An Innovative Reusable Electronic Injection Device for Certolizumab Pegol: Results from a Pilot Market Research Study Examining Patient Preference and Satisfaction

B.P. Pouls,[1] L.E. Kristensen,[2] M. Petersson,[3] B.J. van den Bemt,[1] E. van Bracht,[4] R. Bruggraber,[5] I. Mountian,[6] S. Wiegratz,[7] H. Karlen,[8] L. Ballerini,[9] T.S. Jørgensen[2]

[1]Sint Maartensliniek and Radboud University Medical Center, Nijmegen, The Netherlands; [2]The Parker Institute, Copenhagen, Denmark; [3]Linkoping University, Linkoping, Sweden; [4]UCB Pharma, Breda, The Netherlands; [5]UCB Pharma, Slough, UK; [6]UCB Pharma, Brussels, Belgium; [7]UCB Pharma, Monheim am Rhein, Germany; [8]UCB Pharma, Stockholm, Sweden; [9]UCB Pharma, Bulle, Switzerland

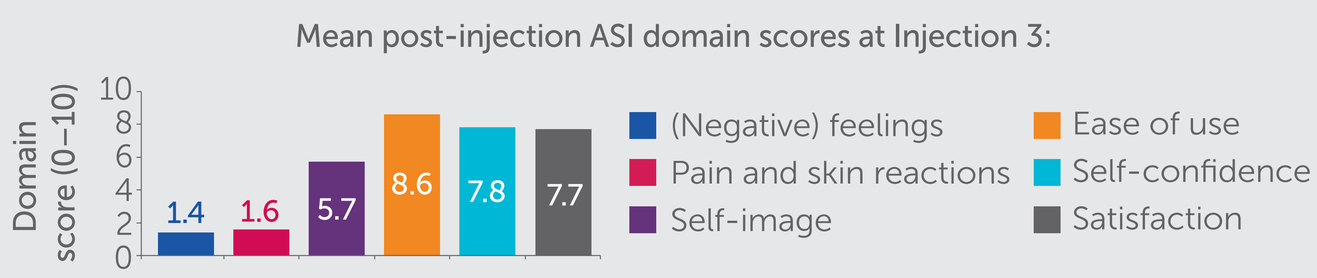
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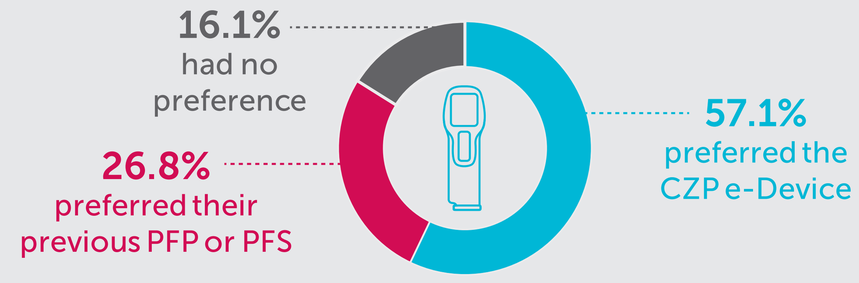
SUMMARY

Question: Do patients have a good experience and prefer the CZP e-Device compared to their previous PFS or PFP?



Results: Assessment of patient self-injection





Main Conclusion: Access to an e-Device may help improve patient experience

ASI: assessment of self-injection; CZP: certolizumab pegol; PFP: pre-filled pen; PFS: pre-filled syringe.

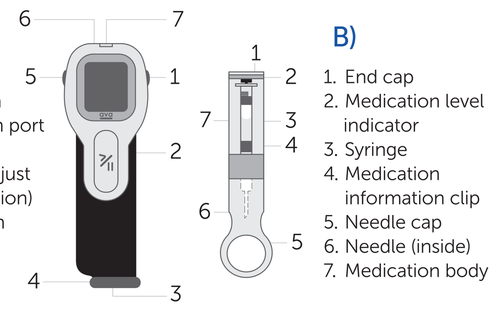
OBJECTIVE

- To assess patient experience of self-injection with the certolizumab pegol e-Device and determine patient preference compared to their previous self-injection device.

BACKGROUND

- Patients may encounter challenges when self-injecting therapies, for example, needle phobia, lack of confidence and remembering self-injection dates.[1,2]
- Self-injection devices have the potential to help address some of these challenges, improving injection experience and treatment adherence.[3]
- ava® is a reusable electromechanical self-injection device (e-Device) designed for use with the anti-TNF certolizumab pegol (CZP),[4] and includes a range of features to improve patient experience of self-injection **(Figure 1)**.[5]

Figure 1. Image of the e-Device and dose dispenser cartridge



A. Image of the e-Device; **B.** Image of the dose dispenser cartridge. Figures taken from CZP Summary of Product Characteristics.[4] CZP: certolizumab pegol.

METHODS

- Patients with rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA), aged 18–85 years and self-injecting CZP using a pre-filled syringe (PFS) or pre-filled pen (PFP) were recruited from the Netherlands, Denmark and Sweden.
- A pre-injection assessment of self-injection (ASI) questionnaire comprised of six questions grouped into two domains, (negative) feelings about self-injection and self-confidence, was completed to evaluate patients' self-injection experience before using the e-Device.
- Patients were trained to self-inject using the e-Device, given a step-by-step guide, and encouraged to watch a training video.
- Patients subsequently carried out three CZP injections at home, each two weeks apart, administering either the loading (CZP 400 mg; 2 x 200 mg CZP injections) or maintenance (CZP 200 mg) dose.
- After each injection, patients completed a post-injection ASI questionnaire comprised of 44 questions clustered into six domains: (negative) feelings about self-injection, self-image, self-confidence, ease of use, satisfaction, and pain and skin reactions.
- Following the third self-injection, patients completed a preference questionnaire assessing device preference.

RESULTS

Patient Characteristics

- Fifty-nine patients participated (Netherlands: 24; Denmark: 15; Sweden: 20). Patients from Sweden did not respond to all questions, therefore only preference questionnaire results and some pre-ASI questionnaire results are reported.
- Patient characteristics are reported in **Table 1**.

Pre-Injection ASI Questionnaire

- In the pre-injection ASI, 4/39 (10.3%) patients stated they were 'very' or 'extremely' afraid of injections, and 33/39 (84.6%) felt 'very' or 'extremely' confident self-injecting correctly with their current device (data not shown).
- The (negative) feelings domain has low ratings, while patients rated the self-confidence domain highly **(Figure 2)**.

Post-Injection ASI Questionnaire

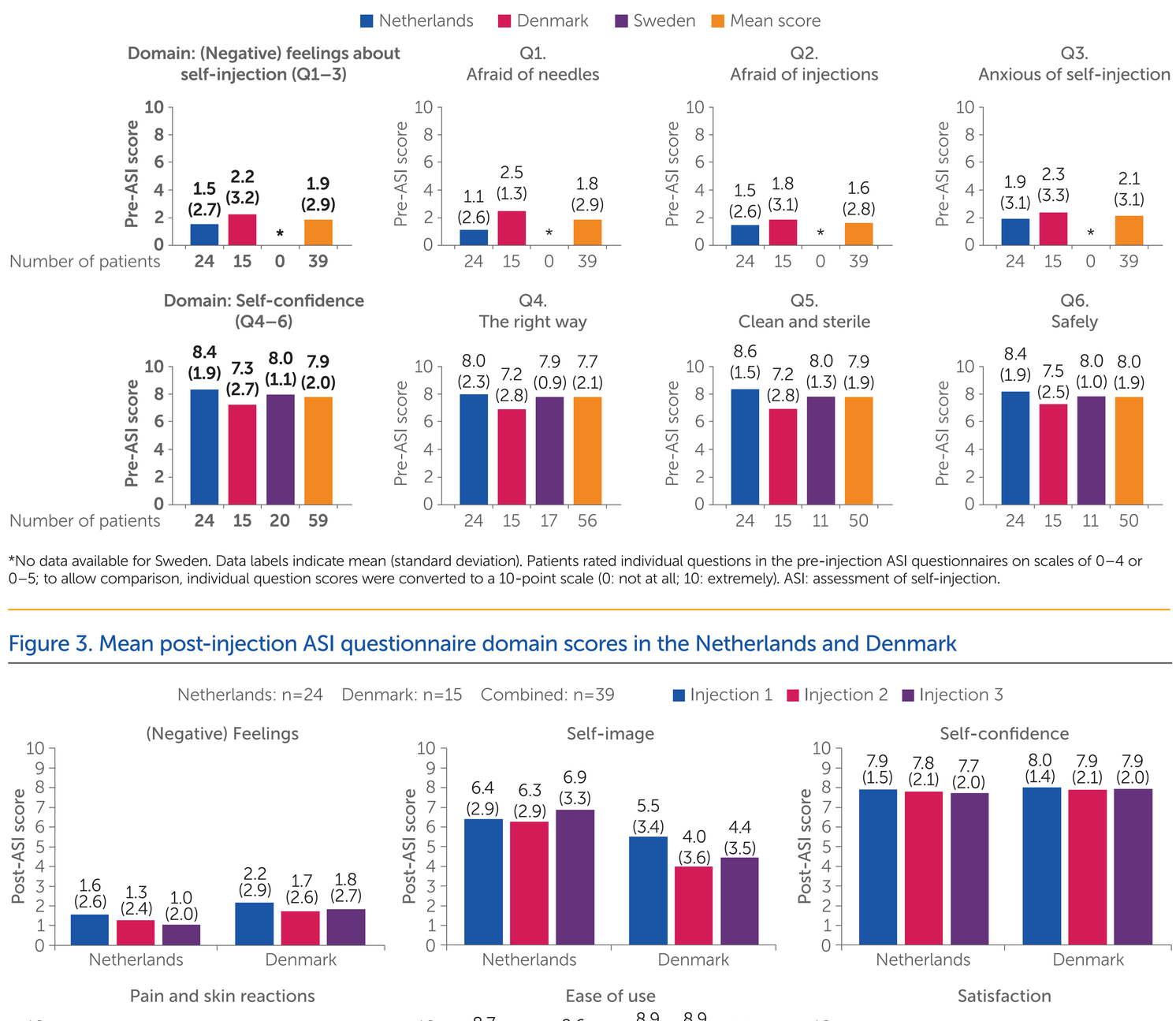
- Patients scored the e-Device favourably across all post-injection ASI domains **(Figure 3)**.
  - The (negative) feelings and pain and skin reactions domains had low ratings. Patients were most bothered by pain at the injection site, and least bothered by cold or itching (results not shown).
  - There was no difference between the (negative) feelings about self-injection and self-confidence domain scores in the pre-injection and post-injection ASI questionnaires.
  - There were no differences in post-ASI questionnaire results over time.

Table 1. Patient characteristics

n (%), unless stated	All patients (n=59)	Denmark (n=15)	Sweden (n=20)	Netherlands (n=24)
Age (years), mean (SD)	54.8 (15.9)	54.5 (15.9)	61.5 (15.2)	49.5 (14.7)
Gender, female	42 (71.2)	6 (40.0)	14 (70.0)	22 (91.7)
Disease diagnosis				
RA	38 (64.4)	9 (60.0)	14 (70.0)	15 (62.5)
axSpA	9 (15.3)	4 (26.7)	2 (10.0)	3 (12.5)
PsA	12 (20.3)	2 (13.3)	4 (20.0)	6 (25.0)

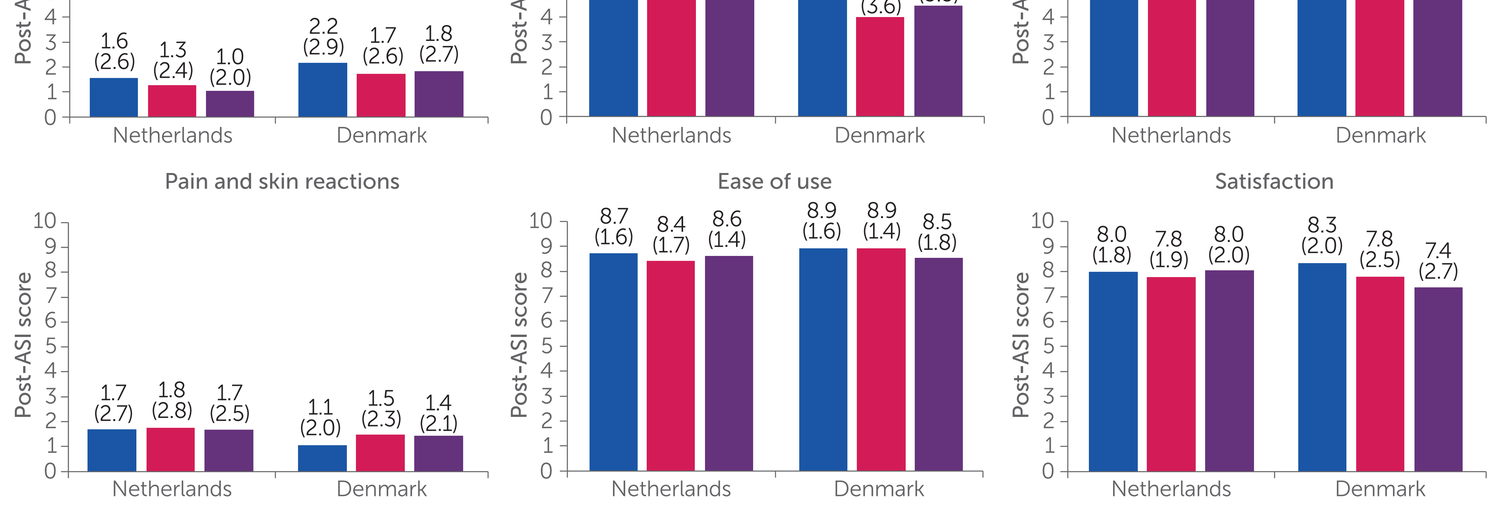
axSpA: axial spondyloarthritis; PsA: psoriatic arthritis; RA: rheumatoid arthritis; SD: standard deviation.

Figure 2. Mean patient responses to the pre-injection ASI



*No data available for Sweden. Data labels indicate mean (standard deviation). Patients rated individual questions in the pre-injection ASI questionnaires on scales of 0–4 or 0–5; to allow comparison, individual question scores were converted to a 10-point scale (0: not at all; 10: extremely). ASI: assessment of self-injection.

Figure 3. Mean post-injection ASI questionnaire domain scores in the Netherlands and Denmark



Data labels indicate mean (standard deviation). Patients rated individual questions in the post-injection ASI questionnaires on scales of 0–4 or 0–5; to allow comparison, individual question scores were converted to a 10-point scale (0: not at all; 10: extremely) and the domain score was calculated as the mean of the item scores included in the domain. Domain scores were only calculated if at least half of the domain items were completed. Post-ASI: post-injection assessment of self-injection.

Table 2. Patient device preference

Preference Question, n (%)	e-Device	Previous device	No preference
Q1. Safe	41 (71.9)	11 (19.3)	5 (8.8)
Q2. Confidence	33 (57.9)	15 (26.3)	9 (15.8)
Q3. Easy to hold	44 (77.2)	10 (17.5)	3 (5.3)
Q4. Control	39 (68.4)	13 (22.8)	5 (8.8)
Q5. Storage	20 (35.1)	24 (42.1)	13 (22.8)
Q6. Travel	13 (25.5)	28 (54.9)	10 (19.6)
Q7. Time	25 (44.6)	16 (28.6)	15 (26.8)
Q8. Convenience	35 (62.5)	12 (21.4)	9 (16.1)
Q9. Overall	**32 (57.1)**	**15 (26.8)**	**9 (16.1)**

Not all patients answered all device preferences questions, therefore, the total number of patients for each question may differ.

Device Preference

- Across all countries, 56/59 patients answered the preference questionnaire; overall 32/56 (57.1%) patients preferred the e-Device, 15/56 (26.8%) preferred the PFS or PFP, 9/56 (16.1%) had no preference **(Table 2)**.

CONCLUSIONS

- Patients were satisfied with the e-Device, found it easy to use and handle, and were able to successfully administer self-injections.
- The e-Device was the preferred device for most patients; this suggests it may address unmet patient needs.
- Some patients preferred their previous self-injection device demonstrating the importance of providing patients with a portfolio of self-injection devices.
- The e-Device, as part of a portfolio of self-injection device options for CZP, may help enhance patient experience, which could improve CZP adherence and patient outcomes.

References

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Author Contributions

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: BPP, LEK, MP, BJvdB, EvB, RB, IM, SW, HK, LB, TSJ; Drafting of the publication, or revising it critically for important intellectual content: BPP, LEK, MP, BJvdB, EvB, RB, IM, SW, HK, LB, TSJ; Final approval of the publication: BPP, LEK, MP, BJvdB, EvB, RB, IM, SW, HK, LB, TSJ.

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