NICE advice

Thora-3Di for assessing asthma in children

Medtech innovation briefing
Published: 2 October 2017

www.nice.org.uk/guidance/mib122

Summary

- The **technology** described in this briefing is Thora-3Di for assessing respiratory function in children with asthma.
- The **innovative aspects** are that the measurements are taken non-invasively without the need for special breathing manoeuvres, and provide information on right-versus-left lung function.
- The intended **place in therapy** would be instead of spirometry in secondary care in children for conditions such as asthma.
- The **main points from the evidence** summarised in this briefing are from 5 prospective, observational studies including a total of 129 patients and 139 healthy controls (young people and children) in secondary care. They show that Thora-3Di may be as effective as spirometry in assessing asthma respiratory parameters in children and young people.

- **Key uncertainties** around the evidence or technology are that it is not clear which of the breathing parameters measured by Thora-3Di are specific to assessing asthma, and that there is limited evidence comparing these measures with spirometry.
- The **cost** of Thora-3Di is £25,000 per unit (exclusive of VAT). The **resource impact** is unclear, but using the device could save costs through quicker testing.

The technology

Thora-3Di uses a structured light plethysmography-based technique to measure respiratory function in children. The system consists of device software (PneumaView) and a 'head unit', comprising a visible-light projector and a single-printed circuit board assembly incorporating 2 video camera modules, a hardware processor and ethernet interface module.

During the measurement, which is non-contact and takes between 1 and 5 minutes, the patient must sit as still as possible. No special breathing manoeuvres (such as a deep breath or maximal forced breathing) are needed, because the device measures tidal (quiet) breathing. The measurement can be made on bare skin or through white, close-fitting shirts. A grid of visible light is projected on to the chest and abdominal wall. The software presents the data as a 3D representation of the chest wall, as well as graphically and numerically. Breathing patterns are described in terms of breathing timings (for example respiratory rate, inspiratory and expiratory time), synchronisation between regions (such as thorax to abdomen, left thorax to right thorax) and other outputs.

Compact Thora-3Di is an identical system which can be dismantled to be transported.

Innovations

The potential innovations are that Thora-3Di measures respiratory parameters during normal breathing through a non-contact procedure, which doesn't need the patient to do any special breathing manoeuvres. This is designed to allow assessment in patients unable or unwilling to have conventional spirometry. In addition, Thora-3Di measures right-versus-left lung function and paradoxical chest-abdominal movements, which are important in neuromuscular disorders. It also provides regional information about thoraco-abdominal wall movement, which spirometry does not.

Current care pathway

NICE is consulting on a draft diagnosing and monitoring asthma guideline which says that young people and children over 5 years who have suspected asthma should have an objective lung function test (including spirometry and a bronchodilator reversibility test). Children under 5 or those unable to perform objective tests should be observed and treated based on clinical judgement and regular clinical review. There is no definitive diagnostic test for asthma; diagnosis relies on assessment of respiration, clinical history and, occasionally, data from tests such exercise, exposure to allergens (skin prick), response to bronchodilators or measuring exhaled nitric oxide.

Population, setting and intended user

Thora-3Di would most likely be used in secondary care instead of spirometry, typically in a children's respiratory clinic or ward, or lung function unit. The device can be used by any trained nurse or doctor or by a respiratory specialist. A half day's training is needed to use the device; specialists interested in advanced interpretation of the results can do a further day of training.

Costs

Technology costs

The company has estimated the cost per Thora-3Di test as £8.33. This is based on a 5-year lifespan of the device and its being used to test 3 patients each day, 5 days per week, for 40 weeks per each year. A similar calculation for Compact Thora-3Di equates to a cost-per-test of £5.00. These calculations do not include staff and consumable costs.

Table 1 Device costs

Description	Cost*	Additional information
Thora-3DI	£25,000	Does not include potential purchase and laundering of white shirts.
Compact Thora-3DI	£20,000	

*As well as capital purchase, the device is available on monthly lease or lease-purchase terms at a total cost equivalent to the capital purchase price.

Costs of standard care

The NICE draft guideline on diagnosing and monitoring asthma estimates the non-staff costs of spirometry to be £2.19 per test, based on an average of 300 tests per year. Combining the draft guideline and company estimates gives a range of costs for spirometry of £13.19 to £17.14 per test. The estimated cost for Thora-3Di is between £11.98 and £15.63 per test. This includes a GP practice nurse spending 10 to 15 minutes for a spirometry test and 5 to 10 minutes for a Thora-3Di test.

Resource consequences

Resource use is unclear as the relationship between the breathing parameters measured and spirometry is not established. Thora-3Di may have the potential to be resource saving by reducing the time taken to measure breathing parameters versus spirometry and so releasing staff time.

Staff using Thora-3Di must be appropriately trained. It would be used in a separate room, but this is similar to the requirements for spirometry.

Thora-3Di is currently used in 9 NHS trusts.

Regulatory information

Thora-3DI was CE marked as a class IIa device in 2011.

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).

No equality issues were identified during the development of this briefing.

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

This briefing summarises 5 studies that were considered to provide the most relevant and highest quality evidence. All 5 studies focus on the use of Thora-3Di in children and young people, and include of a total of 129 patients with asthma and 139 healthy volunteers. One prospective study is published in full and 4 further studies are published as abstracts; 4 of the studies originate from 1 clinical centre.

The studies show that Thora-3Di can measure the inspiration to expiration flow ratio (IE50), which can be used to identify respiration affected by asthma symptoms. The studies also report differences in the variability of breathing patterns and changes in the thorax and abdomen measured using Thora-3Di, which may also be significant in differentiating between obstructed asthmatic breathing and normal function.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The published evidence for Thora-3Di is based on small studies mostly published as abstracts. These are generally relevant to the NHS pathway but are descriptive, comparing a variety of respiratory parameters measured using Thora-3Di with conventional spirometry in healthy volunteers and patients with asthma, both before and after bronchodilator treatment. The studies also use the device to measure timing parameters and anatomical changes associated with breathing but there are no agreed thresholds for

these against conditions diagnosed using spirometry. There are no studies or subgroup analyses specifically on younger children with asthma, in which Thora-3Di may have significant advantages, but they are included in the patient groups. Larger, prospective studies would help to determine the Thora-3Di breath parameters of most diagnostic utility for asthma.

Table 2 Summary of selected studies

Hmeidi (2017)	
Study size, design and location	Prospective, observational, case-control study. 71 children and young people (aged 7 to 16 years), UK.
Intervention and comparator(s)	Thora-3Di compared with abnormal spirometry and bronchodilator challenge test spirometry to measure FEV1 and IE50.
Key outcomes	The asthma group showed a significant increase in spirometry-assessed mean FEV1 after administration of bronchodilator. Median IE50 was higher in children with asthma (before using a bronchodilator) compared with healthy children. After giving bronchodilators to the asthma group, median IE50 decreased from 1.53 to 1.45 (p=0.01).
Strengths and limitations	This is a small observational pilot study. It indicates that some changes in breathing parameters measured by Thora-3Di can be used to tell healthy children from those with asthma and the subsequent effect of treatment. The healthy controls did not have standard spirometry so a full comparison was not possible. It is unclear if the statistically significant changes noted represent clinically significant differences. The study was sponsored by the company.
Hmeidi et al. (2016)	
Study size, design and location	Prospective, observational, case-control study. 93 children (2 to 12 years), 39 with asthma, 54 healthy controls, UK.

Intervention and comparator(s)	Thora-3Di, no comparator.
Key outcomes	Median IE50 was higher is the asthma group (1.47 compared with 1.41; p=0.002) but there was no change in response to bronchodilator treatment (1.47 vs 1.5; p=0.477).
Strengths and limitations	This study was presented as an abstract with limited information. It shows that Thora-3Di can take measurements in children aged 2 to 12 years and some of the respiratory parameters measured may be able to be used to identify asthma in children. The study was sponsored by the company.
Hmeidi et al. (2015a)	
Study size, design and location	Prospective, observational study. 33 children (age not specified), UK.
Intervention and comparator(s)	Thora-3Di, no comparator.
Key outcomes	Rib-cage versus abdominal contribution to breathing decreased significantly following bronchodilator intervention (46% to 42%, p=0.016). The respiratory rate, inspiratory time ratio and IE50 did not significantly change after bronchodilator treatment.
Strengths and limitations	This study was presented as an abstract with limited information. It shows that Thora-3Di can be used in children admitted to hospital with a diagnosis of asthma. The age of the group of children was not defined; this is the same group as that in Hmeidi 2016. The study was sponsored by the company.
Ghezzi et al. (2015)	
Study size, design and location	Prospective, observational study. 27 children with asthma (median age 7.9±3.36 years; 6 patients were preschool children), Italy.

Intervention and comparator(s)	Thora-3Di compared with abnormal spirometry and bronchodilator challenge test spirometry to measure FEV1 and IE50.
Key outcomes	The children with well-controlled asthma had a lower FEV1 measured with SLP compared with spirometry (106.1 vs 69.7, p=0.0002). IE50, measured using SLP, was also lower in the well-controlled group, was 1.16 (0.99 to 1.54) compared with 1.40 in the spirometry group (1.25 to 1.72, p=0.026). The authors concluded that the IE50, from SLP measurements, could differentiate between children having an asthma exacerbation and those with well-controlled asthma, and this matched the FEV1 data from spirometry.
Strengths and limitations	This study was presented as an abstract with limited information. It shows SLP can be used in children with a diagnosis of asthma.
Hmeidi et al. (2015b)	
Study size, design and location	Prospective, observational study on 44 young people and children (aged 3 to 17 years) with asthma in the UK. Company sponsored.
Intervention and comparator(s)	Thora-3Di, no comparator.
Key outcomes	Results of the tidal breathing parameters RR, Ti/Ttot, IE50 and RC2Tot were presented stratified by age groups, with demographic information on height and weight.
Strengths and limitations	This study was presented as an abstract only with limited information. It shows Thora-3Di can be used in healthy young people and children who do not have asthma and presents normative data categorised by age, height and weight. These are the same normal controls as those studied in Hmeidi et al. 2016.
Abbreviations: FEV1, forced expiratory volume in the first second; IE50, ratio of inspiratory to expiratory flow at 50% of tidal movement; RC2Tot, relative contribution of chest wall movement to total movement; RR, respiratory rate; SD, standard deviation; SLP, structured light plethysmography; TA, thoracoabdominal; Ti/Ttot, inspiratory time ratio; VT, tidal volume.	

Recent and ongoing studies

The company stated that 2 small UK-based studies in children were ongoing.

Specialist commentator comments

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

All 4 specialist commentators were familiar with the technology and 2 of the 4 had used it before, both noting they have further unpublished research data on the device.

Level of innovation

The specialist commentators generally agreed that the device is innovative, noting that other systems and devices were available to measure tidal breathing parameters, but none did so in the non-invasive, accessible way that Thora-3Di does.

Potential patient impact

Three specialist commentators said the device had potential in the management of disabled people such as those with neuromuscular disorders who could not perform a standard lung function. One said the ability to measure right-versus-left lung function would be a major advantage in conditions such as scoliosis. All the specialist commentators noted Thora-3Di's advantages in not needing specific respiratory manoeuvres, so being able to measure breathing factors in the very old and young and other people who find conventional spirometry difficult. One noted it does not need a mask or mouthpiece to be used and does not interfere with normal breathing.

Potential system impact

The specialist commentators commented that changes to the patient pathway were possible but would need significant further clinical studies to determine the place in therapy. One noted that there was not enough data to suggest that Thora-3Di should replace spirometry.

One specialist commentator said if more data on healthy patients were collected, it could improve the objective measurement of breathing parameters. In turn, this could potentially contribute to a significant improvement in patient outcome. One said there was not sufficient evidence to use Thora-3Di over existing clinical monitoring and diagnosis techniques.

General comments

Two specialist commentators commented that the technology could have advantages over spirometry as Thora-3Di as it is easier to interpret and quicker to learn, but one cautioned that there is no published evidence on the training for Thora-3Di. Two specialist commentators commented on the large upfront costs of the device and noted the savings in staff time over spirometry may not be realised in the patient groups likely to benefit the most as the patients are required to change into a white t-shirt and to stay still for several minutes. Two specialist commentators noted that the use a dedicated room to house the machine and do the test may limit use, especially in primary care. All experts said the device has potential to be applied to a very large population of people with asthma but all agreed further research evidence on larger populations and comparison with other methods of diagnosis and monitoring were needed.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Michael Shields, professor of child health Royal Belfast Hospital for Sick Children. Retained a rented SLP machine from Pneumacare between 2 separate projects at no extra cost (rent free).
- Dr Cara Bossley, consultant respiratory paediatrician, King's College Hospital, London. No relevant conflicts of interest.
- Dr John Alexander, intensive care and respiratory paediatrician, University Hospitals of North Midlands. Author on 4 studies quoted in this briefing; studies done in their department and a student on the project was funded by a grant from the company.
- Dr Katharine Pike, clinical senior lecturer, University College London and consultant respiratory paediatrician, Great Ormond Street Hospital NHS Foundation Trust. No relevant conflicts of interest.

Development of this briefing

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.

ISBN: 978-1-4731-2698-5