Member-state field report and good-practice examples

Czechia

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Disclosure

- I hereby declare that I have no relevant financial or non-financial interests to disclose in relation to the subject matter of this meeting. This includes, but is not limited to, any personal, professional, contractual, or financial relationships that could be viewed as a potential conflict of interest.
- Some of the information presented in this document is derived from the project TITOSUJB907, which has been supported by the Technology Agency of the Czech Republic (TAČR).

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Disclosure

- Some information might be uns
  the procedures we are now init
  before. Yet, through a series of
  of comedy of errors, these key
  ether, never adequately passed
  interpretation of results or the
  So here we stand, paradoxically
  were writing our own farcical v
  some shout that it's spinning ar
  squeaks when our ears are plug
  whole wheel with oil might not

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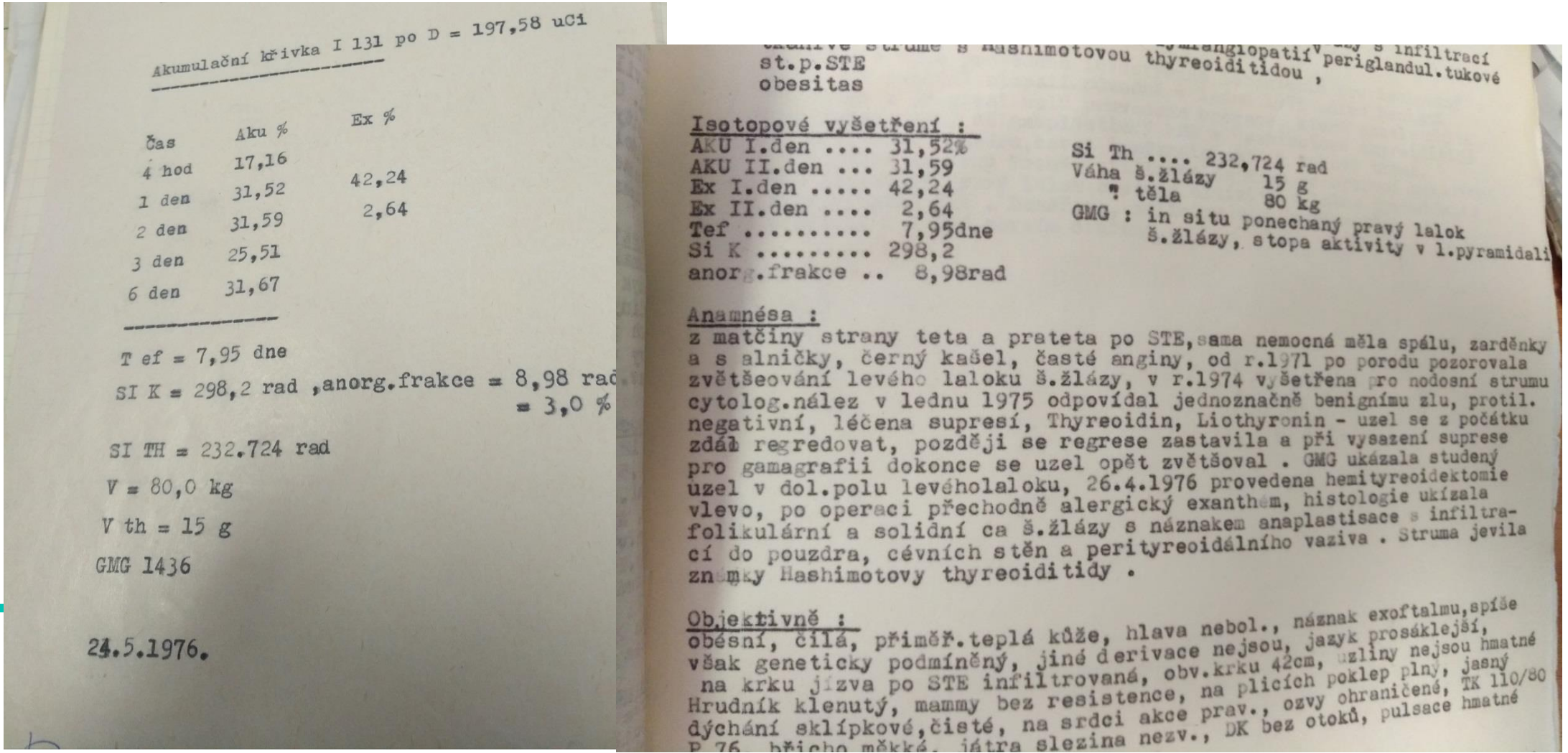
Introduction and background

- The dosimetry used to be set up in treatment planning long time ago



Akumulační křivka I 131 po D = 197,58 uCi

Čas	Aku %	Ex %
4 hod	17,16	
1 den	31,52	42,24
2 den	31,59	2,64
3 den	25,51	
6 den	31,67	

T ef = 7,95 dne

SI K = 298,2 rad ,anorg.frakce = 8,98 rad
= 3,0 %

SI TH = 232.724 rad

V = 80,0 kg

V th = 15 g

GMG 1436

24.5.1976.

st.p.STE
obesitas

thyreoiditidou , periglandul.tukové

Isotopové vyšetření :

AKU I.den	31,52%	Si Th	232,724 rad
AKU II.den ...	31,59	Váha š.žlázy	15 g
Ex I.den	42,24	" těla	80 kg
Ex II.den	2,64		
Tef	7,95dne		
Si K	298,2		
anorg.frakce ..	8,98rad		

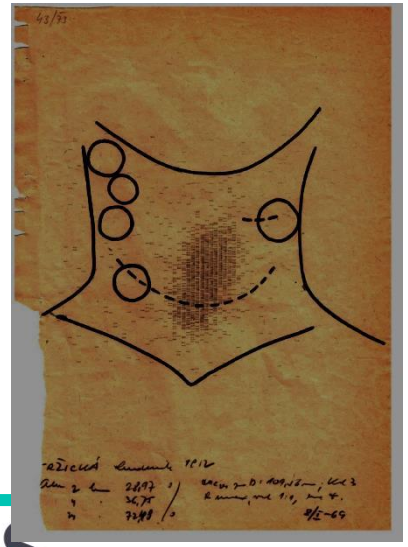
GMG : in situ ponechaný pravý lalok
š.žlázy, stopa aktivity v l.pyramidali

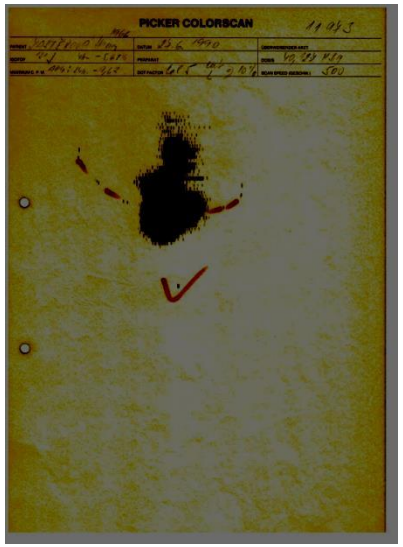
Anamnésa :
z matčiny strany teta a prateta po STE,sama nemocná měla spálu, zarděnky a s alničky, černý kašel, časté anginy, od r.1971 po porodu pozorovala zvětšeování levého laloku š.žlázy, v r.1974 vyšetřena pro nodosní strumu cytolog.nález v lednu 1975 odpovídal jednoznačně benignímu zlu, protil. negativní, léčena supresí, Thyreoidin, Liothyronin - uzel se z počátku zdál regredovat, později se regrese zastavila a při vysazení suprese pro gamagrafii dokonce se uzel opět zvětšoval . GMG ukázala studený uzel v dol.polu levéholaloku, 26.4.1976 provedena hemityreoidektomie vlevo, po operaci přechodně alergický exanthém, histologie ukízala folikulární a solidní ca š.žlázy s náznakem anaplastisace s infiltrací do pouzdra, cévních stěn a perityreoidálního vaziva . Struma jevila známky Hashimotovy thyreoiditidy .

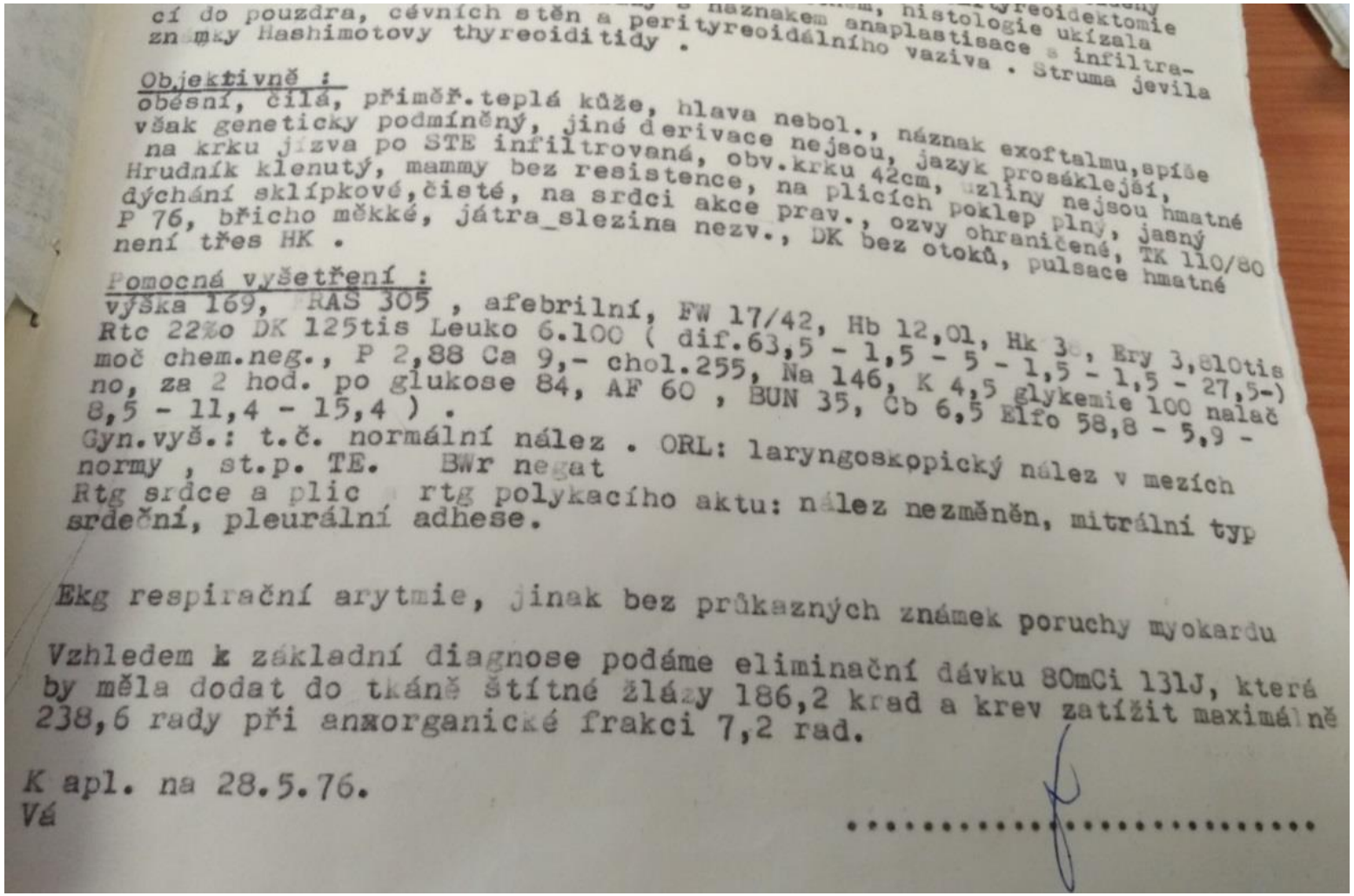
Objektivně :
obésní, čilá, přiměř.teplá kůže, hlava nebol., náznak exoftalmu,spíše však geneticky podmíněný, jiné derivace nejsou, jazyk prosáklejší, na krku jizva po STE infiltrovaná, obv.krku 42cm, uzliny nejsou hmatné Hrudník klenutý, mammy bez resistence, na plicích poklep plný, jasný dýchání sklípkové,čisté, na srdci akce prav., ozvy ohraničené, TK 110/80 P 76, břicho měkké, játra slezina nezv., DK bez otoků, pulsace hmatné

Introduction and background

- Treatment planning was done in accordance with dosimetry results originally







cí do pouzdra, cévních stěn a perityreoidálního vaziva . Struma jevila
znaky Hashimotovy thyreoiditidy .

Objektivně :
obésní, čilá, přiměř.teplá kůže, hlava nebol., náznak exoftalmu,spíše
však geneticky podmíněný, jiné derivace nejsou, jazyk prosáklejší,
na krku jizva po STE infiltrovaná, obv.krku 42cm, uzliny nejsou hmatné
Hrudník klenutý, mammy bez resistence, na plicích poklep plný, jasný
dýchání sklípkové,čisté, na srdci akce prav., ozvy ohraničené, TK 110/80
P 76, břicho měkké, játra_slezina nezv., DK bez otoků, pulsace hmatné
není třes HK .

Pomocná vyšetření :
výška 169, RAS 305 , afebrilní, FW 17/42, Hb 12,01, Hk 3[illegible], Ery 3,810tis
Rtc 22‰ DK 125tis Leuko 6.100 (dif.63,5 - 1,5 - 5 - 1,5 - 1,5 - 27,5-)
moč chem.neg., P 2,88 Ca 9,- chol.255, Na 146, K 4,5 glykemie 100 nalač
no, za 2 hod. po glukose 84, AF 60 , BUN 35, Cb 6,5 Elfo 58,8 - 5,9 -
8,5 - 11,4 - 15,4) .
Gyn.vyš.: t.č. normální nález . ORL: laryngoskopický nález v mezích
normy , st.p. TE. BWr negat
Rtg srdce a plic [illegible] rtg polykacího aktu: nález nezměněn, mitrální typ
srdeční, pleurální adhese.

Ekg respirační arytmie, jinak bez průkazných známek poruchy myokardu

Vzhledem k základní diagnose podáme eliminační dávku 80mCi 131J, která
by měla dodat do tkáně štítné žlázy 186,2 krad a krev zatížit maximálně
238,6 rady při anorganické frakci 7,2 rad.

K apl. na 28.5.76.
Vá

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Introduction and Background

- Council Directive 2013/59/*Euratom*
- 2014 – 2016 preparation of new legislation SÚJB (State Office for Nuclear Safety)
- SÚRO (National Radiation Protection Institute)
  - SÚJB support though no experts on NM (2016)
- Reflection of 2013/59 Euratom issues
  - terminology: Dose [Gy] / „Dose“ [MBq] / Activity
  - Science VS Fiction - treatment is planned individually though not the right „Dose“
  - Why should be anything changed?
  - Dosimetry is just a chimera

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Introduction and Background

- Council Directive 2013/59/*Euratom*
- 2014 – 2016 preparation of new legislation (Atomic Law) SÚJB (State Office for Nuclear Safety)
- 2016 a new Atomic Act, came into effect in 2017.
  - legislation notably incorporated the requirement for dosimetry in nuclear medicine
  - Professional community „MUST averse“ effect – justification, reinbursement, HR
- Much closer colaboration **became** inevitable

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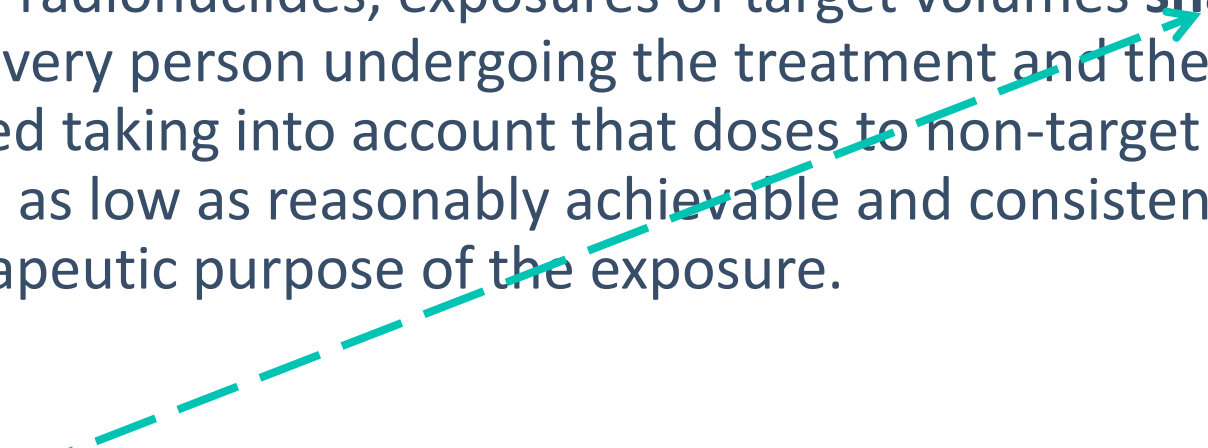
Czech Legal Framework and Implementation

- Atomic Act: Act No. 263/2016 Coll., atomic act
- Decree No. 422/2016 Coll., on radiation protection and security of a radioactive source (official transl.):
  - For medical exposure of patients for radiotherapeutic purposes, including the therapeutical applications of radionuclides, exposures of target volumes **shall** be individually planned for every person undergoing the treatment and their delivery appropriately verified taking into account that doses to non-target volumes and tissues **shall** be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.
- The “Czech” version: MUST



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The position of Czech NM Physicians

- Council Directive 2013/59/*Euratom* does not reflect the clinical reality in the Nuclear Medicine as it is mainly formulated for the purposes of external radiotherapy
- The role wide-scale applied dosimetry in the radionuclide therapy is questionable
  - missing individualisation based on patient, disease characterisation, and type of therapy
  - lack of reliable, reproducible methodologies
  - demanding logistics of current dosimetric procedures (time, costs, reimbursement)
  - limited healthcare providers´ capacity to perform complete dosimetry in every patient with direct influence the availability of the care
  - lack of reliable data supporting the need of dosimetry planning in the view of potential clinical impact

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Czech Legal Framework and Implementation

- Literally strict obligation x Simply recommendation
- Individualisation considering real clinical impact on treatment outcome, patient will and actual health condition!

- Centralisation and international recommendation and studies were expected
- Small-scale projects on dosimetry 2016 -2018
    - basic SUJB recommendation and recherche BETA (2017 – 2018)

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Active Scientific-Regulatory Collaboration in Czechia

- The issue was underlined on several local conferences
- 2017 SÚRO established Working Group in Nuclear Medicine
  - physicists, physicians, inspectors and SÚRO researchers included
  - multidisciplinary approach, elevating safety standards and optimizing dosimetric practices to prevent future problems
- Based on seminars and discussions SÚJB:
  - financially supported small-scale projects on dosimetry
  - few bigger grant request (Ministry of Health) were rejected
  - seek for larger scale solution
- The Czech Society of Nuclear Medicine (ČSNM) collaborating with Working Group for Nuclear Medicine and SÚJB and developing positions and statements

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Active Scientific-Regulatory Collaboration in Czechia

- 2018 – 2019 ČSNM statement on BETA version of recommendations (2017)
  - 131I for benign thyroid use – dosimetry not required (MUST be reasoned why not, fixed activity to be justified by physician)
  - 131I for DTCA dosimetry not required (MUST be reasoned why not), recommended for young patients and generalized illness
  - In general – physician responsibility
  - Lack of solid data in favor and reasoning of dosimetry
  - Few dosimetry done in general

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Active Scientific-Regulatory Collaboration in Czechia

- The problem is to get it paid
- Cooperation of SÚJB and ČSNM
  - Dosimetry reimbursement in the Czech Republic has been actively addressed by professional societies, leading to its formal integration into healthcare practices. This development reflects the collaborative efforts of various stakeholders in standardizing and recognizing the importance of dosimetry
  - Signal (DRG) codes were set up (are being used in case of dosimetry) / for statistical purpose only till today
- Still not solved

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Research 2019-2022

- Technology Agency of the Czech Republic (TAČR) supported project TITOSUJB907
- Main goals:
  - Foreign praxis analysis in planning and verification for therapeutic I131 and Y90 administrations
  - Optimized procedures for planning and verification in the administration of radiotherapy with I-131 and Y-90

T A
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Tento projekt je financován se státní podporou Technologické agentury ČR v rámci programu BETA2
www.tacr.cz
Výzkum užitečný pro společnost

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Research Foreign Praxis Analysis (2021)

- Article 56 of Directive 2013/59/EURATOM is generally not emphasized
- Wider recommendations in general still under preparation
  - Some released during 2021-2023
  - Limited clinical procedure (still improving)
- Some procedures can be locally adapted
  - Best praxis X Summary of Product Characteristics

- For ongoing radionuclide therapies
- dosimetry ***larger scale study*** inevitable

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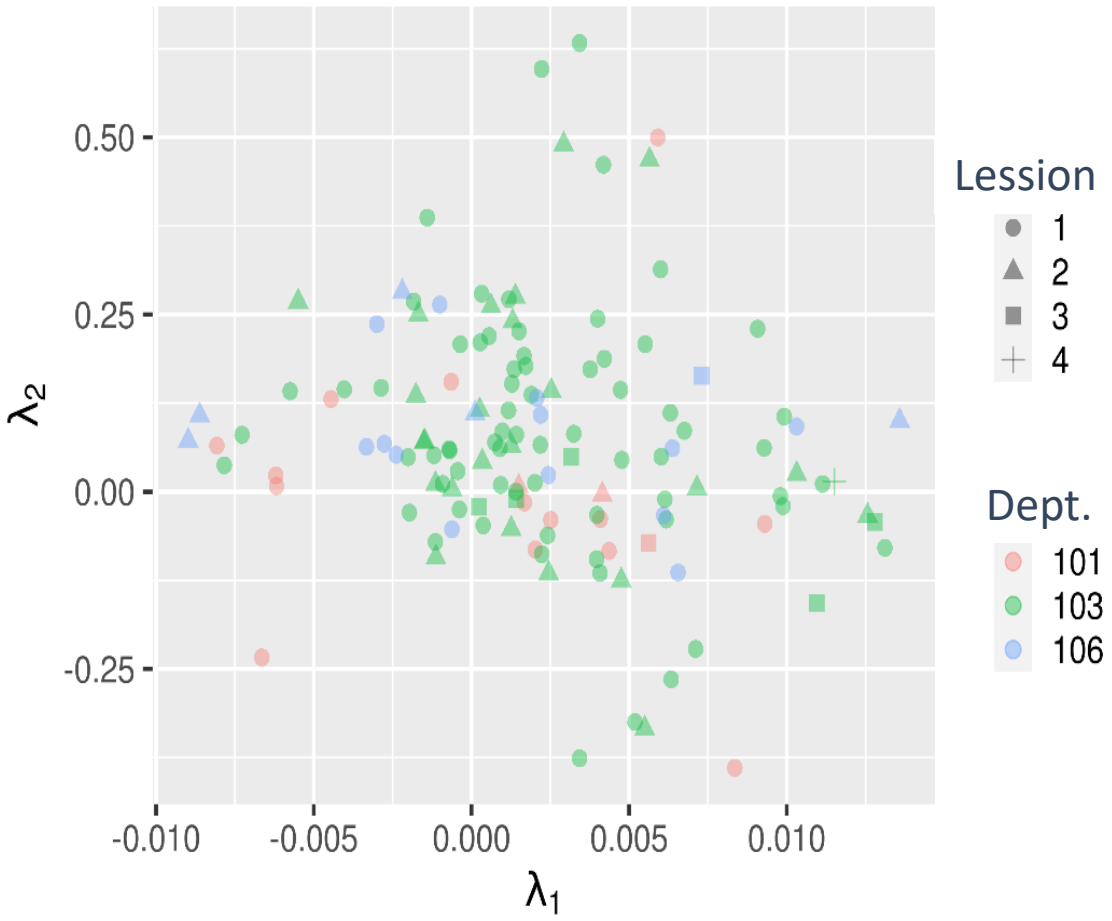
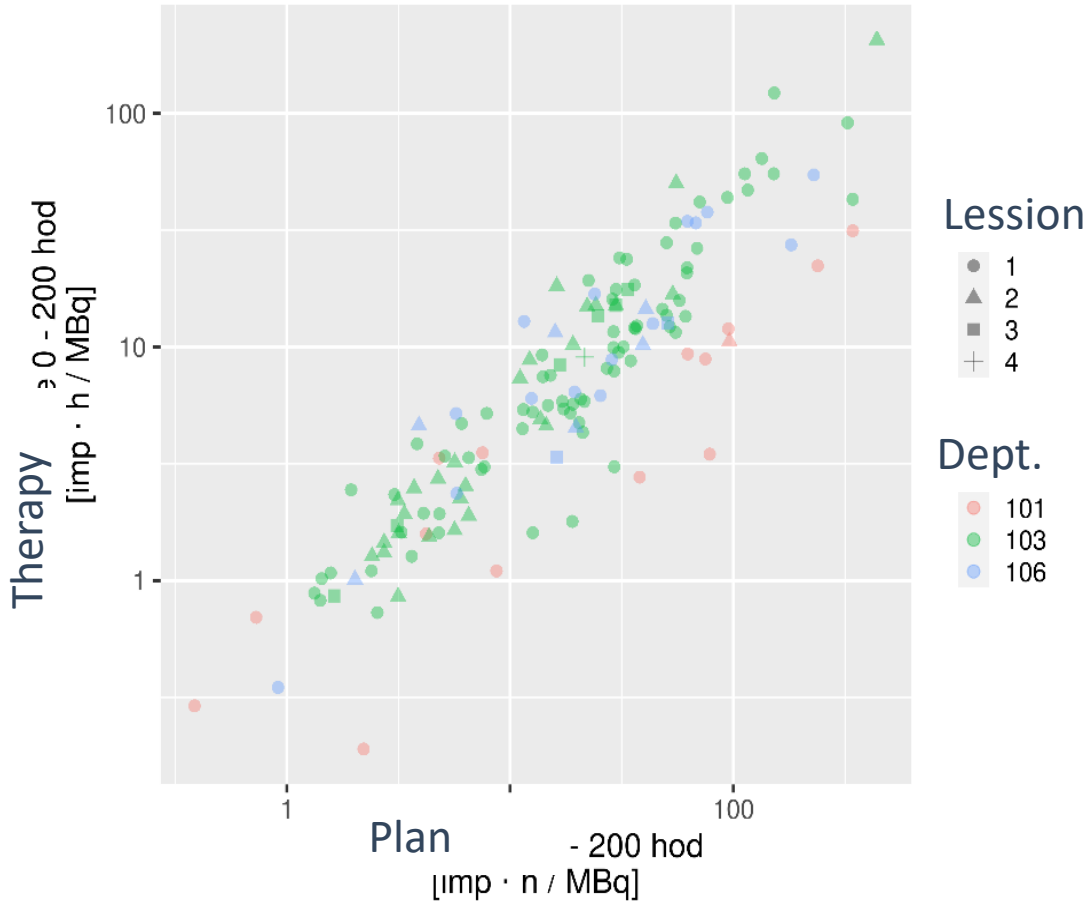
Research - Prospective Study





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Research - conclusion

- Due to collaboration more dosimetry was done and more physicians are willing to require it
- Some treatment procedure deviates – lower treatment effectivity
- Still a lot of work to do
  - few data for fine statistical analysis
  - treatment schedules differ
  - dose calculation is better etimation
- Local dosimetry guide prepared
- **Data gathered, reanalysis and dose effect study can be done!**

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Current Dosimetry State of the Art

- Benign thyroid – planning, verification very limited
  - patient will and wealth
- 177Lu – 1st cycle 6, 24, 48 h; 72 or 168 h kidneys, WB all cycles
- 131I mIBG – for children, adults only limited
- 131I DTCA –limited (targeted tissue, WB – met. dissemation)
  - 2 out of 5 dept. planning and limited verification

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Current Challenges and Future Outlook

- Reimbursement of current dosimetry studies
- Physicians vs Physicists
  - optimisation respecting the providers´ capacities and patients´ comfort
  - obtaining data for individualization and treatment optimization
- New therapies – Shouldn’t dosimetry be obligatory till final recommendation?
- Ethics
  - blinded study radionuclide treatment vs placebo
  - may dosimetry limit the access to the healthcare? **The cost-benefit must be thoroughly evaluated**

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Current Challenges and Future Outlook

- Out/ inpatient challenges in waste management persist and are currently being addressed
- General radiation protection principles are questioned (increasing number of patients, public burden increment)
- Inconsistency in approaches to new therapies
- Unified guidelines and a collaborative international effort to streamline practices in nuclear medicine (current, tested and planned radionuclide therapies including dosimetry) needed / thanks for

Simplerad and others

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Conclusion

Personally: The way to the hell is lined straight. Though Dosimetry in Nuclear Medicine is akin to navigating a minefield marathon; at any moment, you're just a step away from detonating a complex problem or setting off a chain reaction among other stakeholders (non unified historically based treatment scheme, limited finance, HR problems etc.)

- **Unified guidelines and a collaborative international effort to streamline studies, research and practices in nuclear medicine is required including current treatments and all the new ones**

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Thank you for your attention

I would like to conclude this presentation by extending my heartfelt gratitude to everyone involved in this collaboration (SÚJB, SÚRO, ČSFM). A special thank you to my colleagues from TITOSUJB907 for their invaluable collaboration and to our co-researchers for their hard work and dedication, which were instrumental in achieving our goals. I also wish to express my appreciation to the participating hospitals for providing the essential data that made this research possible.

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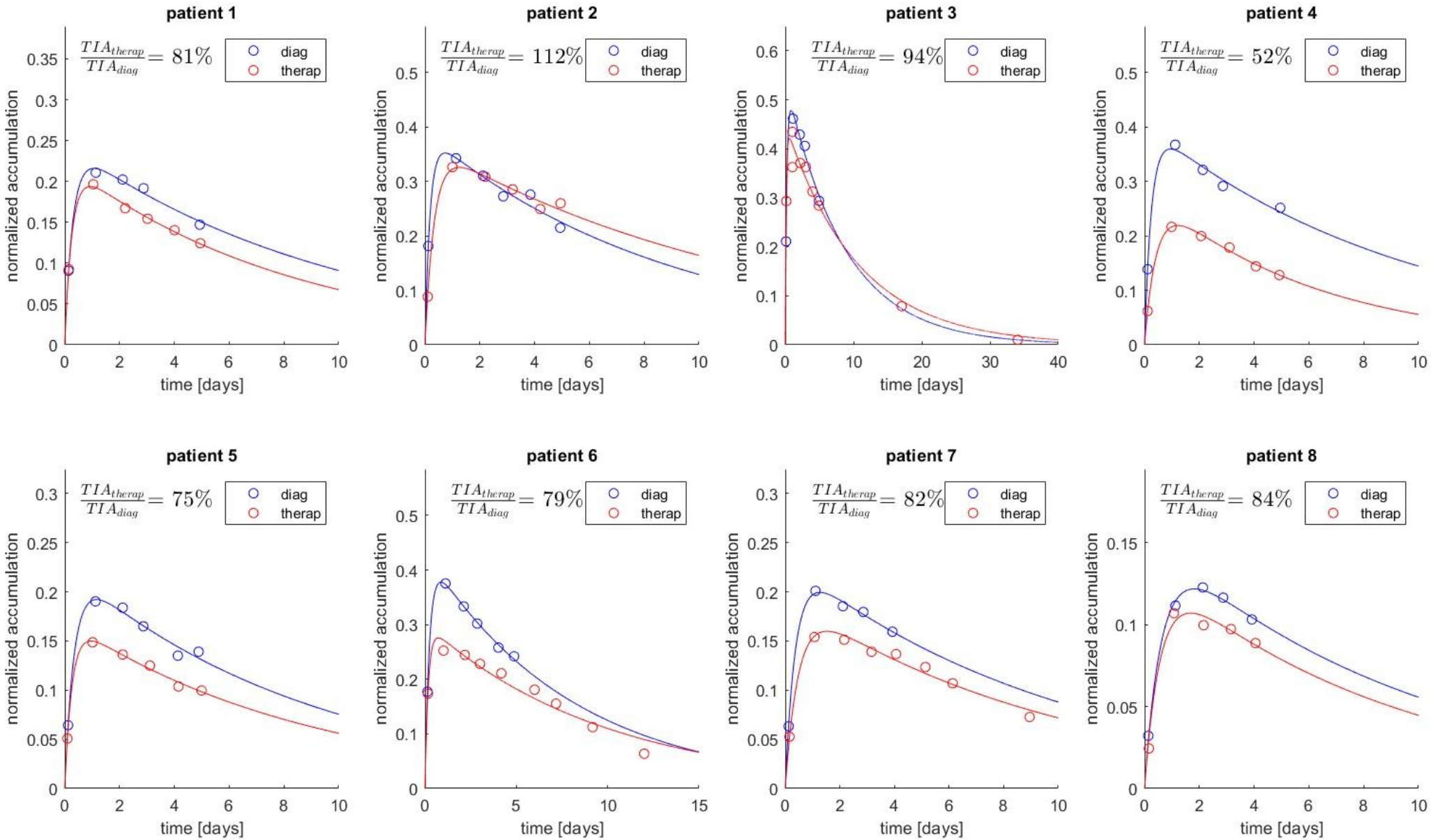
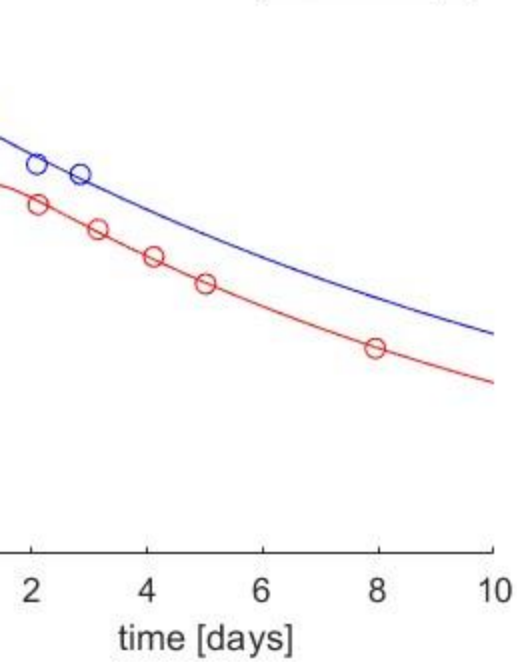
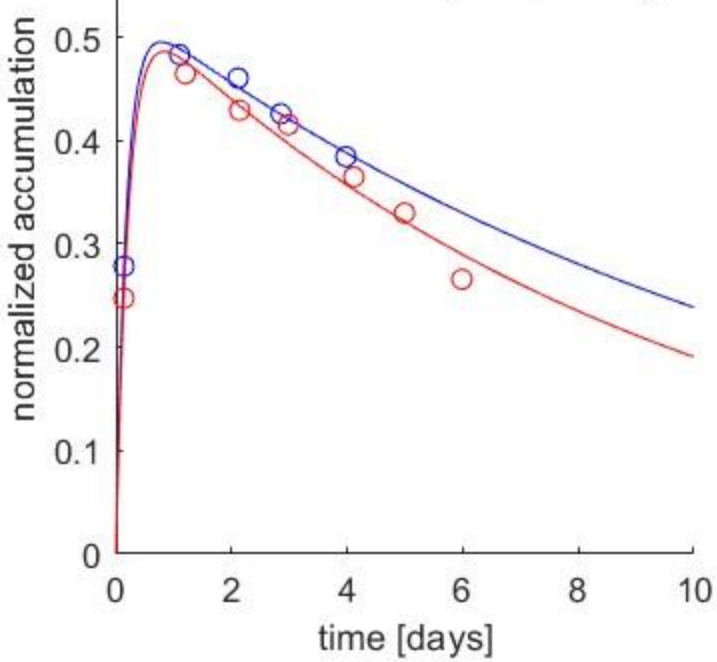
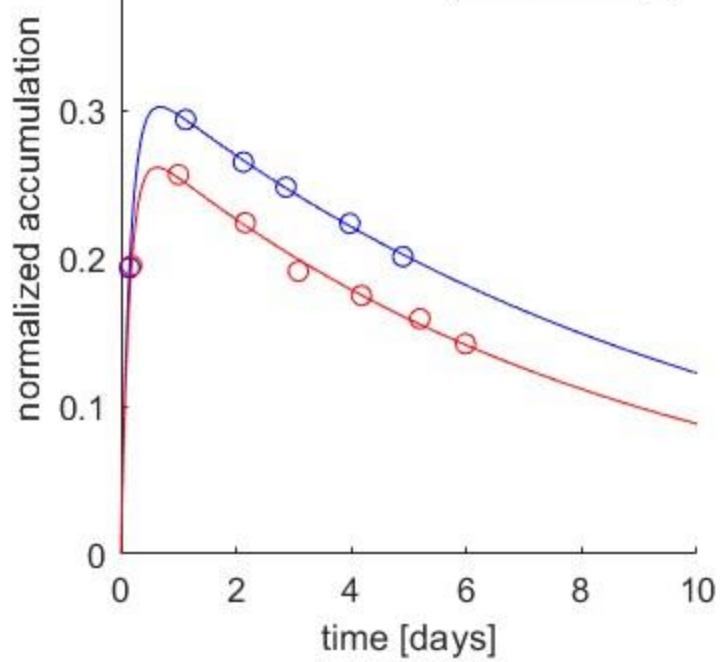
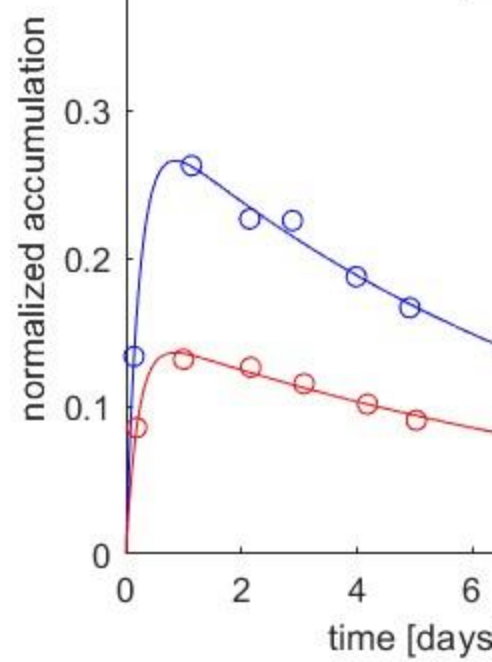

patient 1
$\frac{TIA_{therap}}{TIA_{diag}} = 81\%$
diag
therap
normalized accumulation
time [days]
patient 2
$\frac{TIA_{therap}}{TIA_{diag}} = 112\%$
diag
therap
normalized accumulation
time [days]
patient 3
$\frac{TIA_{therap}}{TIA_{diag}} = 94\%$
diag
therap
normalized accumulation
time [days]
patient 4
$\frac{TIA_{therap}}{TIA_{diag}} = 52\%$
diag
therap
normalized accumulation
time [days]
patient 5
$\frac{TIA_{therap}}{TIA_{diag}} = 75\%$
diag
therap
normalized accumulation
time [days]
patient 6
$\frac{TIA_{therap}}{TIA_{diag}} = 79\%$
diag
therap
normalized accumulation
time [days]
patient 7
$\frac{TIA_{therap}}{TIA_{diag}} = 82\%$
diag
therap
normalized accumulation
time [days]
patient 8
$\frac{TIA_{therap}}{TIA_{diag}} = 84\%$
diag
therap
normalized accumulation
time [days]

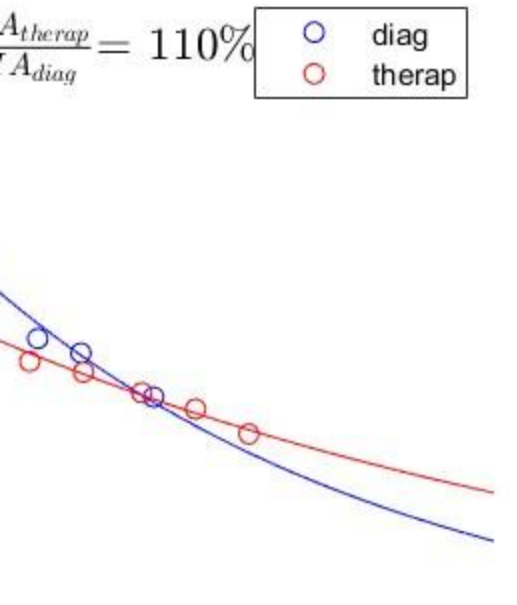




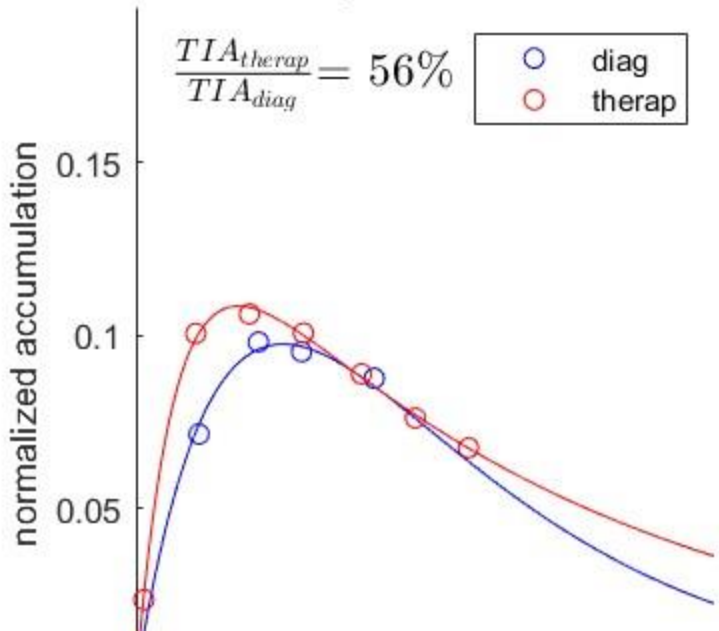




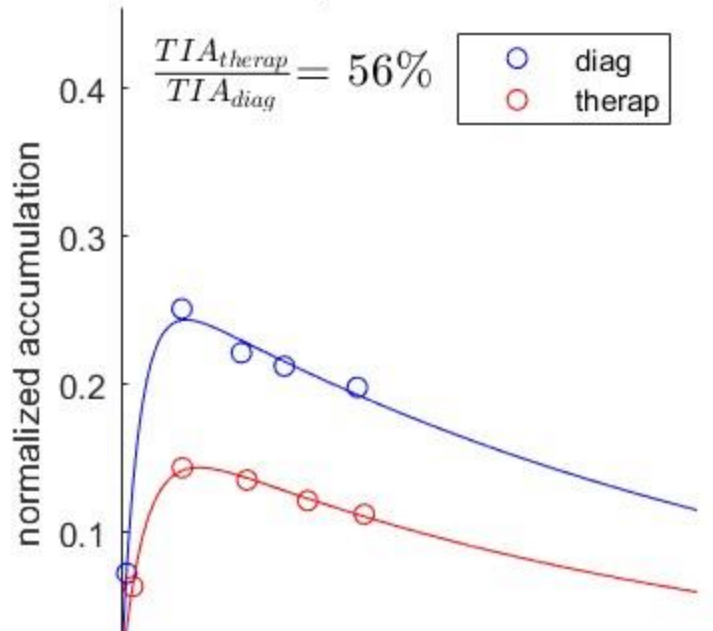
patient 13



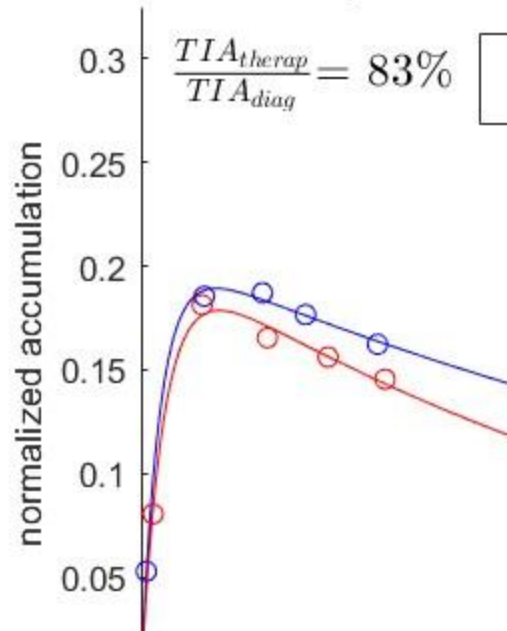
patient 14

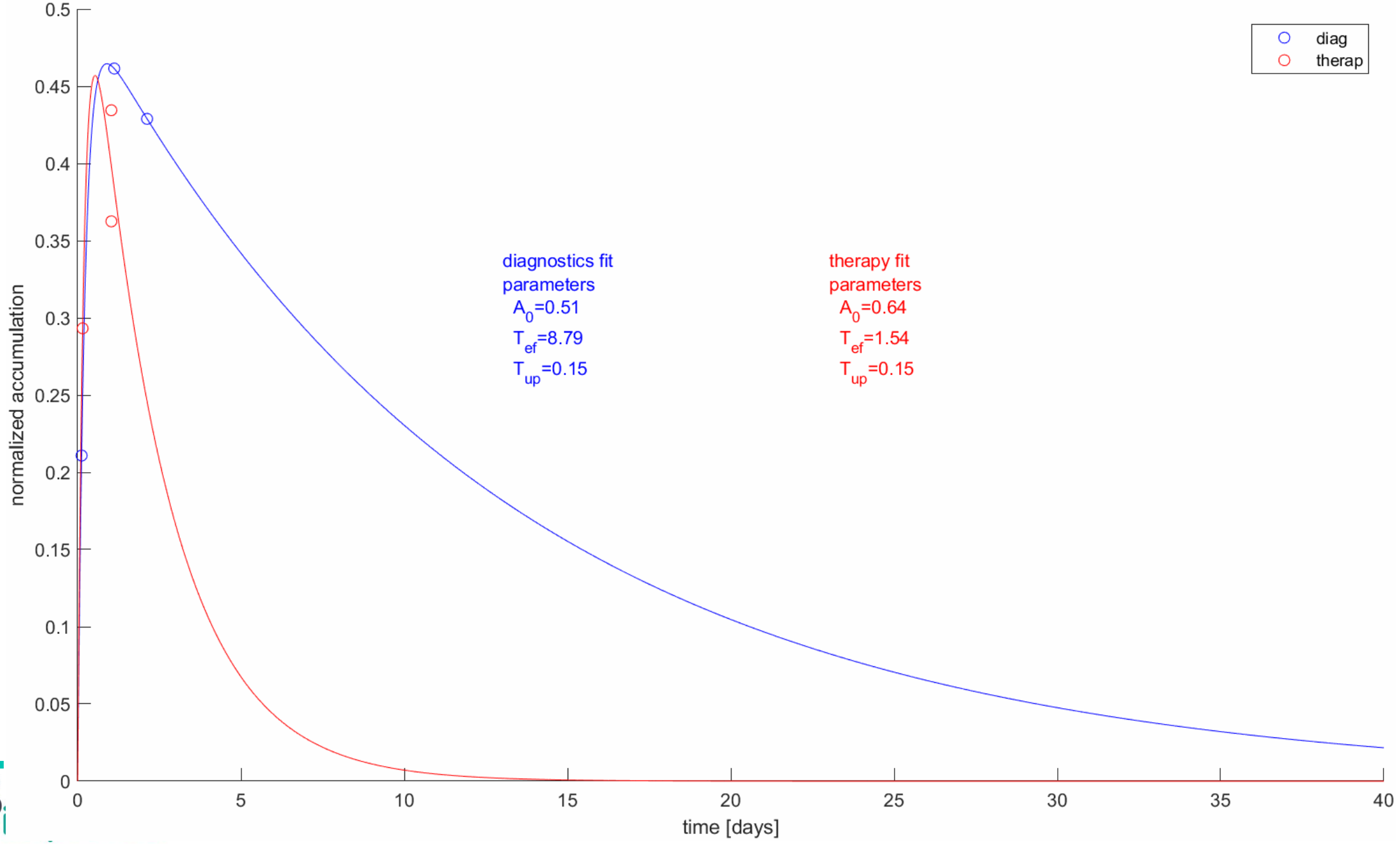


patient 15



patient 16





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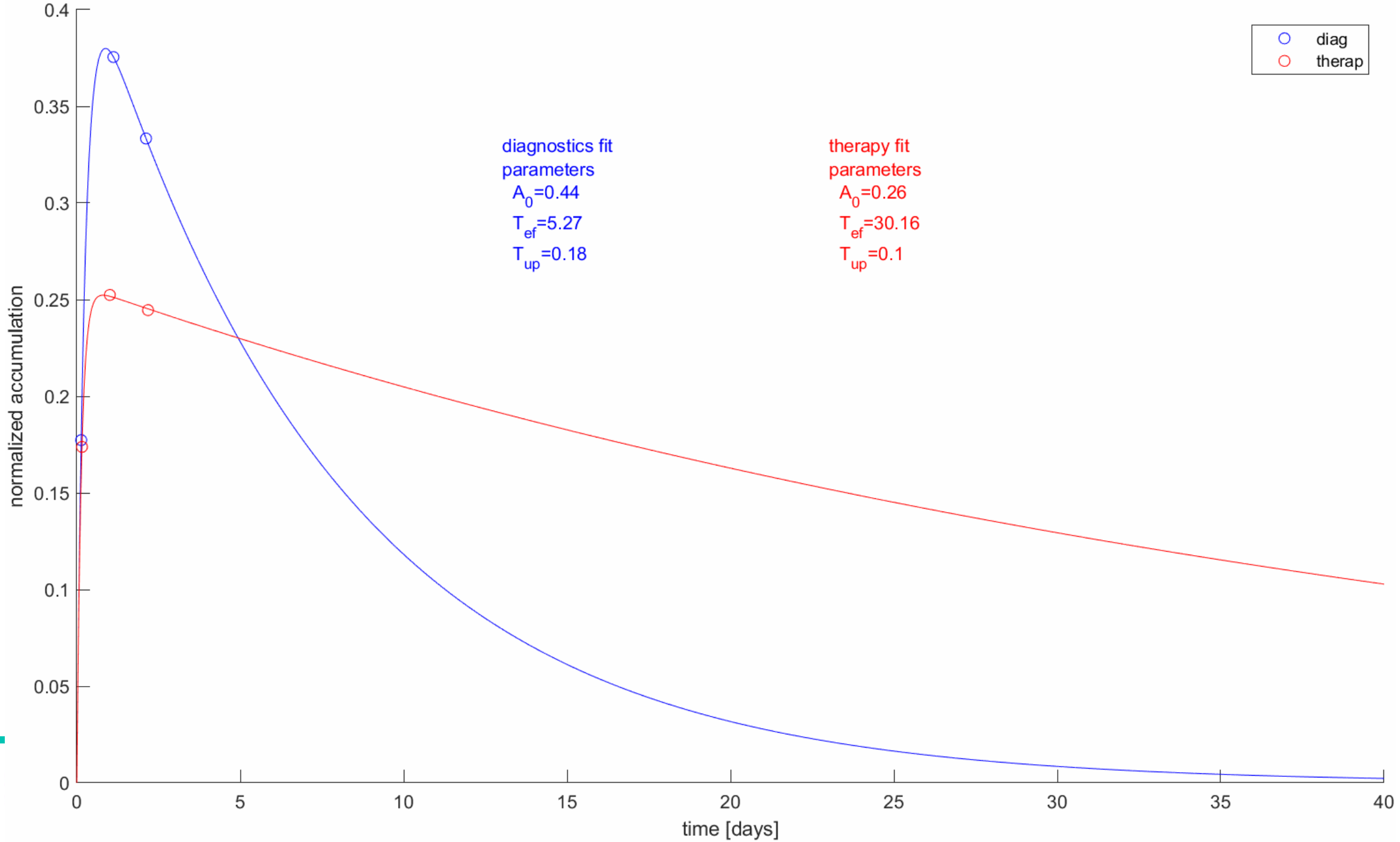
diag
therap
diagnostics fit
parameters
A0=0.44
Tef=5.27
Tup=0.18
therapy fit
parameters
A0=0.26
Tef=30.16
Tup=0.1
normalized accumulation
time [days]
0
0.05
0.1
0.15
0.2
0.25
0.3
0.35
0.4
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5
10
15
20
25
30
35
40