Dose Terapêutica de I^{131}: Quando e como?

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Serviço de Endocrinologia e Metabologia da Universidade Federal do Paraná

- SEM CONFLITO DE INTERESSES

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Caso clínico

- IL, ♀, 76 anos

- Paciente encaminhada por nódulos tireoidanos achados no ecodoppler de carótidas

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- US tireoide (03/2013)
  - – 1/3 médio/inferior de lobo direito, sólido-cístico, com septos grosseiros inclusos na porção cística, medindo 2,6 x 1,9 x 2,2 cm com fluxo preferencialmente periférico ao Doppler
  - 1/3 superior de lobo esquerdo, hipoecoico, com vascularização central, 1,07 x 0,79 x 0,99 cm
- PAAF:
  - Bethesda VI
  - Positivo para malignidade

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- Encaminhada à tireoidectomia total
- AP:
  - Carcinoma papilífero de tireoide variante folicular, moderadamente diferenciado, multicêntrico e encapsulado, o maior foco com 1,2 x 1,0 x 0,8 cm, localizados no lobo esquerdo
  - Invasão angio-linfática presente e multifocal
  - Invasão capsular presente

Qual a conduta?

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- Há indicação de DTI^{131}?
  a) Sim
  b) Não

- Se indicada a dose, quanto você indicaria?
  a) 30mCi
  b) 100mCi
  c) 150mCi
  d) Nenhuma das anteriores

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Roteiro de aula

- Um pouco de história do iodo radioativo no carcinoma de tireoide
- Efeitos colaterais
- Baixas doses x altas doses
- *versus* nenhuma dose
- Indicação do iodo radioativo segundo a ATA 2015
- Estudos em andamento

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Como **era** a indicação de DTI^{131}?

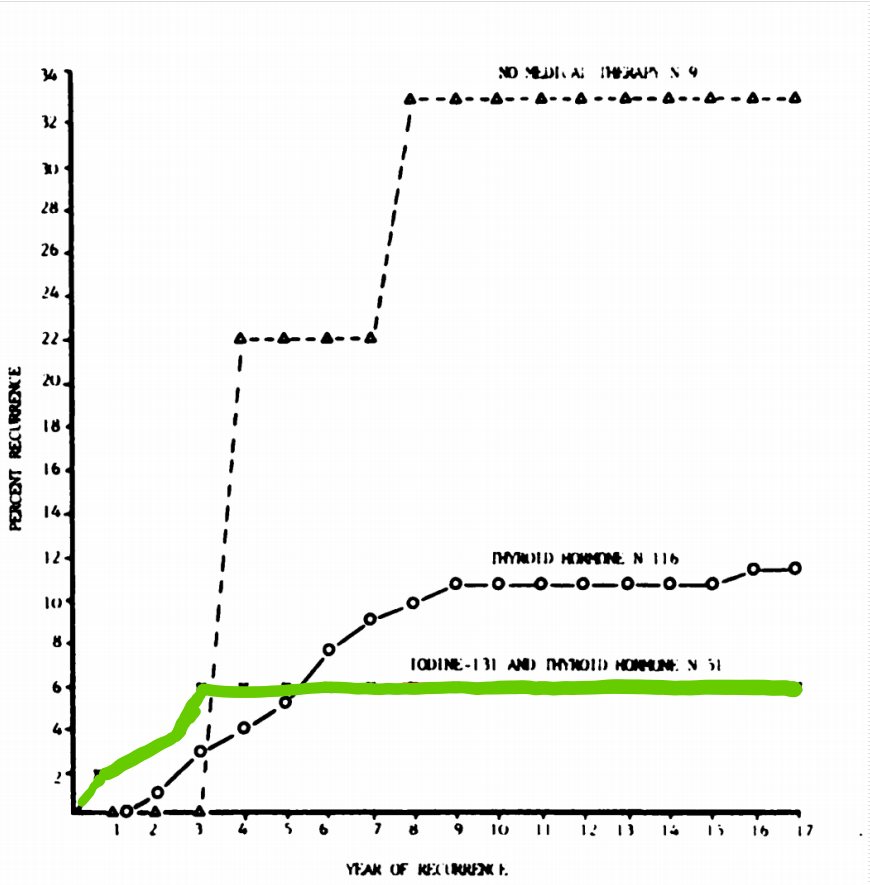

FIG. 1. Cumulative recurrence rate, divided according to type of medical therapy used postoperatively.

- Terapia com I^{131} é indicado em pacientes com **invasão extensa** e somos favoráveis ao seu uso em todos os pacientes.
- Somente carcinoma folicular
- ‘n’ grande de ETE

Young RL, Mazzaferri EL, *et al*. J Nucl Med 21: 733-737,1980

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I^{131} - eficácia e efeitos colaterais

EFEITOS COLATERAIS:

- Sialodenite e xerostomia
  - Alteração do paladar
- Dacriocistite e xeroftalmia
- Alteração transitória da fertilidade
- Alterações da medula óssea

Lamartina L et al, JCEM 100: 1748 –1761, 2015

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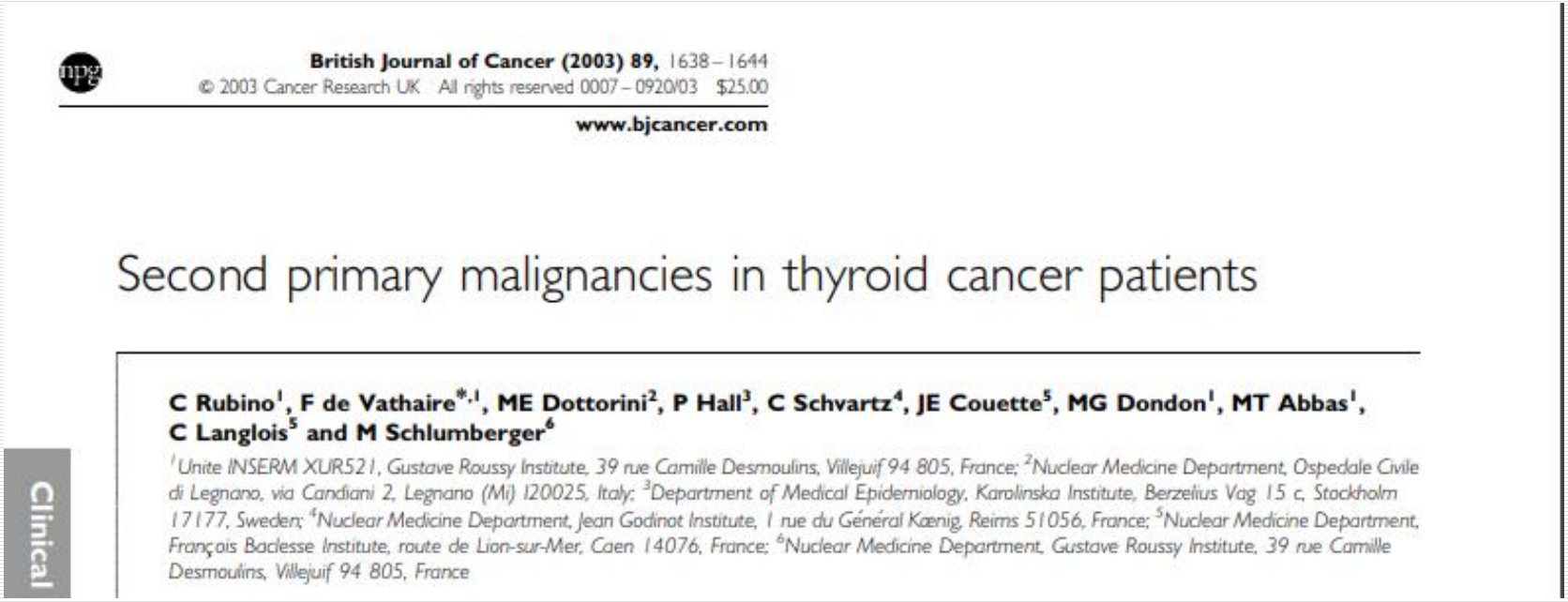
2003…



British Journal of Cancer (2003) 89, 1638 – 1644

www.bjcancer.com

Second primary malignancies in thyroid cancer patients

C Rubino[1], F de Vathaire[*,1], ME Dottorini[2], P Hall[3], C Schvartz[4], JE Couette[5], MG Dondon[1], MT Abbas[1], C Langlois[5] and M Schlumberger[6]

[1]Unite INSERM XUR521, Gustave Roussy Institute, 39 rue Camille Desmoulins, Villejuif 94 805, France; [2]Nuclear Medicine Department, Ospedale Civile di Legnano, via Candiani 2, Legnano (Mi) 120025, Italy; [3]Department of Medical Epidemiology, Karolinska Institute, Berzelius Vag 15 c, Stockholm 17177, Sweden; [4]Nuclear Medicine Department, Jean Godinot Institute, 1 rue du Général Kœnig, Reims 51056, France; [5]Nuclear Medicine Department, François Baclesse Institute, route de Lion-sur-Mer, Caen 14076, France; [6]Nuclear Medicine Department, Gustave Roussy Institute, 39 rue Camille Desmoulins, Villejuif 94 805, France

Clinical

- Aumento da incidência de adenocarcinomas **colorretais**, de **glândulas salivares**, **ósseos** e de **partes moles**.

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Risk of Structural Disease Recurrence

(In patients without structurally identifiable disease after initial therapy)

High Risk
Gross extrathyroidal extension, incomplete tumor resection, distant metastases, or lymph node >3 cm

Intermediate Risk
Aggressive histology , minor extrathyroidal extension, vascular invasion, or > 5 involved lymph nodes (0.2-3 cm)

Low Risk
Intrathyroidal DTC
≤ 5 LN micrometastases (< 0.2 cm)

- FTC, extensive vascular invasion (≈ 30-55%)
- pT4a gross ETE (≈ 30-40%)
- pN1 with extranodal extension, >3 LN involved (≈ 40%)
- PTC, > 1 cm, TERT mutated ± BRAF mutated* (>40%)
- pN1, any LN > 3 cm (≈ 30%)
- PTC, extrathyroidal, BRAF mutated*(≈ 10-40%)
- PTC, vascular invasion (≈ 15-30%)
- Clinical N1 (≈20%)
- pN1, > 5 LN involved (≈20%)
- Intrathyroidal PTC, < 4 cm, BRAF mutated* (≈10%)
- pT3 minor ETE (≈ 3-8%)
- pN1, all LN < 0.2 cm (≈5%)
- pN1, ≤ 5 LN involved (≈5%)
- Intrathyroidal PTC, 2-4 cm (≈ 5%)
- Multifocal PTMC (≈ 4-6%)
- pN1 without extranodal extension, ≤ 3 LN involved (2%)
- Minimally invasive FTC (≈ 2-3%)
- Intrathyroidal, < 4 cm, BRAF wild type* (≈ 1-2%)
- Intrathyroidal unifocal PTMC, BRAF mutated*, (≈ 1-2%)
- Intrathyroidal, encapsulated, FV-PTC (≈ 1-2%)
- Unifocal PTMC (≈ 1-2%)

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2008…

The HiLo Trial: a Multicentre Randomised Trial of High- versus Low-dose Radioiodine, with or without Recombinant Human Thyroid Stimulating Hormone, for Remnant Ablation after Surgery for Differentiated Thyroid Cancer

U. Mallick*, C. Harmer†, A. Hackshaw‡

*Northern Centre for Cancer Treatment, Newcastle General Hospital, Newcastle, UK; †The Royal Marsden Hospital, London, UK; ‡Cancer Research UK & UCL Cancer Trials Centre, London, UK

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2012…

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Ablation with Low-Dose Radioiodine and Thyrotropin Alfa in Thyroid Cancer

Ujjal Mallick, F.R.C.R., Clive Harmer, F.R.C.P., Beng Yap, F.R.C.P., Jonathan Wadsley, F.R.C.R., Susan Clarke, F.R.C.P., Laura Moss, F.R.C.P., Alice Nicol, Ph.D., Penelope M. Clark, F.R.C.Path., Kate Farnell, R.C.N., Ralph McCready, D.Sc., James Smellie, M.D., Jayne A. Franklyn, F.Med.Sci., Rhys John, F.R.C.Path., Christopher M. Nutting, M.D., Kate Newbold, F.R.C.R., Catherine Lemon, F.R.C.R., Georgina Gerrard, F.R.C.R., Abdel Abdel-Hamid, F.R.C.R., John Hardman, F.R.C.R., Elena Macias, M.D., Tom Roques, F.R.C.R., Stephen Whitaker, M.D., Rengarajan Vijayan, F.R.C.R., Pablo Alvarez, M.Sc., Sandy Beare, Ph.D., Sharon Forsyth, B.Sc., Latha Kadalayil, Ph.D., and Allan Hackshaw, M.Sc.

Conclusions

Low-dose radioiodine plus thyrotropin alfa was as effective as high-dose radioiodine, with a lower rate of adverse events.

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Strategies of Radioiodine Ablation in Patients with Low-Risk Thyroid Cancer

Table 3. Follow-up Testing of Thyroid Ablation 6–10 Months after ^{131}I Administration in the 684 Patients Who Could Be Evaluated, According to Thyrotropin-Stimulation Method and ^{131}I Dose.

Characteristic	Recombinant Human Thyrotropin		Thyroid Hormone Withdrawal	
	1.1 GBq (N=177)	3.7 GBq (N=171)	1.1 GBq (N=170)	3.7 GBq (N=166)
Neck ultrasonography — no. (%)				
Normal	171 (97)	161 (94)	163 (96)	157 (95)
Suspicious	6 (3)	10 (6)	7 (4)	9 (5)
Cytologic test normal	1 (<1)	3 (2)	1 (<1)	3 (2)
Cytologic test abnormal	0	1 (<1)	0	2 (1)
Cytologic test not performed	5 (3)	6 (4)	6 (4)	4 (2)
Presence of antithyroglobulin antibody — no. (%)	10 (6)	4 (2)	10 (6)	8 (5)
Total-body scan normal	6 (3)	3 (2)	7 (4)	7 (4)
Total-body scan abnormal	0	0	1 (<1)	0
Total-body scan not performed*	4 (2)	1 (<1)	2 (1)	1 (<1)
Absence of antithyroglobulin antibody				
Local determination				
Thyroglobulin ≤1 ng/ml — no./total no. (%)	157/167 (94)	160/167 (96)	152/160 (95)	152/158 (96)
Central determination				
Thyroglobulin ≤1 ng/ml — no./total no. (%)	148/158 (94)	155/160 (97)	146/152 (96)	142/148 (96)
Thyroglobulin ≤1.4 ng/ml — no./total no. (%)	150/158 (95)	156/160 (98)	146/152 (96)	143/148 (97)
Missing data — no.	9	7	8	10
Thyroid ablation				
With local thyroglobulin determination — no. (%)				
Complete	160 (90)	159 (93)	156 (92)	156 (94)
Incomplete	17 (10)	12 (7)	14 (8)	10 (6)
With central thyroglobulin determination — no./total no. (%)†				
Complete	151/168 (90)	154/164 (94)	150/162 (93)	145/156 (93)
Incomplete	17/168 (10)	10/164 (6)	12/162 (7)	11/156 (7)

* A total-body scan was not performed in patients with a suspicious finding on neck ultrasonography or a thyroglobulin level greater than 1 ng per milliliter.
† For each column, the total number of patients includes both patients for whom central thyroglobulin determination was available (and who had no detectable antithyroglobulin antibody) and patients with antithyroglobulin antibody.

O uso de baixas doses (30mCi) de I^{131} sob TSHrh parecer ser suficiente para tratar pacientes de baixo risco

Schlumberger et al; NEJM 2012; 366:1663-1673

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Na indicação da DTI^{131}, avaliar:

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2016 – ATA Guidelines

São fundamentais
o **ESTADIAMENTO**
e
a **ESTRATIFICAÇÃO DE RISCO!!!!**

2016 – ATA Guidelines

TABLE 14. CHARACTERISTICS ACCORDING TO THE AMERICAN THYROID ASSOCIATION RISK STRATIFICATION SYSTEM AND AJCC/TNM STAGING SYSTEM THAT MAY IMPACT POSTOPERATIVE RADIOIODINE DECISION-MAKING

ATA risk Staging (TNM)	*Description*	*Body of evidence suggests RAI improves disease-specific survival?*	*Body of evidence suggests RAI improves disease-free survival?*	*Postsurgical RAI indicated?*
ATA low risk T1a N0,Nx M0,Mx	Tumor size ≤1 cm (uni-or multi-focal)	No	No	No
ATA low risk T1b,T2 N0, Nx M0,Mx	Tumor size >1–4 cm	No	Conflicting observational data	Not routine[b]—May be considered for patients with aggressive histology or vascular invasion (ATA intermediate risk).
ATA low to intermediate risk T3 N0,Nx M0,Mx	Tumor size >4 cm	Conflicting data	Conflicting observational data	Consider[b]—Need to consider presence of other adverse features. Advancing age may favor RAI use in some cases, but specific age and tumor size cutoffs subject to some uncertainty.[a]
ATA low to intermediate risk T3 N0,Nx M0,Mx	Microscopic ETE, any tumor size	No	Conflicting observational data	Consider[b]—Generally favored based on risk of recurrent disease. Smaller tumors with microscopic ETE may not require RAI.
ATA low to intermediate risk T1-3 N1a M0,Mx	Central compartment neck lymph node metastases	No, except possibly in subgroup of patients ≥45 years of age (NTCTCSG Stage III)	Conflicting observational data	Consider[b]—Generally favored, due to somewhat higher risk of persistent or recurrent disease, especially with increasing number of large (>2–3 cm) or clinically evident lymph nodes or presence of extranodal extension. Advancing age may also favor RAI use.[a] However, there is insufficient data to mandate RAI use in patients with few (<5) microscopic nodal metastases in central compartment in absence of other adverse features.
ATA low to intermediate risk T1-3 N1b M0,Mx	Lateral neck or mediastinal lymph node metastases	No, except possibly in subgroup of patients ≥45 years of age	Conflicting observational data	Consider[b]—Generally favored, due to higher risk of persistent or recurrent disease, especially with increasing number of macroscopic or clinically evident lymph nodes or presence of extranodal extension. Advancing
ATA high risk T4 Any N Any M	Any size, gross ETE	Yes, observational data	Yes, observational data	Yes
ATA high risk M1 Any T Any N	Distant metastases	Yes, observational data	Yes, observational data	Yes

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Quando indicar DTI^{131}???

ATA high risk T4 Any N Any M	Any size, gross ETE	Yes, observational data	Yes, observational data	Yes
ATA high risk M1 Any T Any N	Distant metastases	Yes, observational data	Yes, observational data	Yes

- Evidência de **doença residual**
  - Invasão extratireoidiana grosseira
  - Metástase à distância

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2016 – ATA Guidelines

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- Considerar na presença de **doença linfonodal** e em pacientes **acima de 55 anos**

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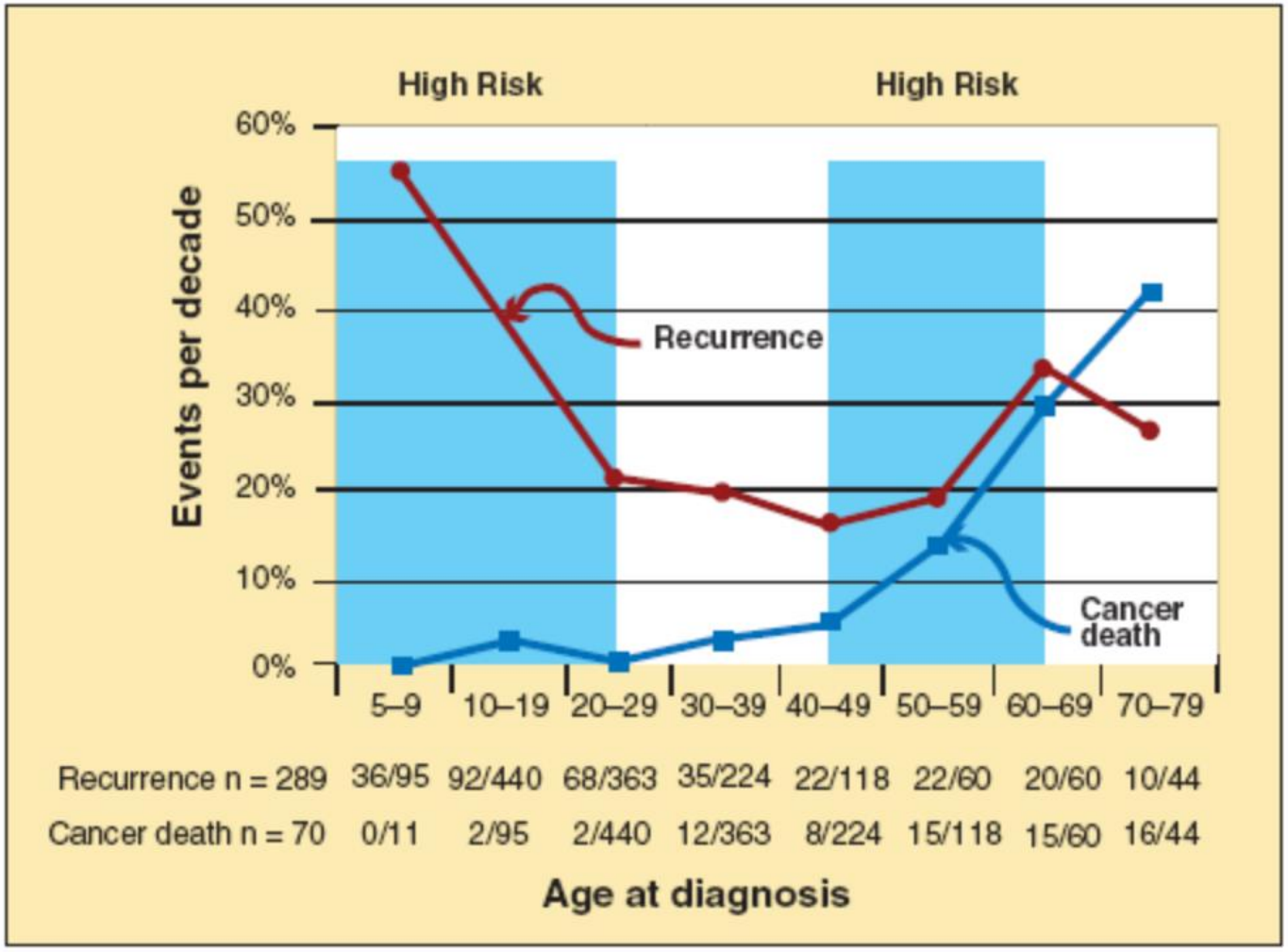
Recorrência e Mortalidade CDT



Mazzaferri EL. Oncology (Williston Park). 2009 Jun;23(7):579-88

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2016 – ATA Guidelines

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Quando NÃO indicar DTI^{131}???

ATA risk Staging (TNM)	*Description*	*Body of evidence suggests RAI improves disease-specific survival?*	*Body of evidence suggests RAI improves disease-free survival?*	*Postsurgical RAI indicated?*
ATA low risk T1a N0,Nx M0,Mx	Tumor size ≤1 cm (uni-or multi-focal)	No	No	No

- Muito baixo risco:
  - Tumor ≤ 1 cm
  - Sem linfonodos comprometidos
  - Sem metástases à distância

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E no baixo risco?
Vale à pena fazer DTI131???

ATA low risk T1b,T2 N0, Nx M0,Mx	Tumor size >1–4 cm	No	Conflicting observational data	Not routine[b]—May be considered for patients with aggressive histology or vascular invasion (ATA intermediate risk).
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NÃO deve ser feito de rotina

Dados conflitantes!

Considerar:

- **Tipo histológico** (carcinoma de células altas, células colunares, variante hobnail, carcinoma folicular com **invasão vascular**)
- Invasão **extratireoidiana mínima**

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Low-Risk Differentiated Thyroid Cancer and Radioiodine Remnant Ablation: A Systematic Review of the Literature

- **Ecografia cervical associada à tireoglobulina** é equivalente à PCI pós-ablação de remanescentes tireoidianos

- Os dados são conflitantes sobre a evolução de pacientes irradiados e os estudos de qualidade são poucos

Lamartina L et al, JCEM 100: 1748 –1761, 2015

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Low-Risk Differentiated Thyroid Cancer and Radioiodine Remnant Ablation: A Systematic Review of the Literature

- A avaliação cuidadosa dos aspectos **patológicos** e das **características** e preferências dos **pacientes** deve guiar a indicação do uso do I^{131} para ablação dos remanescentes tireoidianos

Lamartina L et al, JCEM 100: 1748 –1761, 2015

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- A sobrevida e a sobrevida livre de doença não é afetada por causa da radioiodoterapia

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Clinical outcomes of low and intermediate risk differentiated thyroid cancer patients treated with 30mCi for ablation or without radioactive iodine therapy

	Without RRA (n = 102)	Low dose RRA (30mCi) (n = 87)	p-value
Age	49 (18-86)	43 (19-80)	**0.04**
Gender-female	93.1% (n = 94)	86.2% (n = 75)	0.09
Histology Papillary thyroid cancer	93.1% (n = 94)	95.4% (n = 83)	0.36
ETE	14.7% (n = 15)	29.9% (n = 26)	**0.01**
Multifocality	34.3% (n = 35)	39.1% (n = 34)	0.54
Size (cm)	1 (0.9-9)	1 (0.3-4.0)	0.21
Vascular invasion	8.8% (n = 9)	13.8% (n = 12)	0.35
N1	15.7% (n = 16)	23% (n = 20)	0.26
Post-operative non-stimulated Tg	1.25 (< 0.1-34)	0.77 (< 0.1-15)	0.59
Undetectable post-operative Suppressed Tg	65.7% (n = 67)	49.4% (n = 43)	**< 0.001**
Positive Anti-Tg	6.9% (n = 7)	8.0% (n = 7)	0.78
ATA 2016 risk stratification			
Low	78.4% (n = 80)	57.5% (n = 50)	**0.04**
Intermediate	20.5% (n = 21)	42.5% (n = 37)	
High	1% (n = 1)	0	
Median follow-up (months)	40.5 (1-488)	49.6 (4-321)	0.63
Recurrence/persistence structural disease	1% (n = 1)	1.1% (n = 1)	0.55
Additional therapy	1% (n = 1)	2.3% (n = 2)	0.59
Response to therapy – first 2 years of follow-up			
Excellent	68.6% (n = 70)	81.6% (n = 71)	0.08
Indeterminate	26.5% (n = 27)	13.8% (n = 12)	
Biochemical incomplete	2.9% (n = 3)	2.3% (n = 2)	
Structural incomplete	2% (n = 2)	2.3% (n = 2)	
Tg trend over time (suppressed and/or stimulated)			
Decline	67.6% (n = 69)	56.3% (n = 49)	0.13
Clinical status at final follow-up			
NED without additional therapy	98% (n = 100)	98,8% (n = 86)	0.59
NED after additional therapy	1% (n = 1)	1.2% (n = 1)	
Recurrent/persistent of disease after additional therapy	0%	0%	
Recurrent/persistent of disease without additional therapy	1% (n = 1)	0%	
Death from disease	0%	0%	

Súss SKA et al. Arch Endocrinol Metab. 2018;62(2):149-56

SEMPR

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Recurrent/persistent of disease without additional therapy	1% (n = 1)	0%	
Death from disease	0%	0%	

Nos nossos pacientes (SEMPR e INCA), **não houve diferença** no desfecho se submetidos ou não à DTI131

Súss SKA et al. Arch Endocrinol Metab. 2018;62(2):149-56

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RESPOSTA À TERAPIA (6-24 meses) EM PACIENTES DE RISCO BAIXO (n=153)

Pacientes Baixo Risco	Excelente (n=94)	Indeterminada (n=30)	Bioquímica Incompleta (n=3)	Estrutural Incompleta (n=3)	Valor p
Idade (anos)	44.5 (20-86)	45.5 (26-76)	42 (32-57)	53 (39-79)	0.61
Sexo - feminino	89.4% (n=100)	90% (n=27)	100% (n=3)	100% (n=3)	0.72
Histologia CPT	92% (n=103)	94.3% (n=33)	100% (n=3)	100% (n=3)	0.88
Tg supr pós operatória	**0.1 (<0.1-3.4)**	**1.0 (<0.1-3.0)**	N/D	N/D	**<0.001**
Tamanho (cm)	2.0 (0.1-9.0)	1.0 (0.2-6)	1.7 (x-2.0)	1.2 (1.1-1.4)	0.78
pN1	**8.0% (n=9)**	**11.8% (n=4)**	0%	66.7% (n=2)	**0.04**
RAI	**50% (n=56)**	**32.4% (n=11)**	33.3% (n=1)	33.3% (n=1)	**0.24**

* Ajustado para: idade, sexo, histologia, EET, multifocalidade, tamanho tumoral, invasão vascular, pN1, Tg suprimida pós operatória, Tg indetectável pós operatória, Anti-Tg positivo, estratificação de risco (ATA 2015). N/D: não disponível

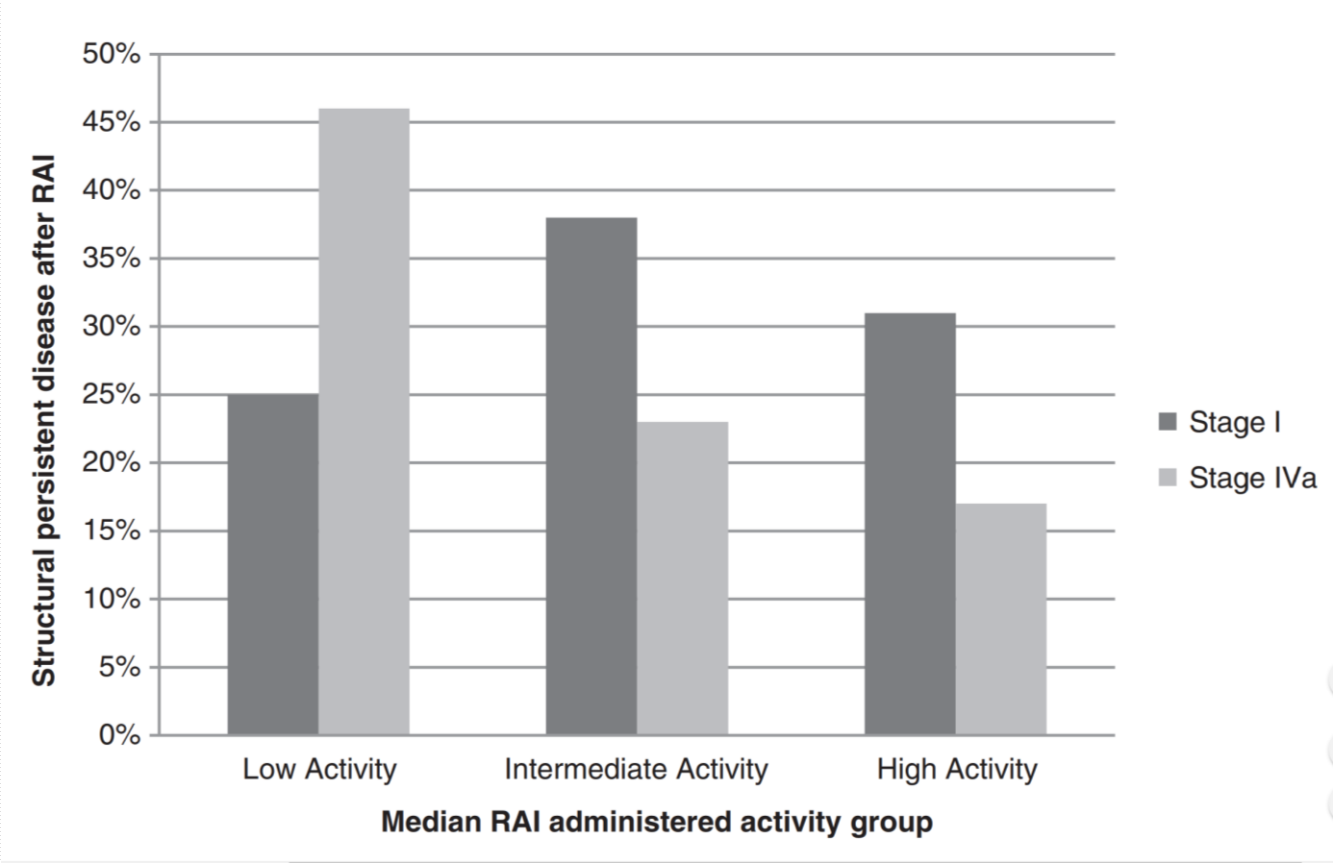
SEMPR

Risco baixo - intermediário

- Tg?

SEMPR

DTI^{131}:< 45 anos (I) x > 45 anos (IVa)



~100mCi ~ 150mCi ~200mCi

Sabra MM *et al*. Thyroid; 2014, 24(7):1088-1095

SEMPR

TABLE 5. PATIENT CHARACTERISTICS BY TNM STAGE

	Stage I (n = *181*)	*Stage IVa* (n = *70*)	p-*Value*
Sex			
Female	81 (72%)	32 (28%)	<0.001
Male	30 (44%)	38 (56%)	
Age at diagnosis (years)	33 ± 7	54 ± 6	<0.001
Histology			
c-PTC	88 (64%)	49 (36%)	
TCV-PTC	11 (44%)	14 (56%)	0.23
FV-PTC	3 (69%)	4 (31%)	
Other PTC	3 (50%)	3 (50%)	
ETE			
Vascular invasion			
None	85 (66%)	43 (34%)	0.09
Present	20 (51%)	19 (49%)	
Size of N1b nodes (cm)	2 ± 1	2 ± 1	0.93
ENE			
None	37 (63%)	22 (37%)	
Present	49 (60%)	33 (40%)	0.72
Method of ablation			
rhTSH	79 (60%)	53 (40%)	0.52
THW	30 (65%)	16 (35%)	
RAI ablation (mCi)			
Mean ± SD	145 ± 37	170 ± 71	0.002
Median	150	150	
Range	75–300	94–468	
24-hour % neck uptake	0.8 ± 0.9	0.8 ± 1	0.90
Follow-up time (years)	5.6 ± 4.6	5.8 ± 5.0	0.78

SEMPR

Alto risco

- Qual a melhor dose?
- 100 – 150 mCi cada 3-6 meses

Klain M *et al*. Eur J Nucl Med (2002) 29 (Suppl. 2):S479–S485

SEMPR

- Encaminhada à tireoidectomia total
- AP:
  - Carcinoma papilífero de tireoide variante folicular, moderadamente diferenciado, multicêntrico e encapsulado, o maior foco com 1,2 x 1,0 x 0,8 cm, localizados no lobo esquerdo
  - Invasão angio-linfática presente e multifocal
  - Invasão capsular presente

Qual a conduta?

SEMPR

Obrigada!!

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- Gisah A. Carvalho
- Hans Graf

- Evandro Vasconcelos
- Nicholas
- Marja

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