Switching to Long-Acting Injectable Antiretroviral Therapy: Experience from our Clinic

D. TOMASONI

SCIENTIFIC RETREAT

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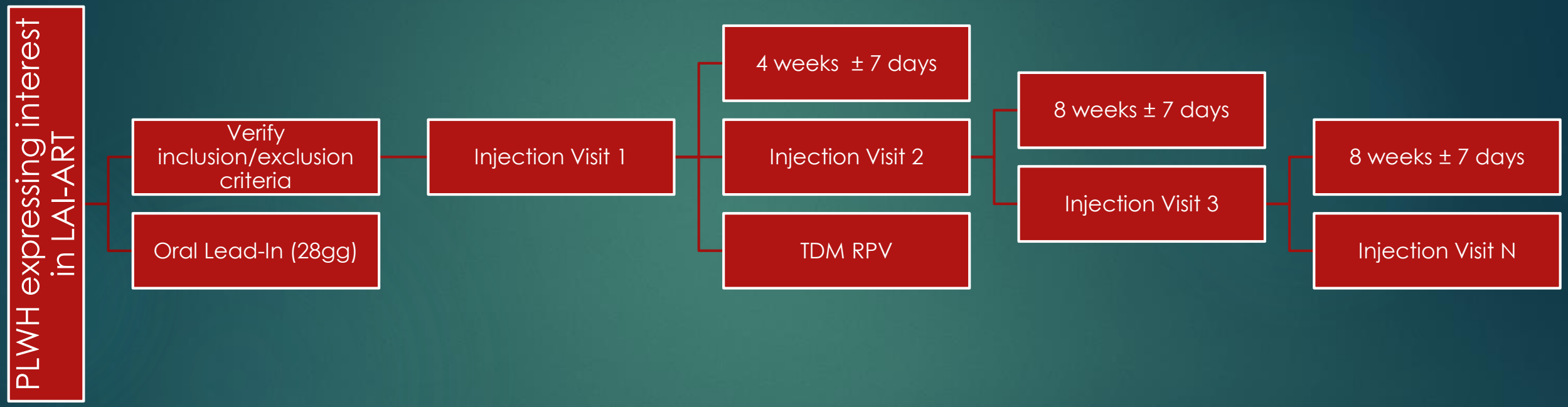
LAI-ART: from Clinicians to PLWH

Main clinical requirements

- Virologically suppressed adults (HIV-1 RNA <50 copies/mL)
- No present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class
- No contraindicated concomitant therapies (rifampicine, carbamazepine, dexhamethasone...)
- No HBV co-infection (HBsAg negative)
- Not recommended during pregnancy

Patient's need and perspective

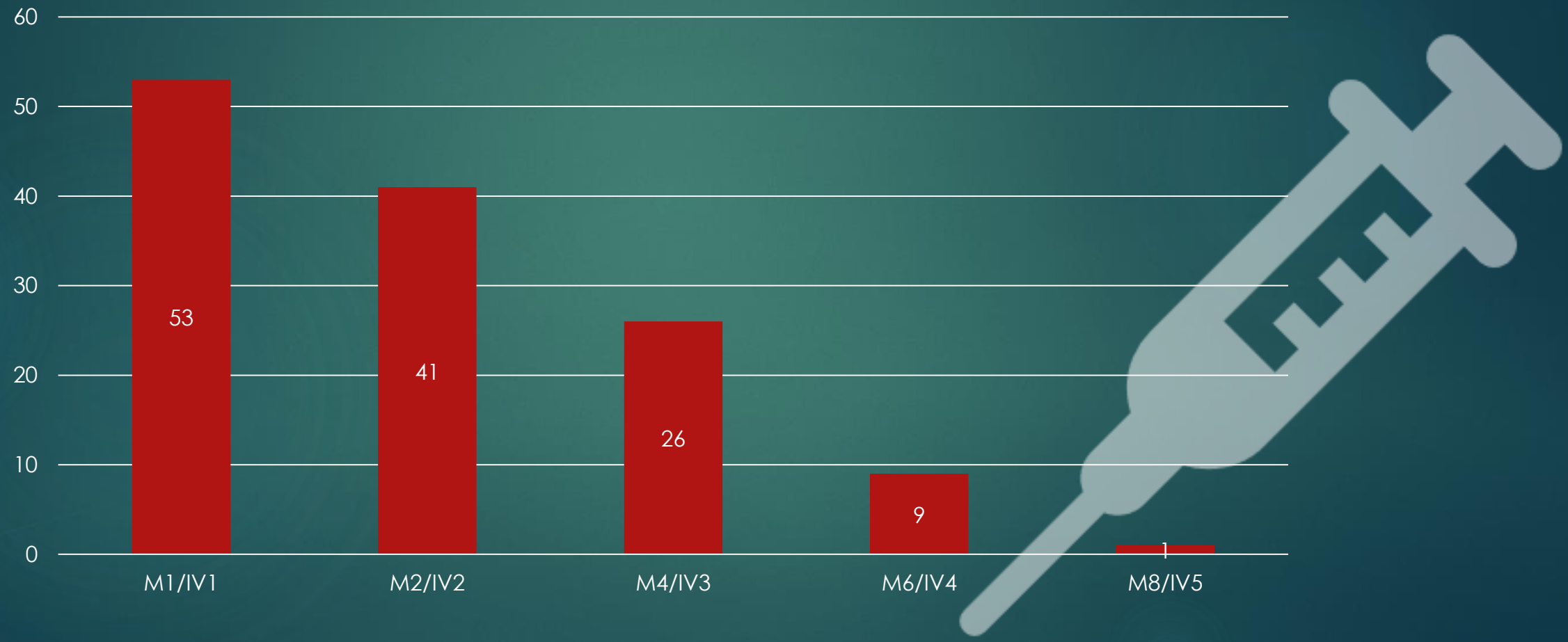
- Has the patient expressed an interest in less-frequent dosing?
- Could the patient benefit from long-acting treatment due to:
  - Concerns about disclosure?
  - Anxiety with staying adherent to oral ARVs?
  - The impact of daily medication as a reminder of their status and associated negative memories?
- Is the patient able to commit to every 2-month visits?
- Does the patient understand the importance of adhering to the schedule?


PLWH expressing interest in LAI-ART
Verify inclusion/exclusion criteria
Oral Lead-In (28gg)
Injection Visit 1
4 weeks ± 7 days
Injection Visit 2
TDM RPV
8 weeks ± 7 days
Injection Visit 3
8 weeks ± 7 days
Injection Visit N

FLOW-CHART-CLINICA

	T0 M1 IV1	M2 IV2	M3	M4 IV3	M5	T6 M6 IV4	M7	M8 IV5	M9	M10 IV6	M11	T12 M12 IV7
Demografica	X											
HIV-related data	X											
Emocromo e biochimica	X	X		X		X		X				X
HIV-RNA	X	X		X		X		X				X
CD4, CD4/CD8	X			X		X						X
HBV-DNA (in tutti gli HBcAb pos)	X					X						
Esami metabolici (a digiuno)	X					X						X
TDM RPV (*se bassa alla IV2)		X		X*								
BMI, misure antropometriche	X	X		X		X		X		X		X
Eventi clinici	X	X		X		X		X		X		X
HIVTSQs	X					X						
HIVTSQc		X										
PIN (dopo 1 settimana)	X	X		X		X		X		X		X
HIVDQoL	X					X						X
HIV-stigma	X					X						X
PHQ-9	X					X						X
PRELIEVO BANCA (3 viola)	X					X						X
CAMPIONE FECI BANCA	X					X						X

130 Injections so far!



Demographics

Population

- 53 patients received at least 1 injection as of May 22nd
- 83% males
- Median age 47 y.o. (39-53)
- 25% foreigner
- 66% MSM, 1 vertical transmission

Comorbidities

- Hypertension/ CVD 13%
- Obesity 7.6%
- Other comorbidities (COPD/asthma, Cancer, Hyper/hypothyroidism, Diabetes): <5% each.
- **AIDS 13%**

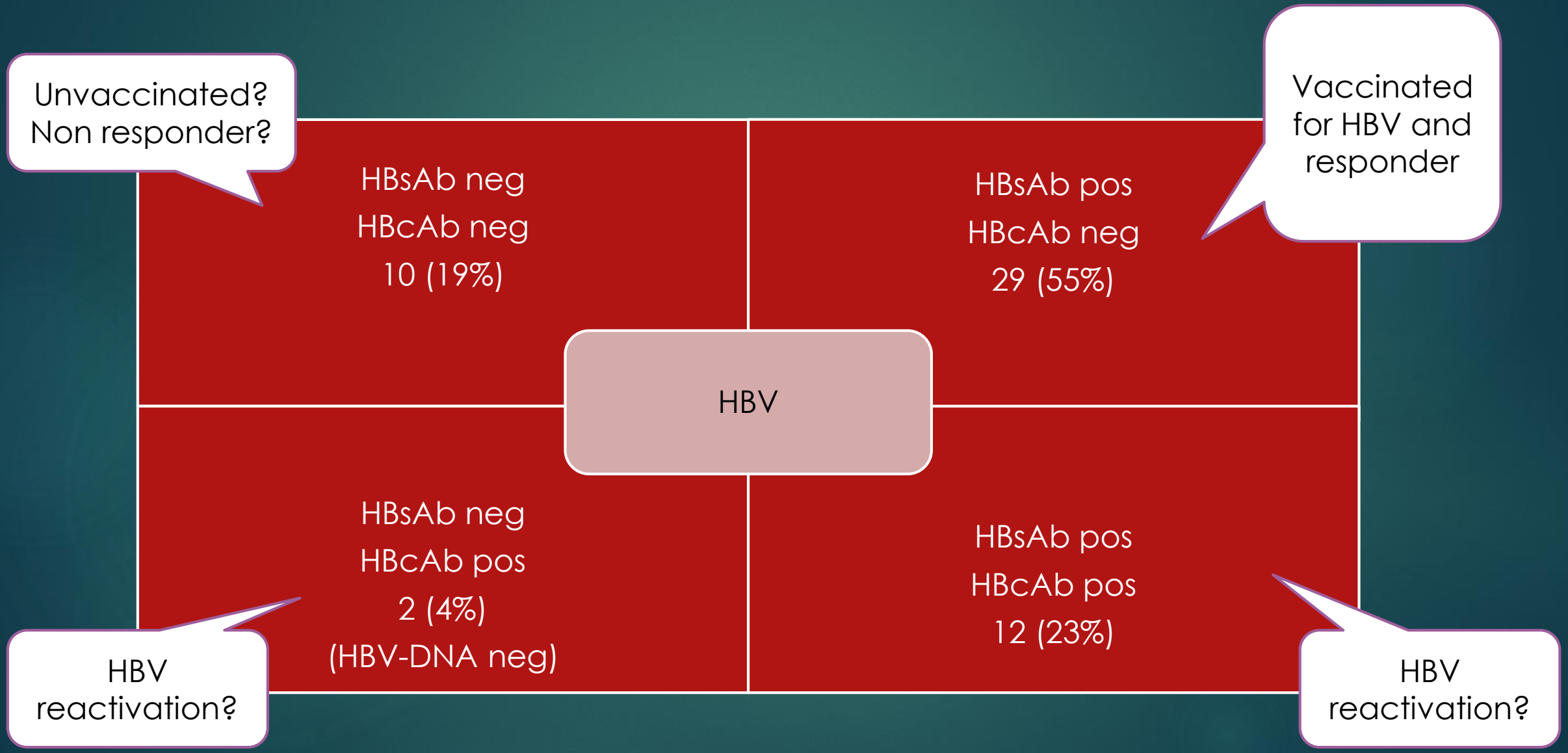
Co-infection

- HCV previous/treated 5 (9.4%)
- 55% HBV vaccinated
- 27% HbcAb pos
- 2 HBcAb pos, HBsAb neg > **all** HBV-DNA neg

HAART History

- Median of 2 (2-4) previous HAART lines
- Median years of HAART: 9 (6-13)
- 60% GRT available; mostly B subtype

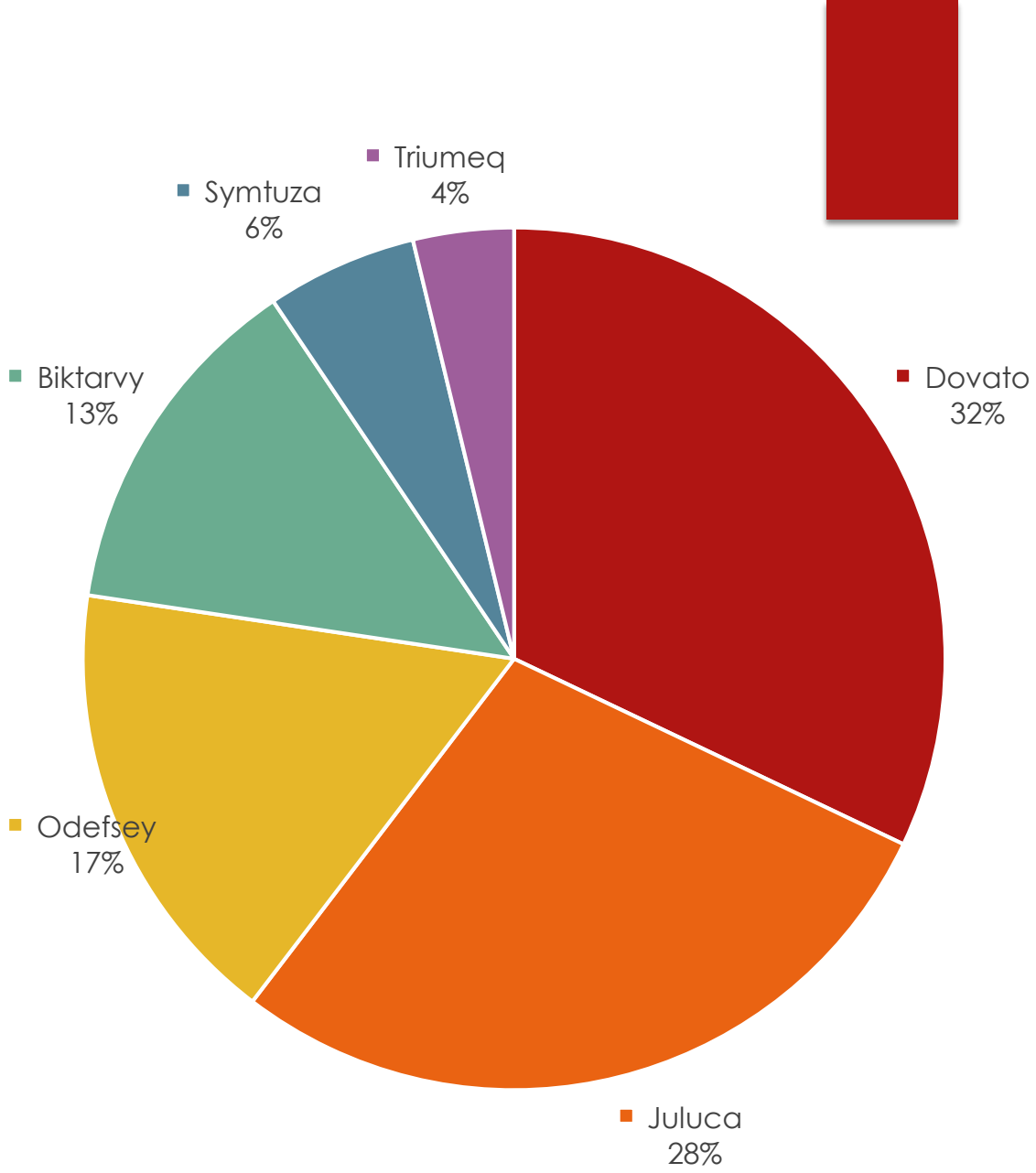
Focus on HBV co-infection



Focus on Previous HAART

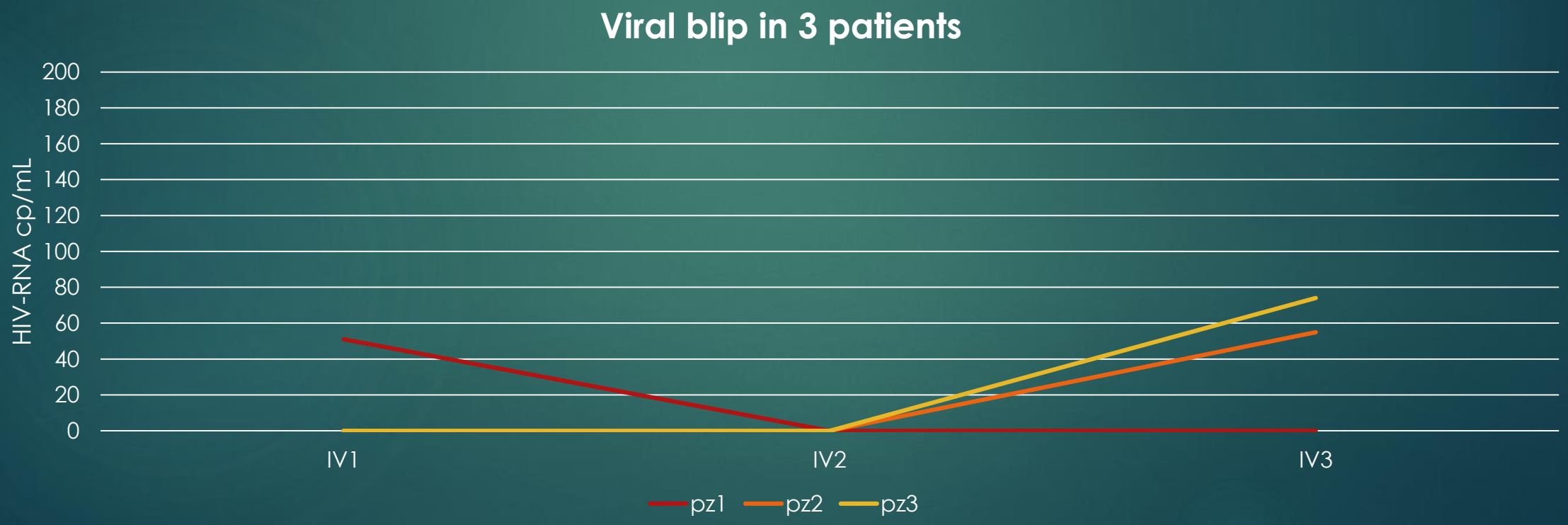
- Previous INSTI exposure: 80%
- Previous RPV exposure: 55%

- Oral Lead-in: 60%



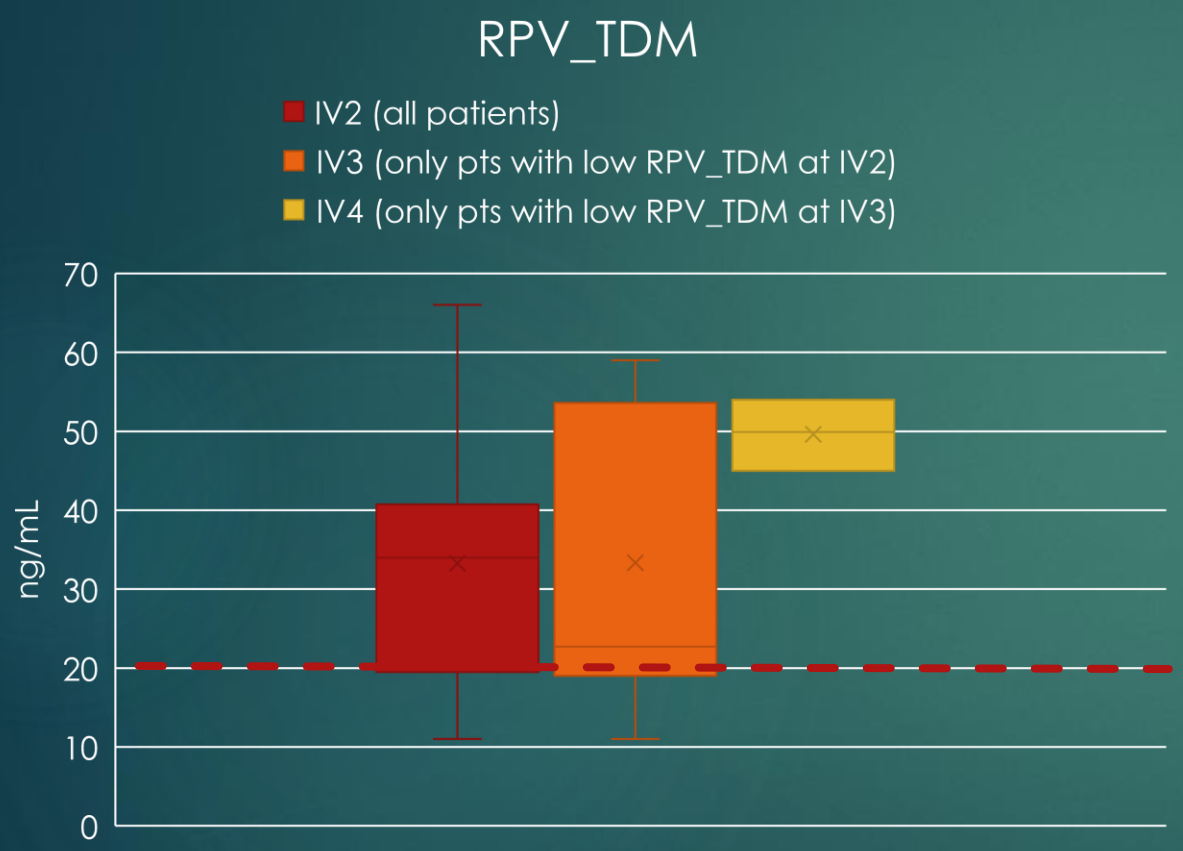
Treatment efficacy

- No Treatment Interruption
- No Virological Failure (two consecutive HIV-RNA>50cp/mL or a single HIV-RNA>400cp/mL)
- Only 3 patients had viral blip (a single HIV-RNA>50cp/mL)



TDM Rilpivirine

6 patients (16%) had TDM RPV <20ng/mL at IV2



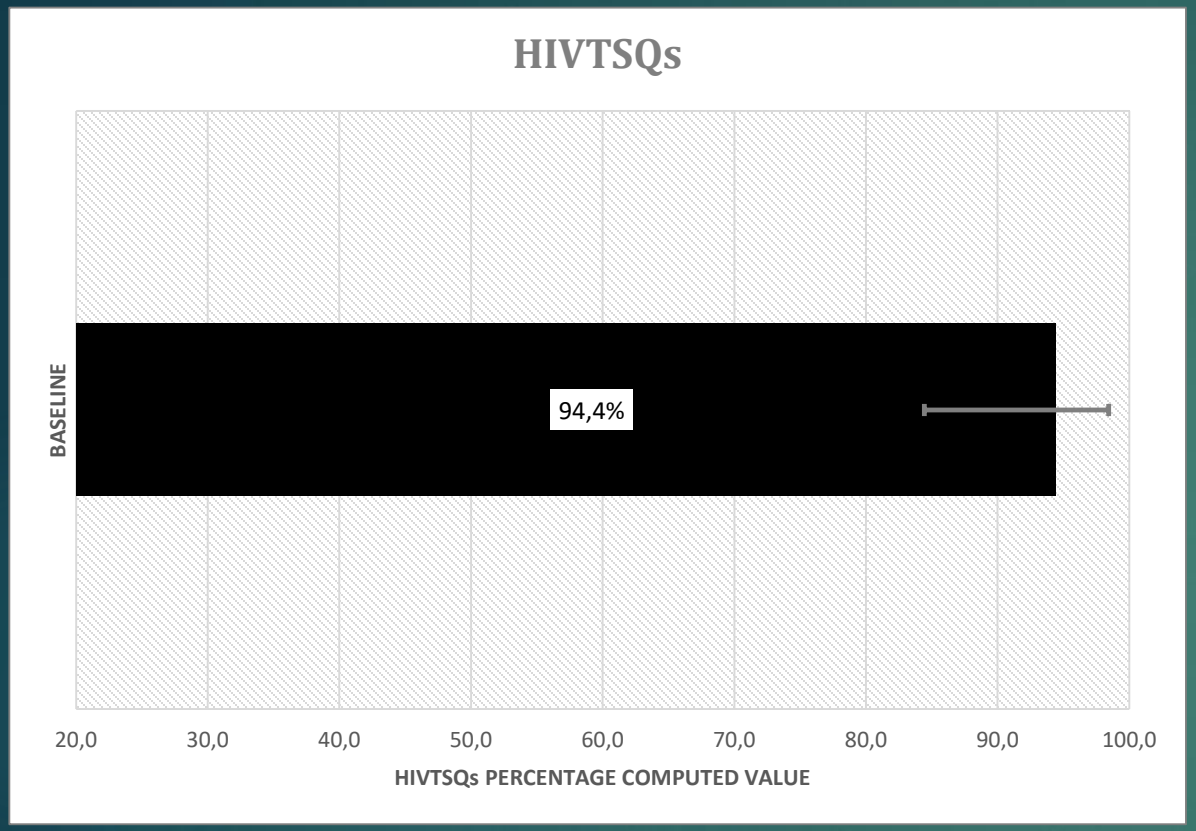
No linear correlation between:

- TDM RPV and BMI
- TDM RPV and hip circumference

Patients with BMI>30Kg/m2 or hip circumference>100cm have an increased risk of TDM RPV<20ng/mL

Univariate	OR TDM RPV <20ng/mL at IV2	p
BMI >30 Kg/m2	7.0 (IC95% 0.7-64)	0.08
Hip circumference >100cm	13 (IC95% 1.7-95)	0.01

Treatment Satisfaction: HIVTSQs/c questionnaires



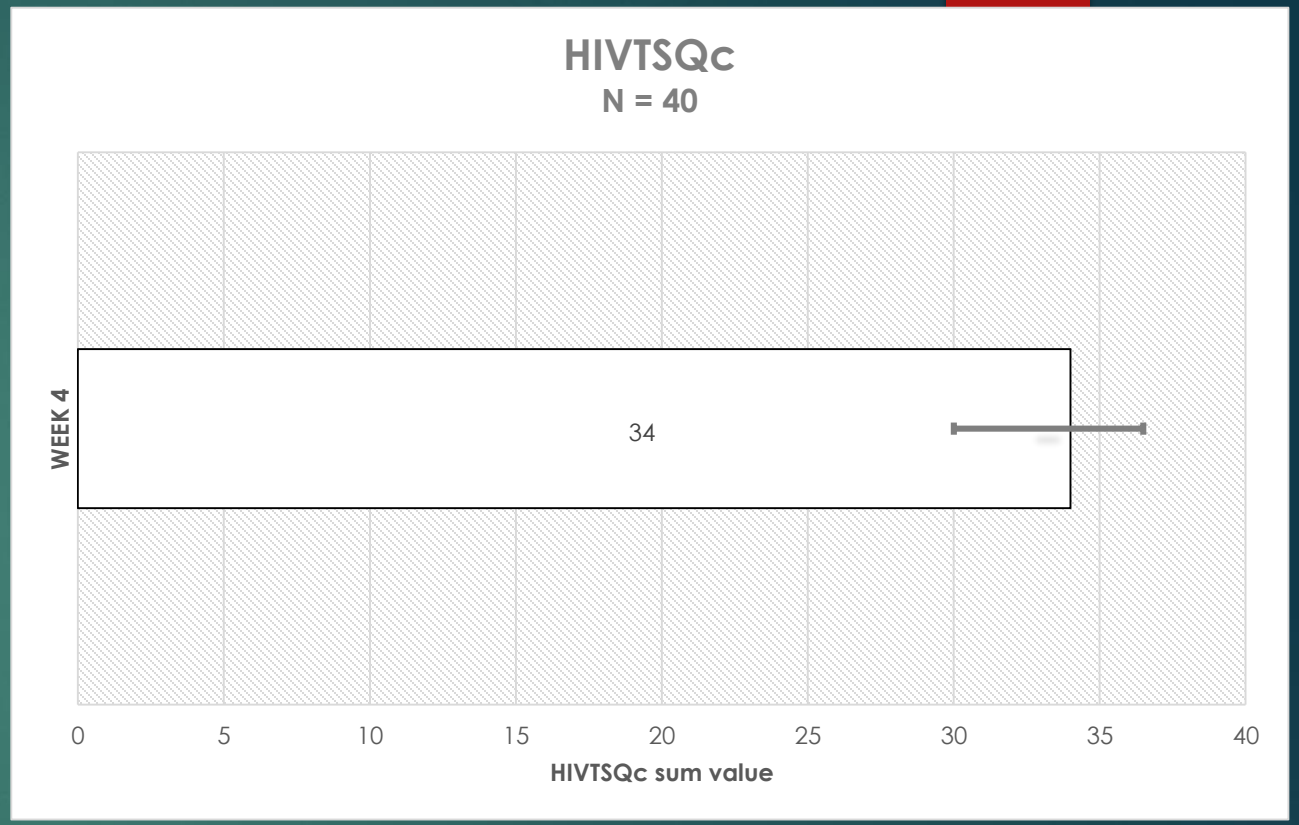


Figure 1A: The HIVTSQs questionnaire results were computed in percentage values ranging from 0% (answer 0 "completely dissatisfied" given to all the items) to 100% (answer 6 or "completely satisfied" given to all the items). The median of the HIVTSQs percentage computed was 94,4%, with an IQR of 83,7-98,6%. **Figure 1B**: the HIVTSQc questionnaire was computed with the algebraic sum of each item composing the interview, ranging from -36 (answer -3 or "completely worse change" given to all the items) to + 36 (answer + 3 or "completely better change" given to all the items). The median of the HIVTSQc total value was 34, with a IQR of 30-36. Notably, all the patients in the study totalized a positive total value in the questionnaire, with a minimum value of 8 and a maximum value of 36, corresponding to the third quartile. **This outcome communicates that the switch to an injectable treatment administered every 8 weeks determined a remarkable improvement in the patient's perception of the HAART.**

Adverse Events: PIN Questionnaire

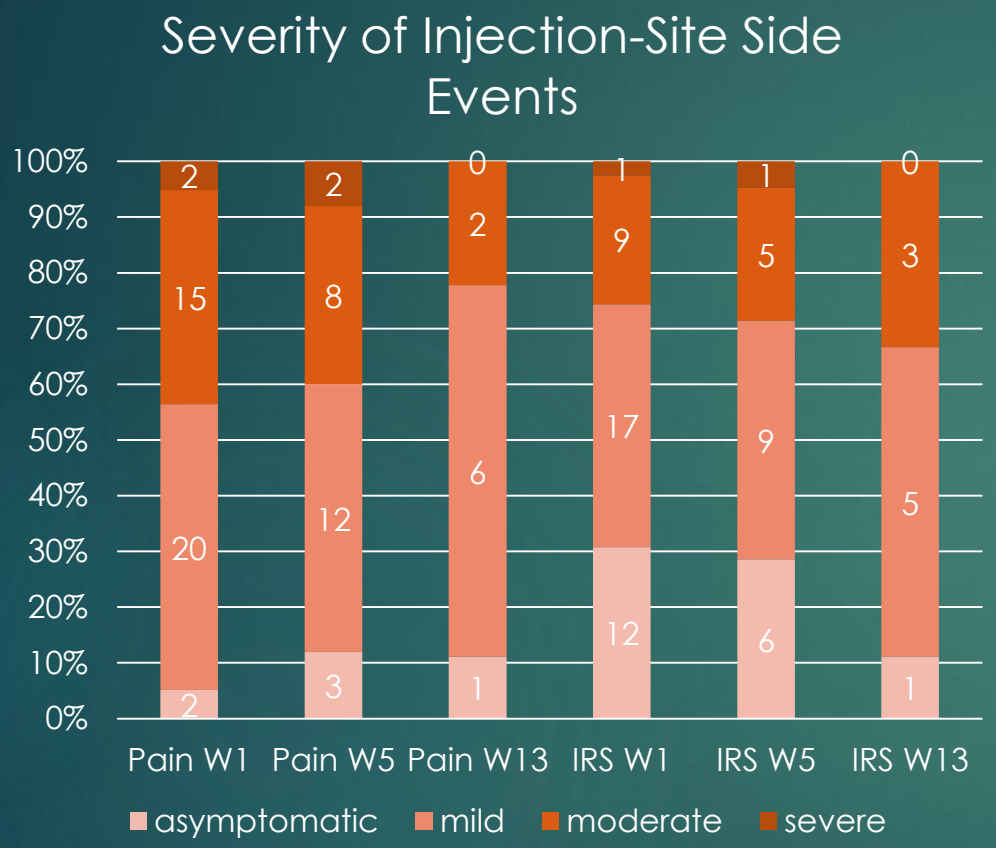


Figure 2A: graphic distribution of the incidence of injection site side effects, divided in pain and injection-related symptoms (redness, swelling, itching, stiffness and bruises) and their severity.

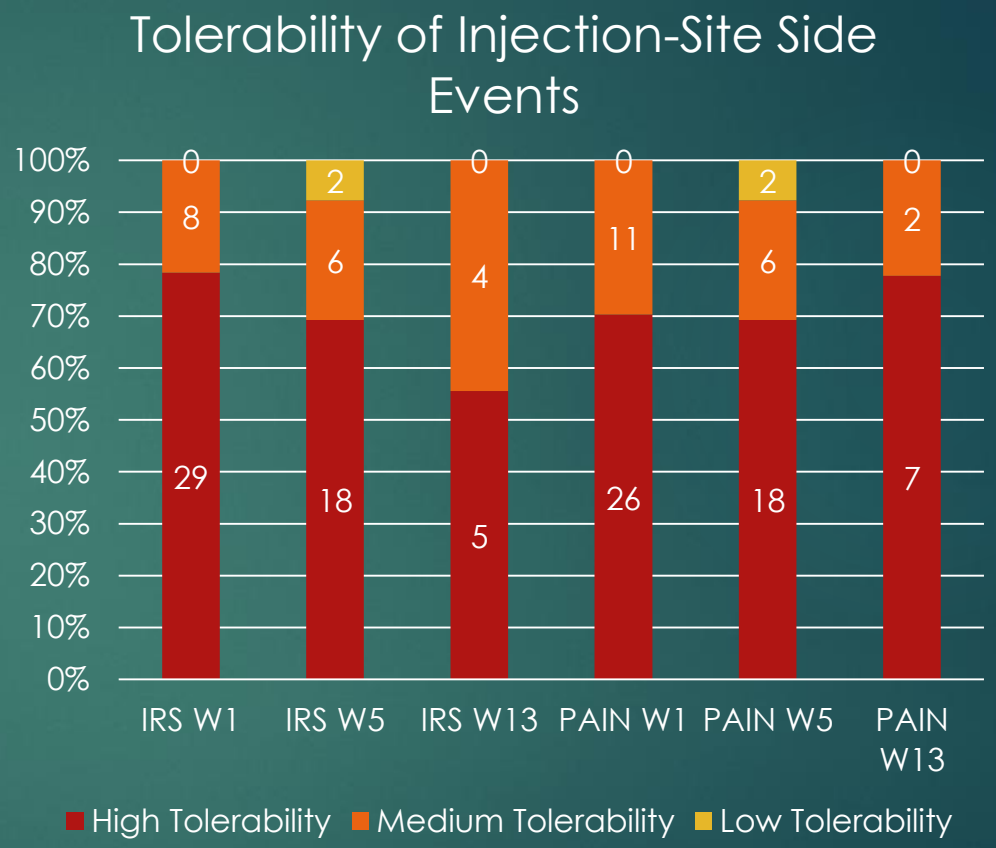


Figure 2B: graphic representation of the overall tolerability of injection site side effects.

Future directions

- Surveillance of treatment interruption and virological failure, identify potential risk factors
- Surveillance on adverse events.
- Patients Reported Outcomes for M6/IV4
- Monitoring HBV-DNA for all HBcAb-positive PLWH and improve HBV vaccination for all susceptible
- Metabolic impact: weight gain, lipid profile, Homa-IR, CVD risk
- Collection of biological specimens (blood samples, fecal samples)

Aknowledgements