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Algorithm for evaluation of the tumor markers for diagnostics and therapy monitoring in cancer diseases

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Background

Tumor markers are currently used in the daily clinical practice particularly for the recurrence detection during the follow-up period of the cancer diseases. Tumor markers are rarely used for the diagnostic purpose or therapy monitoring

Aim of study

- The aim was to propose algorithms for:
  - optimization of the diagnostic approach of the cancer disease
  - optimal therapy choice and monitoring based on the serum levels of the tumor markers
  - therapy effect monitoring based on the serum levels of the tumor markers
  - Not for screening or primary diagnostics

Methods & Materials/Patients

- **Algorithms** were proposed based on the retrospective evaluation of 30 000 results of serum tumor markers from 2 000 patients in the Faculty Hospital in Pilsen during the period of 2005 – 2015
- The following **cancers** were evaluated: breast, colorectal, lung and prostate cancer
- The following **markers** have been evaluated: CEA, AFP, CA, CYFRA, TPA, TPS, PSA, TK, NSE, ChrA,…
  - during the primary diagnosis were correlated with clinical status prior to any therapy
  - all data related to the detailed clinical status and the disease course during the follow-up period were available in all the patients

Results

- Diagnostic algorithms
  - Tumor of unknown origin
  - Differential diagnosis
  - Early diagnosis
- Follow-up and Disease course monitoring
- Therapy effect monitoring
  - Surgery
  - Adjuvant therapy
  - Chemotherapy
- Prognosis estimation

Cancer of unknown origin

Yes – only for prediction of tumor origin

- in patients suffering froma series of diseases
- in case of a confusing histology and imunohistochemistry
- Optimal tumor marker combination:
  - CEA, CA 15-3, CA19-9, CYFRA 21-1, NSE, Chg A

Not – for primary diagnosis

- Poor sensitivity and specificity for early stage of tumor
- False positivity in benign disease

BIANTA software estimates what kinds of diagnoses

"unknown type and location of primary tumor, when metastases are diagnosed or there is high suspicion of cancer disease"

both (tumor and non-tumor) it could be, including the recommendations as to what markers should be measured in addition (the physician can – in order to make the diagnosis more precise) – fill into the requisite form whether metastases has been found and where, whether there are suspected metastases, and whether there is any area wherethe primary tumor might be found

Diferential diagnostics

- Malignat tumor testes x benign
  - AFP+ hCG 82% senzit. /95% spec
  - AFP+ hCG + TK 92% senzit. /95% spec
- Mola hydatidosa x chorioepitheliom
  - HGG 85% senzit. /95%spec
  - HCG + TK + CHrg 93% senzit. /95%spec

Optimization of the early diagnostics **prostate cancer**

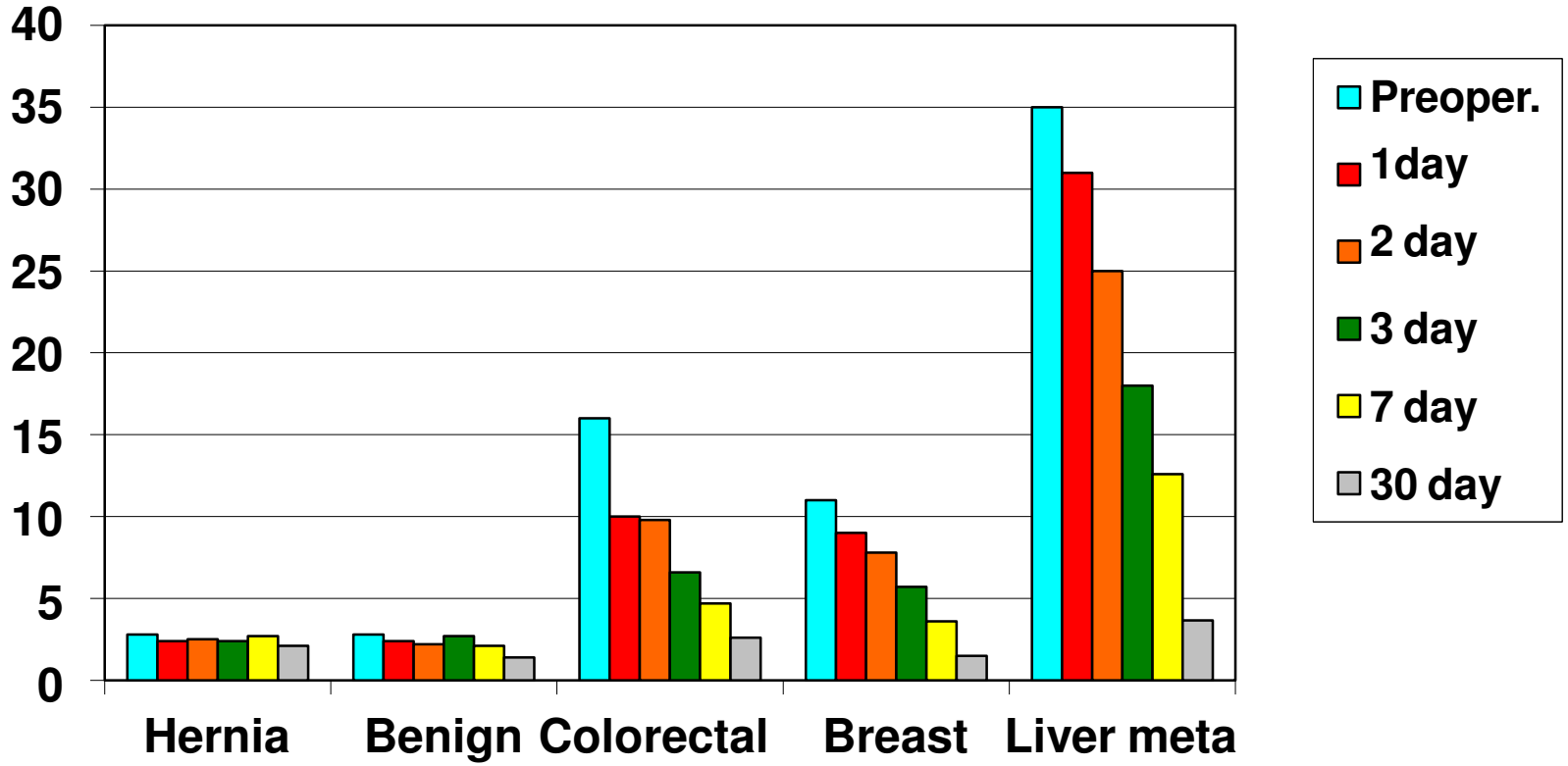
PSA	PHI	MR	PET MR	biopsy
0 - 2		no		no
2 - 10	< 40	no		no
	> 40	yes		yes
10 -20	< 40	yes		yes
	> 40		yes	yes
20 - 50			yes	yes

Optimization of the early diagnostics **prostate cancer** n-1350

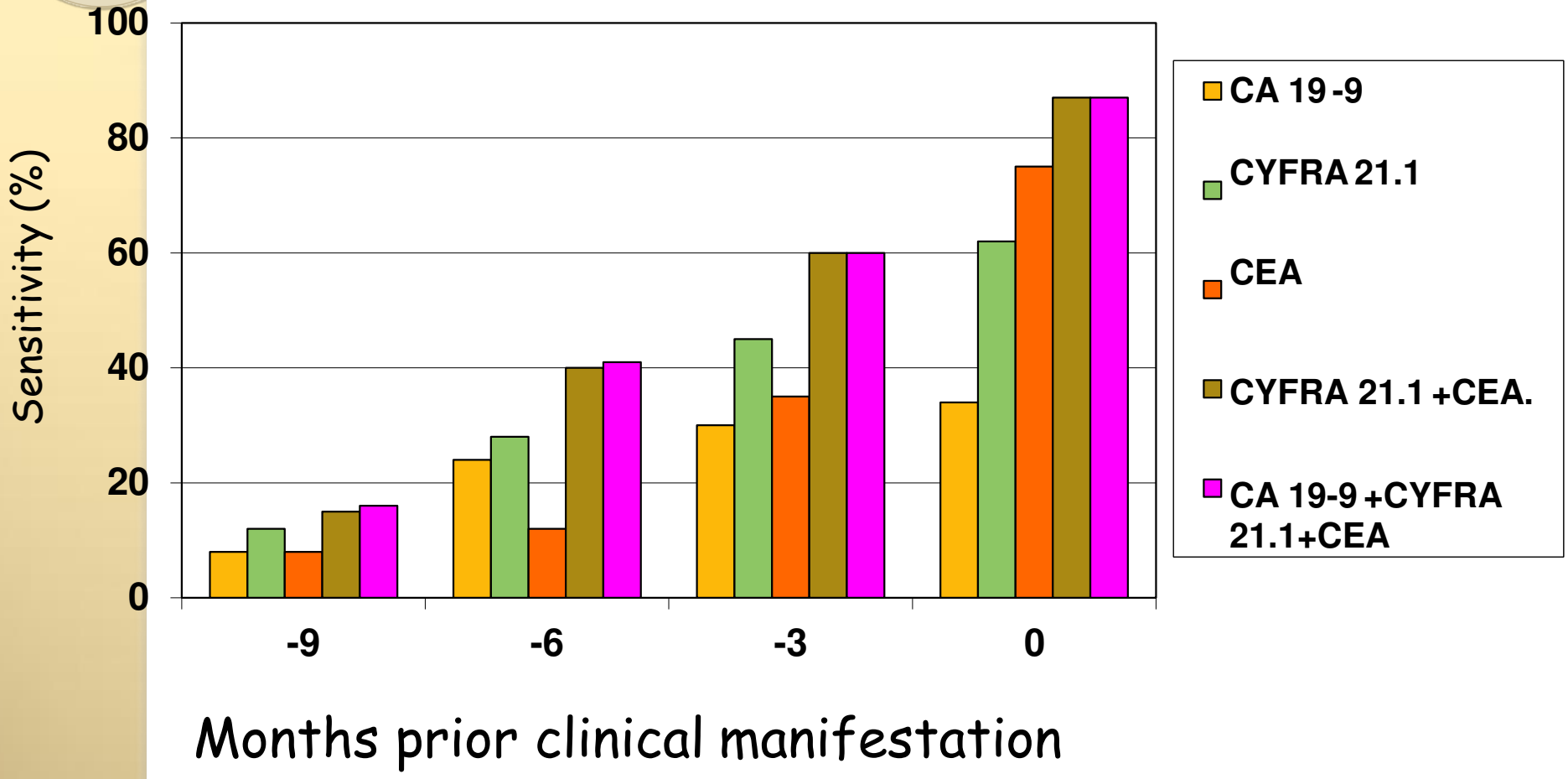
PSA	PHI	n	biopsie	MR	PET MR
0 - 2		400	0	0	0
2 - 10	< 40	200	0(200)	0(200)	0 (50)
	> 40	**400**	400	400	
10 -20	< 40	100	100	100	0(100)
	> 40	200	200	200	200
20 - 50		50	50	50	50
TOTAL		1350	750 (950)	750(950)	250 (400)
Reduction			200	200	150

Disease follow up monitoring

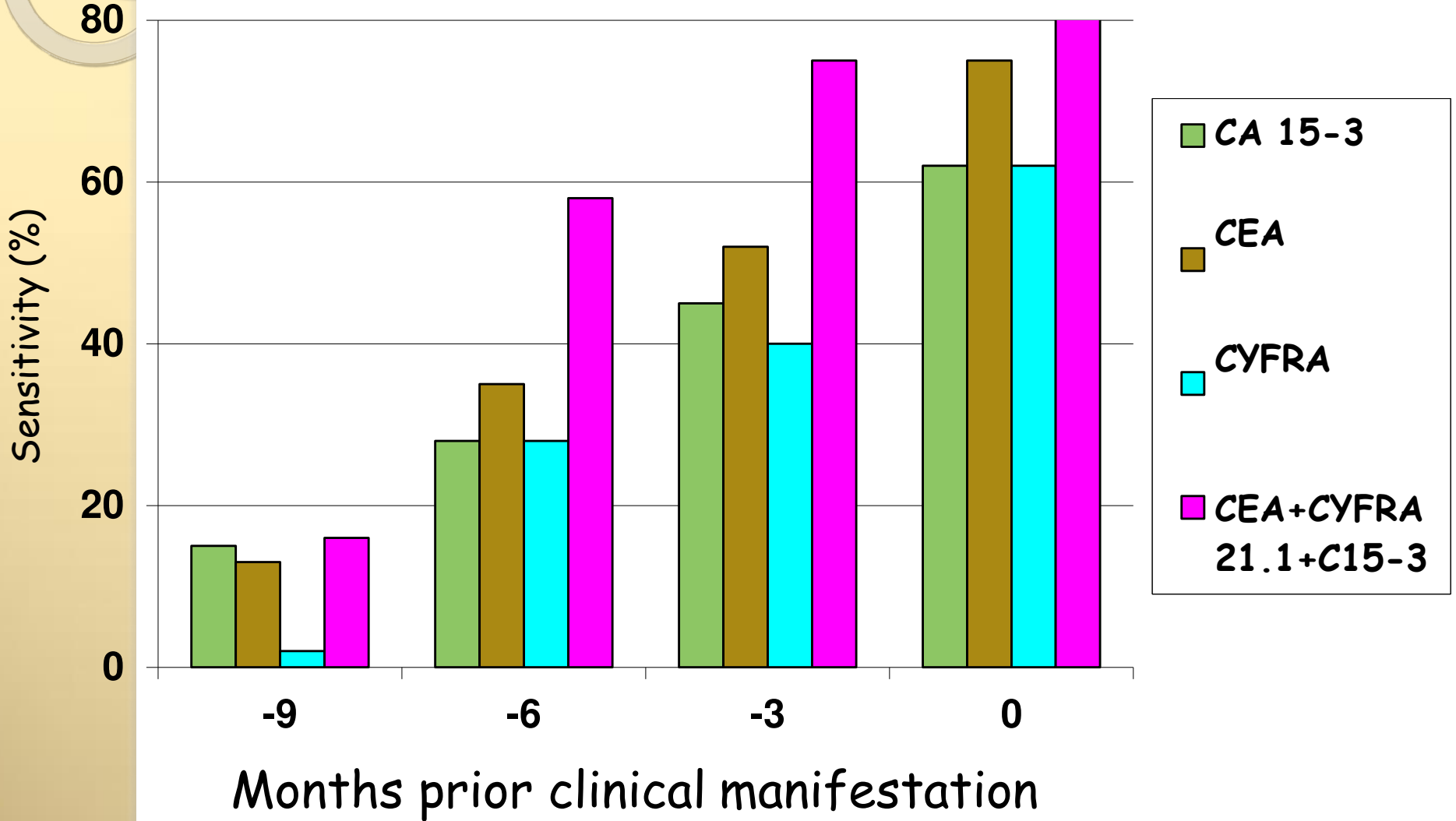
Significant differences of the pre and post-operative CEA examination



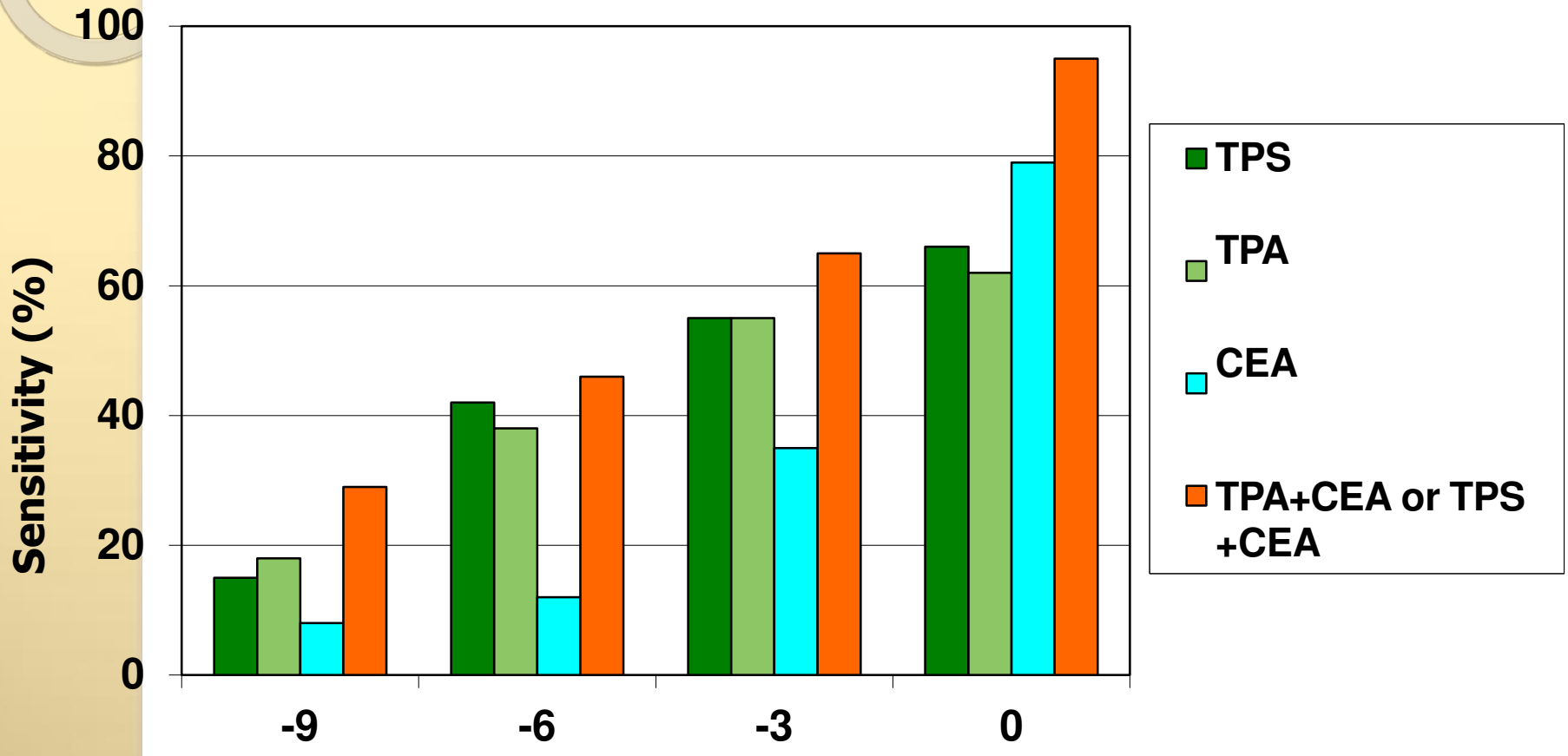
Sensitivity of TM prior clinical signs of progression colorectal cancer C 18 – C 20 (n = 456)



Sensitivity TM
prior clinical signs of progression breast cancer
C 50 (n = 356)



Sensitivity TM prior clinical signs of progression meta to liver (C 78.7) (n = 188)



Months prior clinical manifestation

CRACTES software

estimates the prognosis for certain tumor diagnosis

"Will clinically evident metastases develop in case of a patient in remission by the next check-up?"

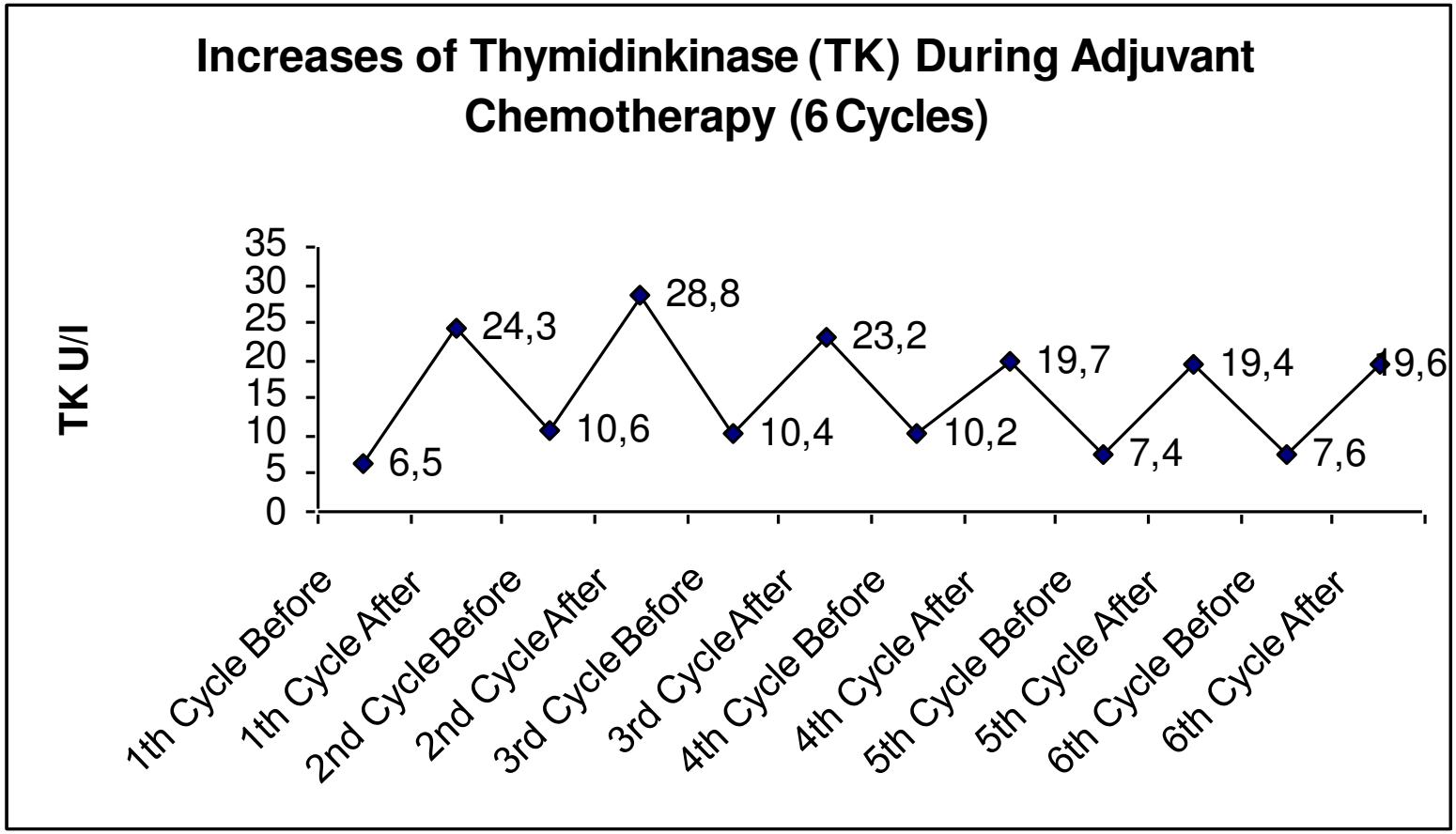
- the risk of development of distant metastases in the course of approx. next 3 months and their location
- the physician can – in order to make the prognosis more precise – fills the patient's clinical status into the requisite form:
  - progression,
  - remission,
  - suspected progression,
  - indeterminable, etc.

Therapy effect monitoring

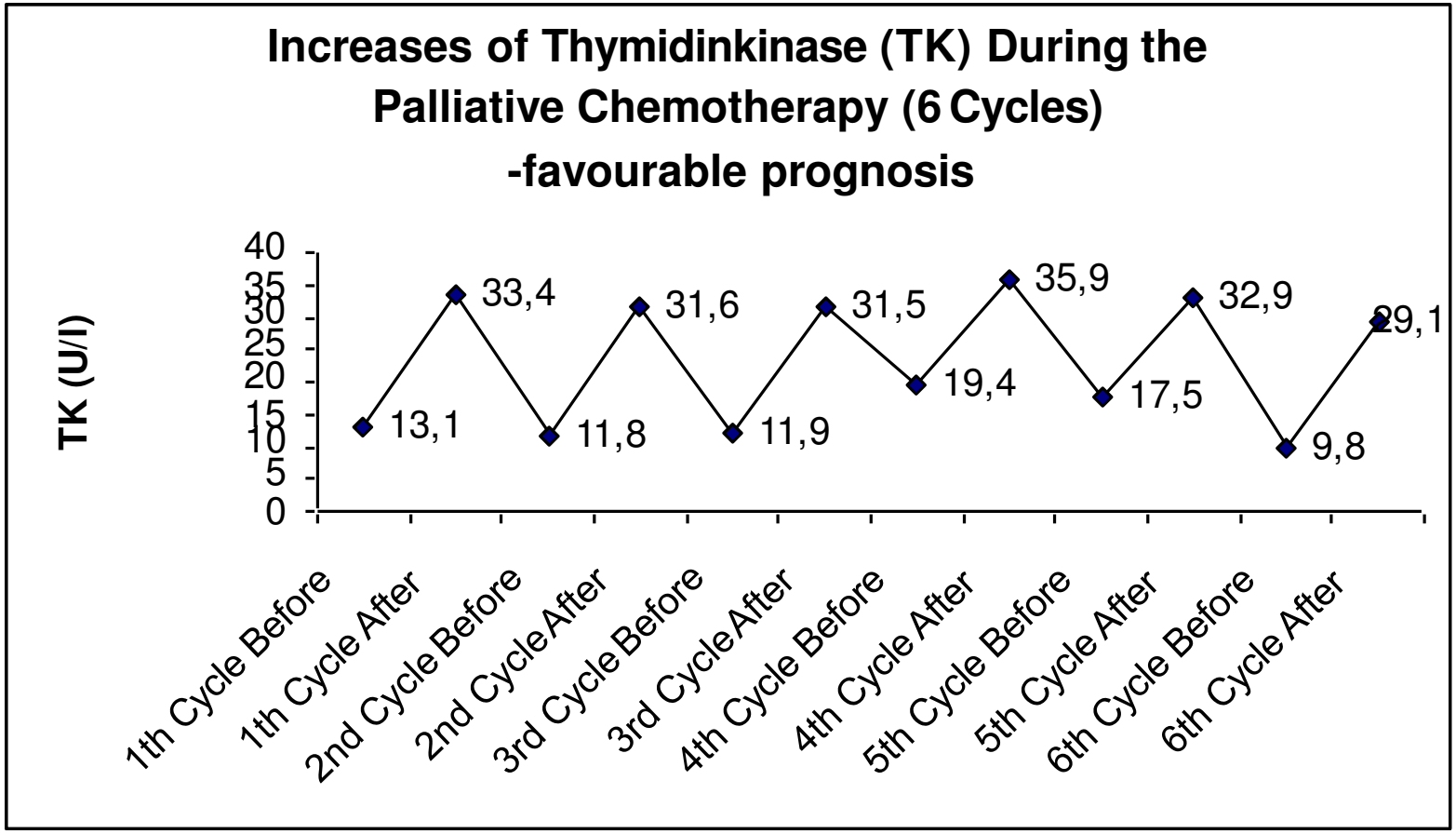
Changes of TK, CEA, CA 19- 9 levels SUCCESSFUL ADJUVANT CHT

CHT Cycle	TK		CEA		CA 19 -9	
	Median	Min -Max	Median	Min -Max	Median	Min -Max
B 1.	4	1 - 6	1.8	1- 3	21	16 -24
A 1.	20	8 -25	1.9	1 -2.5	19	18 -36
B 2.	6	4 - 10	1.5	0.8-2.6	24	20 -25
A 2.	28	16- 40	1.9	1-3	20	14 -25
B 3.	8	5 -13	1.6	0.5 -2	16	12 -20
A 3.	35	16 -45	1.1	0.5 -2	19	17 -26

CHANGES OF TK DURING ADJUVANT CHEMOTHERAPY



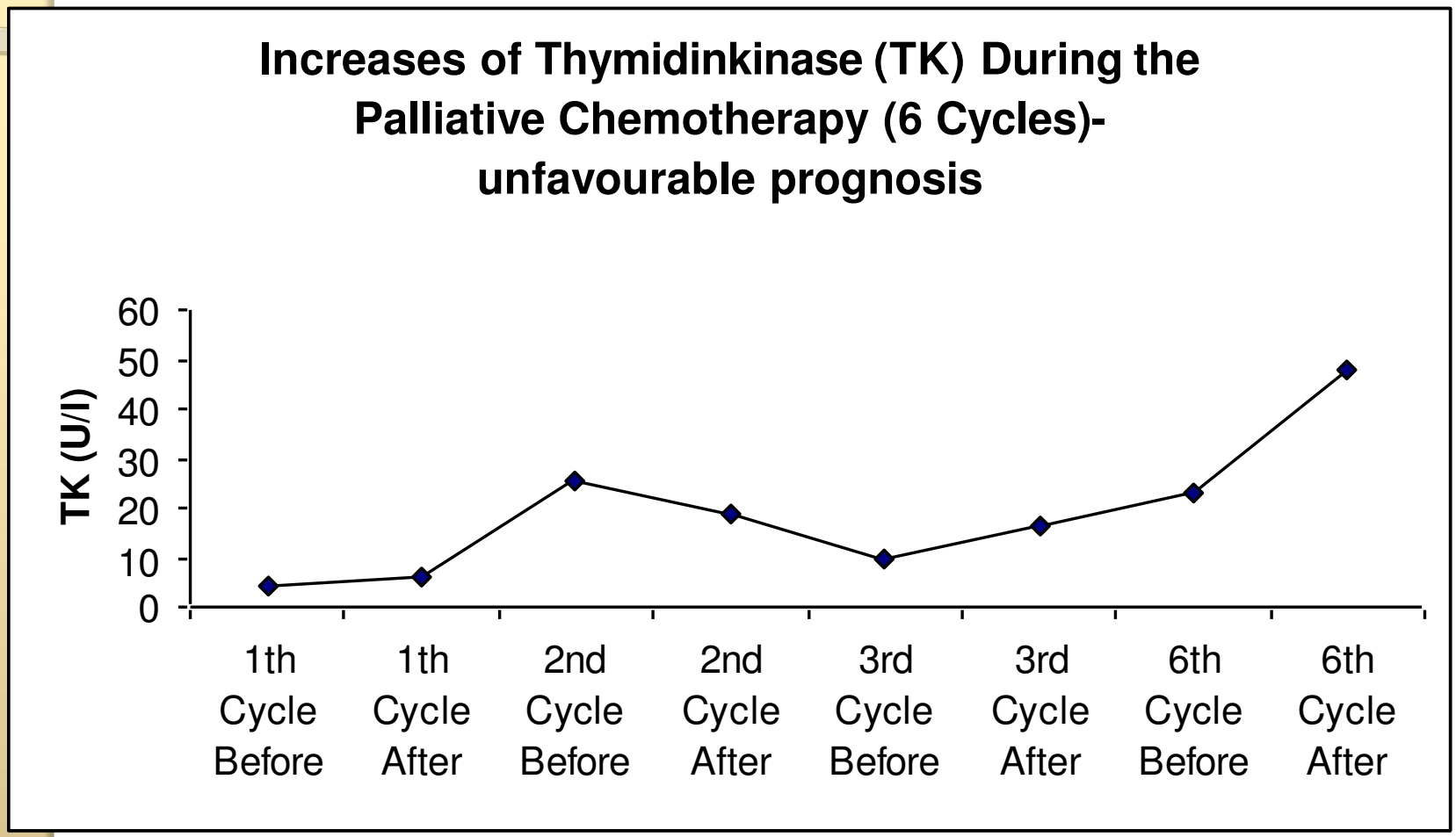
CHANGES OF TK DURING PALLIATIVE CHEMOTHERAPY



CEA and CA 19-9 levels
Successful palliative therapy

Date	CEA	CA 19-9
31. 3.2003	191	321
2. 4.2003	245	350
14. 4.2003	174	202
16. 4.2003	181	184
28. 4.2003	169	141
30. 4.2003	108	181
9. 6.2003	14	90.2
11. 6.2003	14	78.8

CHANGES IN THYMIDINEKINASE (TK) DURING PALLIATIVE CHEMOTHERAPY



CEA and CA 19-9
Unsuccessful palliative therapy

Date	CEA	CA 19-9
17. 2.2003	349	688
19. 2.2003	346	717
18. 3.2003	259	799
20. 3.2003	293	804
15. 4.2003	306	664
17. 4.2003	288	670

Conclusion I

- The optimal diagnostic algorithms were proposed for diagnostics and therapy monitoring of the lung, breast, colorectal and prostate cancer.
- Selected case reports demonstrated the use of them.
- Clinical and economical benefit of these proposed algorithms was evaluated.

Conclusions II

- Multidisciplinary approach based on these algorithms will enable to use the tumor markers for the **routine clinical practice** much more effectively.

Perspectives - Methodology

- Multiparametric and multiplex assay with computer assisted interpretation
- Circulating tumor cells
- Genomic, proteomic and microarrays
- Personalized medicine

Perspectives - Clinical

- Algorithm to individualization of target diagnosis and target therapy
- Correlation of biological activity of tumor with imaging techniques
- Incorporation of tumor markers into clinical and pharmacological trials.

It's all about the Final goal:

Improvement
in quality of life
and better survival rates
for patients with
oncological disease

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