POSTER

EMPOWER: Evaluating Menopausal symPtom treatment Options and WomEns' pReferences

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INTRODUCTION

- Hormone therapy (HT) is effective in treating hot flashes among women who are postmenopausal and is recommended as first-line treatment in medical guidelines
- HT is associated with several risks including breast cancer, venous thromboembolism, and stroke[1], women's perceptions of which means most of those seeking treatment for hot flashes will not be treated with HT.
- This study investigated preferences of women who are postmenopausal in the US, UK, and Germany for hypothetical treatments of hot flashes and related menopausal symptoms.

METHODS

- An online discrete choice experiment (DCE) was developed using insights from a targeted literature review and qualitative interviews[2]; the DCE was tested in pilot interviews and definitions refined prior to fielding.
- Postmenopausal women with current or recent experience of moderate to severe hot flashes in the US, UK, and Germany were recruited. Women with treatment-induced menopause were excluded.
- Participants were repeatedly asked to choose between two hypothetical treatment profiles (Treatments A and B) and a "no treatment" alternative.
  - Each choice task (**Figure 1**) comprised eight attributes for which levels were varied across alternatives and tasks, according to an experimental design (Table S1 via the QR code).
- As part of the online survey, participants were also asked to complete the Menopause-Specific Quality of Life (MENQOL) and Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form 8b (PROMIS SD SF 8b) instruments.
- Choice data were analyzed using a mixed logit mode, with the following outputs:

METHODS (CONT.)

  - Relative attribute importance (RAI) scores capture the maximum percentage contribution of each attribute to treatment preference and sum to 100%, given the attribute levels included in the DCE.
  - Predicted choice probabilities (PCPs) indicate the probability of specific profiles being preferred, given the value associated with each attribute and level and the clinical performance of each profile (Table S2 via the QR code). Profiles included in the PCP analysis were an investigational non-hormonal treatment comparable to elinzanetant, a treatment which reflected an average across two available HT, and no treatment.
- Further details on methods are accessible via the QR code

Figure 1. Example Choice Task*

Attribute	Risk of vaginal bleeding	Risk of increase in liver blood test values	Risk of Blood Clots	Risk of Breast Cancer	Genitourinary syndrome	Risk of Osteoporosis-Related Bone Fractures	Frequency of moderate-to-severe hot flashes	Sleep disturbance	Choice
Treatment A	30 out of 100 (30%)	No risk of increase in liver blood test values	1 out of 100 (1%)	3 out of 100 (3%)	Treatment improves symptoms	3 out of 100 (3%)	39 moderate-to-severe hot flashes per week	2 A little bit	○
Treatment B	30 out of 100 (30%)	Risk of increase in liver blood test values	6 out of 100 (6%)	1 out of 100 (1%)	Treatment does not improve symptoms	3 out of 100 (3%)	3 moderate-to-severe hot flashes per week	2 A little bit	○
No Treatment	0 out of 100 (0%)	No risk of increase in liver blood test values	1 out of 100 (1%)	1 out of 100 (1%)	Treatment does not improve symptoms	12 out of 100 (12%)	56 moderate-to-severe hot flashes per week	4 Quite a bit	○

*The example task shown is one of 36 tasks included in the full design; each participant was shown a subset of nine tasks.

RESULTS

Participants

- A total of 1,697 women (US: 980; UK: 361; Germany: 356) completed the online survey. Brief descriptive characteristics are presented in **Table 1**.

Table 1. Clinical and Sociodemographic Characteristics

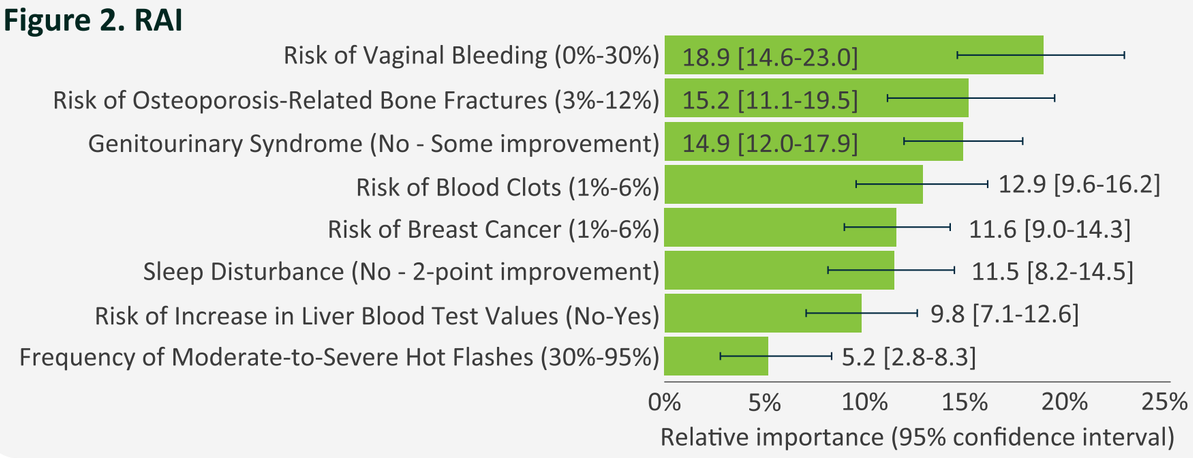
Patient Characteristic	N=1,679
Age (years; mean [SD])	51.76 (4.58)
Moderate to severe hot flashes per day (mean [SD])[a]	11.12 (10.69)
Severe hot flashes per day (mean [SD])	7.68 (5.11)
Bothersomeness of GU symptoms (mean [SD])[b]	4.46 (1.33)
HT experience	
Yes (current)	570 (33.59%)
Yes (previous)	74 (4.36%)
No	1053 (62.05%)
PROMIS SD SF 8b T-score (mean [SD])	58.53 (7.13)
MENQOL overall score (mean [SD])	4.67 (1.67)

Abbreviations: GU = genitourinary; HT = hormone therapy; MENQOL = Menopause-Specific Quality of Life; PROMIS SD SF 8b = Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form 8b
[a]Includes moderate and severe hot flashes; moderate defined as hot flashes with sweating, though no interruption of daily activities, severe defined as sweating and an interruption of daily activities.
[b]Measured on a constructed 0–6 scale, with 6 indicating greater (extreme) symptom bother

RAI Scores

- HT-associated risks and benefits accounted for 43.4% and 35.3% of participants' decision-making, respectively, given the data presented in the DCE.
- Changes in the one-year risk of vaginal bleeding (from 30% to 0%) had the largest impact on participants' preferences, followed by changes in the 5-year risk of osteoporosis-related bone fractures (from 12% to 3%), changes in the symptoms of genitourinary (GU) syndrome (from no improvement to improvement), changes in the 5-year risk of blood clots (from 6% to 1%), breast cancer (from 6% to 1%), and sleep disturbance (from no improvement to a 2-point improvement) **(Figure 2)**.

Figure 2. RAI



Acceptable Trade-offs

- DCE choices revealed the trade offs that participants were willing to make between the attributes (**Figure 3**). For example, participants were willing to forgo an improvement in genitourinary syndrome to lower the risk of blood clots by 9.5%.

Figure 3. Attribute Trade-offs

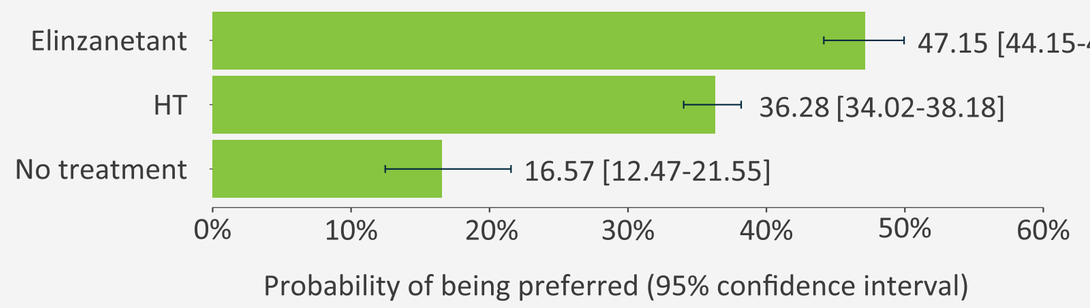
Benefit Attribute	Willingness to tolerate lower treatment benefits… From	…To	…to achieve reduction in important treatment risks: Blood Clots	Breast Cancer	Vaginal Bleeding
Reduction in Frequency of moderate-to-severe hot flashes	95%	30%	-2.4%	-2.1%	-6.5%
Risk of osteoporosis-related bone fractures	6%	12%	-6.4%	-4.7%	-16.6%
Genitourinary syndrome	Improvement	No Improvement	-9.5%	-6.9%	-24.3%
Sleep disturbance	1-point improvement	No improvement	-3.4%	-2.7%	-8.9%

Abbreviations: HT = hormone therapy

Predicted Choice Probabilities

- A profile aligned with that of an investigational non-hormonal treatment comparable to elinzanetant had the greatest probability of being preferred (47.2%), followed by HT (36.3%) and no treatment (16.6%) (**Figure 4**).

Figure 4. Predicted Choice Probability



Abbreviations: HT = hormone therapy

Limitations

- All stated preference methods carry the risk of hypothetical bias. Such biases inherently occur since participants make hypothetical choices, and it is possible that responses may not reflect their actual decisions in a clinical setting. However, recent research suggests that carefully designed preference instruments have the potential to predict real-world choices.[3]
- The findings are a direct function of the attributes and level ranges included in the study

CONCLUSIONS

- The importance of major HT risks outweigh the importance of major HT benefits, suggesting a strong aversion to the risks associated with HT and providing a potential reason for women's HT treatment inertia
- There is a need for safe and effective menopausal symptom treatments as an alternative to HT, as well as shared decision-making with an educational component between patients and clinicians.

Disclosures

- This study was sponsored by Bayer and conducted by Evidera, including medical writing support.

References

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3. de Bekker-Grob EW, et al. Value Health. 2019;22(9):1050-1062.