

## National Institute for Health and Care Excellence

### IP1972 - Image-guided percutaneous laser ablation for primary and secondary liver tumours

IPAC date: 14 March 2024

Com . no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
1.	Consultee 1 Company Elesta EchoLaser	Draft recommendation 1.1	We consider that the evidence reported in “Interventional procedure overview of image-guided percutaneous laser ablation of primary and secondary liver tumours” is strong enough in term of RCT studies, long- term outcomes and patients selection (depending of the type of tumour if HCC or liver metastases). Evaluating other NICE guidelines on thermal ablation technique like RF ablation or MW ablation (radiofrequency( <a href="https://www.nice.org.uk/guidance/ipg2">https://www.nice.org.uk/guidance/ipg2</a> , <a href="https://www.nice.org.uk/guidance/ipg327">https://www.nice.org.uk/guidance/ipg327</a> ); microwave ablation ( <a href="https://www.nice.org.uk/guidance/ipg214">https://www.nice.org.uk/guidance/ipg214</a> ; <a href="https://www.nice.org.uk/guidance/ipg553">https://www.nice.org.uk/guidance/ipg553</a> ), it's possible to see that the supported evidence of these techniques seems to be slightly lower than that reported for laser ablation. We ask to change “special arrangements” in normal arrangements like for the other ablation techniques.	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The committee discussed this comment but considered that more evidence is needed before this procedure can be recommended with standard arrangements.</p> <p>The committee noted that there was still some uncertainty about longer term outcomes and patient selection and noted that there were other ablation techniques that are widely used in the UK with strong supporting evidence. Although the evidence for this procedure included 4 randomised controlled trials, the outcomes in some of these showed a trend towards higher rates of local disease progression and lower cumulative survival after laser ablation compared to RFA, but these did not reach statistical significance. In 1 of the RCTs, there was a statistically significant higher rate of recurrence in</p>

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				Please respond to all comments larger tumours treated by laser ablation compared to RFA.
2.	Consultee 3 Company Ideal Medical Solutions	1.1	It is evident that other methods of destroying liver tumors, such as RF or MW ablation, have been viewed on less supporting evidence than the EchoLaser percutaneous laser ablation therefore we ask for “special arrangements” to be reviewed and changed to normal arrangements, in line with other techniques and international bodies that endorse the laser.	Thank you for your comment. The committee discussed this comment but considered that more evidence is needed before this procedure can be recommended with standard arrangements. Please see additional response above.
3.	Consultee 1 Company Elesta EchoLaser	More research 1.5	See comment on section 1.1	Thank you for your comment.
4.	Consultee 1 Company Elesta EchoLaser	The condition 2.1	We suggest adding colorectum in the list of primary cancers (in the document “Interventional procedure overview of image-guided percutaneous laser ablation of primary and secondary liver tumours”, many studies reported laser ablation treatment of patients with liver metastases from colorectum cancer).	Thank you for your comment. The order of the list of primary cancers has been amended so that bowel appears first in the list.
5.	Consultee 1 Company Elesta EchoLaser	The procedure 2.4	We suggest adding that the fibers work simultaneously in order to benefit of the synergic effect of multiple use to obtain amplification of ablation volume. Having the possibility to use from 1 to 4 fibers, a large range of tumour size can be approached with this technique (from less than 1 cm to 4-5 cm).  The use of thinner needles than RFA and MWA, makes laser	Thank you for your comment.  The procedure description has been amended to state that the fibres work simultaneously.

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			<p>ablation suitable to treat lesions in at-risk or difficult locations, for instance when blood vessels have to be passed through to reach the target. In fact, nodules located in difficult for example, behind large vessels, in the caudate lobe, near the hepatic hilum, or in the liver dome, may be treated more easily and safely using thin needles (Pacella et al, 2006 (in the table 5 of Interventional procedure overview of image-guided percutaneous laser ablation of primary and secondary liver tumours), Francica et al, 2012 (in the tables 2 and 3 of Interventional procedure overview of image-guided percutaneous laser ablation of primary and secondary liver tumours))</p> <p>To simplify the manoeuvre of inserting multiple needles/fibers dedicated guides to be attached to the ultrasound probe were developed (Di Costanzo, 2013). These guides reduce technique variability providing a shorter learning curve and reduced procedure time and allows the insertion of multiple introducer needles in the same probe plan at fixed distances in order to reach lesion that need more than one fiber. These guides have multi-angle possibility offering the user to target and treat lesions in a wide range of positions (superficial but also deep lesions) (<a href="https://www.elesta-echolaser.com/pblite/?lang=en">https://www.elesta-echolaser.com/pblite/?lang=en</a>)</p> <p>The effect of the laser ablation is localized; in fact, the laser energy can be delivered precisely and predictably into any location of the liver. This localized effect makes the treatment possible to lesion at high- risk sites (Di Costanzo, 2014 Review).</p> <p>Laser Ablation exploits lowest power (5W vs &gt;100W) and energy dose to achieve complete tumor ablation with respect to other thermal ablation technique due to an effective mechanism of energy conversion (Orlacchio A, 2014).</p>	<p>A committee comment has been added, noting that the procedure has evolved over time.</p>

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6.	Consultee 2 Liver Unit, Italy	The procedure 2.4	Using thin fibers for laser ablation allows targeting nodules in challenging or risky position. The utilization of thin fibers proves advantageous in reaching deeply located liver nodules, minimizing the risk of damage to vascular and biliary structures.	Thank you for your comment. The committee discussed this comment but decided not to change the guidance.
7.	Consultee 2 Liver Unit, Italy	Committee comments 3.7	Laser ablation using thin needles (21 Gauge) may be performed during conscious sedation that is advantageous mainly in cirrhotic patients with impaired liver function.	Thank you for your comment. Section 3.8 states 'Tumour ablation procedures are commonly done under general anaesthesia to prevent the person moving during treatment.' The committee was informed this was common practice for other forms of tumour ablation in the UK. Section 2.4 has been amended to 'Image-guided percutaneous laser ablation is done under general anaesthesia or local anaesthesia with sedation.'
8.	Consultee 3 Company Ideal Medical Solutions	2.4	We suggest that the procedure is performed under local anesthetic and under conscious sedation. Between 1 and 4 fibres are used to ablate up to 5cm of tumour. The treatment offers a fast, life-extending option for complex patients that are unable to receive treatment due to anesthetic risk. It is also possible to treat difficult lesions in 'at-risk' areas. Due to the fine needles used, they are able to pass through the portal vein to treat tumours	Thank you for your comment. Section 2.4 has been amended to 'Image-guided percutaneous laser ablation is done under general anaesthesia or local anaesthesia with sedation.'
9.	Consultee 3 Company Ideal Medical Solutions	3.7	We suggest that the procedure is performed under local anesthetic and under conscious sedation	Thank you for your comment. Section 3.8 states 'Tumour ablation procedures are commonly done under general anaesthesia to prevent the person moving during treatment.' The committee was informed this was common practice

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				Please respond to all comments for other forms of tumour ablation in the UK. Section 2.4 has been amended to 'Image-guided percutaneous laser ablation is done under general anaesthesia or local anaesthesia with sedation.'
10	Consultee 3 Company Ideal Medical Solutions	3.6	Introducers and Fibres can be retracted after the first laser delivery (termed 'pull-back' ) to elongate the ablation zone and ablate additional tissue not previously treated.	Thank you for your comment. Section 3.7 states that 'Multiple laser fibres can be used for each treatment session and the fibres can be moved.'
11	Consultee 1 Company Elesta EchoLaser	Committee comments 3.8	A device (Echolaser Smart Interface, Elesta SpA) was developed to help user to visualize needles/fiber in the target tissue taking into account the safety distance to maintain to critical structures (website: <a href="https://www.elesta-echolaser.com/echolaser-evo-2/?lang=en">https://www.elesta-echolaser.com/echolaser-evo-2/?lang=en</a> ). The device is supplied with dedicated needle guides to connect to the US probe (as previously described) to help in the insertion of more needles in the same US plane.	Thank you for your comment. A committee comment has been added, noting that the procedure has evolved.
12	Consultee 3 Company Ideal Medical Solutions	3.8	A dedicated device connected with the video output of the Ultrasound system, for real-time user assistance in positioning of introduces/fibers. This device enables clinicians to clearly visualize the laser applicators in the treatment target, ensuring safe distance from critical structure.	Thank you for your comment. A committee comment has been added, noting that the procedure has evolved.
13	Consultee 1 Company Elesta EchoLaser	Overview Population and studies description	Comments for Table 2 Study details  Reference 3: Ferrari et al, 2007 in the table 2 the follow-up column is filled as NOT REPORTED; reading the article we can find that the longer follow-up until 60 months.  Reference 12 Vogl et al, 2013 in the table 2 the follow-up	Thank you for your comment.  Study 3 does not report a mean, median or range of follow-up. Table 2 has been amended to state that follow up was reported 'up to 60 months'.

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			column is filled as NOT REPORTED: reading the article we can find that the outcome measure are reported until 5 years.	Please respond to all comments Study 12 does not report a mean, median or range of follow-up. Table 2 has been amended to state that survival was reported up to 5 years.
14	Consultee 1 Company Elasta EchoLaser	Overview – table 5	<p>Comments for Table 5 :</p> <p>We suggest including in the list of paper also this publication (Percutaneous Laser Ablation of Liver Metastases from Neuroendocrine Neoplasm. A Retrospective Study for Safety and Effectiveness. Sartori et al Cardiovasc Intervent Radiol. 2019 Nov;42(11):1571-1578. doi: 10.1007/s00270-019-02308-4.) on a retrospective study that evaluate the efficacy of laser ablation for the treatment of neuroendocrine liver metastases. We know that the number of patients (21) excluded this kind of paper, but according to the pathology many lesions can be present in a single patient. This study involves the treatment of 189 Liver metastases (Median follow-up was 39 months (range 12–99). 1-, 2-, 3-, and 5-year survival rates were 95%, 86%, 66%, and 40%, respectively). Thanks to the micro-invasiveness of fine needle and the laser source, it's possible to treat in the same session more than one lesions in a safety manner. As reported in the paper up to seven Liver metastases were ablated in a single session; if the number of liver metastases exceeded seven, the remaining liver metastases were ablated in further LA sessions with a time interval of 3–4 week.</p>	<p>Thank you for your comment.</p> <p>Because of the large volume of evidence, observational studies with population size 30 or fewer and papers published before 2000 were excluded from table 5. The number of people rather than the number of tumours was used as the limiting factor.</p> <p>The study cited by the consultee was a retrospective study of 21 people, so it was excluded from the table of additional evidence.</p> <p>The key evidence that was considered by the committee does include people with multiple tumours.</p>

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