NICE advice

IQoro for hiatus hernia

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is IQoro. It is a neuromuscular training device used for improving symptoms related to hiatus hernia by strengthening the oesophagus and diaphragm. It is initially used daily for 3 to 6 months, with follow up maintenance use dependent upon individual need.
- The **innovative aspects** are that IQoro is the only device available for treating hiatus hernia with oral, neuromuscular training and an exercise regime.
- The intended **place in therapy** would be as an alternative to long-term proton pump inhibitor (PPI) treatment or laparascopic fundoplication surgery in people with hiatus hernia.
- The **main points from the evidence** summarised in this briefing are from 3 non-comparative, observational studies including 148 adults in Swedish ear, nose and throat clinics. They show that IQoro may improve symptoms related to hiatus hernia when used for 6 to 8 months in people with long-term hiatus hernia.

- **Key uncertainties** around the evidence are that it is limited in quantity and quality. The effect of IQoro may be overestimated because of a lack of a control group. A study comparing IQoro with standard NHS care would help address this.
- The **cost** of IQoro is £116 per unit (exclusive of VAT). The **resource impact** would be greater than standard care, but costs may be offset by reducing long-term PPI maintenance.

The technology

IQoro (MYoroface AB) is a neuromuscular training device and exercise regime used to relieve symptoms related to hiatus hernia by strengthening the oesophagus and diaphragm.

The device is made of acrylic and consists of a crescent-shaped panel that sits between the teeth and lips and a handle for pulling. The panel, or screen, is gripped between closed lips and the teeth and the handle 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 for treating people with hiatus hernia. NICE has also published a medtech innovation briefing on IQoro for stroke-related dysphagia.

Innovations

IQoro is unique in treating hiatus hernia through an exercise regime with an oral device. The device aims to relieve the symptoms of the condition after 3 to 6 months of use. The exercise regime is designed to permanently strengthen the musculature of the hiatus, addressing the underlying cause of hiatus hernia without needing surgery or long courses

of medication.

Current NHS pathway or current care pathway

NICE's guideline on gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management recommends offering a full-dose proton pump inhibitor (PPI) long-term as maintenance treatment for people with severe oesophagitis (reflux disease).

Laparoscopic fundoplication should be considered for people who have a confirmed diagnosis of acid reflux and enough symptom control with acid suppression therapy but who do not wish to continue with this therapy long term. It should also be considered in people who have a confirmed diagnosis of acid reflux and symptoms that are responding to a PPI, but who cannot tolerate acid suppression therapy.

IQoro would be used to improve symptoms by attempting to address the underlying cause of hiatus hernia. This could potentially remove the need to take PPIs or to have surgery.

Population, setting and intended user

IQoro is intended for treating symptoms related to hiatus hernia, such as misdirected swallowing, hoarseness, chest pain, chronic cough and a feeling of a lump in the throat (globus).

IQoro is intended to be used in a hospital, the home or community setting. In most cases the exercise is done by the user after initial self-instruction. In a few cases initial demonstration by a healthcare professional may be necessary. A carer can help if the patient lacks upper limb mobility or dexterity. The carer does not need to be a healthcare professional.

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.

Costs of standard care

People with severe oesophagitis (reflux disease) stay on a course of full-dose PPIs mainly prescribed by GPs in primary care in the long term. This would result in an approximated cost of between £18 and £60 per person per year.

Laparoscopic fundoplication can provide better long-term outcomes and although the initial cost is £2,076, it can also provide cost savings compared with PPI maintenance. This is because people who have had surgery will no longer need PPIs and there will be a decrease in visits to GPs and hospital attendances.

Costs of standard care taken from the costing statement for NICE's guideline on gastro-oesophageal reflux disease and dyspepsia in adults, published in 2014.

IQoro may be resource releasing compared with long-term PPI maintenance. It also has a cheaper up-front cost than laparoscopic fundoplication.

Resource consequences

According to the company, there are around 10,000 users of the device and around 500 of these are in the UK. Many UK users have purchased the device privately. The company states that over half of this population are using IQoro for hiatus hernia.

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

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 April 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 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).

Hiatus hernia is more common in men, people aged 50 years and over and is more common during pregnancy. Age, sex and pregnancy 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

Three studies including 148 individual adults (21 were included in both of the Hägg 2015 studies) are summarised in this briefing. All of the studies are observational, before-and-after studies done in Sweden.

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

Overall assessment of the evidence

All of the included studies were co-authored by the owner of the IQoro patent. All patients were referred from hospital ear, nose and throat departments, gastrointestinal surgeries and general practices to the specialist speech and swallowing centre at Hudiksvall hospital.

No power calculations were reported to assess for adequate sample size. Inclusion criteria varied between studies, and the company confirmed that 21 patients from the Hägg et al. (2015a) study were also included in the second Hägg et al. (2015b) study. All included

patients had experienced symptoms for more than 1 year. Hägg et al. (2015a) included 21 hiatus hernia patients and 22 patients without a confirmed diagnosis, all of whom had been taking proton pump inhibitors (PPIs) for at least 1 year. These inclusion criteria should capture a population representative of the NHS. The total number of patients with a confirmed hiatus hernia in the 3 studies was 126.

No control group having standard care was present in the studies. It is possible that any effect seen in an uncontrolled design could be overestimated. All studies included long-term hiatus hernia sufferers. Each study compared subjective, self-reported measurements of symptoms related to hiatus hernia before and after a treatment period of 6 to 8 months training with IQoro. Self-reported outcomes can be subject to bias and while necessary, particularly in symptom-based conditions, may need to be supported by more detailed measures. The company confirmed that these assessments were blinded from the researchers. Objective measurements were also taken to rule out the presence of a central nervous lesion. Phone calls and interim swallowing capacity tests were made during the training period to attempt to ensure compliance to the regime. The Hägg et al. studies reported the results of pressure measurements in the hiatus canal and upper oesophageal sphincter for the same 12 patients, to investigate the physical effect of training. Patients were not followed up longer than the training period, so there is no confirmation of long-term benefit. The company confirmed that all patients were advised to continue with their PPI medication during the training period. No information was published on patient's adherence to PPI medication but the company have stated "all patients continued with their PPI medication as advised. As symptoms reduced, patients ceased to medicate. Use or cessation of PPIs was under the control of the patients' doctors. At end-of-training in the 3 studies quoted 93%, 58% and 61% ceased all PPI medication, the remainder mostly reduced dose and intake frequency".

Table 1 Summary of selected studies

Franzén, Tibbling and Hägg (2018)

Study size, design and location	A prospective, before-and-after, observational study on 86 consecutive adults (46 women) referred to a swallowing centre with sliding HH and enduring IED and GERD symptoms, despite PPI medication. The study was done in Sweden, with patients referred between 2014 and 2016. Patients were grouped by BMI: • normal weight, BMI more than 25 (n=37: 19 women of median age 68 years, 18 men of median age 72 years) • moderately obese, BMI 25 to 29 (n=28: 16 women of median age 59 years, 12 men of median age 56 years) • severely obese, BMI 30 to 37 (n=21: 11 women of median age 52 years, 10 men of median age 70 years). All patients had received PPI medication for at least a median 3-year period and were still on this medication at the start of the study.
Intervention and comparator(s)	All patients used IQoro for 6 months for neuromuscular training. The training consisted of pulling the device for 5 to 10 seconds with a gradually increasing strength and repeating this 3 times with 3 seconds of rest in between. The exercise was done 3 times a day, before eating. No comparator.
Key outcomes	All patients did IED, GERD and swallowing self-assessments (VAS from 0 mm [normal] to 100 mm [total inability]) before and after training as well as a SCT and LFT. All IED and GERD symptom scores improved and there were no significant differences between BMI groups except for heartburn, cough and misdirected swallowing which were significantly ($p<0.01$) more reduced in severely obese patients. SCT, LFT and median VAS score was significantly improved ($p<0.0001$). There was no significant difference between the BMI groups except for the value of SCT, which was significantly ($p<0.01$) more improved in the severely obese group, and for the value of LFT, which was significantly ($p<0.05$) more improved in the moderately obese group.

Strengths and limitations	Patients were recruited prospectively and consecutively. Compliance was also checked on 2 to 3 occasions by telephone throughout the study period. There was no group treated with standard care, so it is unclear if improvements were because of the treatment. No power calculation is reported. Follow up was only for the 6-month training period so any effect cannot be confirmed to continue after training has ceased. The inventor of the device is an author of this study.
Hägg, Tibbling and Franzén (2015a)	
Study size, design and location	A prospective, before-and-after, observational study on 43 consecutive adults (21 women) referred to a swallowing centre with non-stenotic oesophageal dysphagia, who were taking PPIs for more than 1 year. The study was done in Sweden, with patients referred between 2012 and 2014. Of the patients, 21 were found to have a HH (median age 52 years, 13 women); the remaining patients were suffering from symptomatic reflux oesophagitis or dyspepsia but did not have a confirmed diagnosis of hiatus hernia. The patients had a median symptom duration of 4 years (range 1 to 28 years). A further 12 patients with HH had oesophageal high-resolution manometry to measure the pressure in the UES and hiatus canal, both while resting and while using the IQoro.
Intervention and comparator(s)	All 43 patients had 6 to 8 months of training with IQoro and were split into group A (patients with HH) and group B (patients without a confirmed diagnosis of HH). The training consisted of pulling the device for 5 to 10 seconds with a gradually increasing strength and repeating this 3 times with 3 seconds of rest in between. The exercise was done 3 times a day, before eating. No comparator.

Key outcomes	All 43 patients had a pathological VAS (0 to 100) at baseline and 100% had improved after training. Between baseline and end-of-training, LFT and VCT scores showed statistically significant improvements in both groups ($p<0.001$) and were taken as measures of good training compliance. OFMT and OST scores were all considered in the normal range at baseline. Self-reported measures of oesophageal dysphagia and reflux symptoms (from 0 to 3) improved in 98% and 86% of patients, respectively, between baseline and end-of-training. No statistically significant difference was found between group A and group B in any test either before or after the intervention. Pressure in the UES (68 to 95 mmHG) and hiatus canal (0 to 65 mmHG) increased when using the IQoro device.
Strengths and limitations	Patients were recruited prospectively and consecutively. Compliance was also checked on 2 to 3 occasions by telephone throughout the study period. Measures of symptom severity were reported by patients on subjective scales. Although 2 groups are included, neither were treated with standard care, so it is unclear if improvements were because of the treatment. No power calculation is reported. Follow up was only for the 6 to 8-month training period so any effect cannot be confirmed to continue after training has ceased. The inventor of the device is lead author of this study.
Hägg, Tibbling and Franzén (2015b)	

Study size, design and location	A prospective, before-and-after, observational study on 28 consecutive adult patients (14 women, median age 59 years) suffering from misdirected swallowing and oesophageal retention symptoms because of HH for more than 1 year. The patients were referred to a swallowing centre in Sweden between 2012 and 2014 and had a median symptom duration of 4 years (range 1 to 28 years). It is not reported if any of the 28 patients were also included in Hägg, Tibbling and Franzén (2015a) above. A further 12 patients with HH had oesophageal high-resolution manometry to measure the pressure in the UES and hiatus canal, both while resting and while using the IQoro. These were the same 12 patients reported in Hägg, Tibbling and Franzén (2015a) above.
Intervention and comparator(s)	All 28 patients had 6 to 8 months of training with IQoro. The training consisted of pulling the device for 5 to 10 seconds with a gradually increasing strength and repeating this 3 times with 3 seconds of rest in between. The exercise was done 3 times a day, before eating. No comparator.
Key outcomes	A statistically significant improvement was found in the self-reported measure of symptoms of misdirected swallowing, cough, hoarseness, oesophageal retention and globus (lump in throat; all $p<0.001$). Statistically significant improvement ($p<0.001$) in LFT, VCT and SCT results was considered a measure of good training compliance. OST and OFMT results confirmed that a central nervous lesion was not present in any patients.
Strengths and limitations	Patients were recruited prospectively and consecutively. Compliance was also checked on 2 to 3 occasions by telephone throughout the study period. Measures of symptom severity are subjective. No comparator group treated with standard care was included, so it is not certain that improvements were because of the treatment. No power calculation is reported. Follow up was only for the 6- to 8-month training period so any effect cannot be confirmed to continue after training has ceased. The inventor of the device is lead author of this study.

Abbreviations: GERD, gastroesophageal reflux disease; HH, hiatal hernia; IED, intermittent oesophageal dysphagia; LFT, lip force test; OFMT, orofacial motor test; OST, oral sensory test; PPI, proton pump inhibitor; SCT, swallowing capacity test; UES, upper oesophageal sphincter; VAS, visual analogue score; VCT, velopharyngeal closure test.

Recent and ongoing studies

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

Specialist 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.

One of the 3 experts was familiar with or had used this technology before.

Level of innovation

None of the specialists thought that IQoro had been superseded or replaced. All 3 thought that the device was a novel concept for treating hiatus hernia.

One specialist mentioned electrical stimulation devices, such as VitalStim and Ampcare, are available for treating oropharyngeal dysphagia but added that these are not marketed for the treatment of hiatus hernia. No other competing technologies were mentioned.

Potential patient impact

One specialist thought that reduced medication burden was a potential benefit of IQoro. A reduced risk of long-term proton pump inhibitor (PPI) use was also mentioned, with another commentator adding that IQoro could be more cost effective than PPI medication or surgery. A third agreed that the main benefits are the non-invasive and non-pharmacological nature of the device. One specialist added that consideration should also

be given to lifestyle changes.

It was suggested that the device would be a particular advantage to elderly patients, because of the higher risk of surgery in this group. Motivated patients were also thought to be more likely to see benefit, along with patients on multiple medications. One expert thought that it was unclear which patient groups would particularly gain from using IQoro. Another thought that all people with dysmotility because of hiatus hernia would most benefit.

One specialist believed that IQoro had the potential to reduce prescription of medications and reduce the rate of surgery. Another thought that potential changes to the current pathway were unclear because of the limited evidence base. A third thought that the device has the potential to change the current pathway but agreed that more robust evidence was needed.

Potential system impact

One specialist believed that IQoro could lead to cost savings for the health and care system, costing less than standard care. Two specialists thought that more evidence was needed to assess IQoro's benefits to the health system, with 1 suggesting that powered, randomised trials with multidimensional evaluation were needed. The resource impact was considered to be a reduction in surgical procedures and outpatient appointments, leading to potential cost savings. Two specialists reiterated that more evidence was needed to show this economic benefit. One also thought that extra evidence could additionally inform patient selection and that regular interim evaluations would also be needed.

Two specialists did not think that any changes to infrastructure or specific training would be needed to use IQoro. One thought that there would need to be training for healthcare professionals. They added that clarity would be needed on the disease being treated to ensure that the most appropriate healthcare professional could be established. It was suggested that while a speech and language therapist may be the most appropriate for oropharyngeal dysphagia, this may not be the case for hiatus hernia. The resource of other healthcare professionals would also need to be taken into consideration.

Two specialists thought that there were no safety concerns around IQoro but 1 thought that this would need to be considered on a case-by-case basis.

General comments

Two specialists felt that the evidence base was limited. One felt that an inability to understand true adherence to exercise programmes could be a fault in the current evidence. They added that the effect of increased contact with healthcare professionals on patient-reported outcomes was not addressed.

One commentator was unsure if the technology would be an addition to or replacement of standard care. Another thought that it would be an addition and a third believed that it could be a prequel or an adjunct to current care. There were considered to be no practical issues with the usability of the device, other than in some patients who would need assistance in doing the training with IQoro.

One commentator was unaware of any issues preventing the adoption of IQoro. Two believed that the lack of evidence was the only issue preventing the adoption of IQoro in their organisation and in the wider NHS. One added that the absence of research done by research groups other than those including the inventor of the device was an obstacle.

One specialist felt that clarification was needed on whether patients recruited to the included studies continued to take PPIs during the training period, as instructed. It was thought to be important to understand if the device is more effective as a replacement or as an adjunct to PPI medication. Another specialist thought that a large randomised trial comparing IQoro to standard care was required. A third believed that an independent, suitably powered, randomised study with a sham treatment group or a no treatment group was necessary to assess IQoro's efficacy. They believed this would need to assess the device's effectiveness in pharyngeal stage dysphagia, oral stage dysphagia, oesophageal dysmotility and hiatus hernia. Further, they felt that outcomes should include clinician rated, patient-reported and instrumental outcome measures across the entire cohort.

Specialist commentators

The following clinicians contributed to this briefing:

- Kevin Barrett, general practitioner. Dr Barrett has received honoraria for attending advisory boards for Yakult and Tillots, and payment for speaking at events by Ferring. He is also the chair of the Primary Care Society for Gastroenterology.

- Andrew Poullis, consultant gastroenterologist, St George's Hospital London, did not declare any conflicts of interests.
- Justin Roe, joint head of speech and language therapy at the Royal Marsden Hospital and clinical service lead in airways/laryngology at Imperial College Healthcare NHS Trust, did not declare any conflicts of interests.

Development of this briefing

This briefing was developed for NICE by 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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