

COMPARATIVE STUDY FOR EVALUATION OF THE PAIN, EASE OF USE AND PREFERENCE BETWEEN TWO ADALIMUMAB ADMINISTRATION DEVICES

STUDY ADAP2017

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BACKGROUND:

Adalimumab is a monoclonal antibody for subcutaneous administration by two different devices: pre-filled syringe and auto-injection pen

PURPOSE:

To assess injection-site pain, the ease of use and patient preference between two delivery systems of adalimumab

MATERIALS AND METHODS:

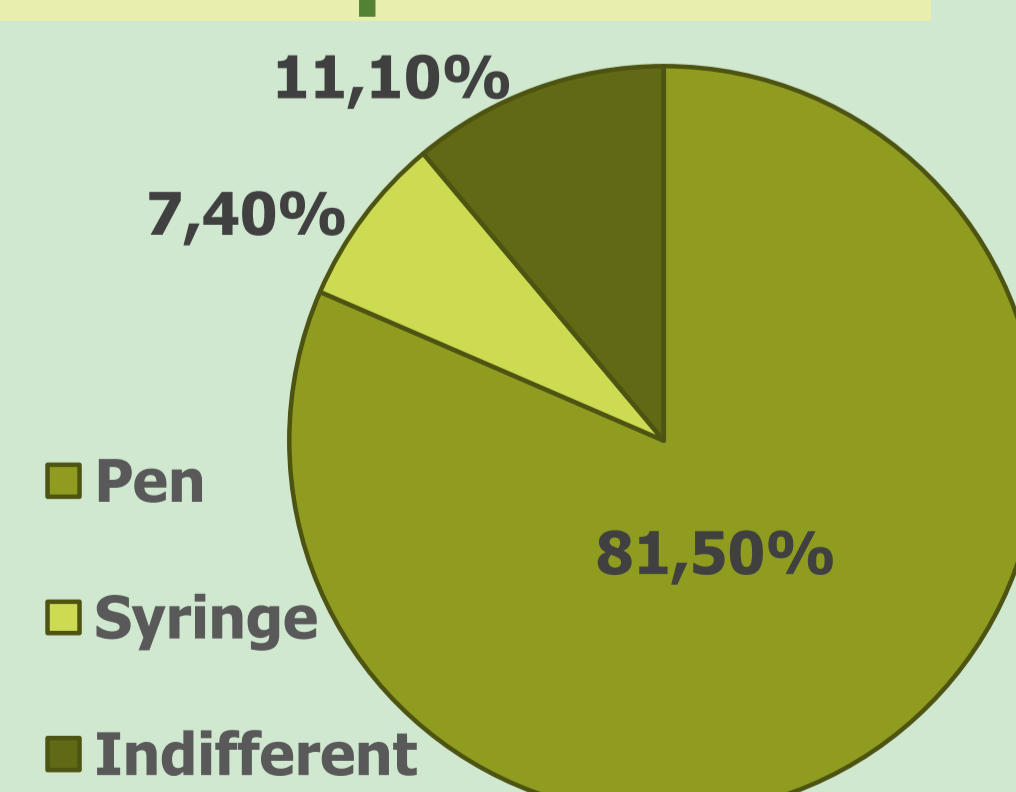
Open-label, single-arm, sequential trial from (March 2017 - September 2017)

- ❖ Inclusion criteria: at least six months from the beginning of the treatment with adalimumab pre-filled syringe, self-administration and signed informed consent
- ❖ Two visits separated by an interval of two months were performed
- ❖ Evaluation of ease of use with a validated questionnaire consisted of 15 questions about device design, inconvenients of self-administration, long injection time, handling and technique of administration (Likert-type scale: 1=very strongly disagree; 7=very strongly agree)
Answers ≥ 5 were considered acceptable (Visit 1: Syringe, visit 2: Pen)
- ❖ Evaluation of the pain: visual analogue scale (VAS) (0=none, 10=the worst pain)
(Visit 1: Syringe; Visit 2: Pen).
- ❖ Preference between devices: a single question with three possible answers

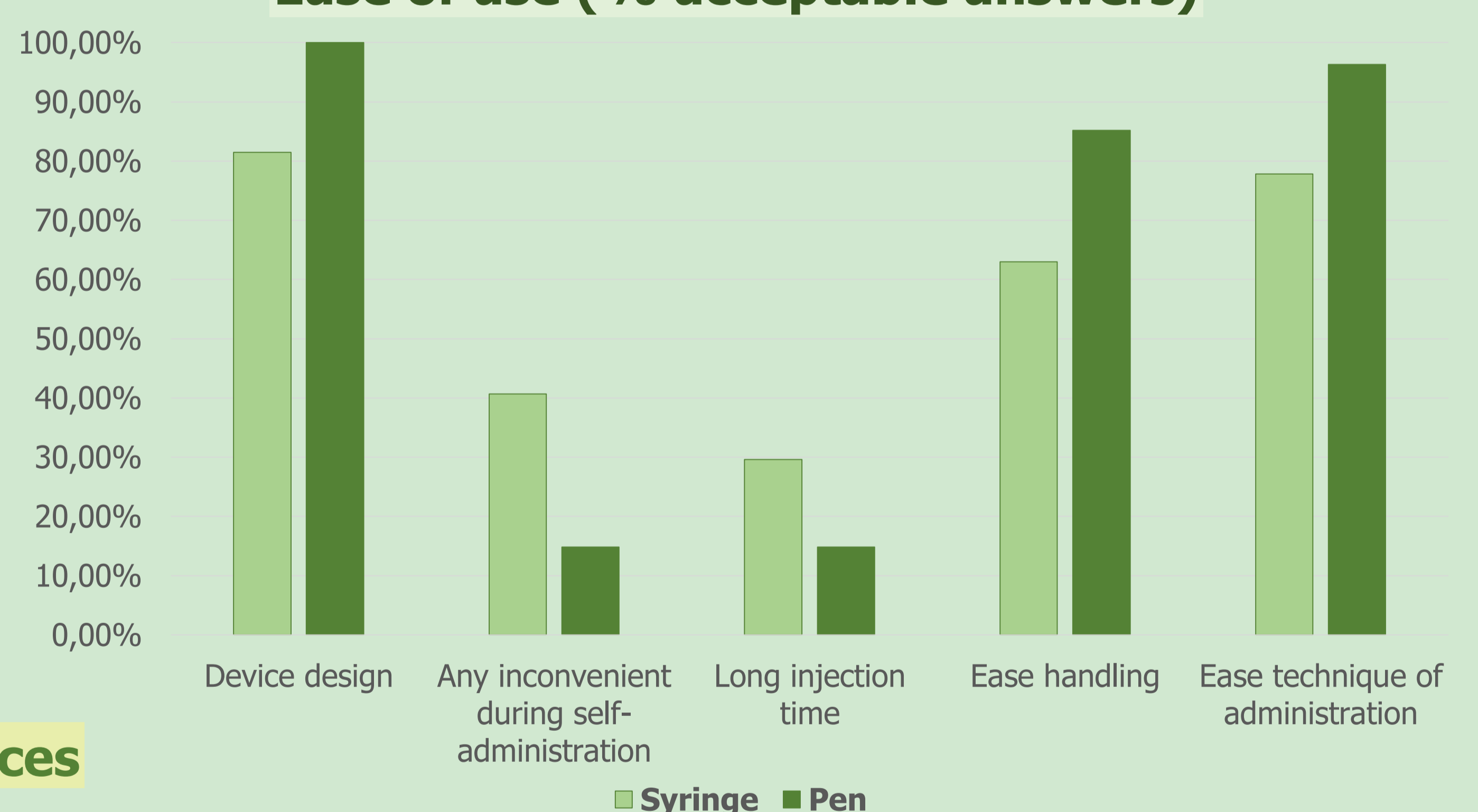
RESULTS:

Patients	27
Sex	
Men	18 (66,7%)
Women	9 (33,3%)
Age	
Median	43 years
Range	(18-73)
Diagnosis	
Psoriasis	9 (33,3%)
Spondylitis	6 (22,2%)
Chron's disease	11 (40,8%)
Psoriatic arthritis	1 (3,7%)
Treatment duration	
Median	2,9 years
Range	(0,5-8,7)

Patient preferences



Ease of use (% acceptable answers)



Injection-site pain

Reduction of pain from pre-filled syringe to pen
Mean difference: -3.04 (IC95%: -4,21 to -1,86; $p < 0,001$)

CONCLUSIONS:

Auto-injection pen has proved superiority than pre-filled syringe in injection-site pain, ease of use and patient preference. Limitations: the pen does not contain citrate, a pain-related excipient.