

Patient-Reported Outcomes regarding adalimumab new formulation

P. LÓPEZ SÁNCHEZ¹, A. GARCÍA SACRISTÁN², R. MARTÍNEZ MORAGO¹, A.V. BECERRA CAÑAS¹, J.J. MÁRQUEZ NIEVES¹, T. SÁNCHEZ CASANUEVA¹, J.M. MARTÍNEZ SESMERO².

¹HOSPITAL GENERAL DE TOMELLOSO, PHARMACY DEPARTMENT, TOMELLOSO, SPAIN.

²COMPLEJO HOSPITALARIO DE TOLEDO, PHARMACY DEPARTMENT, TOLEDO, SPAIN.

BACKGROUND

Adalimumab is currently available in a 40mg/0.4mL formulation with fewer excipients, smaller volume and gauge needle, versus 40mg/0.8mL previous formulation.

PURPOSE

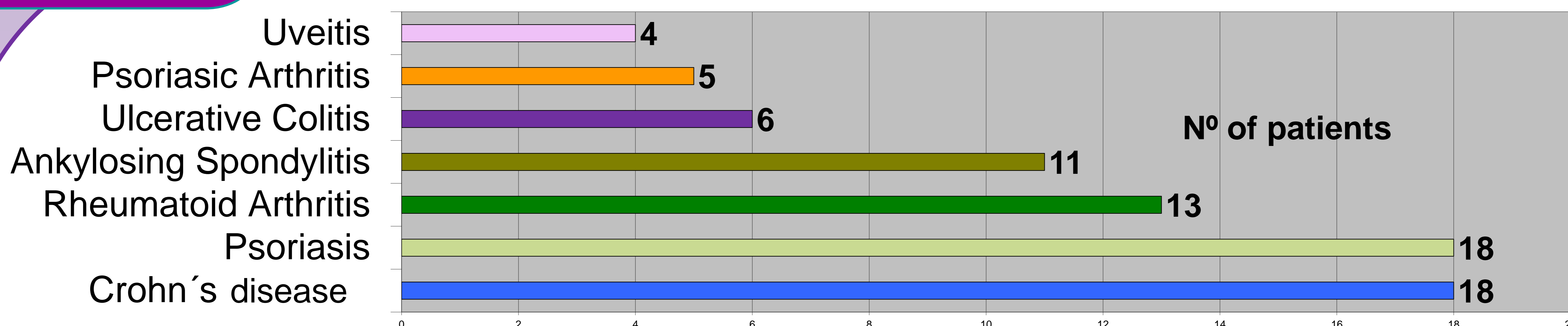
To evaluate injection site-related pain (ISRP) and satisfaction of new adalimumab formulation in comparison with previous one.

MATERIALS AND METHODS

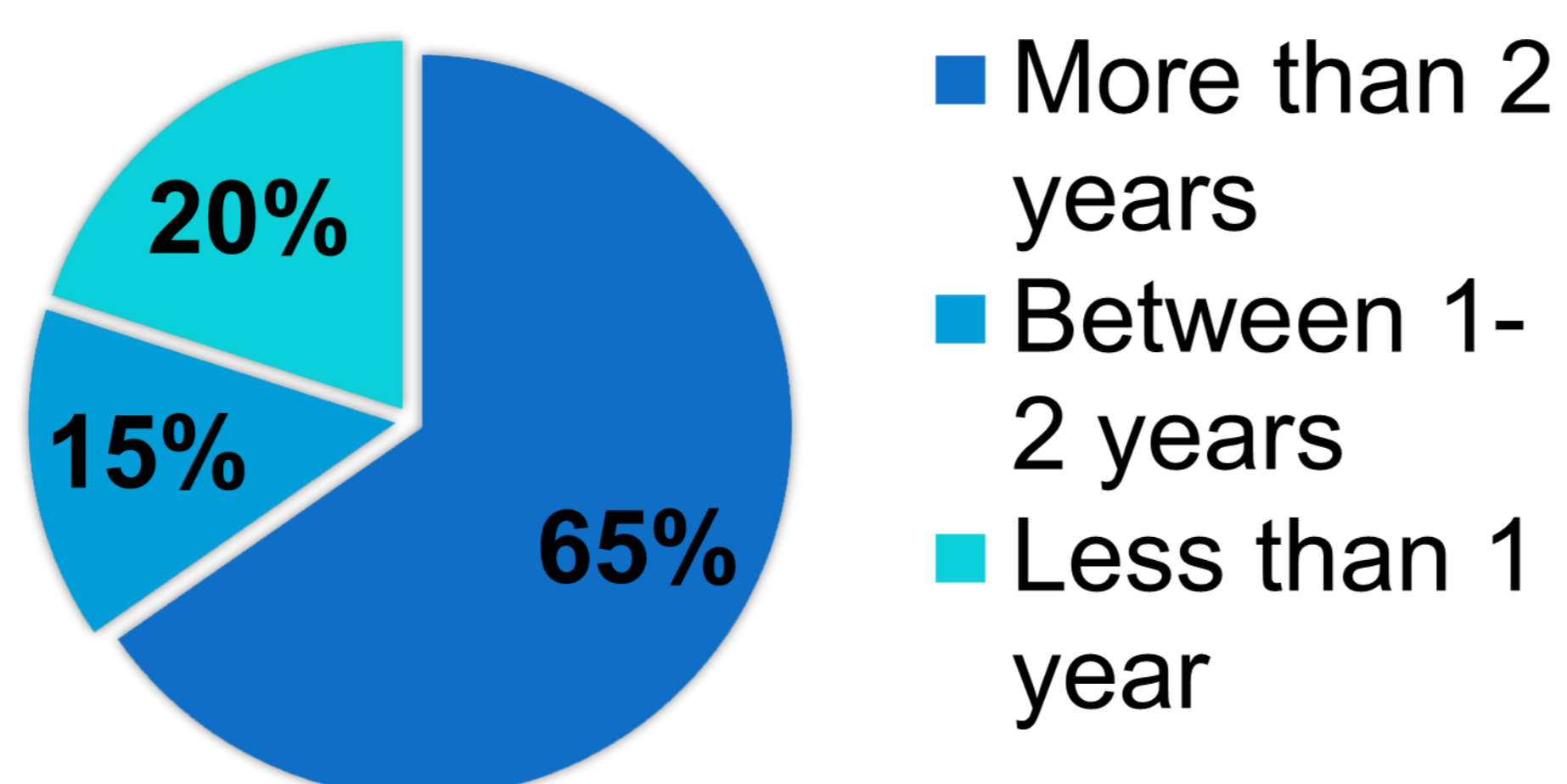
Observational, prospective, analytical study (April-September 2017) in Outpatient Pharmacy Departments of two General Hospitals. We selected patients on adalimumab treatment who changed old formulation to new formulation, and had been with new one at least two months. Data collection interview comprised: sex, age, immune disease, old formulation treatment time, and a questionnaire about the person who administers adalimumab, injection sites, warm up drug before administration moment, ISRP with Visual Analogue Scale (VAS) and satisfaction with adalimumab new formulation. Data were analyzed with SPSS® v.21.

RESULTS

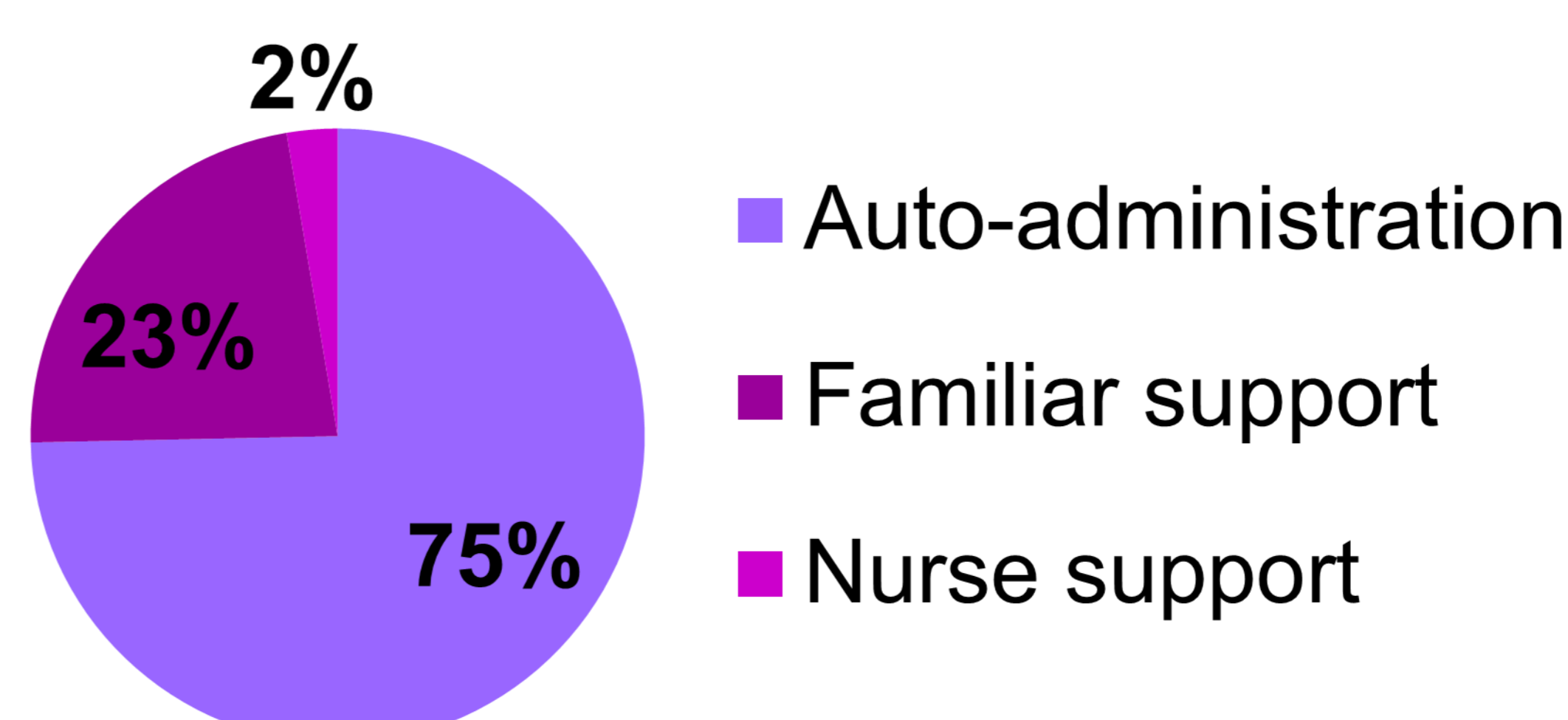
75 patients (pat.) were included, 46 (65.3%) male, mean age 49.8±13.5 years.



Old formulation treatment time



Person who administers adalimumab



Injection sites	N (%)
Abdomen	32 (42.7)
Thighs	22 (23.3)
Arms	8 (10.7)
Abdomen and thighs	12 (16)
Abdomen, arms, thighs	1 (1.3)

Chi-square test did not show statistically significant differences between:

- ISRP absence and auto-administration (p=0.567)
- Warm up and ISRP absence (p=0.404)
- Satisfaction and ISRP absence (p=0.673).

52 pat. (69,3 %) without ISRP
Mean VAS = 2 ± 1.7

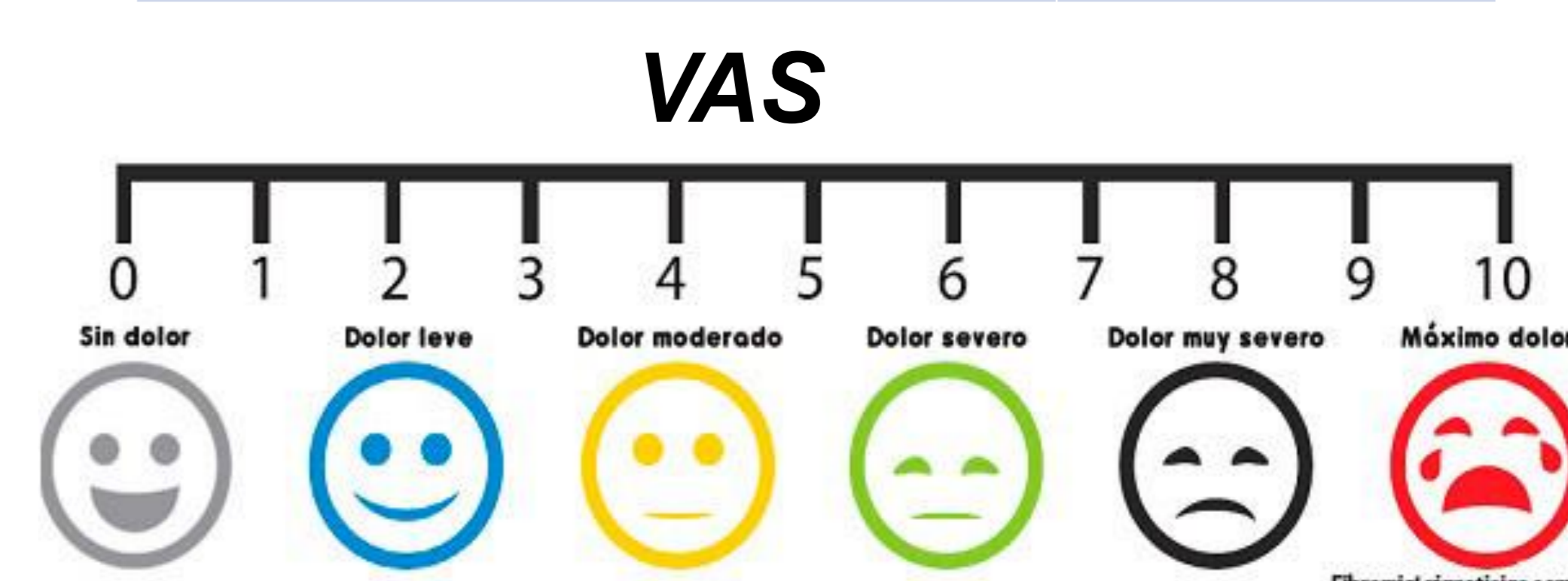
Less ISRP with new formulation	65 pat. (86,7%)
The same ISRP with both formulations	7 pat. (9,3%)
More ISRP with new formulation	3 pat. (4%)

Patients who warm up drug before administration

Always	Sometimes	Never
50 (66,7%)	11 (14,7%)	14 (18,7%)

70 pat. (93.3%) considered formulation improvement.

72 pat. (96%) are totally satisfied with new formulation.



CONCLUSIONS

- New adalimumab formulation was well tolerated and associated with less ISRP than the old formulation, therefore we expect better adherence, and persistence could also improve.
- We must develop new studies to evaluate these aspects.