion service cite the lack of confidence in their own skills as the primary reason not to consider this procedure.

Use of a central venous catheter was present in less than 50% of the self-infusing patients. Community discussions have suggested that port use is heavily physician directed. The AlphaNet experience is that placement of peripheral IVs is usually successful and can be sustained for many years. There was no difference in the mean or longest duration of self-infusion by peripheral IV (Range 1-32 years) compared to by port (Range 1-40 years). The training required for peripheral IV placement is manageable with 3 or less sessions and IV placement is a skill that can be acquired in a variety of home or healthcare settings.

There are opportunities to improve the education, training, supply chain, and details of infusion practice. Some of these are within the mission of AlphaNet, a disease management company dedicated to the Alpha-1 community. In particular, the finding that self-infusing PORT users have higher rates of central venous infections than those using a home nursing service is an educational opportunity for the community of self-infusers. Furthermore, there is likely a self-selection of individuals who choose self-infusion because of ease in finding a vein, lack of anxiety, and better support networks compared to individuals who choose to stay with nurse infusions. Whether all of the same issues will remain if subcutaneous preparations or longer half-life preparations of alpha-1 augmentation become available is not clear.
AATD is not the only health condition in which self-infusion is relevant. There is a long-standing history of self-infusion of intravenous therapies in other health conditions, including hemophilia\(^9\text{-}^{13}\) and hereditary angioedema\(^14\text{-}^{21}\). In hemophilia, self-infusion is associated with a sense of independence and personal freedom\(^9\), improved quality of life, and less missed school or work.\(^10\) In hereditary angioedema, self-infusion is associated with improved quality of life.\(^16\text{-}^{20}\)

Some of the advantages and disadvantages of self-infusion reported by patients with hereditary angioedema are similar to those reported in our study. In hereditary angioedema, advantages of self-infusion included the patient’s ability to manage their own disease and the ability to travel.\(^20\) Disadvantages included the need for training, decreased contact with medical providers, fear of self-infusion, and finding a vein.

There are limitations to our study. This survey included individuals in AlphaNet, a free service offered to all alpha-1 antitrypsin deficient subjects in the US regardless of the medication they are receiving. However, there are individuals that infuse and are not members of AlphaNet. There was non-participation from 628 individuals in the survey and some missing data with each question. Similarly, bias can result from patient-reported medical retrospective data that informed some of our questions, particularly if obtained at differing times in the past. Independent validation of reported central venous complications was not performed. Furthermore, this study occurred during the COVID-19 pandemic and infusion practices before or after the pandemic may be different. We did not evaluate the severity of COPD, liver disease, AATD genotype, or other clinical characteristics to define associations with site of infusion.

There are several strengths to our study. This is the largest survey about infusion practices that has been assembled in AATD. All data was collected via self-report, which is ideal for understanding patients’ experiences with various infusion practices. In addition, this study included more than 400 individuals who self-infuse, which is a rich sample of patients who were able to provide information regarding their experiences with self-infusion. The experience is associated with high patient satisfaction, that is derived from the freedom and flexibility of self-infusion.
Self-infusion is a desirable option for a sub-set of patients who are on augmentation therapy for AATD. Among self-infusers, satisfaction was extremely high and numerous benefits of self-infusion were endorsed. Three-quarters of the self-infusers in our study indicated that they had no concerns regarding self-infusion. However, not all patients want to self-infuse or are able to self-infuse. The majority of participants in this study were not self-infusing, and were highly satisfied with their method of receiving infusions. This highlights the importance of having multiple options for augmentation therapy, including options regarding where (in a clinic versus at home) and how (with or without involvement of a medical professional) augmentation therapy is administered.

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**Declaration of Interests:**
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administration training in various regions of Europe, Canada and the USA in the management of hereditary angioedema. *International Archives of Allergy and Immunology*. 2013;161(Suppl. 1):10-16. doi:10.1159/000351233
Figure and Table Legends

Table 1. Characteristics of the study cohort who use home nursing services, infusion clinics, and who self-infuse.

Table 2. Opportunities to improve the self-infusion experience, use of ancillary help with infusions, concerns of patients, and challenges with self-infusion. (N=422). Multiple responses were allowed for each survey question on help, concerns, and challenges.

Figure 1. Flow diagram of patient cohorts completing the study survey and top reasons for current infusion practices. Missing data is present from individuals who did not answer all survey questions (N=18).

Figure 2. Flow diagram of patient cohorts completing the study survey in relationship to past and present use of a central venous catheter port. Reasons for port removal in that cohort are enumerated. Missing data is present from individuals who did not answer all survey questions (N=34). Pertaining to the question regarding whether an individual “never had a port” versus “had a port”, there were N=9 missing data points. For the question asking those who had a port whether they had ever had a port removed, there was N=25 missing data points. Multiple ports were removed in some individuals for a variety of reasons.
Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Home Nurse</th>
<th>Clinic</th>
<th>Self-Infusion</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=3169</td>
<td>N=1609</td>
<td>N=424</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(60.2%)</td>
<td>(30.6%)</td>
<td>(8.1%)</td>
<td></td>
</tr>
<tr>
<td>Age (Mean years +/- SD)</td>
<td>62.0 ± 10.9</td>
<td>68.2 ± 10.1</td>
<td>61.2 ± 10.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age Range (years)¹</td>
<td>18-90</td>
<td>24-90</td>
<td>23-85</td>
<td></td>
</tr>
<tr>
<td>Sex (% Female)</td>
<td>56.2%</td>
<td>52.2%</td>
<td>48.1%</td>
<td>0.01</td>
</tr>
<tr>
<td>Total Years Infused (Mean +/- SD)</td>
<td>6.9 ± 6.0</td>
<td>7.2 ± 7.2</td>
<td>10.8 ± 7.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Weekly infusions (%)</td>
<td>95.3</td>
<td>88.9</td>
<td>92.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Currently using port/PICC (%)</td>
<td>21.6</td>
<td>23.2</td>
<td>44.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Would consider future self-infusion (%)</td>
<td>20.3</td>
<td>23.3</td>
<td>N/A</td>
<td>0.02</td>
</tr>
<tr>
<td>Currently very satisfied with infusion choice (%)</td>
<td>86.1</td>
<td>72.8</td>
<td>93.1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

¹Age truncated at 90 years to preserve anonymized dataset. Data was missing for 64 participants.
Table 2.

<table>
<thead>
<tr>
<th>Help provided during Infusions (N= 422)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Can you get help if needed?”</td>
<td>Yes – 92.5</td>
</tr>
<tr>
<td>“Receives regular help from spouse/partner/relative/friend”</td>
<td>Yes – 33.2</td>
</tr>
<tr>
<td>“Help was provided with every one of the last 10 infusions”</td>
<td>Yes – 25.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What Help was provided? (N= 422)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of help provided</td>
<td></td>
</tr>
<tr>
<td>Needle</td>
<td>27.9</td>
</tr>
<tr>
<td>Connection</td>
<td>18.2</td>
</tr>
<tr>
<td>Preparation</td>
<td>13.8</td>
</tr>
<tr>
<td>Cleaning</td>
<td>8.7</td>
</tr>
<tr>
<td>Other</td>
<td>2.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concerns with Self-Infusion (N= 422)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Topics of Concern</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>74.9</td>
</tr>
<tr>
<td>Venous Access</td>
<td>9.5</td>
</tr>
<tr>
<td>Air bubbles</td>
<td>4.5</td>
</tr>
<tr>
<td>Infections</td>
<td>4.3</td>
</tr>
<tr>
<td>Lacking oversight</td>
<td>3.8</td>
</tr>
<tr>
<td>Adverse Drug Reaction</td>
<td>1.9</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>0.2</td>
</tr>
<tr>
<td>Other</td>
<td>2.6</td>
</tr>
</tbody>
</table>

Challenges with Self-Infusion (N=422)

<table>
<thead>
<tr>
<th>Challenges</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Finding veins</td>
<td>9.0</td>
</tr>
<tr>
<td>Shipping Issues</td>
<td>5.5</td>
</tr>
<tr>
<td>PORT problems</td>
<td>3.8</td>
</tr>
<tr>
<td>Getting equipment</td>
<td>3.6</td>
</tr>
<tr>
<td>Insurance approval</td>
<td>3.1</td>
</tr>
<tr>
<td>Fear of needles</td>
<td>1.4</td>
</tr>
<tr>
<td>Choosing site</td>
<td>0.7</td>
</tr>
<tr>
<td>Setup</td>
<td>0.7</td>
</tr>
<tr>
<td>Other</td>
<td>2.8</td>
</tr>
</tbody>
</table>
Figure 1.
Figure 2.
Supplemental Files

Additional graphics of interesting findings from our research are included in this supplemental material that demonstrates the infusion practices of the AlphaNet population.

**Figure S1.** Time on infusion therapy is influenced by the age of the individual (N=5266). Age is correlated with time on therapy (R²= 0.04, p<0.001). The mean age at initiation of alpha-1 augmentation therapy is 60 years.
Figure S2. Duration of Self-Infusion among those currently Self-Infusing (N= 422).
Figure S3. How Self-Infusers first heard about the technique (N= 422).
Figure S4. The onboarding process in learning self-infusion (N= 422).

Who primarily trained you to self-administer?

- Nurse at a hospital/clinic/infusion center: 15.9%
- My physician or health care provider: 2.7%
- I taught myself: 9.7%
- Home nursing agency: 60.4%
- Friend or family member: 8.1%

How many training sessions did you have while learning?

- 4 or more: 28.2%
- 2-3: 41.7%
- 1: 16.6%
- 0: 9.7%

How long had you been on augmentation before you started?

- More than 10 years: 8.8%
- Less than 1 month: 20.6%
- 5 - 10 years: 11.8%
- 1 year to less than 5 years: 28.7%
- 1 month to less than 1 year: 28.4%