The Phase 3 ADVANCE study demonstrated that when beginning treatment (AR = 3.79)

- Peginterferon beta-1a injection should be recommended at room temperature (34%)
- Apply heat (7%)
- Injection early in the day (7%)

Additional Pharmacological therapy

<table>
<thead>
<tr>
<th>Strategy</th>
<th>FLS</th>
<th>ISR</th>
</tr>
</thead>
<tbody>
<tr>
<td>% who recommended therapy</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Recommend</td>
<td>Acetaminophen/buprofen</td>
<td>Diphenhydramine, paracetamol, diphenhydramine</td>
</tr>
<tr>
<td>% who recommended therapy</td>
<td>14</td>
<td>0</td>
</tr>
</tbody>
</table>

Nonpharmacological therapy

<table>
<thead>
<tr>
<th>Strategy</th>
<th>FLS</th>
<th>ISR</th>
</tr>
</thead>
<tbody>
<tr>
<td>% who recommended therapy</td>
<td>32</td>
<td>97</td>
</tr>
<tr>
<td>Recommend</td>
<td>Alternating injection timing</td>
<td>Rotation of injection site</td>
</tr>
<tr>
<td>% who recommended therapy</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Recommend</td>
<td>Cold water showers/baths</td>
<td>Patient education (59%)</td>
</tr>
<tr>
<td>% who recommended therapy</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Recommend</td>
<td>Cooling of injection site</td>
<td>Warming of medication to room temperature (52%)</td>
</tr>
<tr>
<td>% who recommended therapy</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Recommend</td>
<td>Caffeine</td>
<td>Applying ice to the site after injection (34%)</td>
</tr>
<tr>
<td>% who recommended therapy</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Recommend</td>
<td>Administering medication all room temperature</td>
<td>Injection before bed (34%)</td>
</tr>
</tbody>
</table>

Responders recommended Management of FLS

- In questionnaire 2, responders reached consensus on management strategies for FLS (Figure 2) and recommended that patients should use acetylsalicylic acid or a nonsteroidal anti-inflammatory drug (NSAID):
  - When beginning treatment (AR = 3.79)
  - On a scheduled basis (AR = 3.31)
  - As long as needed (AR = 3.52)

- In addition, responders agreed that changing the timing of peginterferon beta-1a injection was an additional management strategy for FLS (AR = 3.28).

Responders recommended Management of ISR

- In questionnaire 2, responders reached consensus on management strategies for ISR (Figure 3) and recommended that patients should use acetaminophen or a nonsteroidal anti-inflammatory drug (NSAID):
  - When beginning treatment (AR = 3.07)
  - On a scheduled basis (AR = 3.31)
  - As long as needed (AR = 3.50)

- In addition, responders agreed that changing the timing of peginterferon beta-1a injection was an additional management strategy for ISR (AR = 3.28).

- Management Strategies Utilized in ADVANCE for FLS and ISR

  1. FLS: These recommendations were provided in an open-ended questionnaire 2.
  2. ISR: These recommendations were provided in an open-ended questionnaire 2.

- The use of a 2-part Delphi questionnaire resulted in consensus on the characteristics and management strategies for FLS and ISR.
- Delphi responders recommended prophylactic therapy (acetaminophen/NSAIDs) and change of injection timing to prevent or manage FLS and injection site rotation/cooling and drug administration at room temperature to prevent manage ISR.
- Delphi responders agreed that educating patients on the characteristics and management of FLS and ISR before starting treatment is critical to set treatment expectations and manage FLS and ISR.
- The Delphi responders were a small subset of investigators who participated in the study and their observations were based on the number of patients enrolled at their site in the ADVANCE study. Therefore, this study should be confirmed after gaining more experience with peginterferon beta-1a in clinical practice.

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- Responders recommended Management of FLS

  1. To prevent or manage FLS (Figure 3), responders recommended that patients should be advised to:
    - Rotate injection site (AR = 3.83)
    - Cool the injection site after injection (AR = 3.10)
    - Administer peginterferon beta-1a at room temperature (AR = 3.41).

- Responders recommended Management of ISR

  1. To prevent or manage ISR (Figure 3), responders recommended that patients should be advised to:
    - Rotate injection site (AR = 3.83)
    - Cool the injection site after injection (AR = 3.10)
    - Administer peginterferon beta-1a at room temperature (AR = 3.41).

- Conclusions

  1. Peginterferon beta-1a and Management Strategies for Flu-Like Symptoms and Injection Site Reactions: Obtaining Recommendations Using the Delphi Technique

  2. The use of a 2-part Delphi questionnaire resulted in consensus on the characteristics and management strategies for FLS and ISR.
  3. Delphi responders recommended prophylactic therapy (acetaminophen/NSAIDs) and change of injection timing to prevent or manage FLS and injection site rotation/cooling and drug administration at room temperature to prevent manage ISR.
  4. Delphi responders agreed that educating patients on the characteristics and management of FLS and ISR before starting treatment is critical to set treatment expectations and manage FLS and ISR.
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- References


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