Background

Overactive bladder (OAB) syndrome occurs when the bladder contracts suddenly without the individual’s control or when the bladder is not full. Symptoms of OAB include a sudden urgent desire to pass urine (urgency), going to the toilet often (frequency), waking up to use the toilet more than once at night (nocturia), and the passing of small quantities of urine before a toilet can be reached when an individual feels the urge (urge incontinence). The prevalence of OAB symptoms is higher among those over 40 years and women are more likely to be affected than men. An estimated 10% to 20% (five to ten million people) in England and Wales suffer from OAB symptoms. This means that between 10,000 and 20,000 per 100,000 people have OAB symptoms. While an average GP with a list of 2,000 may have between 200 and 400 patients with OAB symptoms on their books, one estimate is that only 30% of these will consult the GP about their condition. The same source estimated that only 35% would be referred to a specialist. In 2009-10 there were approximately 21,800 hospital admissions for OAB complications in England and Wales.

Current Practice

According to the National Institute of Health and Clinical Excellence (NICE) current initial treatment for adults with OAB includes bladder training, pelvic floor muscle training and anticholinergic drugs. Injection of the bladder wall with botulinum toxins and sacral nerve stimulation may be used in patients for whom these conservative treatments have failed to work. More comprehensive surgical options, including bladder reconstruction or urinary diversion are available for treating OAB.

NICE recommend sacral nerve stimulation for women who have not responded to conservative therapy or drugs. The sacral nerves, located at the base of the spine, control the bladder and muscles related to urinary function. Stimulation of the sacral nerve has been shown to relieve the symptoms of OAB but the underlying mechanism is not fully understood.

There are currently two methods of sacral nerve stimulation, both of which are invasive to some extent. One method involves implantation of a neurostimulator (a
device that produces electrical current to stimulate nerves) and a lead wire under the skin on the lower back. This is a two stage procedure, the first of which is lead placement to see if the therapy will work for the individual and the second stage is placing of the system. Side effects encountered with this form of sacral nerve stimulation include infection, pain, skin irritation, lead migration and the implanted device interacting with other devices or diagnostics. Another form of sacral nerve stimulation is percutaneous posterior tibial nerve stimulation. This is where a fine needle electrode is inserted into the lower part of the leg close to the tibial nerve. An electric pulse, from an external neurostimulator device, then travels to the sacral nerve via the tibial nerve. Percutaneous posterior tibial nerve stimulation was deemed safe and effective for treating OAB by NICE. It is currently the least invasive form of nerve stimulation for OAB.\(^\text{10}\)

**New Technology**

The VERV™ system has been developed by Ethicon Endo-Surgery, a subsidiary of Johnson and Johnson, for non invasive sacral nerve stimulation for OAB. The system is portable and consists of a patch, placement tool and a remote control. The single application patch is water resistant and designed to be worn during most normal activities and is replaced every seven days. The placement tool helps the patient place the patch correctly after proper fitting from the healthcare practitioner. The remote control is portable and handheld and is designed to activate and adjust the signal transmitted by the patch. The VERV™ system can be operated by the patient once they have been instructed on proper patch placement as well as proper use of the system.

The VERV™ system transmits a Transdermal Amplitude Modulated Signal (TAMS), an electrical signal which penetrates the skin tissue and stimulates the sacral nerves. No surgery is necessary for the system. According to the company, there are few adverse events associated with use of the VERV™ system. The company states that response to the treatment is quick which they state is an advantage over drug therapy which may take a few weeks to show improvement.

The VERV™ system is designed for individuals who do not respond to conservative or drug therapies or where drugs are contraindicated. It is likely that the use of this device would be initiated by specialists in urology or gynaecology.

Discontinuing the use of the VERV™ system is simple and immediate as compared to removal of an implanted device or drugs which require a wash out period. The company states the VERV™ system offers a completely non-invasive method of nerve stimulation with possibly increased convenience and fewer surgery associated risks or side effects. The patch is removable meaning a person using the VERV™ system can use other devices and diagnostics such as MRI scans with no potentially harmful interactions.

The VERV™ system was CE marked in December 2010 and is now available in the UK. It is currently not available in the NHS in England and Wales. The cost of the system was unavailable for this report.

**Clinical Studies and Research Questions**

A multicentre study of 74 patients with OAB, reported in abstract only, showed decreased urge incontinence episodes with the use of the VERV™ system.\(^\text{11}\) Initially study participants were randomised into one of two treatment groups in which the patch was positioned by the investigator or the subject.
OAB is a relatively common condition which may significantly reduce quality of life. If shown to be as effective as other modes of delivery of sacral nerve stimulation for OAB symptoms, the VERV™ Patient Managed Neuromodulation System may offer a non-invasive alternative with fewer side effects. This may be more acceptable to patients and increase compliance.

An effective device of this type may have a place in the clinical pathway of care where conservative and drug therapies have not succeeded and prior to use of more invasive treatments such as implantable sacral nerve stimulators, tibial nerve stimulation, botulinum toxin and bladder surgery.

The device is likely to be used by specialists in urology and/or gynaecology in an outpatient setting with some training needing to be provided to the patient. The cost of the device is not known although savings in hospital staff and theatre use are likely compared with implantable sacral nerve stimulators and surgery.

**Potential Impact**

OAB is a relatively common condition which may significantly reduce quality of life. If shown to be as effective as other modes of delivery of sacral nerve stimulation for OAB symptoms, the VERV™ Patient Managed Neuromodulation System may offer a non-invasive alternative with fewer side effects. This may be more acceptable to patients and increase compliance.

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**References**


