

- Title** Assessment of diagnostic and therapeutic parotid and submandibular sialendoscopy
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- Reference** ISBN number: 978-2-11-139082-9, link to full report in French: [http://www.has-sante.fr/portail/jcms/c\\_1164340/fr/evaluation-de-la-sialendoscopie-parotidienne-et-submandibulaire-a-visee-diagnostique-et-therapeutique](http://www.has-sante.fr/portail/jcms/c_1164340/fr/evaluation-de-la-sialendoscopie-parotidienne-et-submandibulaire-a-visee-diagnostique-et-therapeutique)

### Aim

The medical questions in this assessment focus on the sialendoscopy technique (endoscopy of the major salivary ducts: parotid and submandibular gland in order for it to be refunded by National Health Insurance. They have been grouped into three main topics:

- the ability of the technique to diagnose a non-neoplastic condition causing salivary obstruction;
- its ability to treat obstructive-type salivary conditions with a favourable benefit-risk balance by improving patient management;
- the conditions for performing this procedure.

### Conclusions and results

Currently, due to the low level of evidence from identified studies (n=38), literature analysis does not enable a formal conclusion to be drawn on the diagnostic performance or the efficacy and safety of the procedure regardless of the obstructive indication concerned (sialolithiasis, stenoses, sialadenitis and inflammatory or systemic sialodochitis). These are non-comparative studies, mainly series of retrospective cases with short patient follow-up and heterogeneity of the types of conditions treated and the technical methods used (interventional sialendoscopy with retrieval devices, intraductal fragmentation with laser fibres, combined surgical approach with endoscopic guidance). It should be noted that very often, the technique has the advantage of diagnosis confirmation and treatment during the same procedure. The reported complication rates are relatively low.

The position of the working group consulted during this assessment is that sialendoscopy has improved treatment of salivary duct obstructions in children and adults and provided answers for the diagnosis of obstructions not caused by sialolithiasis. It has reduced salivary gland excisions, mainly the number of parotidectomy surgeries, a procedure which carries a high risk of nerve damage.

However, the lack of reliable data on the efficacy and safety of this procedure is recognised and the difficulty performing this procedure is emphasised. This led the working group to release recommendations about the use of this technique. They focus on its place in the diagnostic process proposing it is performed after a complete inconclusive assessment with imaging techniques, starting

with an ultrasound, and on the specific training required for the healthcare professionals involved. The experts believe that its contribution in terms of treatment is major, mainly for sialolithiasis. They confirm that there are less data with stenoses, the cause of which is extremely variable (trauma, inflammation, systemic), and that the efficacy of the technique is not consistent, but they emphasise that no other conservative treatment technique is currently validated. Sialendoscopy cannot be performed during the acute infectious phase of the condition. Preferably, the indicated procedure should be performed in an operating room to guarantee pain management, patient monitoring and sterile conditions under which to perform this endoscopic technique.

### Recommendations

Considering the spread in clinical practice of the sialendoscopy technique, the lack of currently validated therapeutic alternatives for some of its indications and the lack of negative reports on the safety aspects of this procedure, HAS considers that sialendoscopy has its role in the therapeutic arsenal for non-neoplastic obstructive diseases of the major salivary glands, subject to compliance with the process of employing this technique and the conditions of performing it suggested by the working group members.

From a diagnostic standpoint, using sialendoscopy is only justified after a complete inconclusive assessment with imaging techniques, starting with an ultrasound.

The benefit of sialendoscopy resides in its dual diagnostic and therapeutic abilities during the same procedure, in around 80% of cases, providing a benefit to patients for the management of their obstructive salivary disease, which without intervention is likely to progress into a debilitating chronic condition. It constitutes a minimally invasive treatment method, the various interventional components of which are chosen by the surgeon depending on the specific pathological condition in each patient and the local possibilities. Sialendoscopic procedures are performed for clinical assessment and imaging, in a controlled environment in accordance with hygiene rules and recommendations relating to the endoscopy technical platform. As a general rule, they require an operating room environment and enable outpatient management.

The surgical team must have undergone previous training in all or part of the technique variations (calculi fragmentation, combined approach) and practise them regularly to ensure patient safety. The staff managing and sterilising the medical devices must pay particular attention to the precautions for handling endoscopes which are very fragile and could therefore be managed by a specific system implemented in the facilities.

To confirm the validity of its position, HAS recommends that studies with satisfactory methodology are implemented, in particular regarding stenoses.

### **Methods**

The assessment of diagnostic and therapeutic parotid and submandibular sialendoscopy is based on the critical analysis of clinical data identified up to February 2015 through a systematic review. The results of this analysis have been discussed by a multidisciplinary working group of experts (12 experts from 6 specialties and one patient representative).

Thus, the conclusions of the assessment are based on the data collected. These conclusions are reviewed by the National Commission for the Assessment of Medical Devices and Health Technologies and then validated by the HAS Board.

### **Written by**

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