



Roma, 9-12 novembre 2017



ITALIAN CHAPTER



# Termoablazione laser dei noduli benigni

Prof. Pierpaolo De Feo

Dott. Giovanni Gambelunghe



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# Conflitti di interesse



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Ai sensi dell'art. 3.3 sul conflitto di interessi, pag 17 del Regolamento Applicativo Stato-Regioni del 5/11/2009, dichiaro che negli ultimi 2 anni **NON** ho avuto alcun rapporto di finanziamento con nessun soggetto portatore di interessi commerciali in campo sanitario.



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# Noduli solidi NON tossici



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Numerosi sono gli studi che provano la efficacia e sicurezza della metodica ablativa laser ModìLite (Elesta, Firenze), con efficacia che, come tutte le metodiche invasive, è operatore e centro-dipendente.



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# Clinical Outcomes of Patients with Symptomatic Benign Thyroid Cold Nodules Treated with PLA



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Author	Pts/Nodules no.	RCT	Mean Baseline Vol (ml)	Laser source	Number of session (mean)	FU months	Volume Reduction % (mean)
Dossing <i>et al</i> (2002)	16		10.0	Diomed 15 plus, 810 nm	1	6	46
Spiezia <i>et al</i> (2003)	5		11.1	Nd:Yag smart , 1064nm	2.2	12	61
Pacella <i>et al</i> (2004)	8		22.7	Nd:Yag smart , 1064nm	4.1	6	63
Papini <i>et al</i> (2004)	20		24.1	Nd:Yag smart , 1064nm	2.2	6	64
Dossing <i>et al</i> (2005)	15vs15 <sup>a</sup>	yes	8.2	Diomed 15 plus, 810 nm	1	6	44(median)
Dossing <i>et al</i> (2006)	15vs15 <sup>b</sup>		10.1/10.8	Diomed 15 plus, 810 nm	1/3	6	44/57
Amabile <i>et al</i> (2006)	23		15.0	Quanta D-Plus, 980 nm	1.2	3	36
Gambelunghe <i>et al</i> (2006)	13vs13 <sup>a</sup>	yes	8.2	Nd:Yag smart , 1064nm	1	30 weeks	44 (median)
Cakir <i>et al</i> (2006)	12/15		11.9	Diomed 15 plus, 810 nm	1.5	12	82
Papini <i>et al</i> (2007)	21vs21vs 20 <sup>c</sup>	yes	11.7	Nd:Yag smart , 1064nm	1	12	44
Valcavi <i>et al</i> (2010)	122 <sup>d</sup>		23.1	Echolaser, 1064nm	1	36	48
Dossing <i>et al</i> (2011)	78	yes	8.2	Diomed 15 plus, 810 nm	1	67	51 (median)
Amabile <i>et al</i> (2011)	51 <sup>e</sup>		53.5	Quanta D-Plus, 980 nm	3.2 cycle	12	81
Gambelunghe <i>et al</i> (2013)	20/20 <sup>f</sup>		15/14	Echolaser, 1064nm	1	36	+11/57
Gambelunghe <i>et al</i> (2013)	50/50 <sup>g</sup>		21/21	Echolaser, 1064nm	1	6	55/56 (median)
Papini <i>et al</i> (2014)	101vs99 <sup>b</sup>	yes	12	Echolaser, 1064nm	1	36	57
Pacella <i>et al</i> (2015)	1531/1534		27	Echolaser, 1064nm	1.2	12	72
Achille <i>et al</i> (2016)	45		24	Echolaser, 1064nm	1	12	84
Negro <i>et al</i> (2016)	56		15.7	Echolaser, 1064nm	1	48	56
Shuhua Ma <i>et al</i> (2016)	90/118		6.1	Echolaser, 1064nm	1	18	99 <sup>b</sup>
Mauri (2016)	31		20.3	Echolaser, 1064nm	1	12	70
Pacella <i>et al</i> (2017)	449		21.5	Echolaser, 1064nm	1	12	63

Pts=Patients; <sup>a</sup> laser session vs control group; <sup>b</sup> one laser session vs three laser sessions; <sup>c</sup> pts treated with laser energy vs patients treated with L-T4 or no treated; <sup>d</sup> the energy was delivered continuously while retracting the applicators in a single session; <sup>e</sup> the energy was delivered continuously while extracting the needle in multiple sessions; <sup>f</sup> retrospective comparison between a group treated with low amount of energy and one treated with a high amount of energy; <sup>g</sup> retrospective comparison between patients treated with local anesthetic and patients treated without local anesthetic; <sup>h</sup> only 48 nodules have the 18months follow-up



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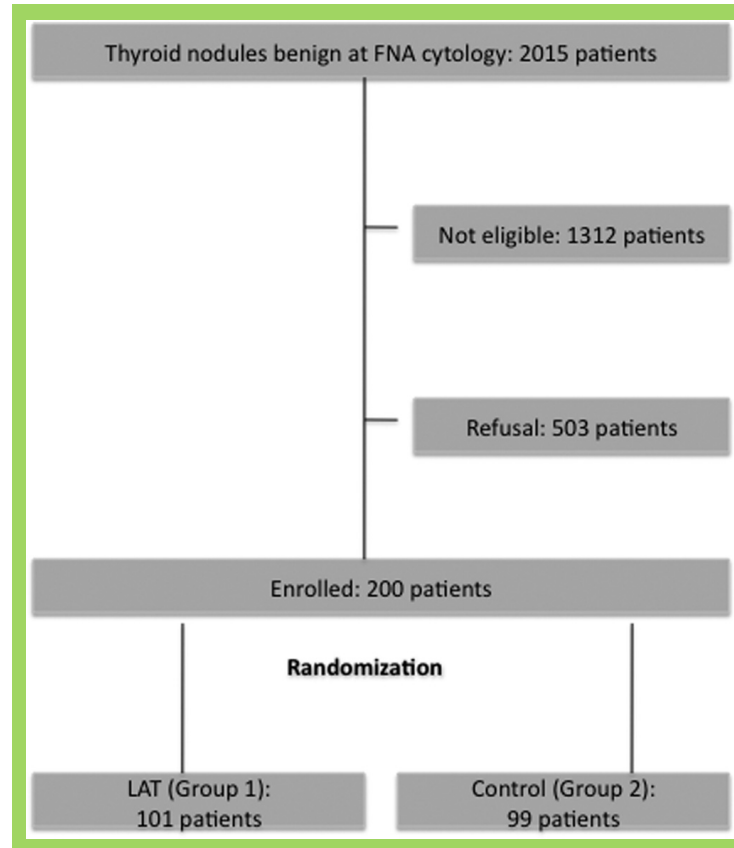


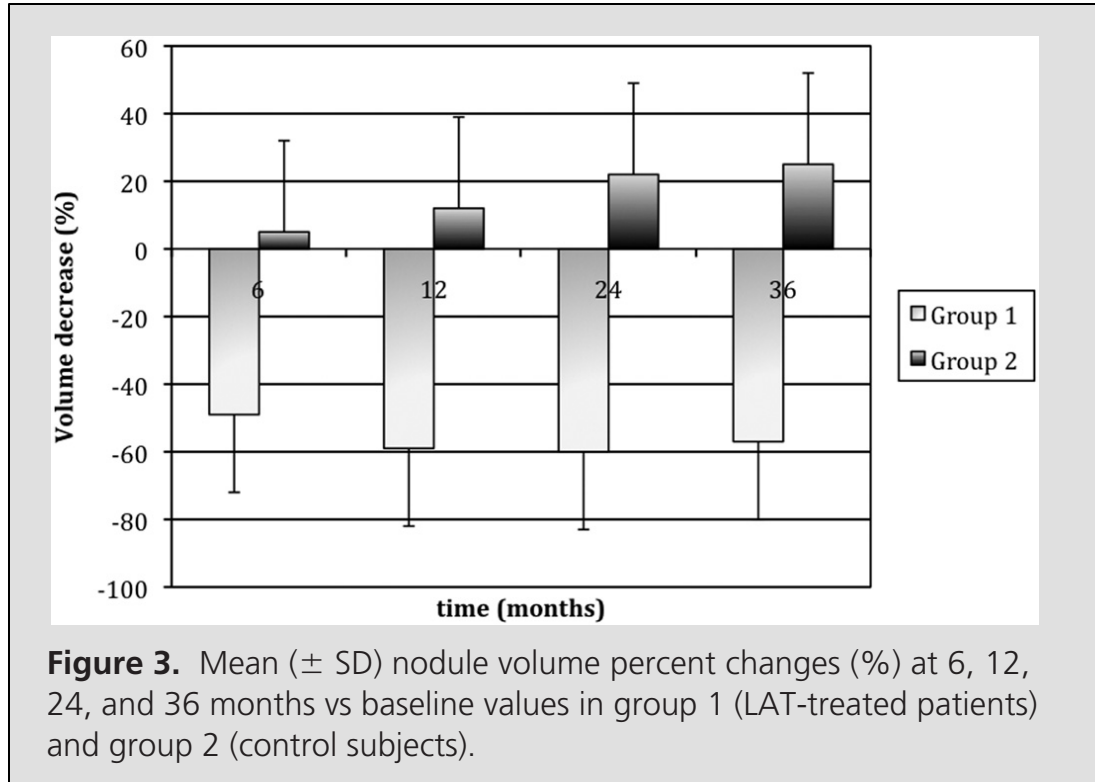
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# Long-term Efficacy of Ultrasound-guided Laser Ablation for Benign Solid Thyroid Nodules. Results of a Three-year Multicenter Prospective Randomized Trial

Papini E\*, Rago T, Gambelunghe G<sup>o</sup>, Valcavi R<sup>''</sup>, Bizzarri G<sup>\*\*</sup>, Vitti P, De Feo P<sup>o</sup>, F. Riganti<sup>''</sup>, Misischi I\*, Di Stasio<sup>oo</sup>, and Pacella CM<sup>\*\*</sup>







# Conclusioni



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- Una singola seduta laser con due fibre induceva una significativa riduzione di volume dei noduli trattati (60%), con conseguente miglioramento dei sintomi compressivi nella maggioranza dei noduli solidi, scintigraficamente freddi, sottoposti a trattamento. I risultati venivano raggiunti progressivamente in 6-12 mesi e si mantenevano stabili nei successivi 3 anni.



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## Outcomes and Risk Factors for Complications of Laser Ablation for Thyroid Nodules. A Multicenter Study on 1531 Patients

Pacella CM\*, Mauri G°, Achille G°, Barbaro D<sup>°°</sup>, Bizzarri G\*, De Feo P\*\*, Di Stasio E<sup>+</sup>, Esposito R, Gambelunghe G\*\*, Mischischi I\*\*\*, Raggiunti B, Rago T, Patelli GL<sup>#</sup>, D'este S<sup>#</sup>, Vitti P, and Papini E\*\*\*

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Hospital	No. of Pts <sup>1</sup> M/F	Age <sup>2</sup>	No of BTNs <sup>3</sup>	Vol. of BTNs <sup>2,3</sup>	Sessions mean	VR at 12th month	No. of Pts treated with two or more BTNs	Local Anaesthesia	Sedation yes/no	Major Complications No(%) <sup>4</sup>	Minor Complications no(%) <sup>4</sup>	Side Effects No(%) <sup>5</sup>
<b>Albano L.</b>	341 110/231	51.5 ± 13.7	341	13 ± 12 (2–126)	1,5	6.7 ± 10		yes	no	1 (0,3)	1 (0,3)	37 (10,9)
<b>Atri</b>	138 22/116	52.1 ± 12.1	138	13 ± 9 (1,5–45)	1	7.6 ± 8		yes	yes	3 (2,2)	2 (1,4)	20 (14,5)
<b>Alzano L</b>	36 4/32	58.6 ± 15.0	36	5 ± 3 (2–21)	1	8.4 ± 5		yes	yes	0 (0,0)	0 (0,0)	1 (2,8)
<b>Bari</b>	45 10/35	52.0 ± 13.3	45	24 ± 19 (1,4–93)	1	9.2 ± 13		yes	yes	1 (2,2)	0 (0,0)	13 (28,9)
<b>Cosenza</b>	242 62/180	54.4 ± 11.8	242	19 ± 13 (1,9–84)	1	7.6 ± 8		yes	no	0 (0,0)	0 (0,0)	54 (22,3)
<b>Livorno</b>	334 111/223	51.6 ± 31.1	337	49 ± 18 (10–78)	1.4	6.8 ± 8	3	no	no	1 (0,3)	0 (0,0)	184 (54,6)
<b>Perugia</b>	58 26/32	58.1 ± 8.9	58	25 ± 29 (7–215)	1.1	7.6 ± 7		yes	yes	2 (3,4)	2 (3,4)	51 (87,9)
<b>Perugia</b>	189 81/108	56.1 ± 9.9	189	20 ± 24 (3–216)	1.1	7.3 ± 11		no	yes	0 (0,0)	4 (2,1)	71 (37,6)
<b>Pisa</b>	148 18/130	52.6 ± 13.0	148	47 ± 27 (6–172)	1.1	7.2 ± 11		no	yes	0 (0,0)	0 (0,0)	32 (21,6)
<b>Combined Hospitals</b>	1531 444/1087	54.1 ± 14.3	1534	27 ± 24 (1,4–216)	1.2	7.2 ± 11	3			8 (0,5)	9 (0,6)	463 (30,2)

<sup>1</sup> Patients; <sup>2</sup> mean ± sd; <sup>3</sup> BTNs = Benign Thyroid Nodules; <sup>4</sup> value calculated per LAT sessions; <sup>5</sup> the values include all side effects intra-operatively and within 24 h days after the procedure



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Type of complications (SIR Class) <sup>1</sup>		Complications and Side Effects no. (%) <sup>2</sup>			
		Time of Detection			Time to Recovery (days)
		Intra-operatively	Immediate post-operative (within 24 h)	Peri-procedural (within 30 days)	Delayed (after 30 days)
<b>Major</b>					
	Voice change (C)		8 (0.5)*		2-84
<b>Minor</b>					
	Hematoma (B)		8 (0.4)		2-10
	Skin burn (B)		1 (0.1)		10
<b>Side Effects</b>					
Pain (A)					
	mild	194 (10.6)	61 (3.3)		1
	moderate	30 (1.6)	34 (1.9)		1-2
	severe		4 (0.2)		2-3
Vasovagal reaction (A)		12 (0.7)			
Cough (A)		1 (0.1)			
Fever (A)			141 (7.7)		1-4
(37.5 C-38.5 C)					



# Conclusioni



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- La riduzione di volume dei noduli era  $73 \pm 10\%$ .
- Notevoli miglioramenti si avevano sia sul “Local symptoms score” che sui “cosmetic signs”.



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# Esperienza nel centro di Perugia



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Volume (ml)	Pre-T.	3 mesi	6 mesi	1 anno	3 anni
<u><i>N = 633</i></u>					
Mediana	16	7,5 (- 53 %)	5,8 (- 64%)	5,8 (- 64%)	5,9 (- 64%)
Minimo	10	4	2,4	2,4	2,2
Massimo	289	197	114	44*	31*

\* II° trattamento



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# Dati di laboratorio



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	<b>Tempo 0</b>	<b>1 giorno</b>	<b>1 anno</b>	<b>3 anni</b>
<i>TSH</i> (uUI/ml)	$1,6 \pm 0,9$	$1,3 \pm 0,8$	$1,5 \pm 1$	$1,4 \pm 0,9$
<i>FT4</i> (pg/ml)	$10,1 \pm 1,9$	$15,7 \pm 4,9$	$10,1 \pm 1,9$	$10,3 \pm 1,2$
<i>TG</i> (ng/ml)	$72 \pm 378$	$4891 \pm 9346$	$77 \pm 327$	$79 \pm 311$



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# Complicazioni



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Febbricola	12%
Dolore di lieve entità	10%
Ematoma sottocutaneo	0,5 %



## *Clinical Report*

# **The Administration of Anesthetic in the Thyroid Pericapsular Region Increases the Possibility of Side Effects During Percutaneous Laser Photocoagulation of Thyroid Nodules**

**Giovanni Gambelunghe, M.D.,<sup>1\*</sup> Vittorio Bini, PHSc,<sup>1</sup> Massimo Monacelli, M.D.,<sup>2</sup> Nicola Avenia, M.D.,<sup>2</sup> Michele D'Ajello, M.D.,<sup>2</sup> Renato Colella, M.D.,<sup>3</sup> and Pierpaolo De Feo, M.D.<sup>1</sup>**

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<sup>3</sup>*Institute of Pathological Anatomy, University of Perugia, Perugia, Italy*







	Group A	Group B	OR	<i>P</i>
Fever	30/50 (60%)	12/50 (24%)	4.75	0.0003
Pain	21/50 (42%)	5/50 (10%)	6.51	0.0006
Dysphonia	1/50 (2%)	0/50		NS



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# Ultrasound-Guided Interstitial Laser Ablation for Thyroid Nodules Is Effective Only at High Total Amounts of Energy: Results From a Three-Year Pilot Study

**Giovanni Gambelunghe, MD, PhD<sup>1</sup>, Raffaella Fede, MD<sup>1</sup>, Vittorio Bini, PHSc<sup>1</sup>, Massimo Monacelli, MD<sup>2</sup>, Nicola Avenia, MD<sup>3</sup>, Michele D'Ajello, MD<sup>2</sup>, Renato Colella, MD<sup>1</sup>, Giovanni Nasini, MD<sup>1</sup>, and Pierpaolo De Feo, MD, PhD<sup>1</sup>**

Surgical Innovation

XX(X) 1-6

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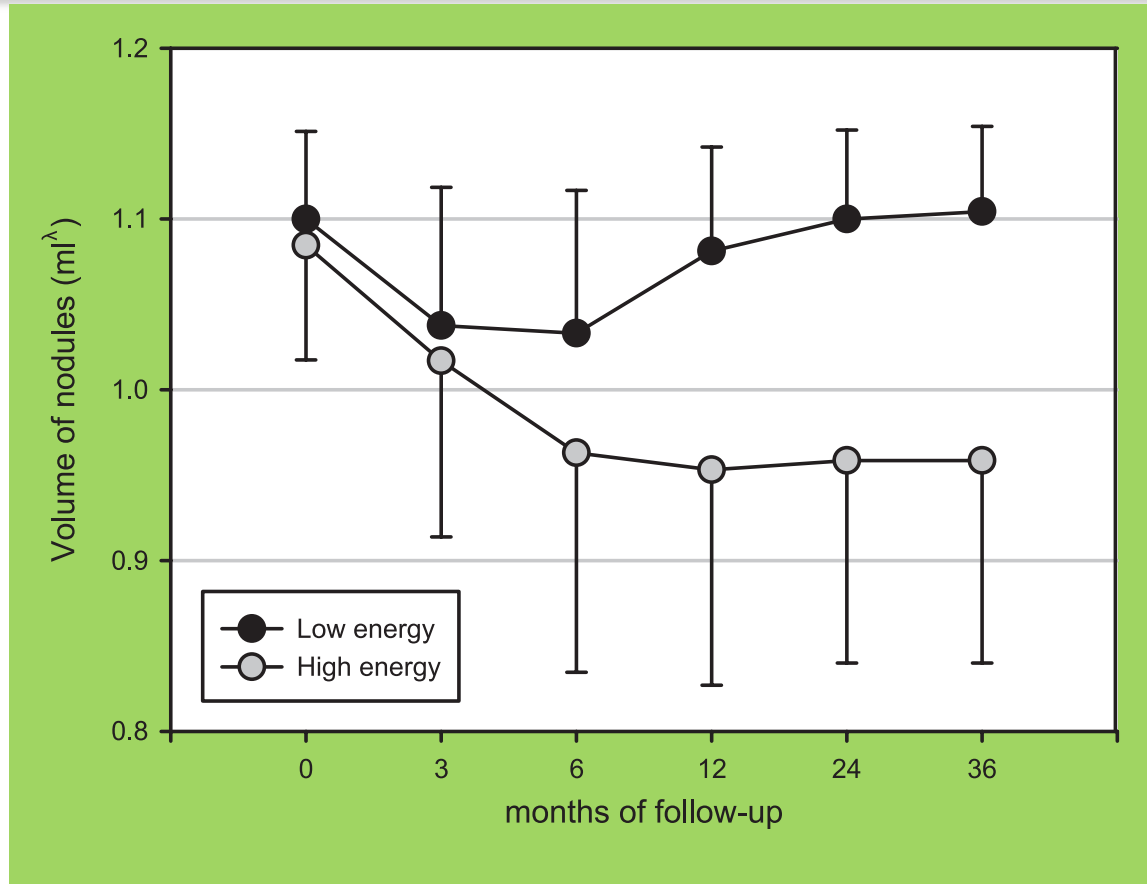
DOI: 10.1177/1553350612459276

<http://sri.sagepub.com>



**Table 1.** Case Summaries

Volume of Nodules (mL)	Pretreatment	After 3 Months	After 6 Months	After 1 Year	After 2 Years	After 3 Years	Energy (J/mL)
<b>Total population (N = 40)</b>							
Median	14	10	8.5	9.5	11.5	11.5	245
Minimum	7	4	3	3	3	3	16.5I
Maximum	142	110	102	121	134	135	640
<b>Group 1 (n = 20)</b>							
Median	15	11	9.5	13.0	16	16.5	71.5I
Minimum	8	5	5	7	8	8	16.5
Maximum	132	110	102	121	134	135	179
<b>Group 2 (n = 20)</b>							
Median	14	7.5	6.5I	6	6	6	578.5
Minimum	7	4	3	3	3	3	31I
Maximum	142	89	58	49	52	52	640





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International Journal of  
**Hyperthermia**

<http://informahealthcare.com/hth>  
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Int J Hyperthermia, 2014; 30(7): 486–489  
© 2014 Informa UK Ltd. DOI: 10.3109/02656736.2014.963701

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healthcare

RESEARCH ARTICLE

## Thyroid nodule morphology affects the efficacy of ultrasound-guided interstitial laser ablation: A nested case-control study

Giovanni Gambelunghe<sup>1</sup>, Vittorio Bini<sup>1</sup>, Elisa Stefanetti<sup>1</sup>, Renato Colella<sup>3</sup>, Massimo Monacelli<sup>2</sup>, Nicola Avenia<sup>2</sup> and Pierpaolo De Feo<sup>1</sup>

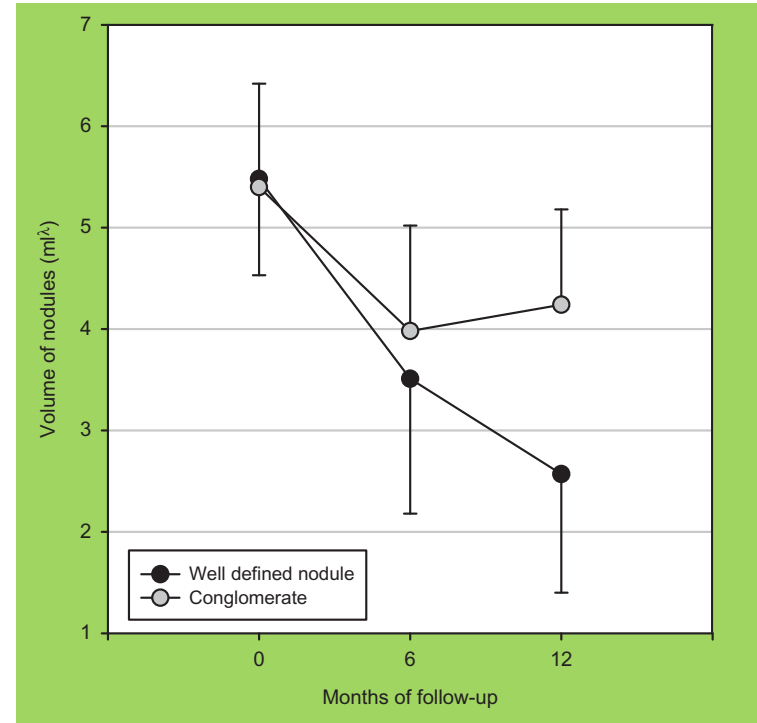
<sup>1</sup>Department of Internal Medicine, Section of Internal Medicine and Metabolic and Endocrine Diseases, University of Perugia, Perugia,  
<sup>2</sup>Endocrine Surgery, Azienda Ospedaliera di Perugia e Terni, Perugia, and <sup>3</sup>Institute of Pathological Anatomy, University of Perugia,  
Perugia, Italy





	Group 1	Group 2	<i>p</i> Value
<i>n</i>	20	20	–
Volume of nodules (mL) at baseline	17.7 (11.5–32.5)	17.6 (10.2–32)	0.779*
Volume of nodules (mL) at 6 months	8.7 (2.4–23)	10.2 (6–21)	0.220*
Volume of nodules (mL) at 1 year	5.3 (1.8–12.5)	11.4 (6.3–23)	<0.0001*

Data are expressed as median (min–max).  
\*Student's *t*-test.





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# Noduli tossici o pre-tossici



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Anche sul trattamento dei noduli tossici vi è una casistica abbastanza ampia, che dimostra come la metodica ablativa laser ModìLite (Elesta, Firenze) sia efficace e sicura



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# Clinical Outcomes of Patients with Symptomatic Benign Thyroid Hot Nodules Treated with PLA



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Author	Pts/Nodules no.	RCT	US pattern. <sup>a</sup>	Mean Baseline Vol (ml)	Laser source	Number of session (mean)	FU months	Volume Reduction % (mean)
Dossing et al (2003)	1		solid	8.2	Diomed 15 plus, 810 nm	1	9	40
Spiezia et al (2003)	7		solid	3.2	Nd:Yag smart , 1064nm	2.2	12	74
Pacella et al (2004)	16			7.9	Nd:Yag smart , 1064nm	2.7	6	61
Barbaro et al (2007)	18			21.1	Nd:Yag smart , 1064nm	3 (median)	12	59
Dossing et al (2007)	14			26.2	Diomed 15 plus, 810 nm	1	6	44
Valcavi et al (2008)	1			2.5	Nd:Yag smart , 1064nm	1	-	95
Rotondi et al (2009)	1		solid	55.0	diode laser operating at 980 nm	4.0	10	91
Amabile et al (2011)	26			55.3	Quanta D-Plus, 980 nm	3		82
Chianelli et al ( 2014) laser + I131	15		solid	27.7	Echolaser, 1064nm	1.5	24	71

Pts=Patients; <sup>a</sup> uniformly solid or predominantly solid with not more than 20% fluid component







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# Esperienza nel centro di Perugia



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Volume (ml)	Pre-T.	3 mesi	6 mesi	1 anno	3 anni
<u><i>N = 92</i></u>					
<b>Mediana</b>	12	7,5 (- 38%)	5,1 (- 58%)	5,1 (- 58%)	5 (- 59%)
<b>Minimo</b>	5	1,1	1,2	1,2	1,2
<b>Massimo</b>	278	191	107	42*	30*

\* II° trattamento



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# Esperienza nel centro di Perugia



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- La nostra esperienza suggerisce che i noduli tossici o pre-tossici, forse per la maggiore vascolarizzazione e quindi tendenza alla dispersione dell'energia termica somministrata, necessitano di energie maggiori per raggiungere la stessa efficacia, in termini di riduzione volumetrica, rispetto ai noduli non funzionanti.
- Il pre-trattamento con metimazolo, sia nei noduli tossici che in quelli pre-tossici, riduce la vascolarizzazione ed aumenta la possibilità di somministrare una dose adeguata di energia.
- Il 90% dei pazienti con noduli di volume inferiore a 15 ml sospendevano la terapia tireostatica, mantenendo un quadro di eutiroidismo



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# Conclusioni



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- *Efficace*: riduzione di volume superiore al 65% in una singola seduta
- *Sicuro*
- *Micro-invasivo*: procedura ambulatoriale della durata di pochi minuti



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# Indicazioni



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Sono del tutto sovrapponibili a quelle della chirurgia  
tradizionale



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Thyroid: LA vs Surgery	Laser Ablation	Surgery
Endpoint	Remove or relief from compressive symptoms and or aesthetic damage	Remove compressive symptoms and or aesthetic damage
How	Thermal destruction “in situ” with shrinkage of the nodule	Surgical removal of the mass (lobe or whole gland)
Advantage	Preservation of the healthy tissue and organ functionality	Definitive
Way to operate	Mini-invasive approach (inserting fine needles)	Incision of skin (3 cm or more) and excision of the gland
Anesthesia	No general anesthesia, no local anesthesia required	General anesthesia
Time duration	Shorter duration (30-45 minutes including patient’s preparation)	Surgical procedure requires 2 hours
Recovery time	Fast recovery time (one hour)	One week
Signs Immediately After	Absence of signs	Surgical wound with sutures and drainage
Signs Long-time after	Absence of signs	Scar with risk of keloid formation; risk of discomfort in the neck
Hormone substituting therapy	Not required	Required for life
Pain	Absence or reduced postoperative pain	Mild to severe postoperative pain
Complications	Rare complications without affecting quality of life	Risk of severe complications affecting quality of life
Hospitalization	Day Hospital/ Outpatient	Hospitalization
Repeatibility	Can be easily repeated	Compromised repeatability in case of relapse
Further therapeutic action	Non compromising	Not applicable



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