Socio-demographics, clinical characteristics, and management of Generalized Pustular Psoriasis patients in Spain (IMPULSE study).

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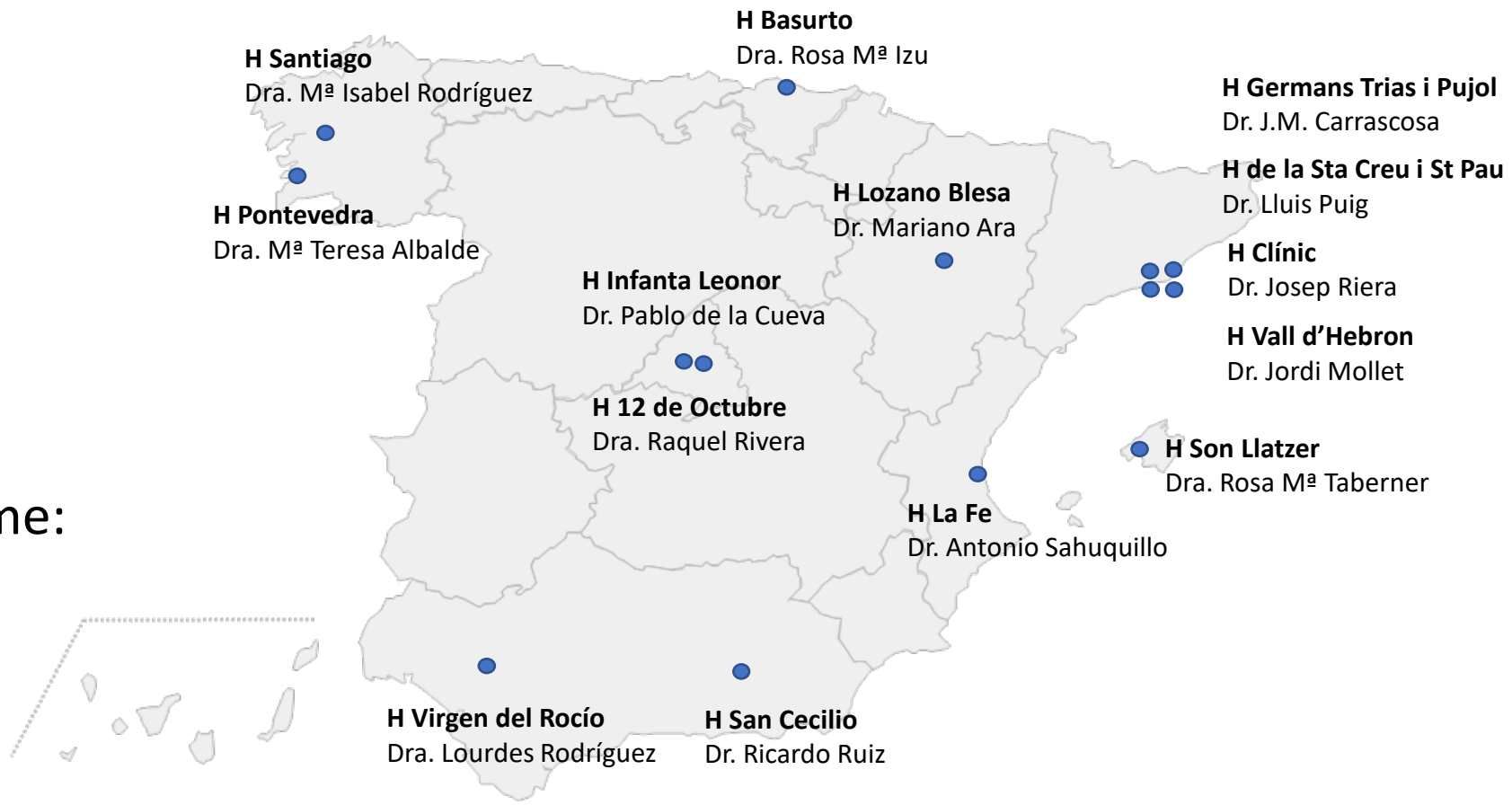
IMPULSE: GPP retrospective chart review

- ✓14 sites
- ✓56 patients
- ✓Mean follow-up time:

3.65 years



INCLUSION/EXCLUSION CRITERIA

- **Non-interventional, descriptive, multicentre, retrospective chart review study**

- **<u>Inclusion criteria</u>**

- Patients of all ages with a confirmed **diagnosis** of **GPP** made **after 2011** (included), treated and managed for GPP.
- Patients with GPP **diagnosis at least 6 months prior to data collection** in the eCRF.
- Patient with **at least 2 records related with GPP during the study period** (including the GPP diagnosis visit).

- **<u>Exclusion criteria</u>**

- Patients with a **confirmed diagnosis of AGEP** in the absence of a history of GPP.

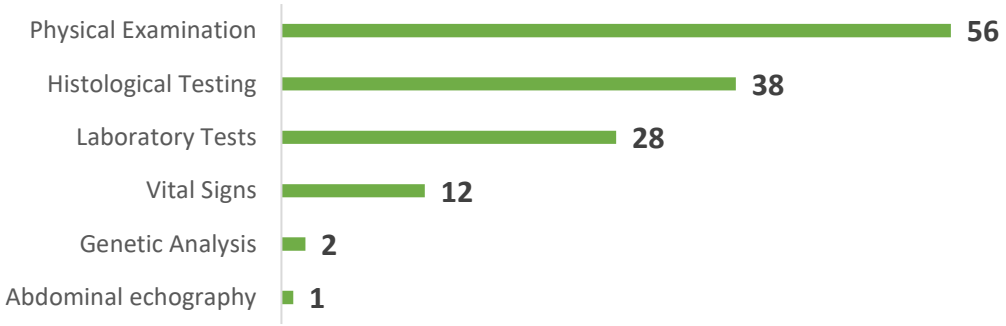
RESULTS- Socio-demographics characteristics

Variable	Total	Valid n
Age, at diagnosis (years): mean (SD)	53.7 (20.5)	56
Gender, male: n (%)	28 (50.0)	56
Race/ethnicity (White caucasian and/or european descent): n (%)	46 (82.1)	56
BMI: kg/m^2 mean (SD)	26.6 (6.5)	38
Pregnancy status	1 (3.8%)	25
Mean % BSA	41.3% (21.3)	15

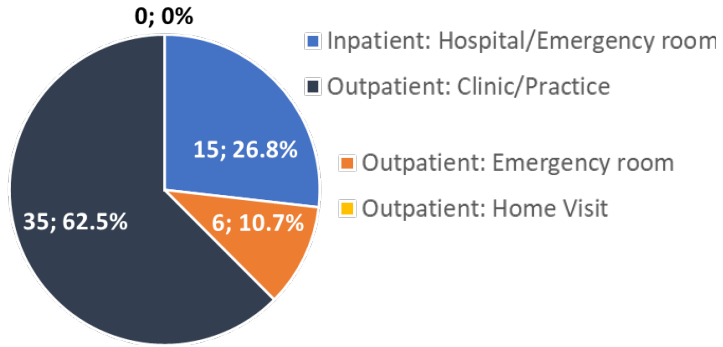
- ✓ 50% ♀ and 50% ♂
- ✓ Mean age of 53.7 years old.
- ✓ 1 patient was pregnant at diagnosis
- ✓ Mean percentage of BSA was 41.3%
- ✓ In 80% of patients, GPP diagnosis was associated with a flare

RESULTS- Examinations, type of visits and risk factors of GPP to determine diagnosis

Patients with examinations and/or tests (N=56)

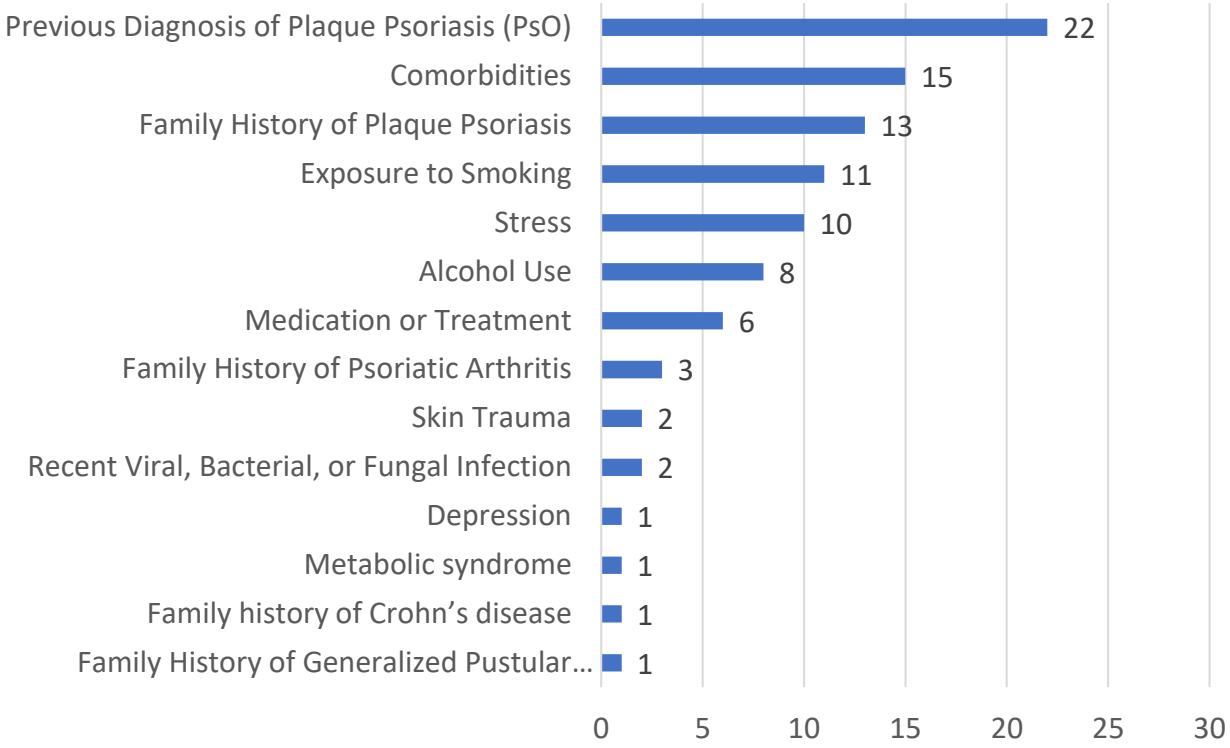


Patients with type of visit which resulted in the diagnosis of GPP (N=56)



- ✓ GPP diagnosis was clinical (physical examination). Histology and lab tests can be done.
- ✓ Most patients were diagnosed in an outpatient clinical visit (62.5%).

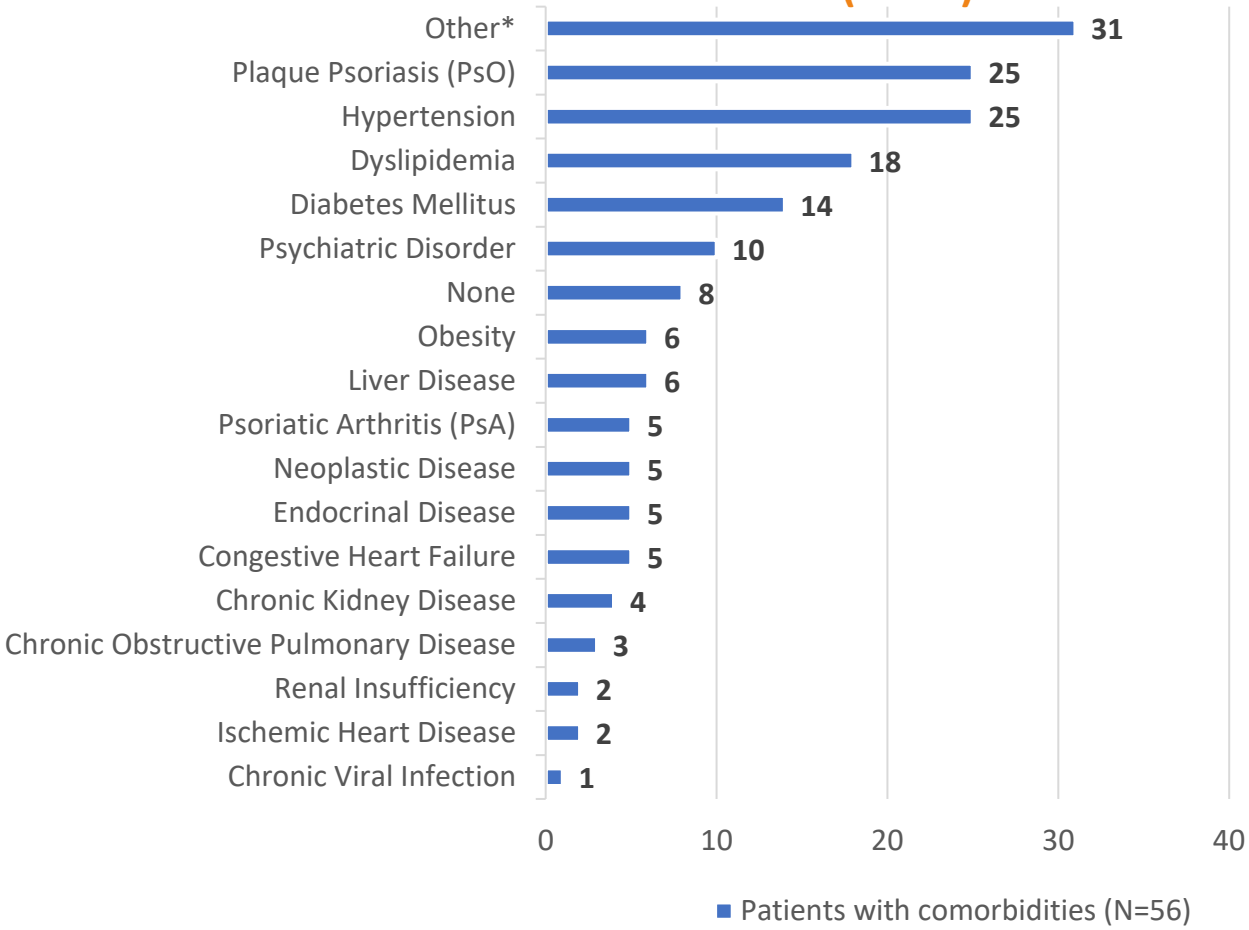
Comorbidities and Potential Triggers for GPP at diagnosis (N=55)



- ✓ 37 patients (67.3%) had any comorbidities and potential triggers for GPP development at diagnosis. The most frequents were: **previous diagnosis of Plaque PsO, family history of plaque PsO, or comorbidities**.

RESULTS- Comorbidities

Patients with comorbidities (N=56)



* The most common (n=2; 3.6%) **Other** comorbidities were: atrial fibrillation, cerebral ischemia, Crohn's disease, latent tuberculosis, osteoporosis, iron deficiency anemia and benign prostatic hyperplasia.

Patients and number of comorbidities

Patients with at least n comorbidity	Total
1 Comorbidity	49 (85.7%)
2 Comorbidities	41 (73.2%)
3 Comorbidities	29 (51.8%)
4 Comorbidities	24 (42.9%)
5 Comorbidities	19 (33.9%)
6 Comorbidities	14 (25.0%)
Valid N	56 (100%)

- ✓ Mean number of **comorbidities per patient was 3.52 (2.84);** 14 patients presented 6 or more.
- ✓ **Hypertension and plaque psoriasis** were the most common ones, both presented in 25 patients (44.6%).

RESULTS- Clinical characteristics of GPP flares

Patients with cutaneous signs and symptoms of GPP flare (multi-response); N=26

Pustules	**23 (88.5%)**
Scaling	**20 (76.9%)**
Erythema (Redness of the skin)	**20 (76.9%)**
Plaque	**17 (65.4%)**
Skin Lesions	14 (53.8%)
Oedema	9 (34.6%)
Pain	8 (30.8%)
Burning Sensation	6 (23.1%)
Stinging Sensation	5 (19.2%)
Itchiness	4 (15.4%)
Tightening Sensation	4 (15.4%)
Lakes of pus	2 (7.7%)

Patients with extra-cutaneous signs and symptoms of GPP flare (multi-response); N=26

Fatigue	**4 (15.4%)**
Fever	**4 (15.4%)**
Acute Respiratory Symptoms	**3 (11.5%)**
Anorexia	**3 (11.5%)**
Cheilitis	2 (7.7%)
Myalgia	2 (7.7%)
Nail Abnormalities	2 (7.7%)
Altered Mental Status	1 (3.8%)
Flush	1 (3.8%)
Joint Swelling and/or Pain	1 (3.8%)

- ✓ Most common cutaneous signs and symptoms were **pustules and scaling/erythema**.
- ✓ Regarding extracutaneous signs and symptoms, **fatigue and fever** were the higher reported.

Mean number of GPP flares: 0.55 flares per patient per year

5 (8.9%) deaths were reported: cardiac arrest, congestive heart failure, hip fracture and sepsis. 1 case with missing information.

Mean BSA of flares: 21.3% (19.1)

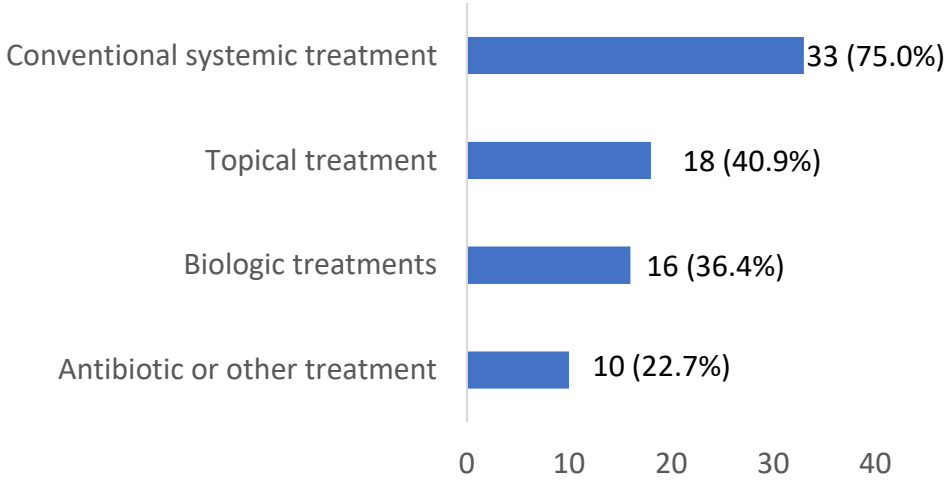
9 patients (16.1%) had at least 1 complication.

23 (41.1%) patients had at least 1 hospitalization

**Flare defined by physician based on medical records*

RESULTS- Treatment patterns: GPP flares

Drug-based treatment for GPP flares by group (multi-response); N=44



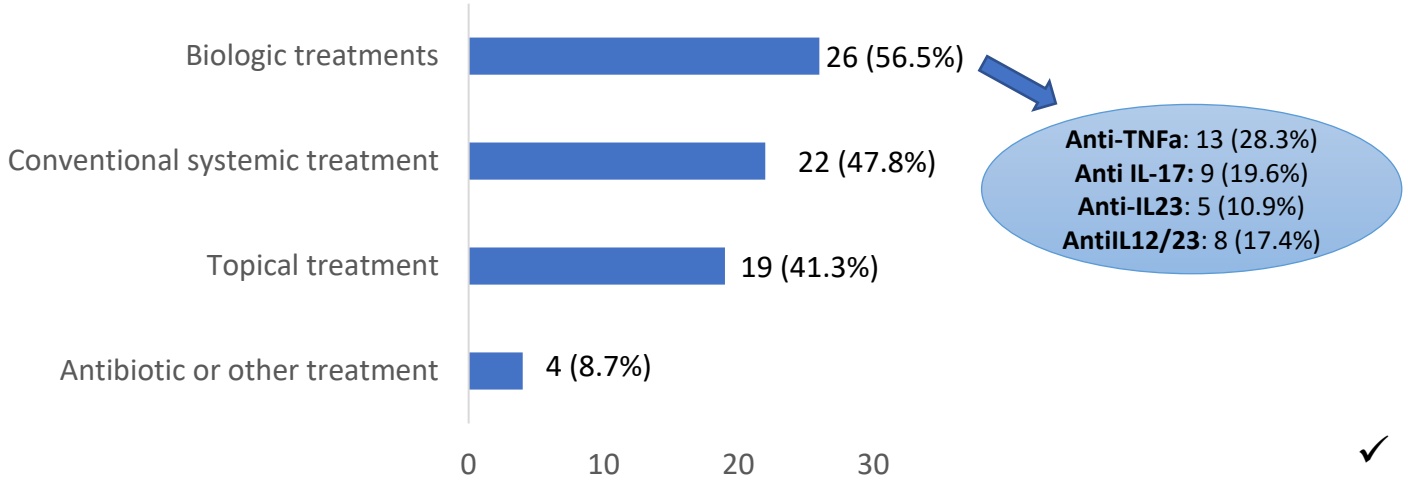
Drug-based treatments for GPP flares

Drug-based treatment (multi-response)	Number of patients (%)
Corticosteroids	**22 (50.0%)**
Cyclosporin	**15 (34.1%)**
Acitretin	**13 (29.6%)**
Antibiotics	7 (15.9%)
Methotrexate	7 (15.9%)
Secukinumab	5 (11.4%)
Etanercept	4 (9.1%)
Brodalumab	2 (4.6%)
Ixekizumab	2 (4.6%)
Vitamin D3	2 (4.6%)
Adalimumab	1 (2.3%)
Guselkumab	1 (2.3%)
Infliximab	1 (2.3%)
Ustekinumab	1 (2.3%)
Other	10 (22.7%)

✓ The most common **treatments used in flare** setting were **conventional systemics** (in 75% of patients): mostly **corticosteroids, cyclosporine and acitretin.**

RESULTS- Treatment patterns between flares

Drug-based treatment for GPP excluding flares by therapeutic group (multi-response); N=46



		Total
Patients with reasons for drug-based treatment termination (multi-response)	GPP clinical trial enrollment	0 (0 %)
	Lack of efficacy (clinician judgement)	26 (54.2%)
	Treatment- related adverse event	10 (20.8%)
	Death	3 (6.3%)
	End of flare	24 (50.0%)
	Other	17 (35,4%)
	- Change of doses	1 (2.1%)
	-Completed course	2 (4.2%)
	-Completed course-lack of febrile episodes	1 (2.1%)
	-Corticoid-ev	1 (2.1%)
	-End-prednisone	1 (2.1%)
	N valid	48 (86.7%)

Persistence by time drug-based treatment group for GPP (excluding flare)

(months)	Persistence (SE)*			
	Biological	Conventional systemic	Topical	Other
6	0.83 (0.05)	0.66 (0.09)	0.80 (0.18)	0.71 (0.09)
12	0.63 (0.07)	0.37 (0.09)	0.80 (0.18)	0.66 (0.09)
18	0.55 (0.08)	0.24 (0.08)	0.80 (0.18)	0.61 (0.10)
24	0.36 (0.08)	0.21 (0.08)	0.80 (0.18)	0.61 (0.10)

* According to Kaplan-Meier survival curve

- ✓ **In the follow up period, off-label biologics were used in 56.5%,** including anti-TNFa, anti-IL-17, anti IL12/23 and anti-IL-23.
- ✓ **No treatment pattern for biologics as there is no standard of care is defined for GPP.**
- ✓ **Persistence of treatments decreases over time and the main reason for discontinuation was lack of efficacy (54.2%)**

CONCLUSIONS

- ✓ This is the **first multicenter study in Spanish GPP patients** (N=56), providing new evidence on this rare and severe inflammatory skin disease.

- ✓ The **profile of patients** included in our study was patients in **the fifth decade, with family and personal history of plaque psoriasis, stress, exposure to smoke and other comorbidities as the main potential triggers**.

- ✓ The **development of flares was frequent with a mean of 0.55 flares/patient/year,** although there was variability between patients (0-4).

- ✓ Regarding the burden of GPP, **most of patients presented comorbidities and required hospitalization at some point of follow-up**. 9 patients (16.1%) had at least 1 complication and 5 deaths (8.9%) were reported. Death causes included sepsis and cardiovascular disease.

- ✓ **There is no standard of care in GPP management.** The most common **treatments** used in **flare** setting were **conventional systemic**: mostly corticosteroids, cyclosporine and acitretin although without a clear pattern for flare management. In the **follow up period**, **off-label biologics** were used, including anti-TNFa, anti-IL-17, anti IL12/23 and anti-IL-23. The main cause of treatment discontinuation was **lack of efficacy**.