NICE advice

IQoro for stroke-related dysphagia

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is IQoro. It is a neuromuscular training device used for stimulating the nerves and strengthening the muscles in the face, mouth, throat, oesophagus, and diaphragm.
- Swallowing therapy is the usual treatment for dysphagia (difficulty starting to swallow) after a stroke. The **innovative aspect** is that the company claims swallowing exercises can be more accurately and effectively done using IQoro. No similar technologies are currently recommended in care guidelines.
- The intended **place in therapy** would be as well as standard speech and language therapy in people with stroke-related dysphagia.
- The **main points from the evidence** summarised in this briefing are from 4 observational studies including 113 adults in Sweden with stroke-related dysphagia. They show that IQoro may be at least as effective as swallowing exercises done with a prosthetic device (palatal plate). One study found improvement with IQoro use regardless of whether the patients had early or late intervention.

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- **Key uncertainties** around the evidence are the lack of high-quality, randomised studies and the unclear effect of IQoro compared with NHS standard care or spontaneous improvement.
- The **cost** of IQoro is £116 per unit (excluding VAT). The **resource impact** would be additional to standard care. This may be offset if less time is needed for swallowing therapy with a speech and language therapist, or there is reduced need for enteral tube feeding.

The technology

IQoro (MYOroface AB) is a neuromuscular training device and exercise regime used to relieve symptoms from stroke-related dysphagia by strengthening the muscles in the face, mouth, throat, oesophagus and diaphragm.

The device is made of acrylic and comprises a crescent-shaped panel that sits between the teeth and lips and a handle for pulling. The panel, or screen, is gripped in front of the teeth between closed lips and teeth and the loop is pulled outwards with the hand. To exercise, the user presses their lips together and pulls forward strongly for 5 to 10 seconds, repeating the exercise 3 times with 3 seconds of rest between repetitions. Training should be done 3 times each day, preferably before meals. People who cannot grip the device between their lips can use a 'jaw grip' technique. This involves the user using their fingers to pinch their lips closed while pulling with the other hand. People who cannot use the jaw grip technique can be helped by a carer. The device can be washed using soap and water, with toothpaste or in the dishwasher. IQoro is available in 2 sizes (small for children and large for adults).

The product is marketed for use in people with dysphagia and in people with a hiatus hernia and reflux symptoms. This briefing focuses on IQoro delivering swallowing therapy for treating dysphagia after a stroke. NICE has also published a medtech innovation briefing on IQoro for hiatus hernia.

Innovations

Swallowing exercises are typically used for treating dysphagia. The company claims exercises can be more accurately and effectively done using IQoro. No similar technologies are currently recommended in existing care guidelines.

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Current NHS pathway or current care pathway

NICE's guideline on stroke rehabilitation in adults recommends offering swallowing therapy at least 3 times a week to people with dysphagia, after stroke, who are able to take part, for as long as they continue to make functional gains. Swallowing therapy could include compensatory strategies, exercises and postural advice.

The Royal College of Physicians National clinical guideline for stroke states that a number of treatments for dysphagia after stroke have been studied, including swallowing exercises, acupuncture, drugs, neuromuscular electrical stimulation, pharyngeal stimulation, thermal stimulation, and transcranial direct current or magnetic stimulation, but evidence on these is limited. Enteral tube feeding intervention can also be used, especially for people who may be at risk of aspiration. The guideline notes that outcomes of treatment should focus on freedom from tube feeding, quality of life and the duration of treatment effect.

IQoro would be used as well as standard treatment for stroke-related dysphagia, such as swallowing therapy.

Population, setting and intended user

IQoro is intended for use in the treatment of dysphagia, facial paralysis and other related conditions including speech difficulties, especially after stroke.

The device may be used in a hospital, community, or home setting. In most cases, the exercise is done by the patient after initial training by a healthcare professional. A carer can help if the patient lacks upper limb mobility or dexterity. The carer does not need to be a healthcare professional. The device does not need modification before use.

Costs

Technology costs

The cost of a single IQoro device is £116 (excluding VAT). The cost per unit is lower if the devices are ordered in bulk. There are no consumables or licence fees.

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Costs of standard care

The standard alternative treatment for dysphagia is speech and language therapy to learn new swallowing techniques. NICE's guideline on stroke rehabilitation in adults recommends swallowing therapy at least 3 times a week. If a band 6 speech and language therapist provides a 30-minute session (£43 per working hour), it would cost about £65 per week.

While 20% of patients after a stroke may need enteral tube feeding during the acute phase, 8% will need long-term enteral tube feeding for more than 6 months. The cost of enteral tube feeding in the home setting is about £95 per week.

Resource consequences

According to the company there are currently around 10,000 users of the device in total, and around 500 of these are in the UK. Many UK users are private individuals. The company states that 15% of this population use IQoro to treat dysphagia.

No published evidence was found on the resource consequences of adopting the technology.

Device costs may be offset if less time is needed for swallowing therapy with a speech and language therapist or the need for enteral tube feeding is reduced.

No practical difficulties or changes in facilities and infrastructure are associated with adopting the technology.

Regulatory information

IQoro was CE marked as a class I device in 2018.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender

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reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Stroke incidence increases with age and is highest in people over 70 years old. Men are at a higher risk of having a stroke at a younger age than women. Black people are almost twice as likely to have a stroke as white people. On average, people of black African, black Caribbean and South Asian descent in the UK have strokes earlier on in their lives. Age, gender and ethnicity are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Four observational studies (2 before-and-after, 2 comparative) including 113 patients with stroke-related dysphagia are summarised in this briefing.

Clinically relevant outcomes reported include results of oropharyngeal motor function testing (function of the lips, jaw, tongue, and velum; lip force; velopharyngeal closure ability), swallowing capacity testing and facial activity testing for facial dysfunction.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

All of the included studies were authored by the owner of the IQoro patent. All studies were done in Sweden in either a home setting or centre for speech and swallowing rehabilitation.

The study populations were relatively small and no power calculations were reported to assess for adequate sample size. The inclusion criteria were clear (people with clinically

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diagnosed dysphagia after a stroke, who were referred to a centre for swallowing and speech rehabilitation). There was, however, significant individual variability within the study populations for time between stroke and start of training (between 2 days and 10 years over all groups). Most patients with dysphagia after a stroke recover spontaneously over time, though 11% to 50% still have dysphagia at 6 months (Cohen et al. 2016), therefore spontaneous improvement may have been a confounding factor.

No statistical analysis was done in the 2 comparative studies on whether the groups were adequately matched. In both comparative studies, the study groups were recruited during different periods and were not assessed at the same time which may add sources of bias, but the clinical teams and standard care pathways were consistent. No information is given about the type, severity or location of stroke, which may affect the likelihood and speed of recovery.

None of the studies included a standard care group or a group with no intervention as a control. This would help compare the effect of IQoro with spontaneous improvement. The comparator in 2 studies (the palatal plate) is not typically used in the UK as part of standard care. However, Hägg and Tibbling (2016) found similar improvements in oropharyngeal motor function and mean swallowing capacity regardless of whether the patient group had early or late intervention. The authors noted that if spontaneous improvement was a factor, it would be more prevalent in the early-intervention groups, therefore improvement is likely an effect of IQoro training.

Outcomes were assessed using objective, relevant measures and subjective patient-reported measures. The study authors were blinded from all end-of-treatment assessments. The lip force testing was blinded from all investigators. Outcomes at follow-up were reported on both a shorter-term (for example, 3 months after training began) and a longer-term basis (for example, year after the end of training).

Table 1 Summary of selected studies

Hägg and Anniko (2008)

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Study size, design and location	A prospective, before-and-after observational study in people with stroke-related dysphagia (n=30) at a Swedish centre for swallowing and speech rehabilitation (median age 70 years, range 49 to 88, 12 women). Inclusion criteria were: ability to cooperate, to be able to be fed orally and a pathological SC. Data were collected between October 2003 and March 2005. All patients in the early-intervention group had their stroke on average 1 month before treatment (range 2 days to 6 weeks). In the late intervention group patients had suffered stroke on average 2 years before starting treatment (range 2 months to 10 years). A follow-up examination was done between 5 and 8 weeks in 14 patients, after 9 to 24 weeks in 15, and after 1 year in 1 patient.
Intervention and comparator(s)	IQoro 3 times daily for at least 5 weeks, no comparator. Outcomes were assessed before and after treatment.
Key outcomes	The median lip force was 7 Newton (range 0 to 27) before treatment and 18.5 Newton (range 7 to 44) after treatment ($p<0.001$). The median swallowing capacity increased from 0 ml/s (range 0 to 9.1) before treatment to 12.1 ml/s (range 0 to 36.7) at follow-up ($p<0.001$). The interval between stroke and start of treatment, ranging from a few days up to 10 years, had no statistically significant influence on the treatment results, nor did age or gender.
Strengths and limitations	There was no difference in lip force or SC between early or late intervention groups suggesting that recovery was not only because of spontaneous improvement, but the presence of a comparator treatment would have made this clearer. No power calculation is reported.
Hägg and Tibbling (2013)	

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Study size, design and location	A prospective, comparative observational study in people with stroke-related dysphagia (n=26) in Sweden in a home setting (median age 69 years, range 55 to 81, 9 women). Inclusion criteria were: patients suffering from their first-ever stroke, diagnosis of dysphagia according to a referring clinician. Data were collected from 1997 to 2002 in the PP group (n=12) and from 2003 to 2008 in the IQoro group (n=14). Training lasted for 13 weeks. Patients in the PP group started training at a median of 20 months (range 1 to 69) after stroke. In the IQoro group, 7 patients started training within 3 weeks after stroke and 7 patients began training on average 12 months (range 1 to 108) after stroke. A follow-up examination was done after 13 weeks and again an average of 22 months after completion of training in the PP group, and on average 13 months after completion of training in the IQoro group.
Intervention and comparator(s)	IQoro (3 times per day for 30 seconds before a meal) compared with PP (3 times per day for 10 to 30 minutes before a meal).
Key outcomes	Normal swallowing capacity was restored in 33% of the PP group, and in 71% of the IQoro group. There was a greater median SC improvement in the IQoro group compared with the PP group in the period from baseline to late follow-up (an increase of 11.6 ml/s compared with 5.0 ml/s, $p<0.002$). Patient self-assessed improvement tested at baseline and at end of treatment did not differ significantly between the 2 groups.
Strengths and limitations	Patients were recruited prospectively but were not contemporaneous. No power calculation is reported. The median length of the time between stroke and start of training was several months longer in the PP group than in the IQoro group. The authors recorded the training compliance, noting that training compliance was optimal in both groups and could reasonably not have had any influence on the difference of training results.
Hägg and Tibbling (2015)	

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Study size, design and location	A prospective, comparative observational study in people with stroke-related dysphagia (n=31) in a Swedish centre for swallowing and speech rehabilitation and the home setting. Inclusion criteria were: patients suffering from their first-ever stroke and a diagnosis of dysphagia according to referring physicians. Patients were either allocated into the IQoro group (n=18, median age 66 years [range 53 to 81 years], 9 women) or a PP group (n=13, median age 68 years [range 46 to 82 years], 2 women). Patients were included during 2 periods: 13 patients between 2005 and 2008 trained with a PP, while 18 patients between 2009 and 2012 trained with an IQoro. Training began a median of 5 weeks after stroke in the IQoro group and 59 weeks after stroke for the PP group. Follow-up examination was done after 3 months training and at a later follow-up (at least 1 year after the end of training).
Intervention and comparator(s)	IQoro (3 times per day for 30 seconds before a meal) compared with PP (3 times per day for 10 to 30 minutes before a meal) over 3 months.
Key outcomes	FA and SC statistically significantly improved ($p<0.001$) in both groups, however no statistically significant differences were found between the 2 training modalities in terms of improving facial dysfunction and dysphagia in patients after stroke.
Strengths and limitations	Patients were recruited prospectively but were not contemporaneous. No power calculation is reported.
Hägg and Tibbling (2016)	

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Study size, design and location	A prospective, before-and-after observational study in people with stroke-related dysphagia (n=26) in a Swedish centre for swallowing and speech rehabilitation and a home setting (median age 68 years, range 49 to 82, 11 women). Inclusion criteria were: patients suffering from their first-ever stroke and a diagnosis of dysphagia according to referring physicians. Group 1 comprised patients included in a first period (more than half a year after stroke; n=15, median age 67 years) and group 2 comprised patients included in a second period (within 1 month after stroke; n=11, median age 69 years). Patients in group 1 started IQoro training a median of 48 weeks (range 24 to 520 weeks) after stroke. Patients in group 2 started training a median of 3 weeks after the stroke event (range 1 to 4 weeks). Patients assessed before and after 3 months of IQoro training and at a later follow-up (median 59 weeks after end of training). 4 patients in the late- and 1 in the early-intervention group presented at baseline with PEG feeds and were unable to eat or drink orally.
Intervention and comparator(s)	IQoro, 3 times each day for 30 seconds, 3 times per day before a meal, no comparator. Outcomes were assessed before and after treatment, and at late follow-up.
Key outcomes	Statistically significant improvement in postural control and OPMD measures was seen after the completion of IQoro training in both intervention groups ($p<0.01$). The improvements were still present at the later follow-up ($p<0.01$). At end of training all 5 people with PEG feeds were on normal, oral diets including the ability to drink water. There was no statistically significant difference in improvement measures between group 1 and 2 ($p>0.05$).
Strengths and limitations	There was no significant difference between early or late intervention groups suggesting that recovery was not only because of spontaneous improvement, but the presence of a comparator treatment would have made this clearer. No recruitment dates are reported. There is a small sample size and no power calculation is reported.
Abbreviations: FA, facial activity; OPMD, oropharyngeal motor dysfunction; PEG, percutaneous endoscopic gastrostomy; PP, palatal plate; SC, swallowing capacity.	

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Recent and ongoing studies

Swallowing Function, Oral Health, and Food Intake in Old Age (SOFIA). ClinicalTrials.gov identifier NCT02825927. Completed November 2017, awaiting publication.

Specialists commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two of the 3 commentators were familiar with this technology. One expert is using IQoro with current patients.

Level of innovation

Two commentators felt that IQoro is a new concept. One noted other more complex devices for swallowing treatment are more costly. Another highlighted that there may be rehabilitation fatigue involved with lengthy exercises and felt that IQoro would offer a novel approach. Though the device would not replace a speech and language therapist, it could be a useful adjunct to therapy for patients who have continuing dysphagia either after treatment has stopped or in addition to continuing treatment.

None of the commentators was aware of any competing or alternative technologies.

Potential patient impact

Two commentators noted various potential benefits of IQoro. One felt that the benefits were unclear from the current evidence. One highlighted that IQoro is a relatively simple device that does not need modification, therefore it would be easy for healthcare professionals and patients to use. No training is needed for speech and language therapists to use the device and it would be easy to show to the patient, so treatment can be started immediately. The recommended amount of practice is 1.5 minutes of treatment, 3 times per day. The perceived ease of use and portability may help make sure the patient uses the device often enough. One commentator noted that the company claims IQoro exercises muscles throughout the oropharyngeal tract, and if so, patients would be able to exercise several components of swallow at the same time.

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One commentator indicated that patients with oropharyngeal dysphagia are the main group that may benefit from use of IQoro. Another stated that IQoro may benefit patients with long-term dysphagia where other treatment is no longer available.

Two commentators felt that IQoro had the potential to change current pathways or clinical outcomes. One felt that this was unlikely. If IQoro improves swallowing outcomes, another felt this would allow patients to return to an oral diet sooner and reduce length of stay in hospital, and a second expert felt that this could result in fewer visits and less invasive treatment.

Potential system impact

Two commentators felt that IQoro was potentially cost effective, for example the device is low cost compared with some other high-tech electronic swallow treatment devices. One did not envisage cost savings but 2 felt that initial costs for IQoro may be more than standard care. If swallowing improvements are greater with IQoro, this could result in potential cost savings because of shorter lengths of stay in hospital and fewer medical complications and interventions (such as enteral feeding or antibiotic use). One commentator explained that IQoro could potentially be used to help reduce time needed for speech and language therapy in the community, which is helpful if there are shortages in this service. Another highlighted that IQoro can be used in inpatient, outpatient, and community settings, so treatment could continue after hospital discharge.

All 3 commentators felt that no changes to infrastructure or training would be necessary to use IQoro. One suggested IQoro would fit easily into the current clinical pathway in speech and language therapy for treating swallowing disorders.

General comments

One specialist noted that IQoro has been used with a small number of patients as part of their Early Adopter Programme, highlighting a patient who had shown improvements in swallowing after use of IQoro. A second noted that 2 patients had used IQoro and had noticed improvements in their swallowing. Both mentioned that these numbers were too low to draw conclusions. One specialist stated that they had received interest from patients (longer-term dysphagia patients in particular) who wanted to try the device.

Two commentators provided estimates for how many people might be eligible for IQoro

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per year. One suggested 30% of stroke patients in stroke units, reducing to about 5% to 10% of discharges. Another estimated 50 to 100 people per year might be eligible for speech and language therapy from a population of 180,000 and a hospital with 450 beds.

Two commentators felt further studies would be helpful. Future studies could include assessing changes to swallowing resulting from IQoro treatment as measured by video fluoroscopy or a study of IQoro treatment compared with a no treatment control group of similar stroke types, for example a blinded randomised control trial.

Patient organisation comments

The Stroke Association had no further comments to add to the briefing.

Specialist commentators

The following clinicians contributed to this briefing:

- Diana Day, consultant nurse for stroke, Cambridge University Foundation Hospital Trust, did not declare any conflicts of interests.
- Lisa Hirst, head of service for speech and language therapy, Salisbury NHS Foundation Trust, did not declare any conflicts of interests.
- Nassif Mansour, GP with extended role in adult medicine, neurology and community rehabilitation, Surbiton Health Centre, did not declare any conflicts of interests.

Representatives from the following patient organisations contributed to this briefing:

- Stroke Association.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC). The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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