National Institute for Health and Care Excellence

IP1268 – Ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules Consultation Comments table

IPAC date: 14 April 2016

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee no. 1 Company	**General**	**Introduction & Background** Thyroid cancer is a rare form of cancer, accounting for less than 1% of all cancer cases in the UK. Each year, around 2,700 people are diagnosed with thyroid cancer in the UK. It's most common in people aged 35 to 39 years and in those aged 70 years or over. Women are two to three times more likely to develop thyroid cancer than men. Risk factors for thyroid cancer include: having a benign (non-cancerous) thyroid condition; having a family history of thyroid cancer (in the case of medullary thyroid cancer); having a bowel condition known as familial adenomatous polyposis; acromegaly; having a previous benign (non-cancerous) breast condition; weight and height; radiation exposure.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.
2	Consultee no. 1 Company	**General**	**Types of thyroid cancer** There are four main types of thyroid cancer - papillary carcinoma; follicular; medullary thyroid carcinoma and anaplastic thyroid carcinoma.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.

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3	Consultee no. 1 Company	**General**	**Treatment options and Issues** The commonest types of thyroid cancers (differentiated thyroid cancers or DTCs) are treated using a combination of surgery to remove the thyroid gland (thyroidectomy) and radiotherapy that destroys any remaining cancer cells and prevents the thyroid cancer returning. Medullary carcinomas tend to spread faster than DTCs, so it may be necessary to remove any nearby lymph nodes, as well as your thyroid gland.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.
4	Consultee no. 1 Company	**General**	**Thyroidectomy** In almost all cases of thyroid cancer it's necessary to either remove some of your thyroid gland in a procedure called a hemithyroidectomy, or all of your thyroid gland (total thyroidectomy). A thyroidectomy is carried out under a general anaesthetic and usually takes around two hours. The operation will leave a scar on the neck. In a small number of cases, it may cause permanent hoarseness. Hospital stays can involve up to three to five days after having thyroid surgery. Followed by rest at home for two to three weeks and avoid any activities that could put a strain on your neck, such as heavy lifting.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.
5	Consultee no. 1 Company	**General**	**Replacement hormone therapy** If some or all of your thyroid gland is removed, it will no longer be able to produce the hormones that regulate your metabolic system. This means you'll experience symptoms of an underactive thyroid (hypothyroidism), such as fatigue (extreme tiredness), weight gain and dry skin. To compensate, you'll need to take replacement hormone tablets for the rest of your life. If your surgery is to be followed by radioactive iodine treatment, it's likely you'll be given a hormone tablet called triiodothyronine. After radioactive iodine treatment is completed, you'll be prescribed an alternative hormone tablet called thyroxine, which most people only need to take once a day.	Thank you for your comment.

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6	Consultee no. 1 Company	**General**	**Radioactive iodine treatment** After having thyroid surgery, a course of radioactive iodine treatment may be recommended. This will help destroy any remaining cancer cells in your body and prevent the cancer returning. If you're taking thyroid hormone replacement tablets, you'll need to stop taking them for two to four weeks before having radioactive iodine treatment. This is because they can interfere with the effectiveness of the iodine treatment. If withdrawing your hormone replacement treatment is problematic, you may be given a medicine called recombinant human thyroid stimulating hormone (rhTSH). This is given as an injection on two consecutive days.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.
7	Consultee no. 1 Company	**General**	**External radiotherapy** Where radioactive waves are targeted at affected parts of the body, is usually only used to treat advanced or anaplastic thyroid carcinomas. The length of time you'll need to have radiotherapy for will depend on the particular type of thyroid cancer you have and its progression. Side effects of radiotherapy include: nausea; vomiting; tiredness; pain when swallowing; dry mouth. These side effects should pass two to three weeks after your course of radiotherapy has finished.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.
8	Consultee no. 1 Company	**General**	**Chemotherapy** Chemotherapy is usually only used to treat anaplastic thyroid carcinomas that have spread to other parts of your body. It involves taking medicines that kill cancerous cells. It's rarely successful in curing anaplastic cancer, but can slow its progression and help relieve symptoms. Possible side effects of chemotherapy include: nausea; vomiting; tiredness; loss of appetite; hair loss; mouth ulcers.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.

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9	Consultee no. 1 Company	**General**	**Recurrence** Cancerous cells will return in an estimated 5-20% of people with a history of thyroid cancer. In approximately 10-15% of people the cancerous cells will come back in other parts of their body, such as their bones. They can sometimes return many years after surgery and radioactive iodine treatment has been completed.	Thank you for your comment. This guidance is specifically for the treatment of benign thyroid nodules.
10	Consultee no. 1 Company	**General**	**Benefits of ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules to doctors/nurses from the current treatment.** As a point of reference, total thyroidectomy procedures can take a long time to perform - 3 to 4 hours, in most cases. In a partial thyroidectomy, only the cancerous thyroid lobe is removed. This surgery typically takes 1.5 to 2 hours to perform. Ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules procedure time is approximately 30- 40mins performed on an outpatient basis using the selected capital equipment and consumable appropriate for the patient. Patients are treated for local anaesthesia at the puncture site. Under ultrasound guidance, radiofrequency ablation is performed using trans-isthmic approach and a “moving shot” technique. The nodule is divided into several conceptual units and ablated unit by unit. The ablation starts from the deepest layer, and the electrode is slowly withdrawn toward the surface. This approach allows avoidance of the “danger triangle” in the trachea-oesophageal groove, prevent significant complication such as avoiding injury of the recurrent laryngeal nerve, trachea, and oesophagus and nerve injury. Pain, usually transient and mild, is the most frequent side effect during procedure. Voice change due to laryngeal dysfunction is reported, although very rare, and may be prevented paying special attention when the treatment is performed in nodular tissue close to laryngeal nerve. Haemorrhage, vagal symptoms, skin burns, and nodule rupture may also infrequently occur.	Thank you for your comment. The complications mentioned have all been described in section 5 of the guidance.

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11	Consultee no. 1 Company	**General**	Following radiofrequency treatment, the patient can be ambulated within 1-2 hours under the doctor's advice and resume daily activity (eating, drinking etc) with no specific contraindications. As there are no complications, overnight stay in hospital is not required. Following the radiofrequency procedure, unlike conventional surgery (thyroidectomy) the patient will not require thyroid hormone replacement treatment/pharmaceutical intervention as the function of the thyroid remains intact. The patient will also not require radioactive iodine therapy. Ultrasound guidance, radiofrequency ablation can treat both hot and cold thyroid nodules. With existing surgical treatments - total thyroidectomy, because the thyroid gland is removed, this procedure causes hypothyroidism, where no thyroid hormone is released. To compensate, the patient will need to take thyroid hormone replacement therapy (pharmaceutical intervention) to ensure that your body has healthy levels of thyroid hormones. With partial thyroidectomy which does not result in hypothyroidism. Though one lobe is removed, the remaining lobe can still produce healthy amounts of thyroid hormone. However, depending on the pathology and your thyroid function tests, patient might still need to take thyroid hormone medication to suppress the remaining thyroid lobe. Radiofrequency of benign thyroid nodules is a minimally invasive alternative technique, effective in reducing nodular volume and compressive and cosmetic symptoms, without causing thyroid dysfunction or life-threatening complications. The use of radiofrequency energy has been proposed because of the ease of handling, perfect consistency, and controllability of the ablation site. Surgeons are already familiar to radiofrequency ablation, which is generally used in treatment of liver malignancies and other soft tissue tumours.	Thank you for your comment.

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12	Consultee no. 1 Company	**General**	**Efficacy** Please see reference for your consideration J Ultrasound; DOI 10.1007/-015-0169-y Radiofrequency ablation for thyroid nodules: which indications? The first Italian opinion statement. Roberto Garberoglio et al	Thank you for your comment. The reference cited is not included in the overview because it is a letter to the editor.
13	Consultee no. 1 Company	**General**	Comment has been removed because it is covered by NICE's Policy on Managing Sensitive Information in Consultation Comments under which NICE may redact comments containing information that appears to be advertising or promotional material.	
14	Consultee no. 1 Company	**General**	**How will Aquilant support training and proctoring for this procedure** With the support of the supplier (Starmed) a proctor or clinical specialist will be available to provide training for the procedure in the UK. The doctor wishing to be trained has committed to preforming the procedure on a number of patients. The doctor will also be able to attend other training centres to observe live cases at the Trusts own decision making time. Training for the nursing team – no special training is required other than guidance on preparation of the scrub table. The doctor is trained to use the machine independent of a nursing team as they control the machine through the use of a footpedal. Aquilant territory manager will provide ongoing training, clinical support and service once the centre is setup and confident in performing the procedure Workshops are currently organised at congresses such as CIRSE, European Conference on Interventional Oncology and European Thyroid Association Currently there are no training centres in the UK, however as this procedure is new to the NHS, Aquilant will be looking to work with experts in the field to setup training and centres of excellence and generate clinical data/evidence from patient registries and trials.	Thank you for your comment.

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15	Consultee no. 1 Company	**General**	**Costings** Costs for capital and consumables are available upon request from Aquilant	Thank you for your comment. The NICE Interventional Procedures Programme does not consider cost-effectiveness.
16	Consultee no. 1 Company	**General**	Comment has been removed because it is covered by NICE's Policy on Managing Sensitive Information in Consultation Comments under which NICE may redact comments containing information that appears to be advertising or promotional material.	
17	Consultee no. 1 Company	**General**	**Technology Appraisal** Capital and Consumables are CE marked	Thank you for your comment.

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18	Consultee no. 1 Company	**General**	**Additional references you may find useful for your consideration** "Eur Radiol. 2013 Apr;23(4):1044-9. doi: 10.1007/s00330-012-2671-3. Epub 2012 Oct 25. Radiofrequency ablation of benign non-functioning thyroid nodules: 4-year follow-up results for 111 patients. Lim HK1, Lee JH, Ha EJ, Sung JY, Kim JK, Baek JH." "AJNR Am J Neuroradiol. 2015 Jul;36(7):1321-5. doi: 10.3174/ajnr.A4276. Epub 2015 Mar 26. Treatment of Benign Thyroid Nodules: Comparison of Surgery with Radiofrequency Ablation. Che Y1, Jin S2, Shi C3, Wang L4, Zhang X4, Li Y5, Baek JH6." "Endocr Pract. 2015 Aug;21(8):972-4. doi: 10.4158/EP15797.CO. Radiofrequency Ablation for Benign Thyroid Nodules – A look towards the Future of Interventional Thyroidology. Lupo MA." "J Clin Endocrinol Metab. 2015 May;100(5):1903-11. doi: 10.1210/jc.2014-4077. Epub 2015 Feb 19. Comparative efficacy of radiofrequency and laser ablation for the treatment of benign thyroid nodules: systematic review including traditional pooling and bayesian network meta-analysis. Ha EJ1, Baek JH, Kim KW, Pyo J, Lee JH, Baek SH, Døssing H, Hegedüs L."	Thank you for your comment. Lim HJ (2012) is included in table 2 of the overview. Che Y (2015) is included in table 2 of the overview. Lupo MA (2015) is not included in the overview because it is a commentary. Ha EJ (2015) is included in appendix A of the overview.

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19	Consultee no. 1 Company	**General**	"J Cancer Res Ther. 2014 Nov;10 Suppl:C144-9. doi: 10.4103/0973-1482.145844. Ultrasonography-guided percutaneous radiofrequency ablation for cervical lymph node metastasis from thyroid carcinoma. Wang L, Ge M, Xu D1, Chen L, Qian C, Shi K, Liu J, Chen Y." "Eur Radiol. 2015 Jan;25(1):163-70. doi: 10.1007/s00330-014-3405-5. Epub 2014 Sep 9. Efficacy and safety of radiofrequency ablation for treating locoregional recurrence from papillary thyroid cancer. Lim HK1, Baek JH, Lee JH, Kim WB, Kim TY, Shong YK, Hong SJ." "J Ultrasound. 2015 Jun 19;18(4):423-30. doi: 10.1007/s40477-015-0169-y. eCollection 2015. Radiofrequency ablation for thyroid nodules: which indications? The first Italian opinion statement. Garberoglio R1, Aliberti C2, Appetecchia M3, Attard M4, Boccuzzi G5, Boraso F6, Borretta G7, Caruso G8, Deandrea M9, Freddi M10, Gallone G11, Gandini G12, Gasparri G10, Gazzera C12, Ghigo E1, Grosso M13, Limone P9, Maccario M1, Mansi L14, Mormile A9, Nasi PG15, Orlandi F16, Pacchioni D17, Pacella CM18, Palestini N10, Papini E19, Pelizzo MR20, Piotto A20, Rago T21, Riganti F1, Rosato L22, Rossetto R1, Scarmozzino A23, Spiezia S24, Testori O25, Valcavi R26, Veltri A27, Vitti P21, Zingrillo M28." "AJR Am J Roentgenol. 2011 Aug;197(2):W331-6. doi: 10.2214/AJR.10.5345. Locoregional control of metastatic well-differentiated thyroid cancer by ultrasound-guided radiofrequency ablation. Baek JH1, Kim YS, Sung JY, Choi H, Lee JH."	Thank you for your comment. Wang L (2014) is not included in the overview because it is for a different indication. Baek JH (2015) is not included in the overview because it is for a different indication. Garberoglio R (2015) is not included in the overview because it is a letter to the editor. Sung JY (2011) is not included in the overview because it is for a different indication.

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20	Consultee no. 1 Company	**General**	"Jpn J Radiol. 2014 Nov;32(11):661-3. doi: 10.1007/s11604-014-0350-9. Epub 2014 Aug 19. Needle track tumor seeding after radiofrequency ablation of a thyroid tumor. Lee CU1, Kim SJ, Sung JY, Park SH, Chong S, Baek JH." "Int J Endocrinol. 2012;2012:919650. doi: 10.1155/2012/919650. Epub 2012 Oct 22. Radiofrequency ablation of thyroid nodules: basic principles and clinical application. Shin JH1, Baek JH, Ha EJ, Lee JH." "Ann Surg Oncol. 2011 Sep;18(9):2564-8. doi: 10.1245/s10434-011-1619-1. Epub 2011 Feb 23. Inoperable symptomatic recurrent thyroid cancers: preliminary result of radiofrequency ablation. Park KW1, Shin JH, Han BK, Ko EY, Chung JH." "Curr Opin Oncol. 2013 Jan;25(1):14-9. doi: 10.1097/CCO.0b013e32835a583d. Radiofrequency and ethanol ablation for the treatment of recurrent thyroid cancers: current status and challenges. Shin JE1, Baek JH, Lee JH." "Korean J Radiol. 2014 Nov-Dec;15(6):817-26. doi: 10.3348/kjr.2014.15.6.817. Epub 2014 Nov 7. Radiofrequency ablation to treat loco-regional recurrence of well-differentiated thyroid carcinoma. Lee SJ1, Jung SL2, Kim BS2, Ahn KJ2, Choi HS2, Lim DJ3, Kim MH3, Bae JS4, Kim MS5, Jung CK6, Chong SM1."	Thank you for your comment. Baek JH (2014) is not included in the overview because it is for a different indication. Shin JH (2012) is not included in the overview because it is not a systematic review. Park KW (2011) is not included in the overview because it is for a different indication. Shin JE (2013) is not included in the overview because it is for a different indication. Lee SJ (2014) is not included in the overview because it is for a different indication.

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21	Consultee no. 1 Company	**General**	"Thyroid Disorders Ther 2015, 4:1 Radiofrequency Ablation for the Papillary Thyroid Micro-carcinoma in the Highrisk Surgical Patient Eon Ju Jeon, Ho Sang Shon and Eui Dal Jung*"	Thank you for your comment. Jeon EJ (2015) is not included in the overview because it is for a different indication.

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