

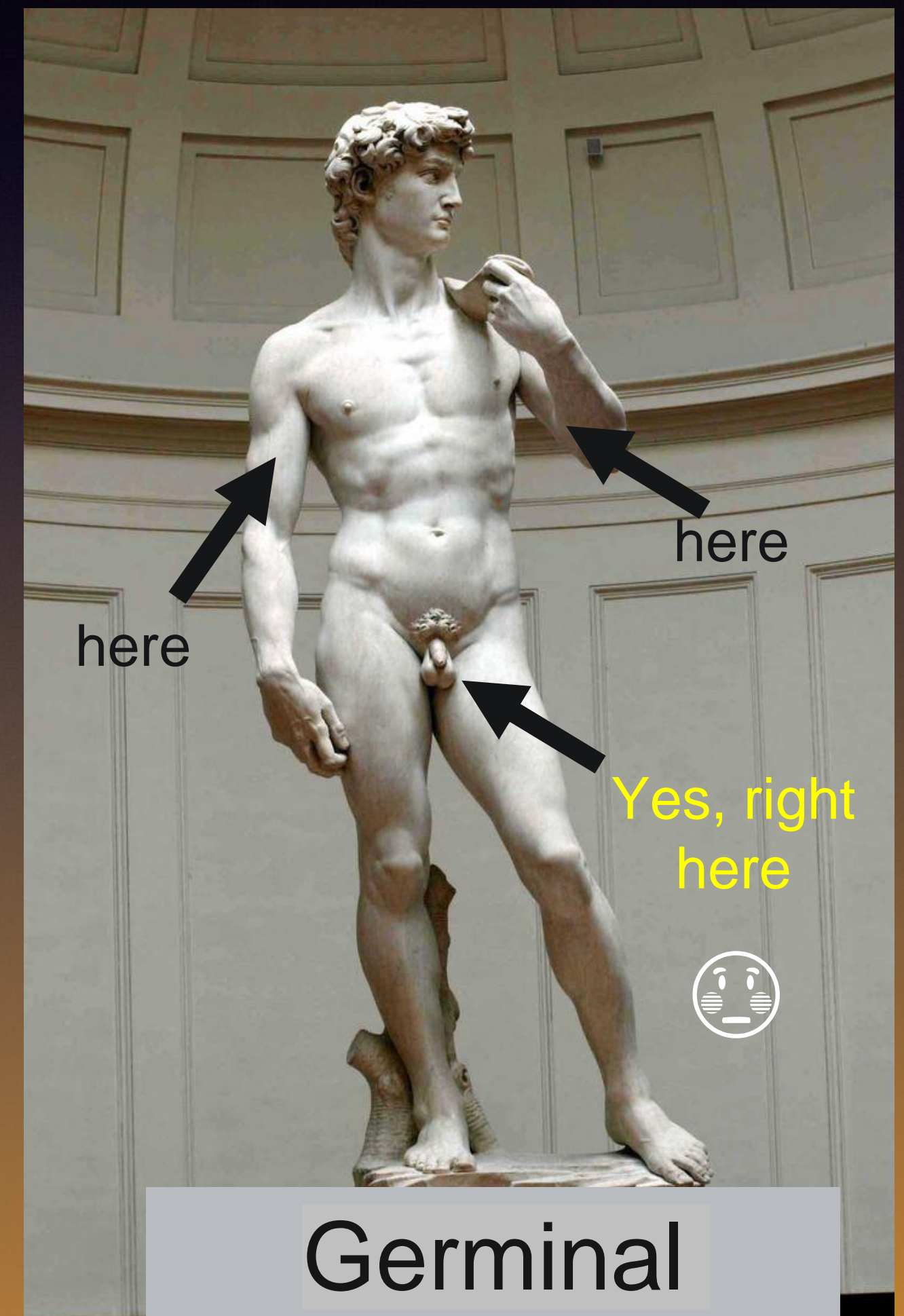
CRYODESMO-01

Final results

Kurtz JE, Buy X, Deschamps F, Sauleau E, Bouhamama A, Toulmonde M, Honoré C, Bertucci F, Brahmi M,
Chevreau C, Duffaud F, Gantzer J, Garnon J, Blay JY, Gangi A

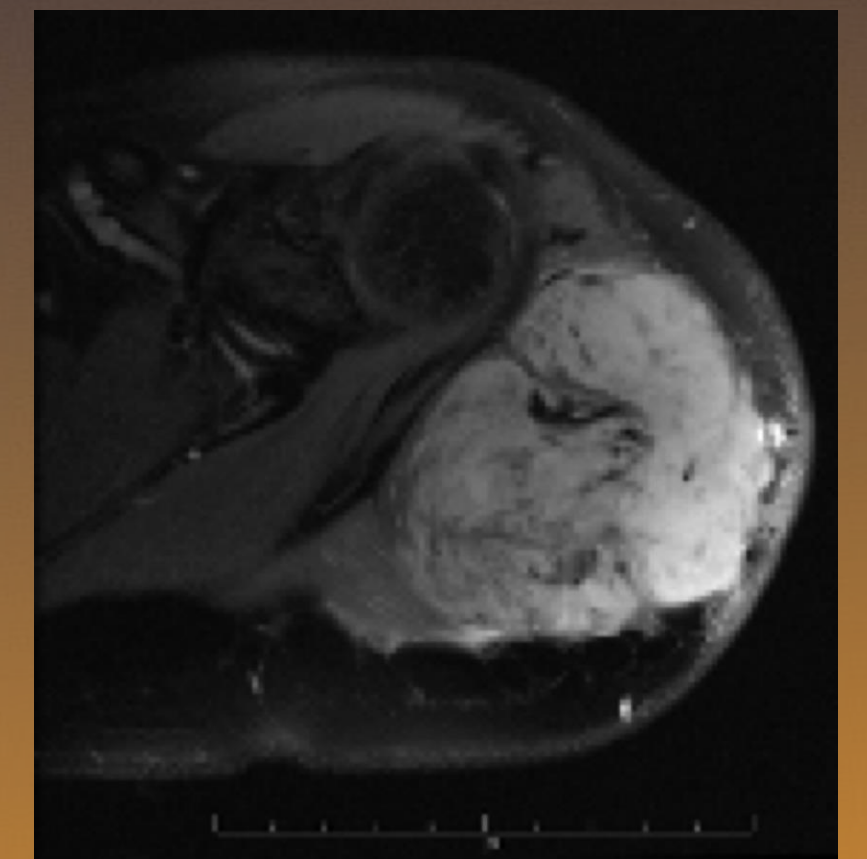
BACKGROUND

- Rare tumor (2-4 /million/year) from musculoaponeurotic structures
- Ubiquitous, unpredictable behavior, pain, disability, rarely death
- Can be either sporadic (beta-catenin mutations) or inherited (APC mutations) in FAP syndromes

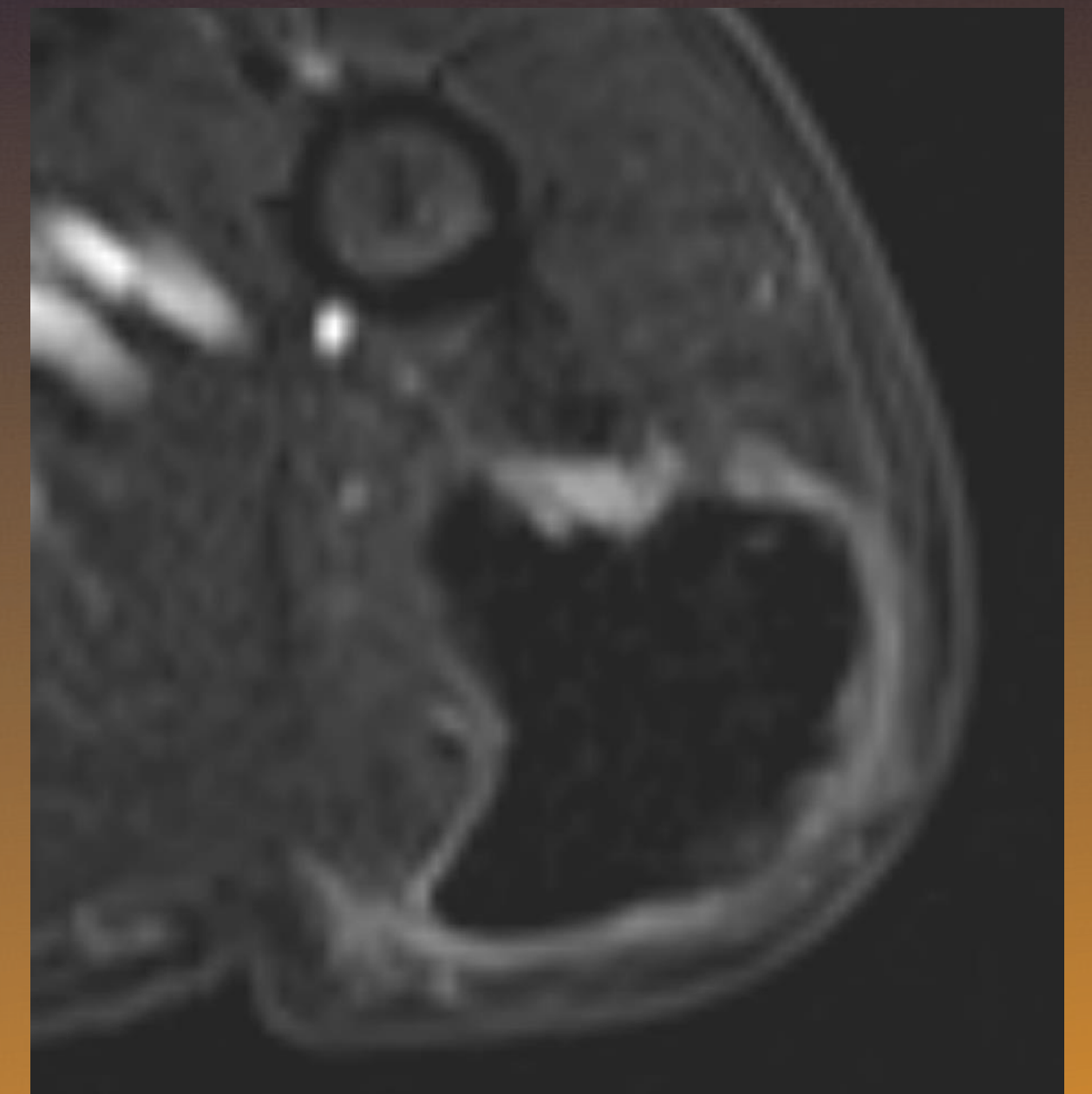
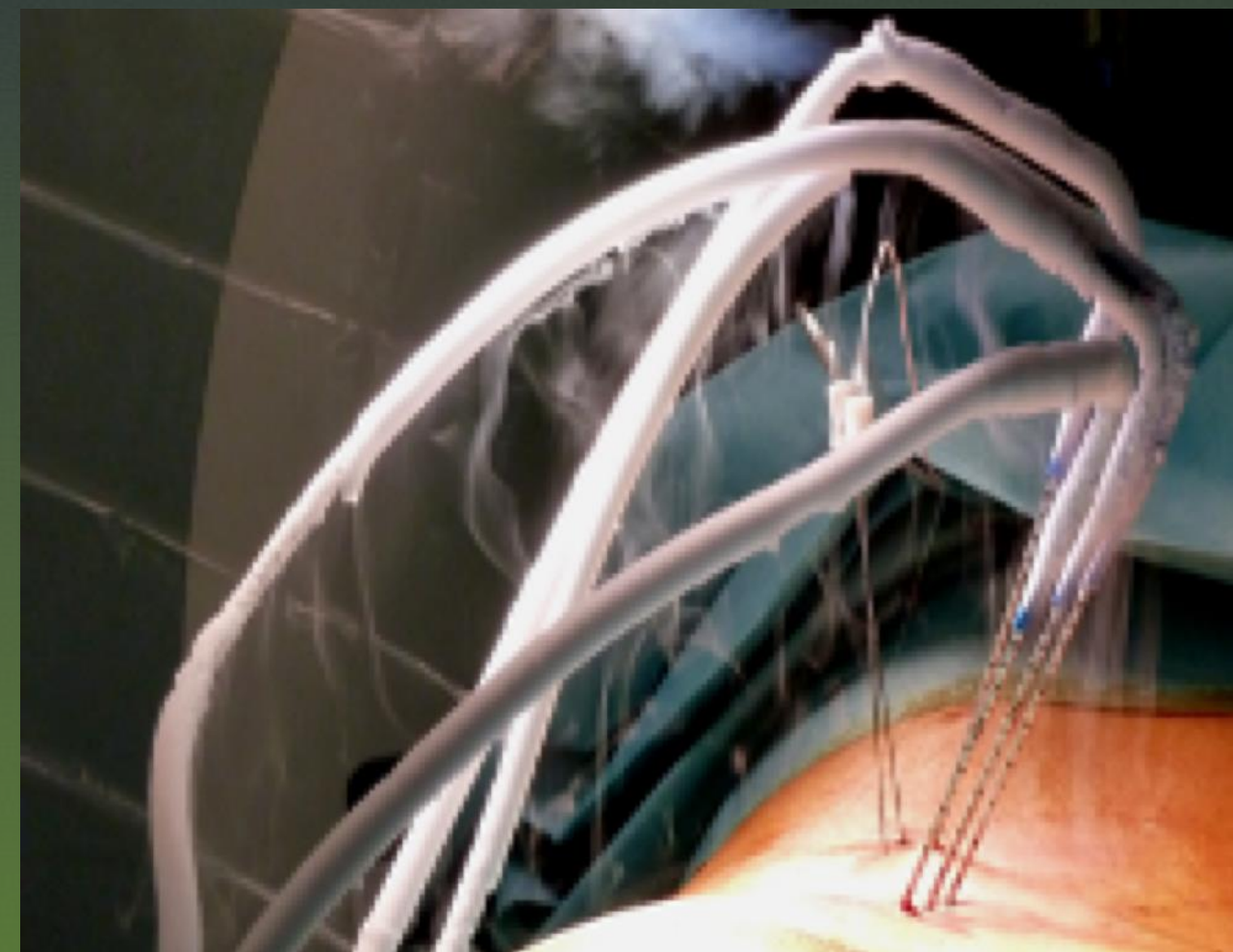
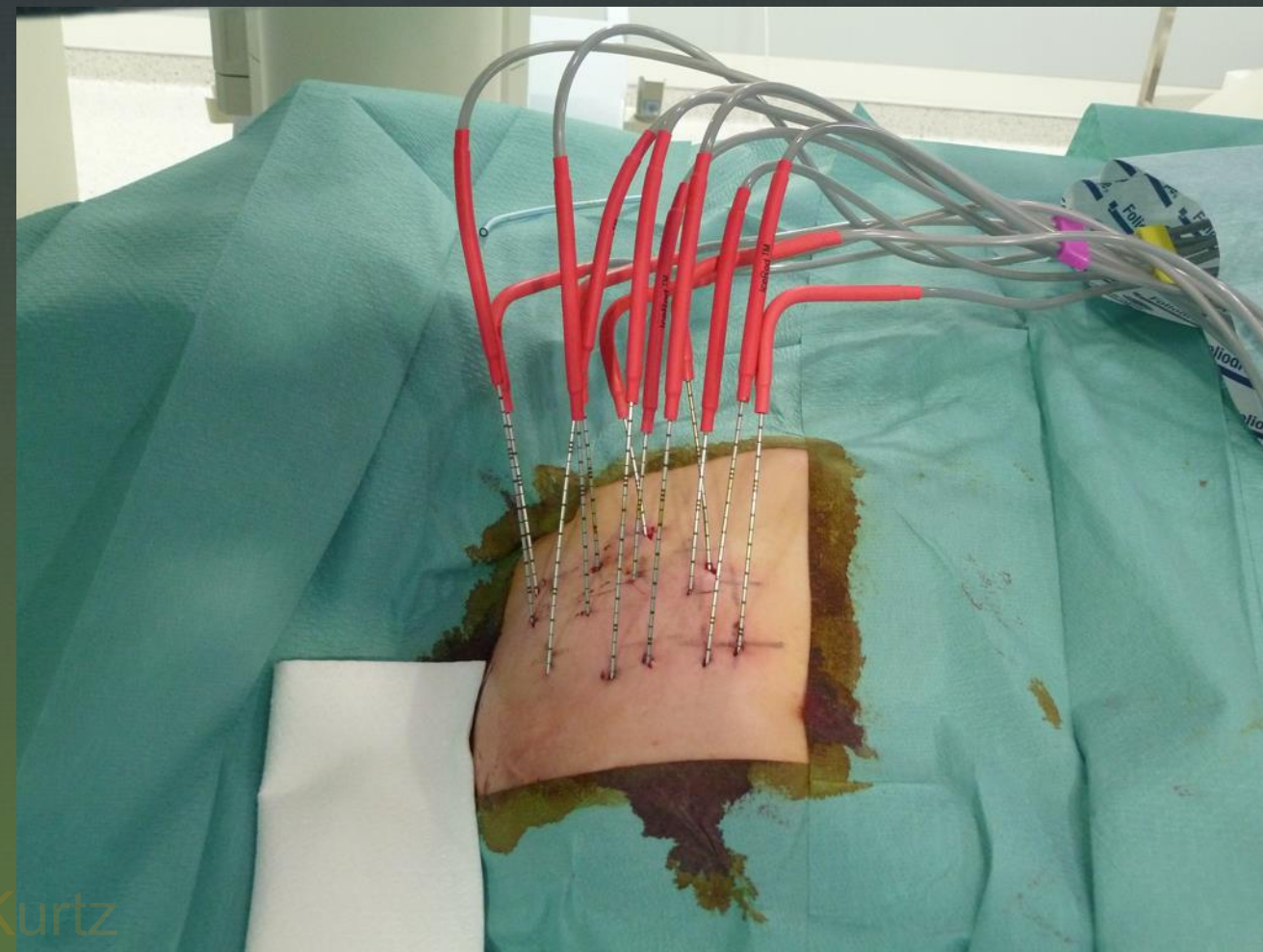
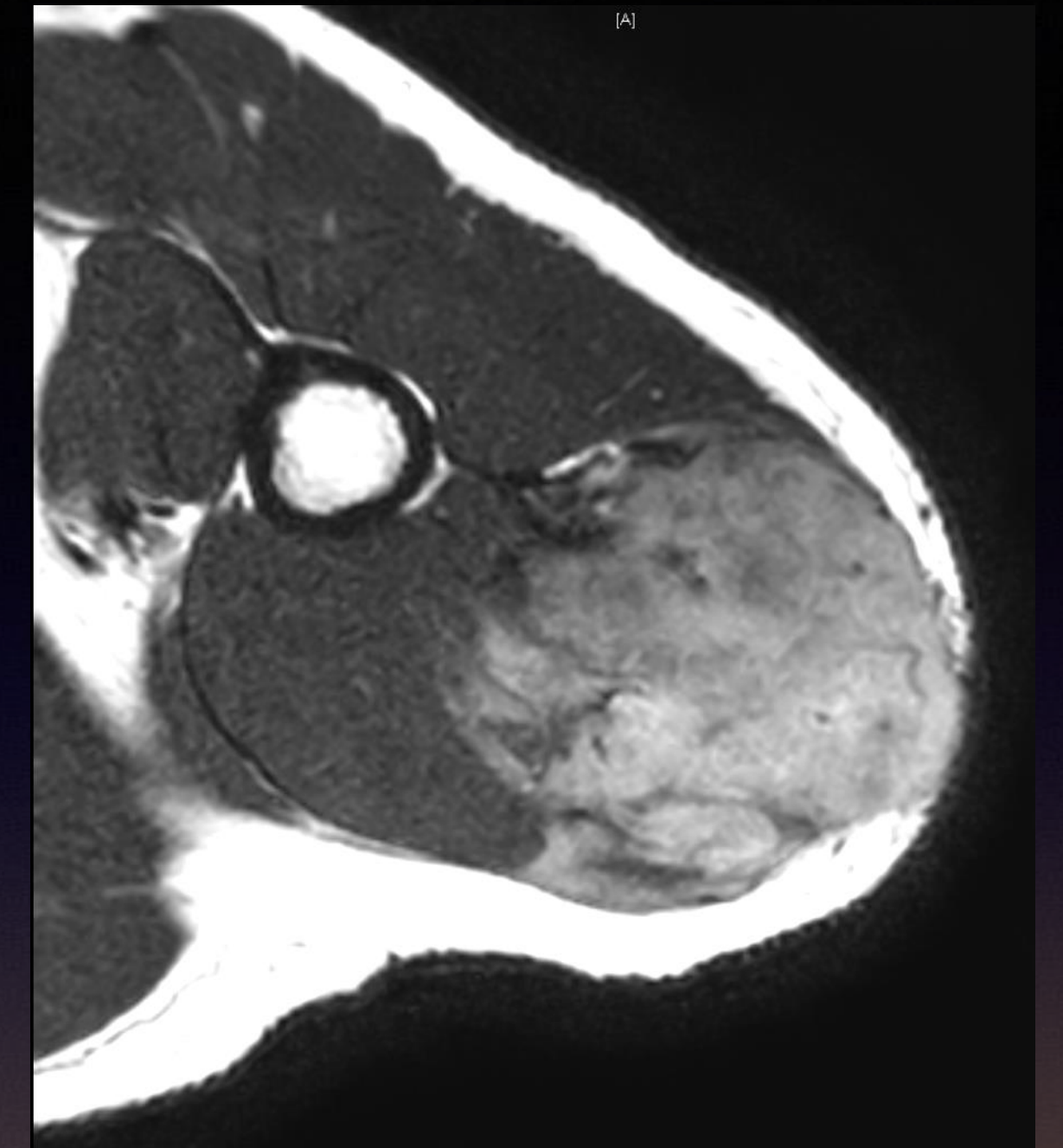
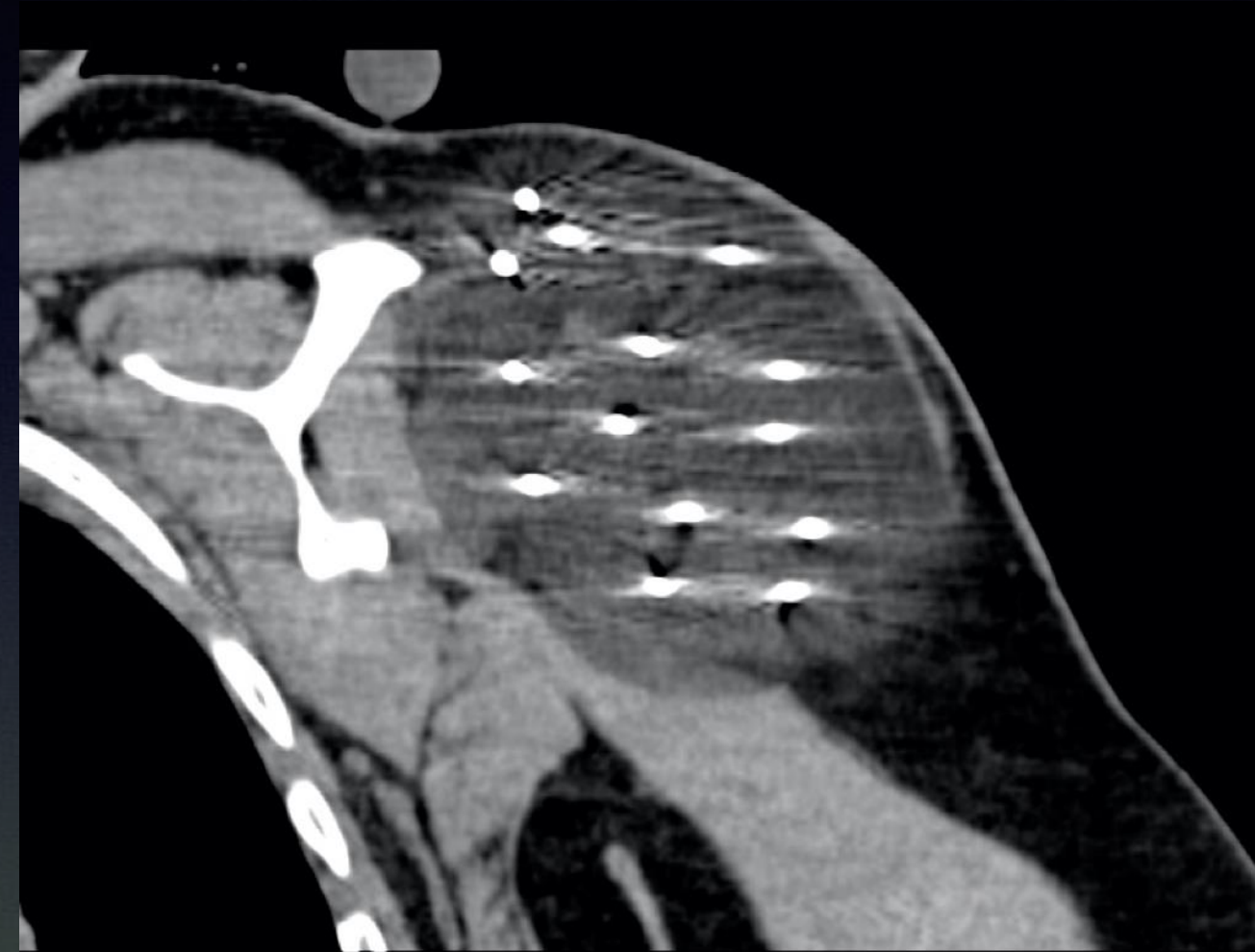


TREATMENTS

- Watchful waiting in expert centers
- NSAIDs, tamoxifen, low-dose chemotherapy (vinorelbine) or IV (MTX/Vindesine)
- Sorafenib or pazopanib (antiangiogenic drugs)
- Radiation therapy
- A clear unmet need



CRYOABLATION

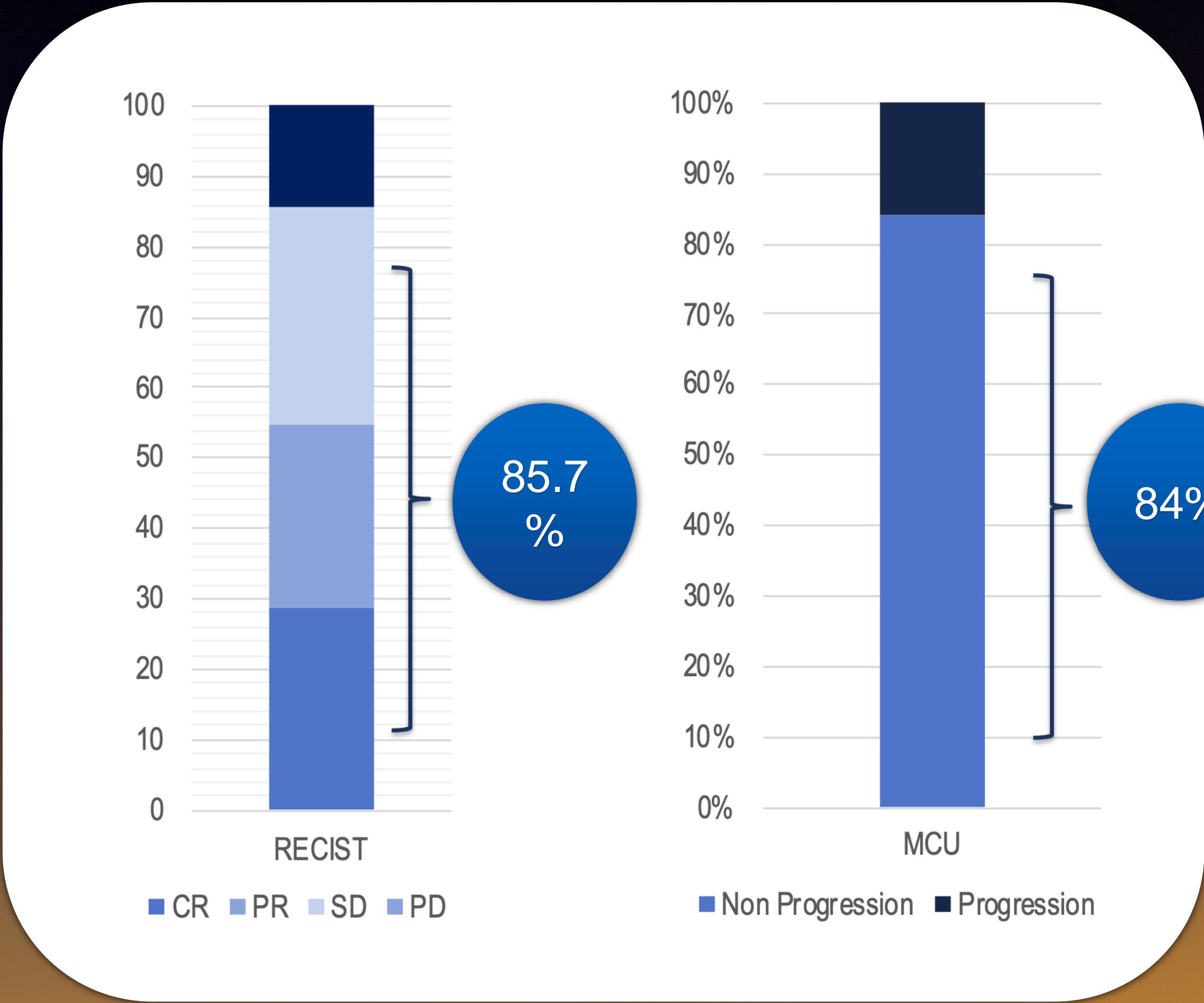


THE CRYODESMO-01 STUDY

- First prospective trial of cryoablation in DTs ever
 - Adult extra-abdominal DT progressing after ≥ 2 lines of medical therapy
 - Primary endpoint: non-progression rate @12 months
 - Secondary endpoints: QOL and pain, safety
-
- Non resectable DT; ≥ 2 lines of adequate medical therapy, progression or SD with symptoms
 - At least 90 % of tumor ablation deemed feasible; measurable lesion (mRECIST) w/ MRI (gadolinium)

RESULTS: EFFICACY/PRIMARY ENDPOINT

	N [range or %]
Nb of patients	50
Mean Age (range)	41 [19-73]
Sex ratio M/F	0.78
Tumor Volume	111cm ³ [0.6 – 1068]
Tumor location	
Limbs	18 (36%)
Trunk	30 (60%)
Neck	2 (4%)



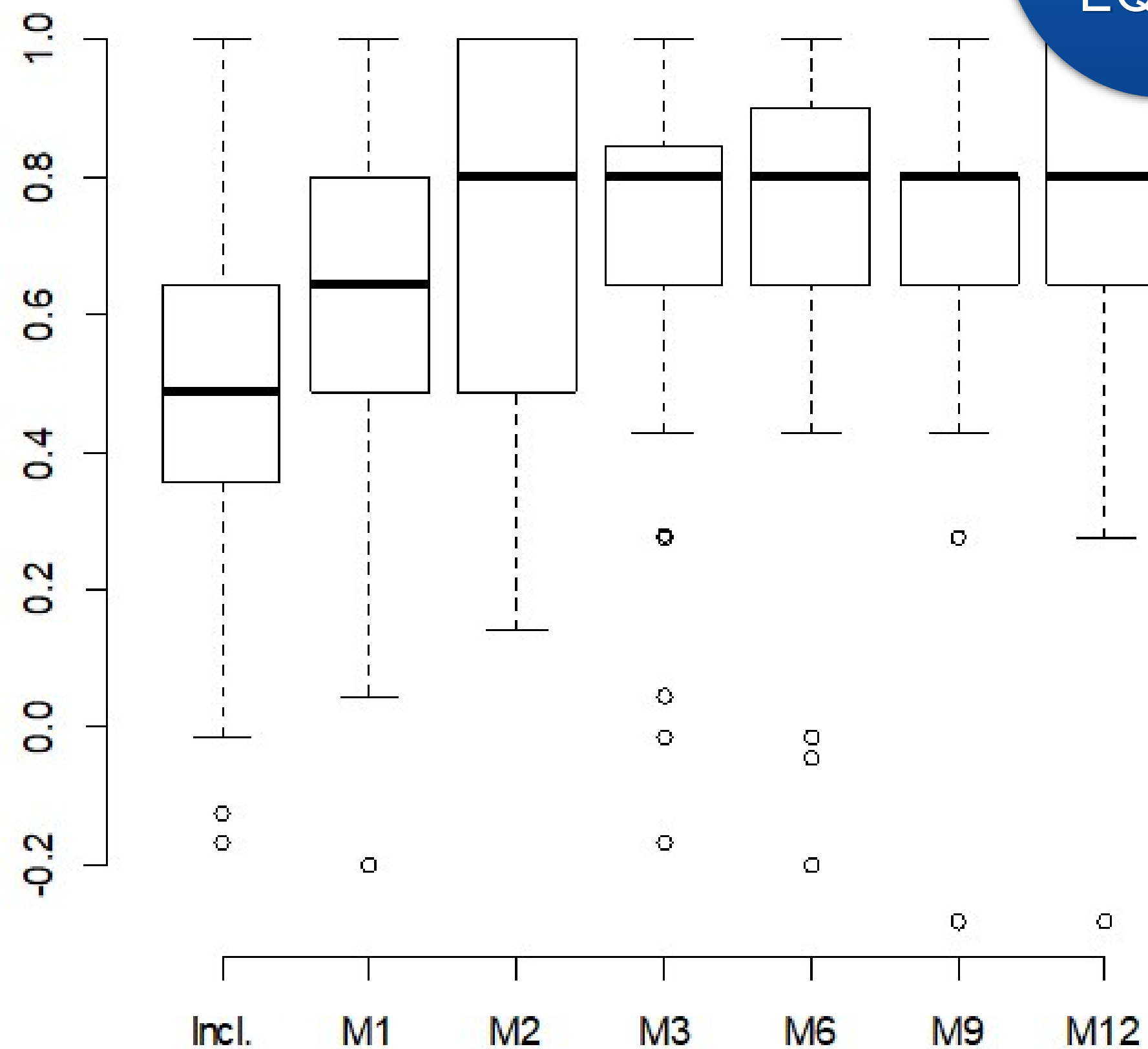
SIDE EFFECTS

Side effect	All grades (N, %)		Grade 1-2 (n, %)		Grade 3-4 (n, %)	
Pain	30	21,6	29	20,9	1	0,7
Paresthesia/Dystesthesia/neural impairment	22	15,8	20	14,4	2	1,4
Edema	21	15,1	21	15,1	0	0
Musculo-skeletal impairment	11	7,9	11	7,9	0	0
Skin burn	8	5,8	7	5,0	1	0,7
Rhabdomyolysis (CPK increase)	8	5,8	1	0,7	7	5,0
Bleeding	4	2,9	2	1,4	2	1,4
Asthenia/fatigue	6	4,3	5	3,6	1	0,7
Elevation of liver transaminases	3	2,2	2	1,4	1	0,7
Cutaneous fistula	3	2,2	2	1,4	0	0
Anemia	2	1,4	2	1,4	0	0
Pleural effusion	2	1,4	2	1,4	0	0
Hyperleucocytosis	2	1,4	0	0,0	2	1,4
Malaise	2	1,4	1	0,7	1	0,7
Nausea	2	1,4	2	1,4	0	0
Pruritus	2	1,4	1	0,7	0	0
Stroke	1	0,7	0	0	1	0,7
Erythema	1	0,7	1	0,7	0	0
Fever	1	0,7	1	0,7	0	0
Hypokaliemia	1	0,7	1	0,7	0	0
Acute renal failure	1	0,7	0	0	1	0,7
Bowel stoppage	1	0,7	0	0	1	0,7
Ocular dryness	1	0,7	1	0,7	0	0
Heart rythm disorder	1	0,7	0	0	1	0,7

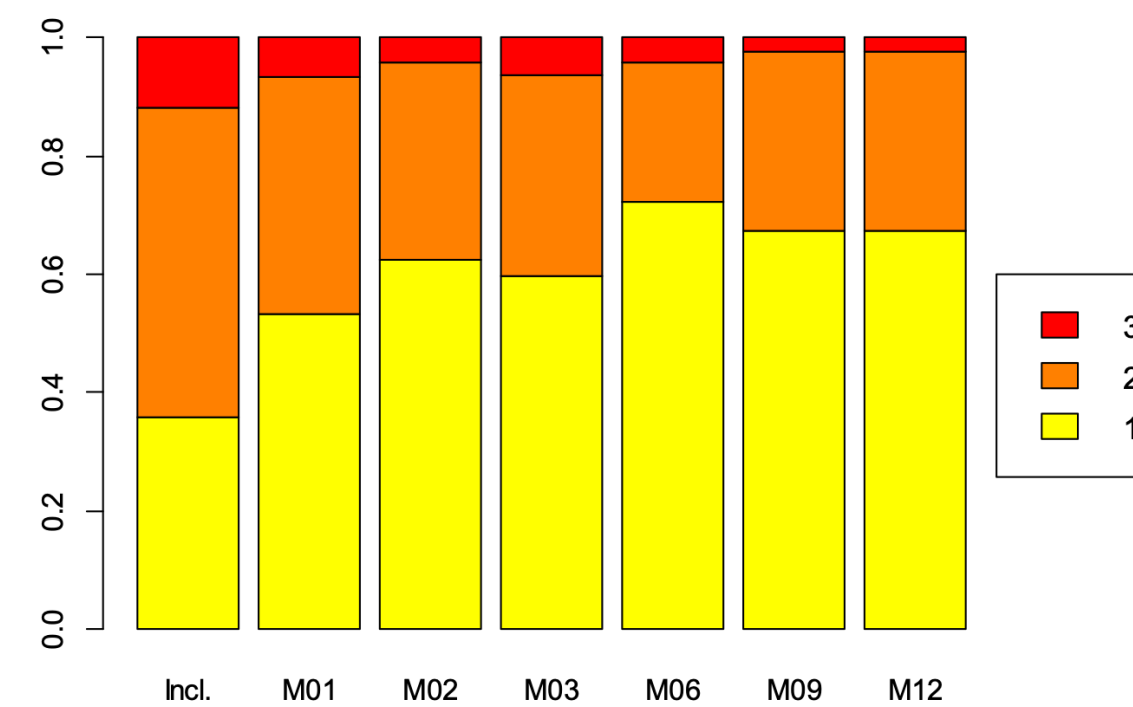
- Most of side effects (79%) expected from prior experience and were mild/moderate
- Pain, transient nerve palsy, edema, rhabdomyolysis, skin burn
- All manageable and recovered

QUALITY OF LIFE

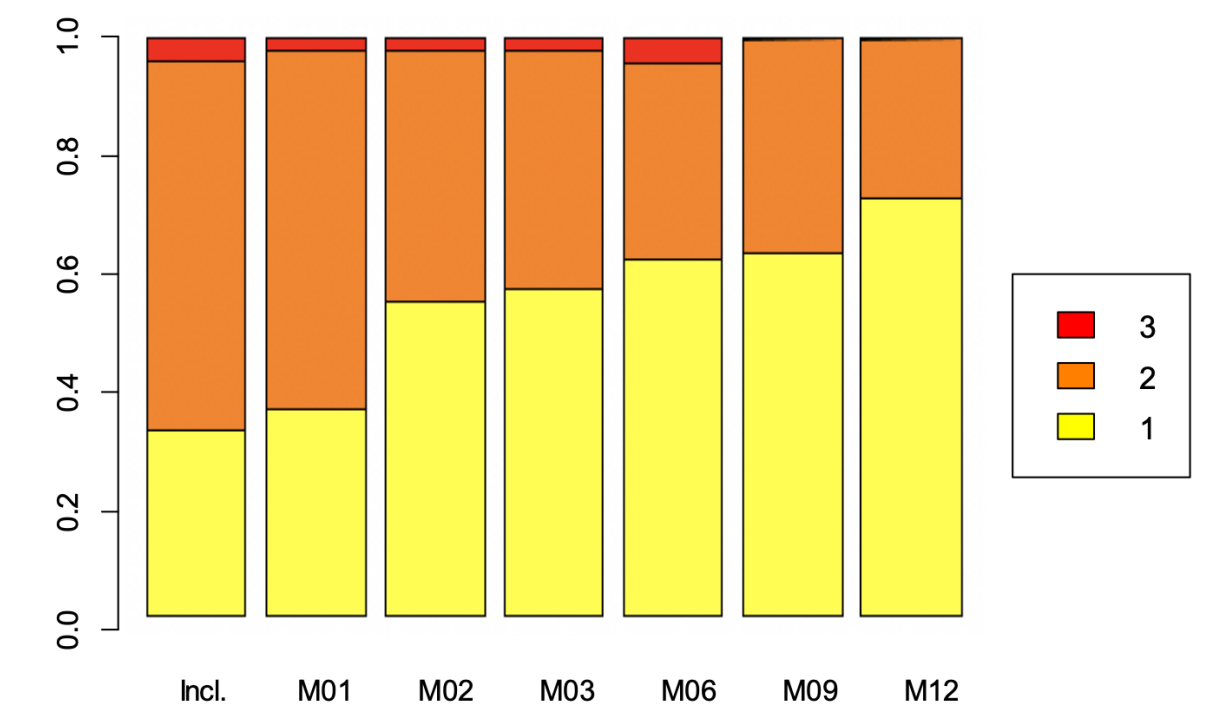
QOL
(utility,
EQ5D)



- Increase in QOL scores over time
- Less anxiety & depression
- Increase in daily activities

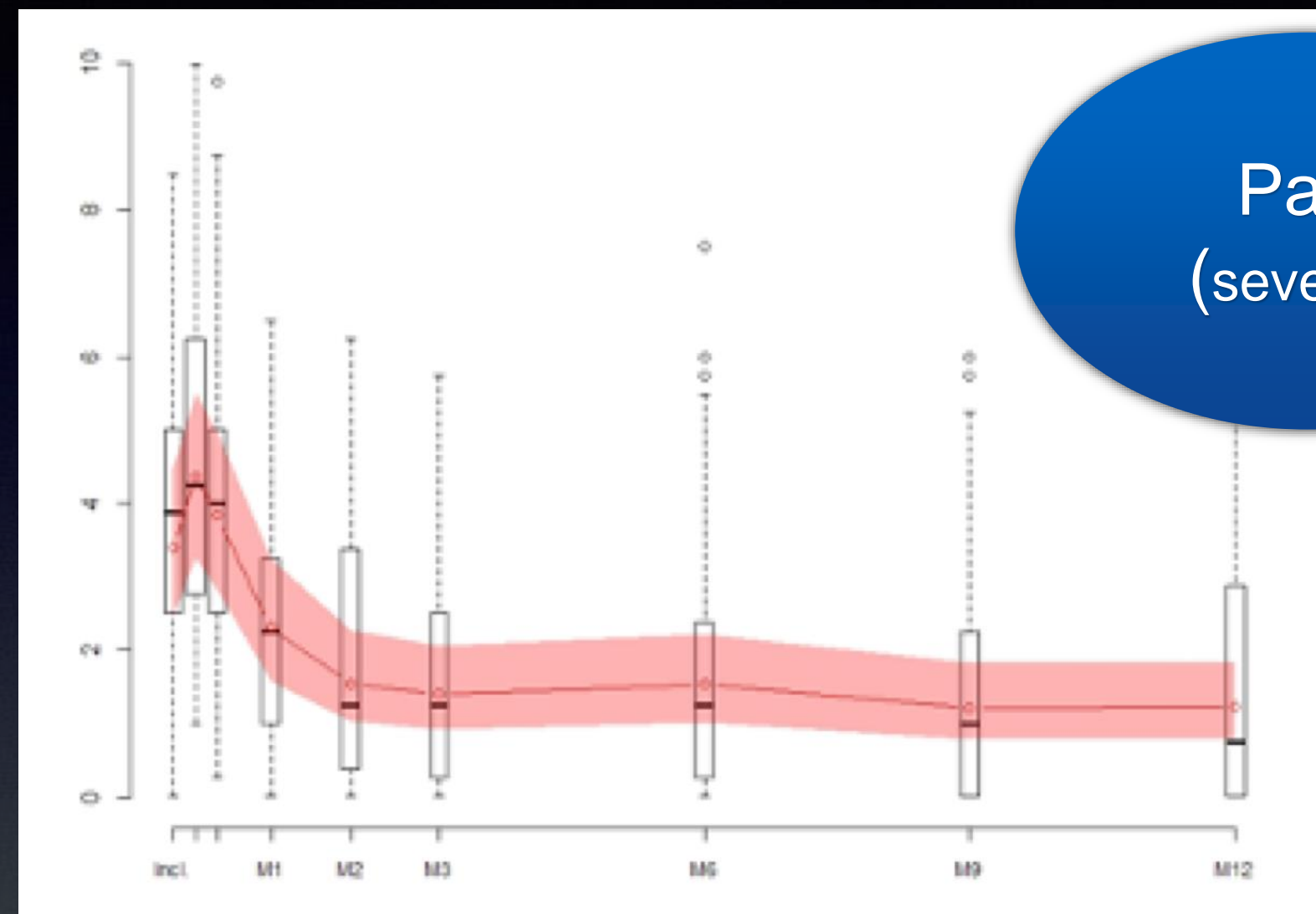


A & D

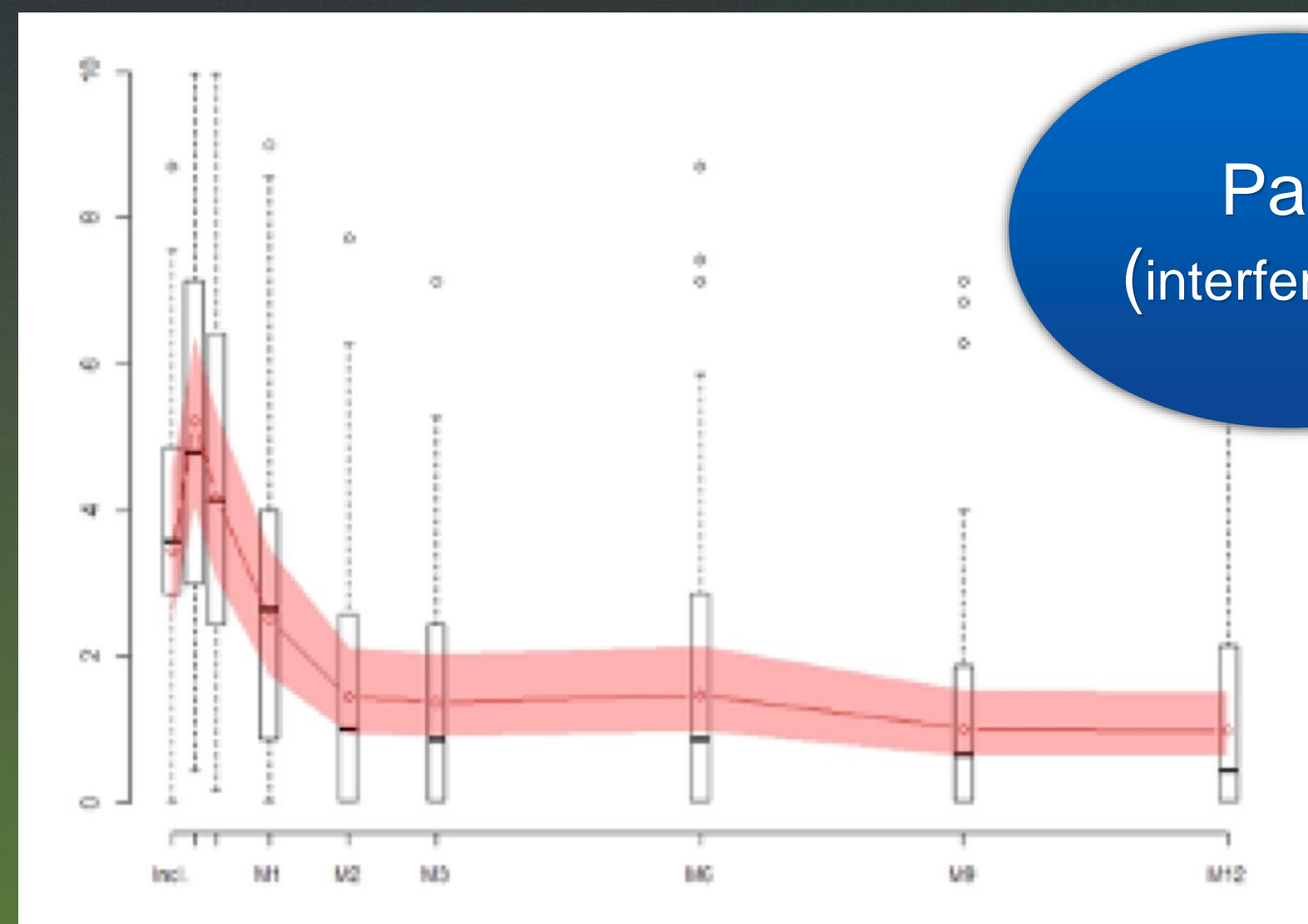


Activités

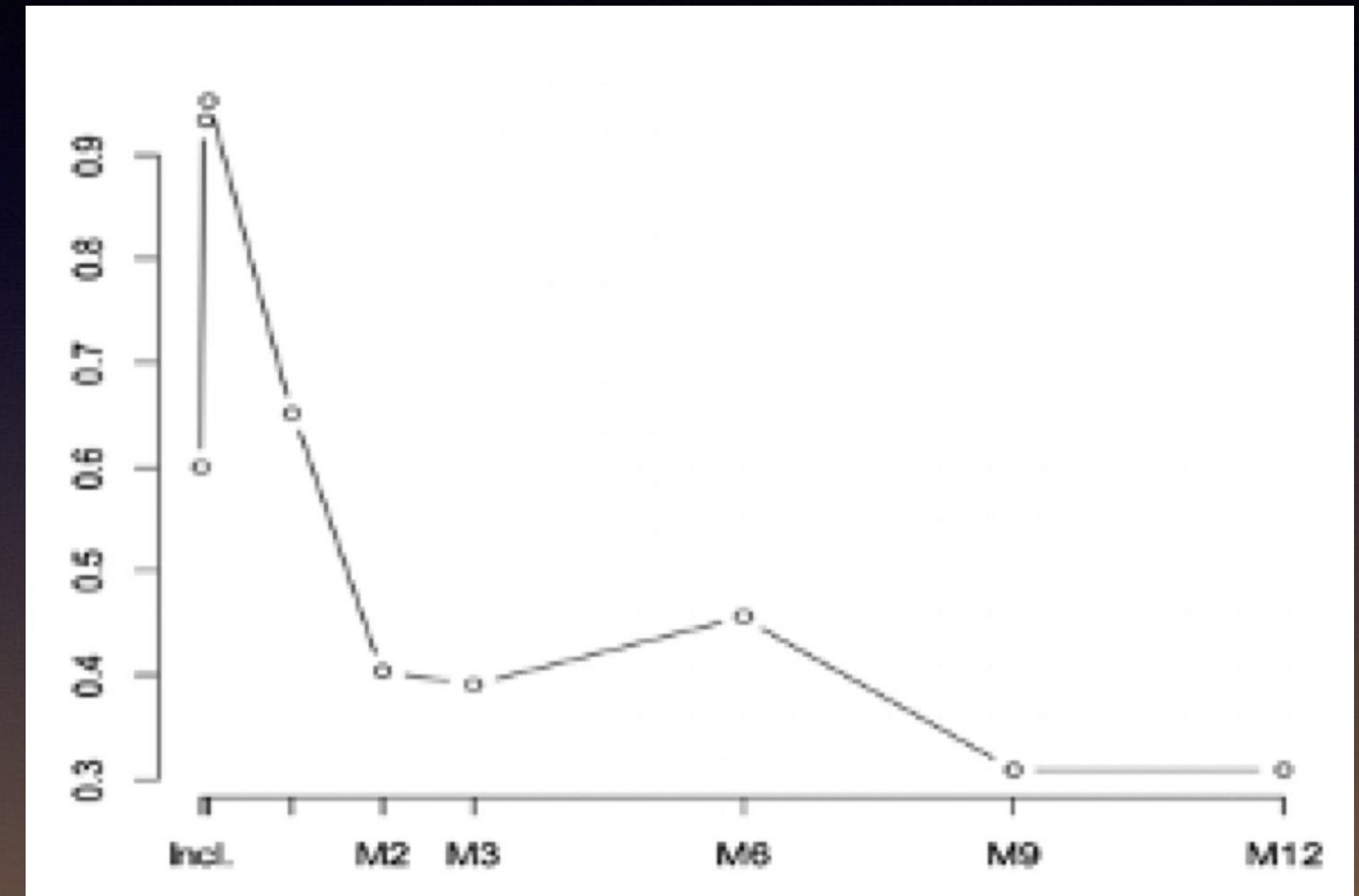
PAIN



Pain
(severity)



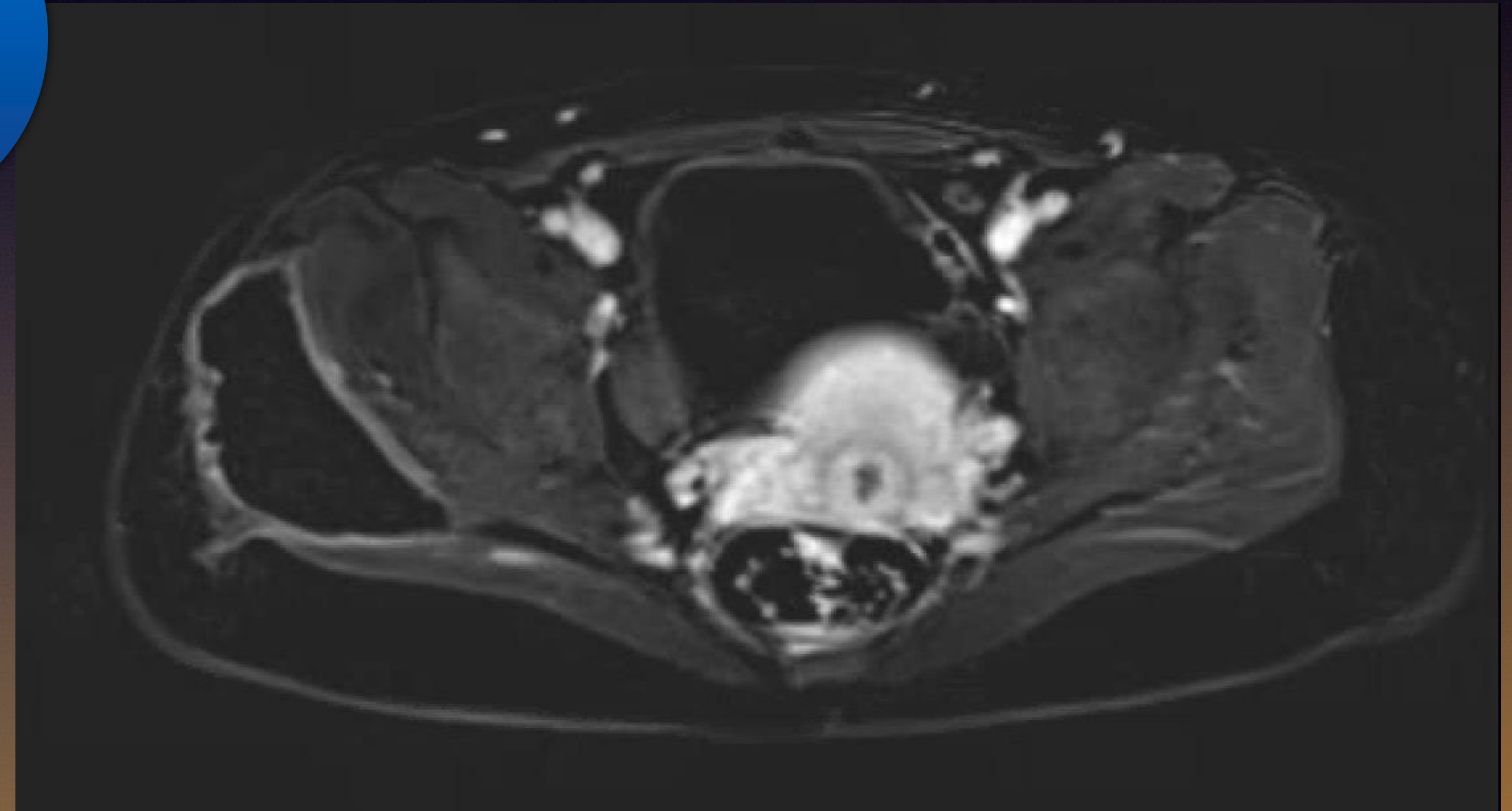
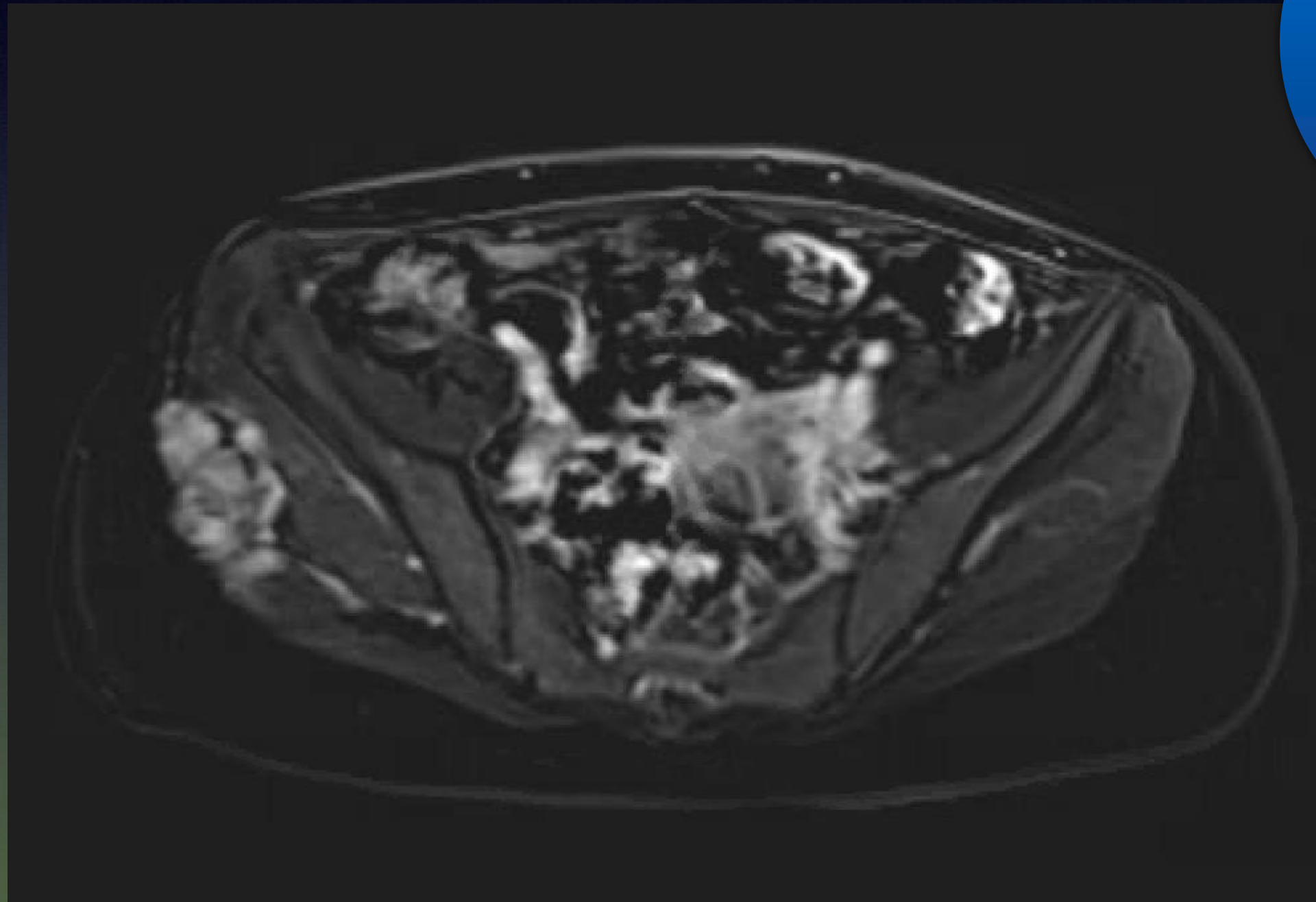
Pain
(interference)



- Decrease in analgesics intake
- Even in patients

BEFORE/AFTER

AXIAL T1
VIBE
SUB
2min

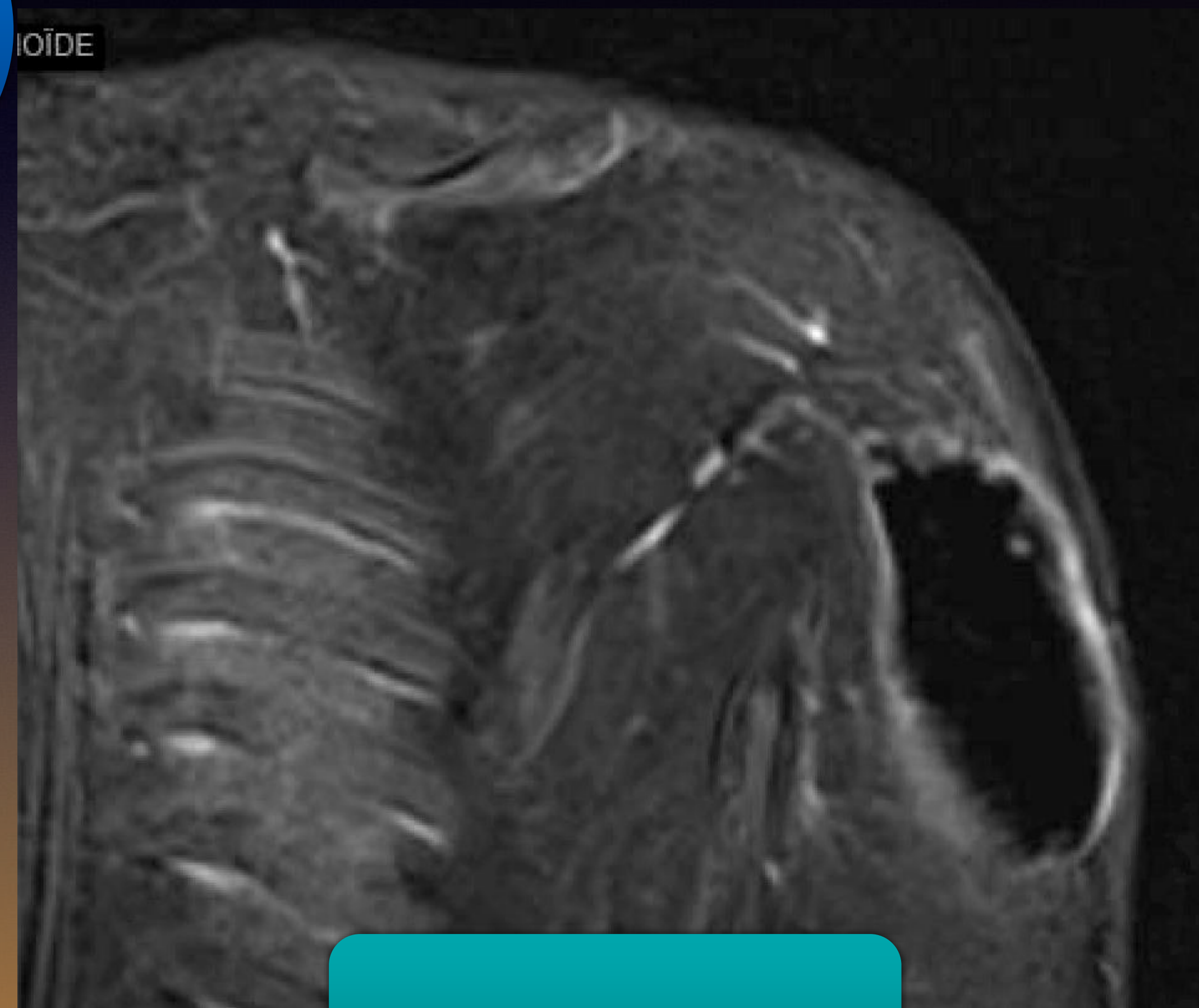


EVEN IN LARGE TUMORS



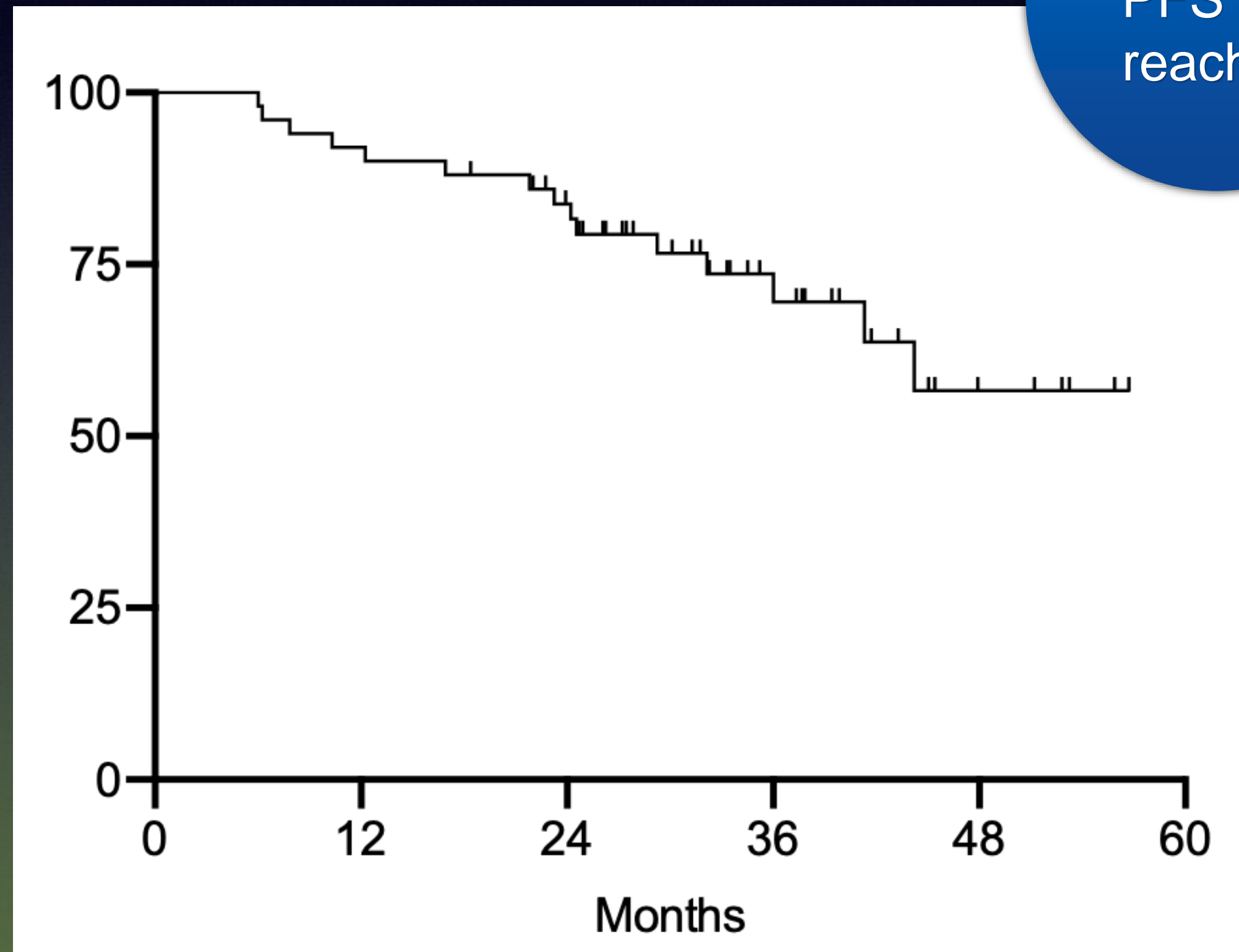
April, 2018
before cryo

CORO
T1 VIBE
SUB
2min



November, 2020

RISK FACTORS FOR PROGRESSION

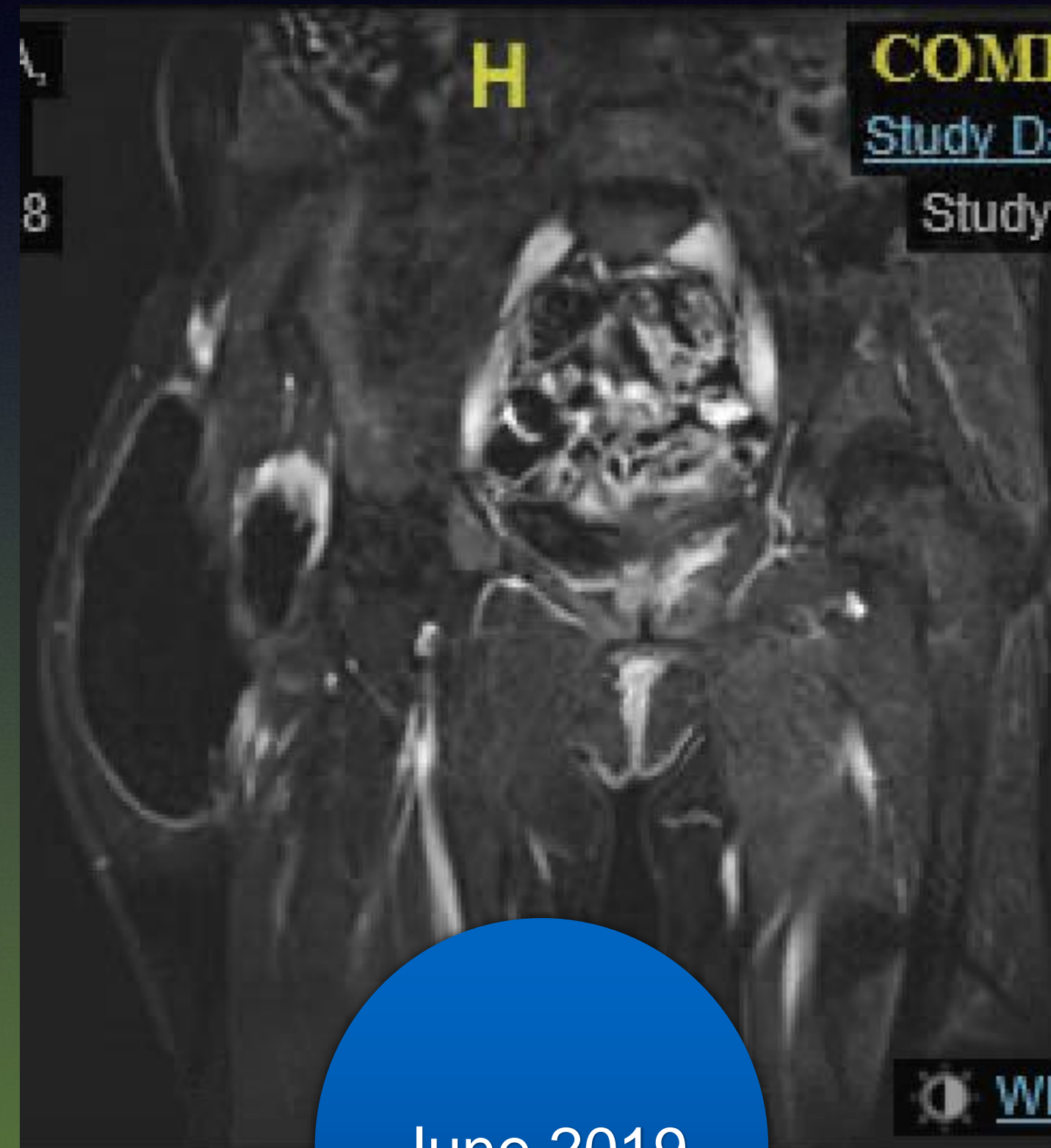


- Tumor size is the only variable that correlates with progression
- No failure was observed in the cryoablated zone
- Treatment planification (volume) is mandatory

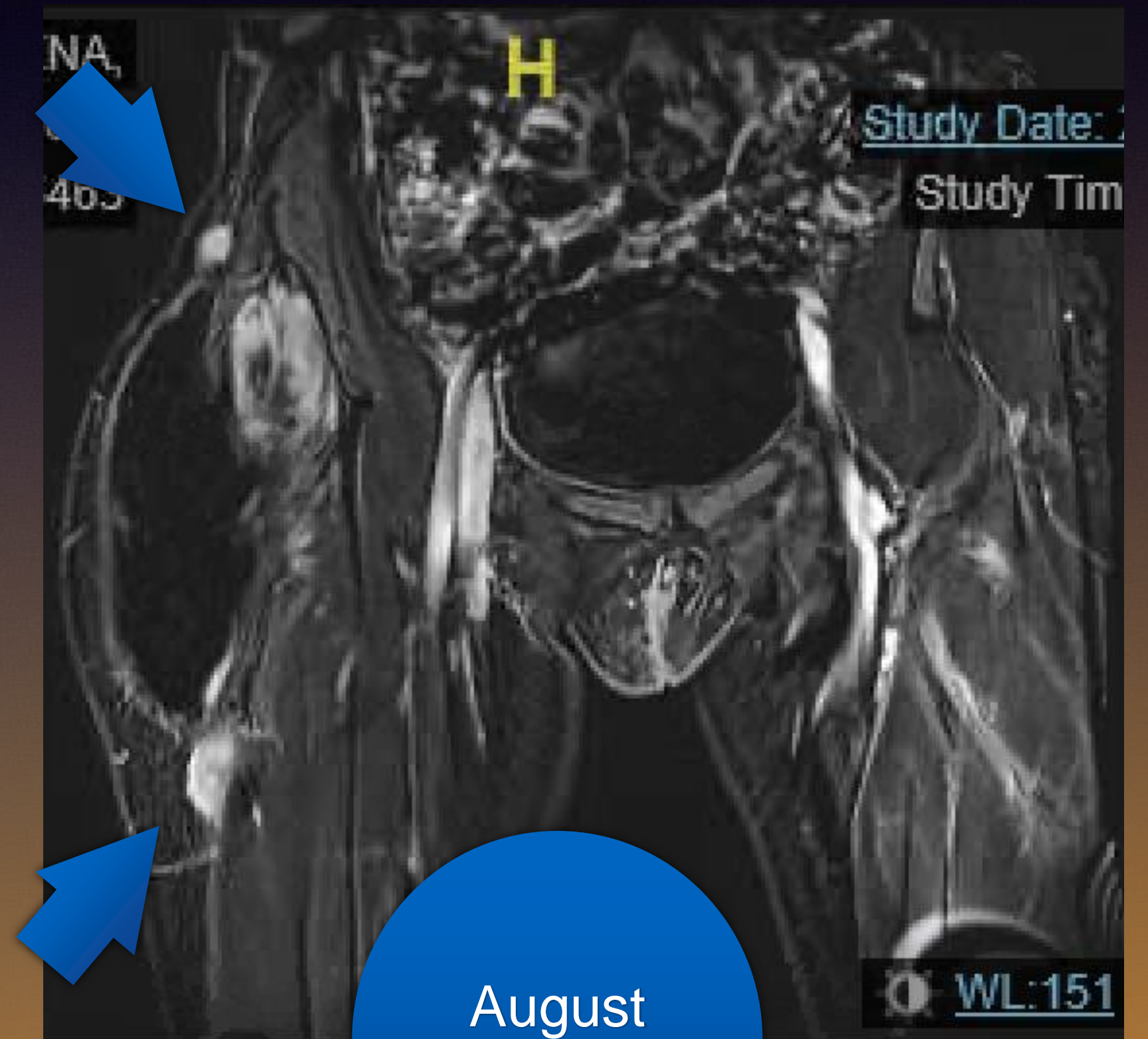
PATTERNS OF FAILURE



January
2018



June 2019

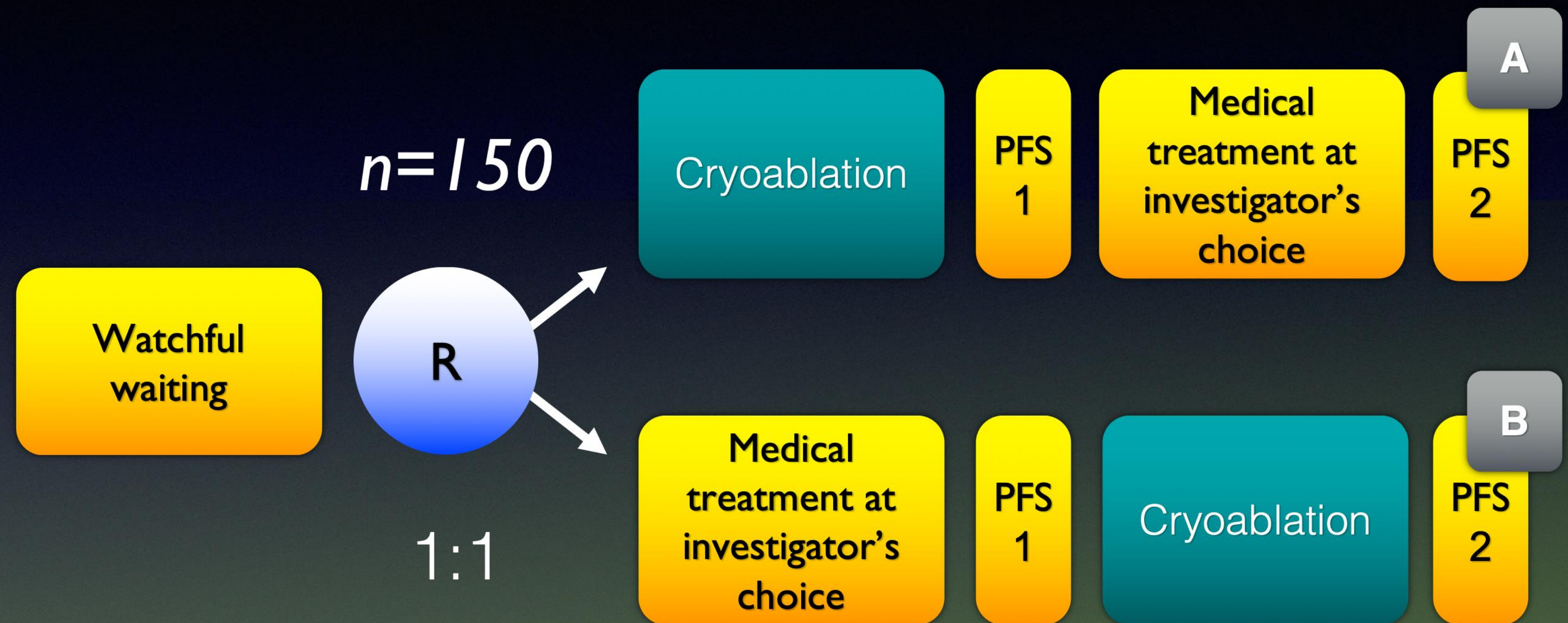


August
2020

CRYODESMO-02 is coming

- Pathologically proven DT
- Extra-abdominal
- Progressing or symptomatic after WW
- Deemed accessible to complete cryoablation
- Adults & adolescents >12

Any prior medical therapy or surgery



Primary endpoint

- Superior PFS 1 (A vs B)

Secondary endpoints

- Safety, QoL
- Sequence comparison PFS2/QoL/PAin (A vs B)

Final Design

THANK YOU

