The CONFIDeNT trial: Are we missing the point?
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Dear Editor,

We read with great interest the article reporting the results of the CONFIDent trial which aimed to assess the short-term efficacy of PTNS against sham electrical stimulation in adults with faecal incontinence (FI).¹ The authors should certainly be congratulated for completing the study since surgical trials are notoriously difficult to implement but we would like to comment on its conclusions in view of our great experience administering the therapy and treating such patients.²,³

The authors conclude that PTNS did not confer any significant clinical benefit after 12 weeks because the primary outcome (i.e. 50% reduction in weekly incontinence episodes) was not found to be statistically different between PTNS (38% achieved the primary outcome) and sham (31%) patients. Firstly, it is debatable whether the selection of this outcome is an appropriate metric to quantify symptom improvements particularly after a very short period of three months when patients had symptoms for 48-60 months. We do wonder whether physicians in other specialties would render a treatment ineffective if a 50% reduction, in cholesterol levels for example, was not achieved within a few weeks. Interestingly, the 25%, 75% and 100% reduction in incontinence episodes all showed a trend favouring PTNS, albeit not statistically significant. Despite the (in)appropriateness of the chosen primary outcome, it is can
be argued that if the treatment was administered for a longer time period or even with different neurostimulation parameters, dependent on patients nerve conduction characteristics, the result might have different.

The authors also reported that the mean number of incontinence episodes significantly decreased in the PTNS group (2.26, 95% CI 4.19 to 0.34, p=0.02) although their group consisted of a large number of patients with passive FI for which bulking agents might be more appropriate. It is interesting that the results of anorectal physiology, a standard test performed in all patients, are not given and, hence, we do not know whether the two groups are truly matched at baseline physiological characteristics. Furthermore, a significant reduction in the mean number of urge incontinence episodes was noted (1.46, 95% CI 2.69 to 0.22, p=0.02) and accompanied by reduction in the use of loperamide (29% PTNS patients reduced their loperamide intake vs 11% sham patients) and, more importantly, by a significant improvement in patient-reported outcomes yet the authors conclude that the improved symptoms “might or might not be helpful to patients”. FI treatments aim to control symptoms rather than cure them with the aim to improve their quality of life, reducing social isolation and allowing patients to achieve some form of normality pursuing their activities of daily living. This probably explains why all domains of the Rockwood Faecal Incontinence Questionnaire and the SF-36 scores appeared to improve in the PTNS group but not in patients that received sham stimulation.

In conclusion, this study has confirmed the findings of previous large prospective studies with longer follow-up\(^2\) that PTNS has an excellent safety profile, which is well-tolerated by patients resulting in improved symptoms and quality of life scores even in the short-term.\(^3,4\) The real question is not whether there is a placebo effect but whether careful patient selection, modification of the initial treatment protocol, or
of the neurostimulation parameters and the frequency of maintenance sessions can result in even greater improvements. We are concerned that the findings of this study may be interpreted incorrectly by the National Institute of Clinical Excellence in the United Kingdom to deny patients a potentially excellent treatment, particularly since all other current FI treatments commit patients to complex and invasive procedures with an uncertain outcome.

References


