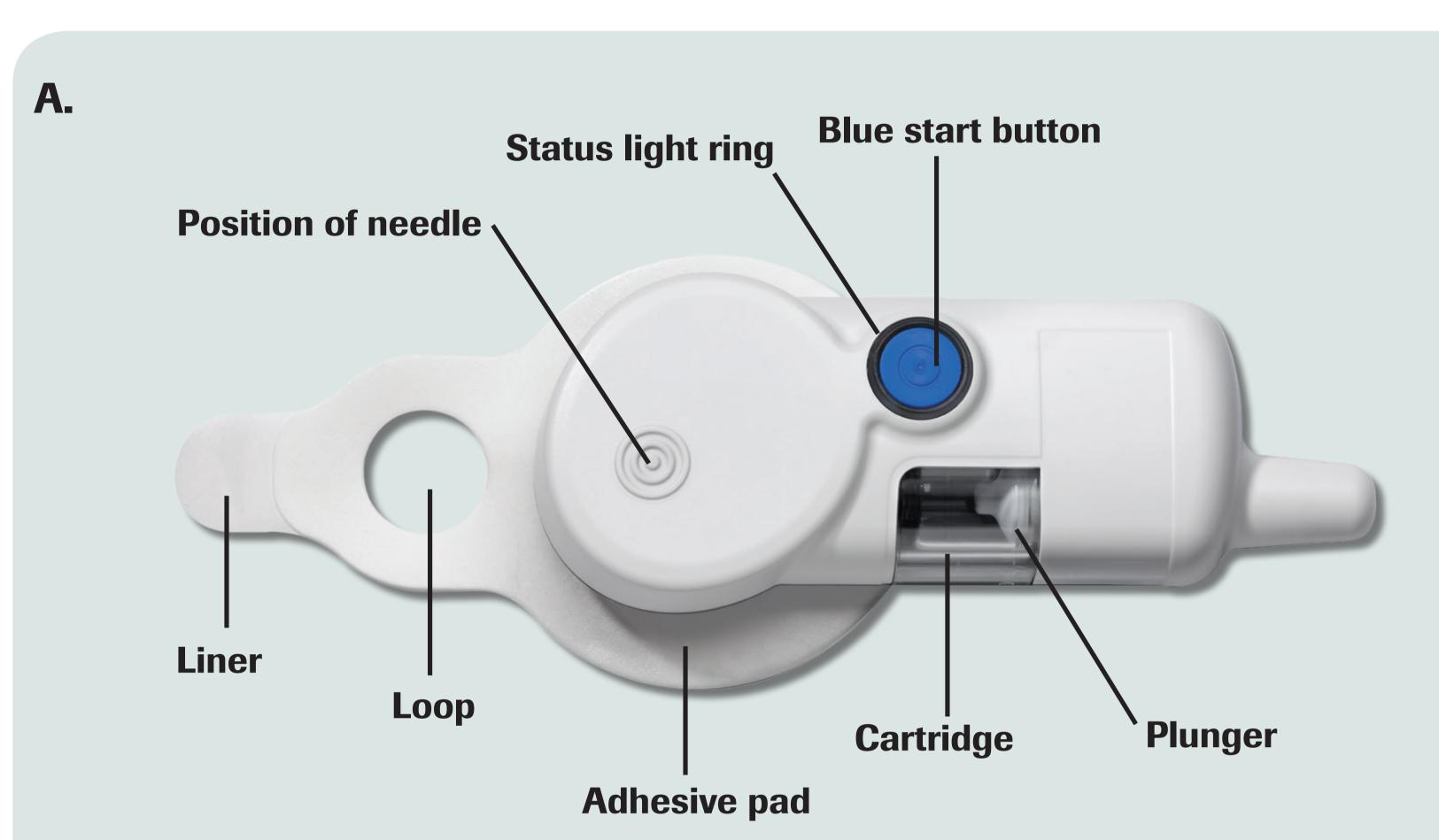
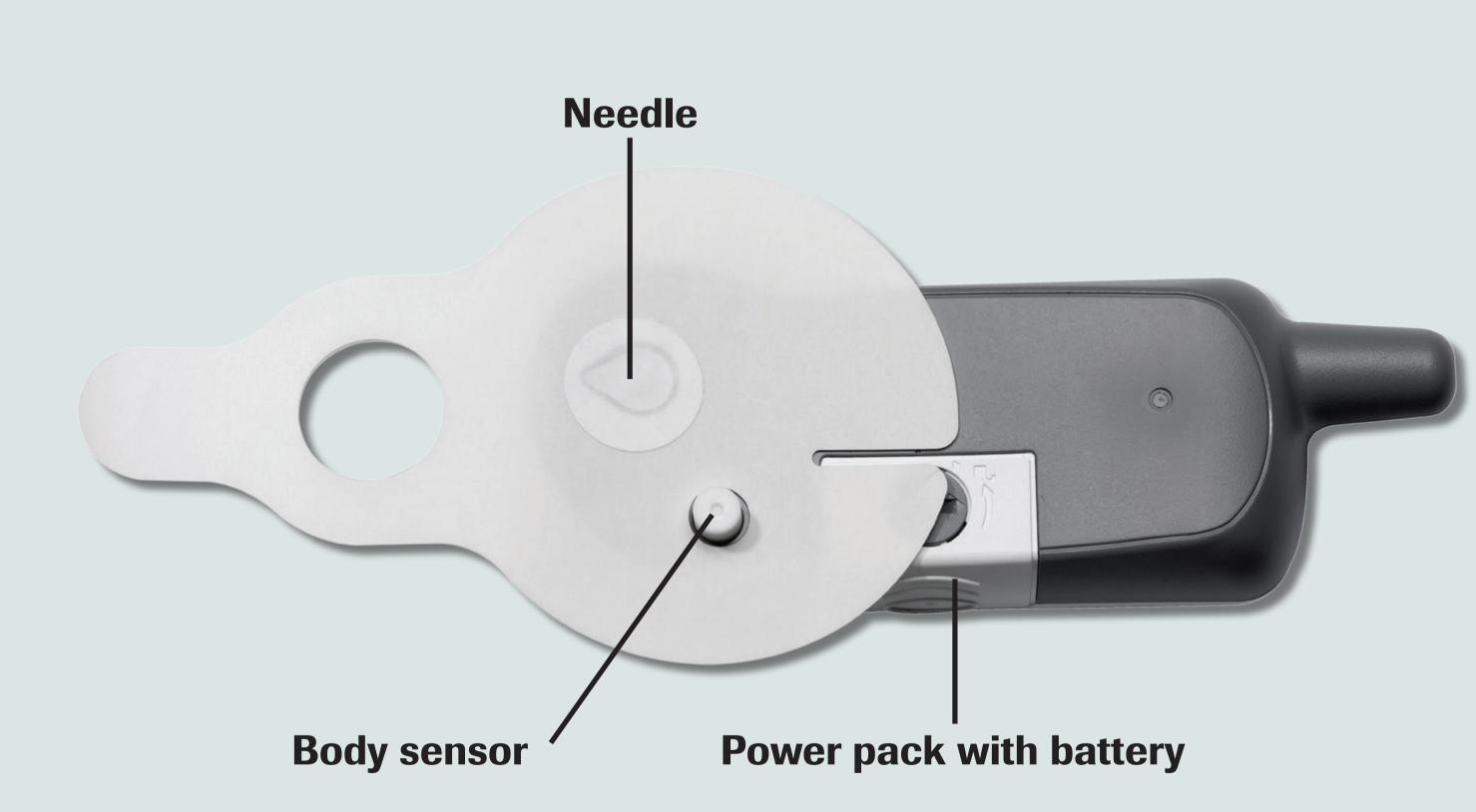
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Background

- Subcutaneous (SC) trastuzumab (Herceptin® SC, F. Hoffman-La Roche Ltd, Basel, Switzerland) provides a valid alternative to intravenous (IV) infusion for treating HER2-positive breast cancer.
- SC trastuzumab is administered as a 600 mg fixed dose by hand-held syringe or single-use injection device (SID, Figure 1).
- The HannaH study showed that the SC formulation delivered by hand-held syringe has non-inferior efficacy and a comparable pharmacokinetic and safety profile to the IV formulation.^{1,2}
- The SC formulation delivered by the SID was shown to have comparable pharmacokinetics to the SC formulation delivered by hand-held syringe in the CP3 study.3

Figure 1: SC trastuzumab SID (A) top view, (B) bottom view and (C) placement.

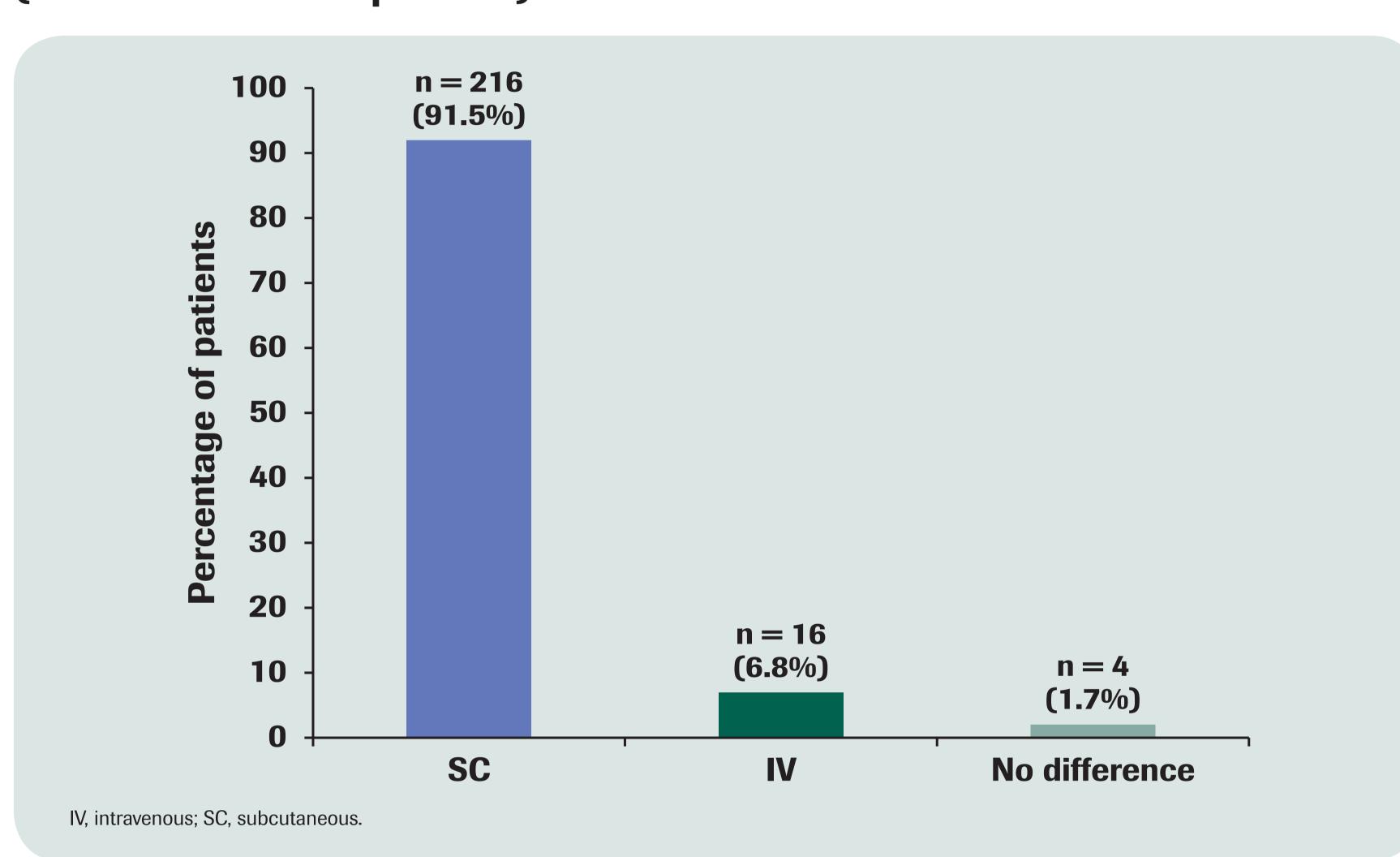




A and B courtesy of F. Hoffmann-La Roche Ltd. C taken from the PrefHer healthcare professionals' training DVD and courtesy of SHORE-C and F. Hoffmann-La Roche Ltd. SC, subcutaneous; SID, single-use injection device.

- The SC trastuzumab formulation contains a fixed dose of 600 mg trastuzumab plus 10 000 units of the rHuPH20 enzyme in a total volume of 5 ml.
 - rHuPH20 temporarily degrades the polysaccharide hyaluronan just beneath the skin and allows this large volume of fluid to be absorbed.4
- The SID may also allow self-administration by patients.3
- The PrefHer trial assessed patients' preferences for SC trastuzumab via SID (Cohort 1) and hand-held syringe (Cohort 2), compared with traditional IV infusion using standardised telephone patient interviews (PINTs).5
- Previously reported results from Cohort 1 of PrefHer showed that 91.5% of patients preferred SC trastuzumab via the SID (Figure 2).5

Figure 2: Patients' preferences in Cohort 1 of PrefHer (N = 236 evaluable patients).



- The majority of healthcare professionals were also more satisfied with SC (73.8%) than IV administration of trastuzumab (1.9%). The rest of the healthcare professionals had no preference.⁵
- Here we present further results from Cohort 1 of PrefHer, investigating the reasons patients gave for their preferences during interviews.

Methods

- In Cohort 1 of PrefHer, 248 patients from Europe and Canada who had completed surgery and (neo)adjuvant chemotherapy were given 4 cycles of SC trastuzumab followed by 4 of IV, or vice versa (the cross-over period).⁵
- Patients may have received IV trastuzumab previously.
- Before and after receiving their 8 cycles of cross-over SC and IV, patients were interviewed at home by phone by experienced interviewers.⁵
- Before the cross-over period, factors potentially influencing preferences, including type of venous access device used and experiences during previous IV administration, were collected across 37 questions (PINT1).
- After completing the cross-over period, patients' final preferences, reasons for these and strength of preferences were elicited across 61 questions (PINT2).
- Interviews were quality-controlled and regularly checked to ensure impartial questioning, specifically:
- Interviewers were trained and given a manual and standard operating procedures to follow.
- No study patient interviews were conducted until each interviewer had performed 'dummy' interviews satisfactorily.
- Responses to the question "What are the two main reasons for your preference?" were recorded verbatim by the interviewer. Four experienced researchers independently scrutinised the responses and divided them into thematic categories.

Results

When asked "What are the two main reasons for your preference?"

• The primary reasons for SC preference are shown in Table 1. The majority of reasons were categorised under time saving, less pain/discomfort and convenience.

Table 1: Main reasons for SC preference in Cohort 1 of PrefHer.

Category	n*5	Example
Time saving	195	"It does affect me being there so many hours. With this it was 'Hello' and 'Bye' without having to spend hours with patients"
Less pain/discomfort	88	"The SC method was a lot less painful to me and my bruises faded faster than in the case of the intravenous method"
Convenience to patient	35	"Busy mum with four young children – want to get on with life"
Ease of administration	33	"Nurses can take care of many patients at the same time"
Problems with IV	25	"No veins to be found as my veins are collapsing"
Less stress/anxiety	15	"IV reminds one of chemo and isn't very pleasant for the head"
Other	6	"Safer – less risk of infections" [†]

• The primary reason given by the 16 patients with an IV preference was fewer reactions

(less pain, bruising, irritation, etc. [11/16]),⁵ e.g. "Irritation due to the SC."

Statement based on patient preference and not reflective of clinical data.

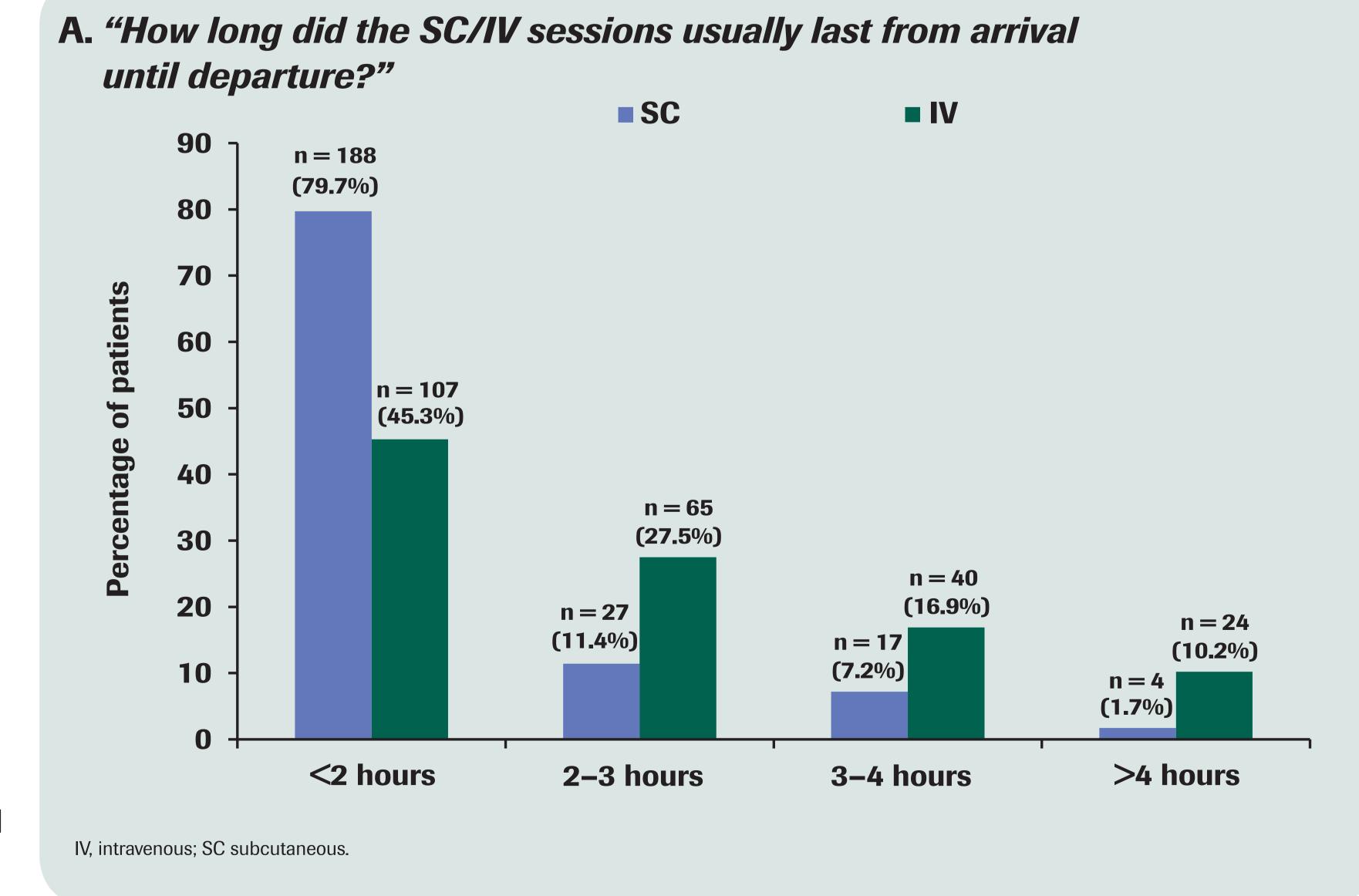
*Some patients gave only 1 reason.

IV, intravenous; SC, subcutaneous.

The PINTs had questions probing many areas that contributed to the preferences

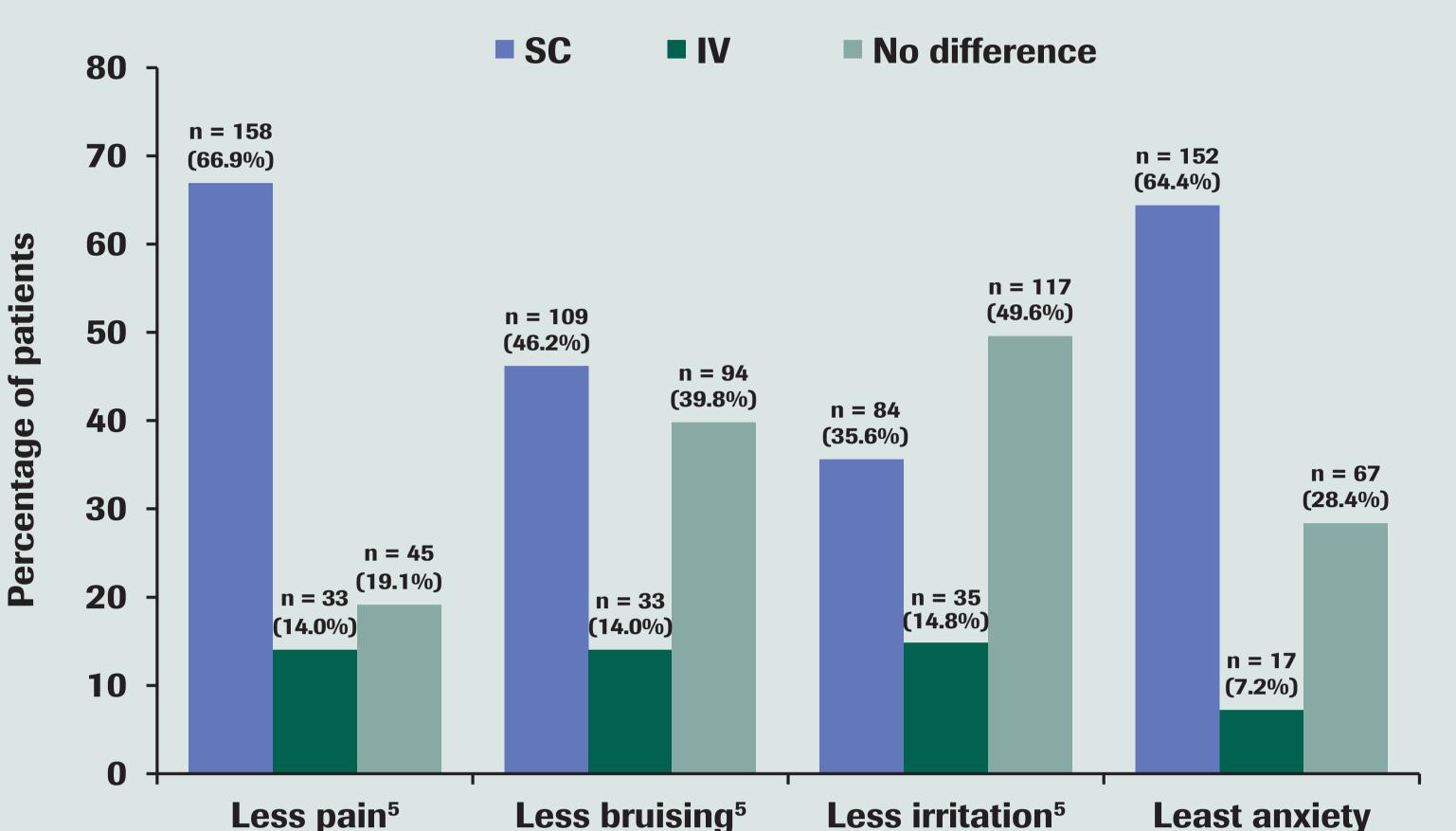
 Figure 3 shows that with SC trastuzumab, patients spent less time at the treatment centre, experienced less pain, bruising and irritation,⁵ and found SC to be more convenient and to cause least anxiety. Furthermore, patients thought that staff found SC easiest to administer.

Figure 3: Responses to selected PINT questions related to (A) time saving, (B) pain/discomfort and (C) convenience.

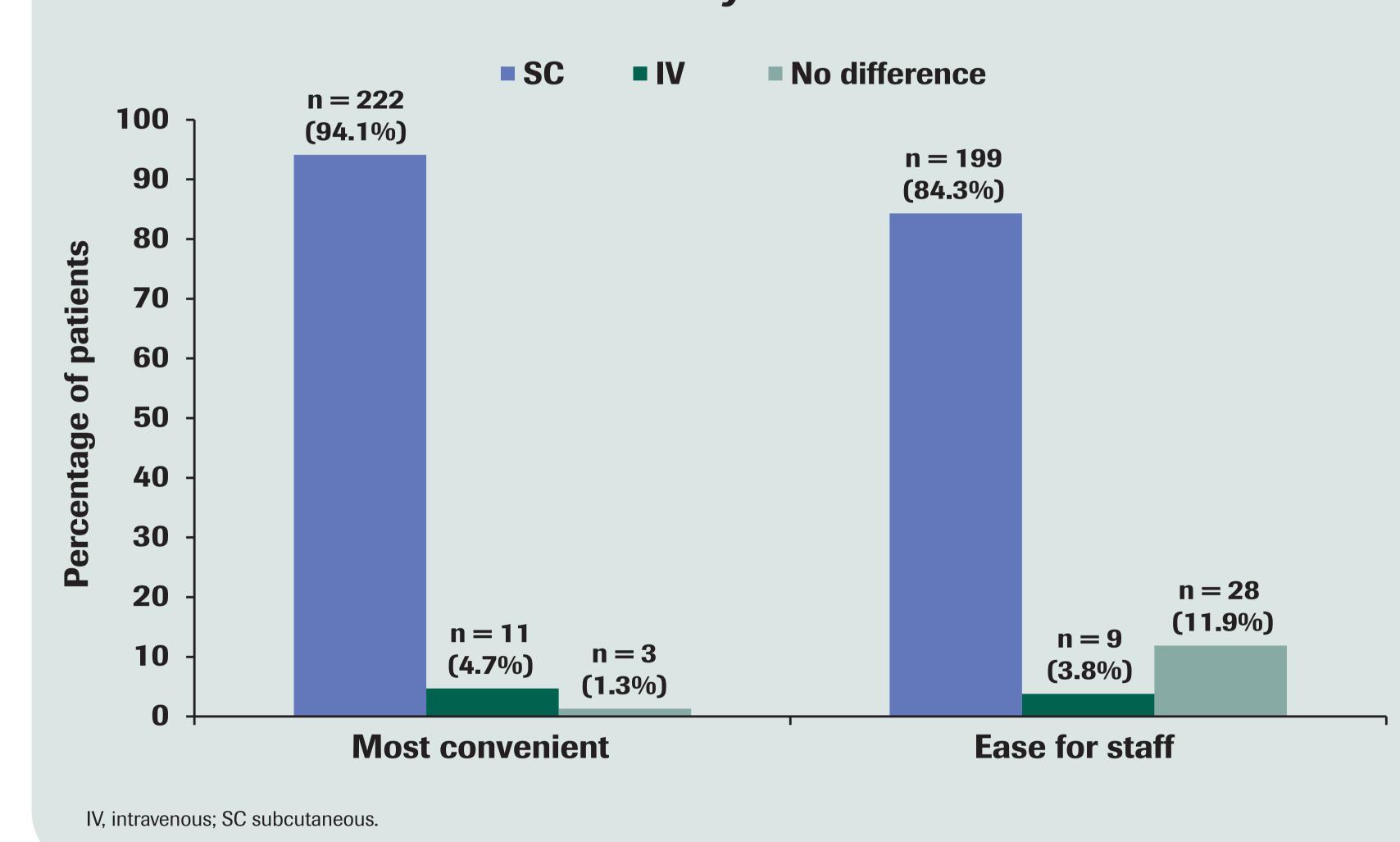


B. "Which administration method:

- ... was the least painful?"
- ...usually caused less bother from bruising?"
- ...usually caused less irritation to the injection site?"
- ...caused you least anxiety?"



C. "Which administration method was the most convenient for you?" "Which method did the staff usually find easiest to administer?"



Conclusions

- In PrefHer, patients very strongly preferred SC trastuzumab using the SID, mainly because it saved them time, caused them less pain/discomfort and was more convenient than IV administration.5
- The Phase III HannaH study has shown non-inferior efficacy and a comparable pharmacokinetic and safety profile to the IV formulation.^{1,2}
- Together, these studies indicate that SC trastuzumab offers an efficacious and preferred alternative to IV infusion for the treatment of patients with HER2-positive breast cancer.

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NB: There may be associated costs for downloading data. These costs may vary depending on your service provider and may be high if you are using your smartphone abroad. Please check your phon tariff or contact your service provider for more details

