Mepolizumab Prefilled Autoinjector and Prefilled Syringe Real World Use: The Patient Experience

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Background

- Mepolizumab is approved for the treatment of severe eosinophilic asthma in the US, EU, Japan, and other countries, and for eosinophilic granulomatosis with polyangiitis in several countries, including the US and Japan.
- Mepolizumab is currently delivered as a prefilled powder requiring reconstitution and is administered in clinical settings by healthcare professionals (HCPs).
- To improve the convenience and ease of treatment with mepolizumab, a liquid drug product in a ready-to-use prefilled autoinjector (AI) and prefilled syringe (PFS) has been developed to enable at-home, self-administration, in addition to in-clinic HCP administration.

Objective

- To capture the patient experience of self-administering mepolizumab treatment via AI and PFS.

Methods

- A 28-day, open-label, single-arm, repeat-dose, multicenter, International Phase IIIa studies that included patients aged ≥12 years, diagnosed with severe eosinophilic asthma were conducted to evaluate the real-world use (RWU) of mepolizumab administered via AI (NCT02153563) and PFS (NCT02665817). Mepolizumab (100 mg SC) was administered by the patient/carer QW with a 12 week treatment period.
- The first and third dose (Weeks 0 and 12, respectively) were self-administered under observation in-clinic, while the second dose (Week 6) was self-administered, unobserved.
- To capture the patient experience of self-administering treatment, quantitative variables were administered to participants at the end of study assessment or following study withdrawal (AI: n=153; PFS: n=56 completed questionnaires), and in a subset, additional semi-structured, qualitative exit interviews were conducted. The phone were collected within 6 weeks of end of study visit or early withdrawal (AI: n=7; PFS: n=7). Interviews were digitally recorded and transcribed, translated (if not in English originally), and qualitative data analyzed in ATLAS.ti. 2 data collection methods were embedded directly into the clinical study and were predescribed clinical endpoints.
- The structure and content of the quantitative questionnaires and qualitative exit interviews were similar to allow the interviews to bring depth, context, and allow for improved interpretation of the quantitative results.
- Exit interviews were conducted between September and November 2017 (AI: n=153) and May and August 2017 (PFS: n=56).

Results

- Overall 80% of patients in each study were female with a mean age of approximately 50 years (Table 1).
- A total of 25 patients in the AI study (Germany, France, US, Canada and Australia) and 4-10 patients in the PFS study (US, EU, Russia)

Table 1. Demographic and clinical characteristics of patients included in the quantitative interview

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Autoinjector (n=153)</th>
<th>Prefilled syringe (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>46 (27)</td>
<td>53 (15)</td>
</tr>
<tr>
<td>Gender, male</td>
<td>32 (41)</td>
<td>24 (42)</td>
</tr>
<tr>
<td>Who injected</td>
<td>45% (n=71)</td>
<td>47% (n=26)</td>
</tr>
<tr>
<td>Current mepolizumab use, %</td>
<td>84% (n=129)</td>
<td>85% (n=48)</td>
</tr>
<tr>
<td>Prior experience with injection of inhalation, %</td>
<td>64 (n=101)</td>
<td>65 (n=37)</td>
</tr>
</tbody>
</table>

Values are median, number (%) unless otherwise indicated.

- The results of the qualitative interviews provided additional complementary details to the results from the quantitative questionnaires.
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Confidence in self-administration

- 96% of patients using the AI and 98% of patients using the PFS were at least moderately confident in self-administering mepolizumab based on the qualitative interview results (Figure 1).
- AI – Patient 1: “So the first time you used the pen in your own outside of the doctor’s office, how confident did you feel in your ability to use the pen? Did you get the needle in correctly and had I to feel comfortable... I kind of cleaned my thumb with a little bit of alcohol and I tried myself.”
- Within the exit interviews 15/27 of patients in the AI and PFS groups respectively reported that their confidence improved and did not change in the course of study. Most of the patients who did not report an improvement reported during the exit interview that they were “extremely” very confident at study start.
- AI – Patient 1: “Did your level of confidence change over the course of the study?” So, let’s say from the first time to the last question? “Oh, yes, definitely because by that injection you knew what to expect and how to do it much more comfortably on the third one. Because, you’ve already had two and the second one you did it, and the third one you felt more comfortable, yeah, definitely."

Ease of use

- Most patients reported that it was easy to self-administer using the AI or PFS at home and were generally “satisfied” or “very satisfied” with using the devices at home (Figure 1). Within the exit interviews, patients reported that their satisfaction was driven by ease of use, safety and convenience. One PFS patient reported the device to be “moderately easy” to use during the exit interview due to having to find the right angle to connect the prefilled syringe.

Convenience of use at home

- 94% of patients using the AI and 82% of patients using the PFS reported that it was “very” extremely convenient to use the device at home (Figure 1). The exit interviews revealed the predominant reason being time saved.

Training satisfaction

- Overall 77% of patients reported satisfaction with training, patients felt “very” extremely satisfied. One patient reported, “I would just keep going that at home, every month or whatever if it comes to market which will be very, very good thing to do, because at the moment what I have to get the injection from my pharmacy and I have to get it out again...and then the GP does the injection for me. This will ease me doing that every month and you just do it at home.”

Recommendation

- One PFS patient stated “a little” to moderately convenient,” explaining that it was not as easy as injection where the needle retracts. Additional patients provided a rating of a “little convenient” as administration involved more steps than using an inhaler.

Preference at home self-administration or in-clinic administration by HCP

- In patients who had previously received mepolizumab 95% preferred self-administration at home or the prefilled syringe, over in-clinic administration by a HCP.
- Within the qualitative interviews convenience was reported as the main reason for this preference.

PFS – Patient 3: “Would you prefer to receive the injection from a safety syringe given at the doctor’s office or an injection that you give yourself at home?” “Injection I give myself at home...because I don’t have to drive to a doctor’s office and take part of their day... I would be more convenient for everybody...it’s one more thing that I don’t have to add to their day, I don’t have to waste the time or the day to leave the house and do it.”

Conclusions

- The real-world-use studies for the mepolizumab prefilled AI and PFS show that for the majority of patients, both devices provide a convenient, easy route of administration. 94% of patients using the AI and 82% using the PFS reported that it was “very” or “extremely” easy to use the device at home. 90% of patients using the AI and 88% using the PFS reported that it was “very” or “extremely” easy to use the device at home.

- In the subset of patients asked who had previously received mepolizumab self-administration at home was preferred by most patients compared to in-clinic injection by a HCP. The results of the qualitative interviews provide complementary details to the results from the quantitative questionnaires.

Acknowledgments

- The authors are grateful to the mepolizumab trial participants, data collectors, and the following companies who contributed to this study: Evidera, Indicia, and the following companies who contributed to this study: Evidera, Indicia, and the following companies who contributed to this study: Evidera, Indicia.