EDITORIAL

Alternative Approaches to the Treatment of Fecal Incontinence

Heinz Becker and Stephan Samel

This editorial accompanies the article "Triple-Target Treatment vs. Low-Frequency Electrostimulation for Anal Incontinence: A Randomized, Controlled Trial," by Thilo Schwandner, Claudia Hemmelmann, et al., which appears on the following pages

Biofeedback and anal electrostimulation are considered to be established techniques for the treatment of chronic fecal incontinence when the involuntary loss of stool cannot be stopped by surgery, by general measures such as optimizing stool consistency, or by the treatment of an underlying proctological condition. In fact the terms "biofeedback" and "electrical stimulation" cover a wide range of therapies, which have been subjected to varying methods of evaluation. The available literature on the subject does not allow a systematic comparison of different forms of treatment (1).

No general recommendation to treat fecal incontinence in any particular way can be derived from the individual studies published to date (2). Despite this, certain types of treatment without any clear evidence of efficacy are now reimbursable by the statutory health insurance carriers in Germany, while others cannot be ordered. The frequent result is a fruitless struggle with the Medical Service of Health Insurance Companies in Germany (*Medizinischer Dienst der Krankenversicherung, MDK*) and with the statutory health insurance carriers (*Gesetzliche Krankenversicherungen, GKV*), ending in the refusal of payment for indicated treatment. Such conflicts are annoying, and the denial of treatment for our patients is regrettable. Yet there is a real lack of evidence-based treatment due to the inadequacy of scientific study in this area.

Comparing different treatments

Fortunately, Thilo Schwandner and colleagues have now carried out a systematic investigation of various methods of anal electrostimulation to treat fecal incontinence.

In a trial whose findings were published last year (3), the authors compared treatment with electromyographically triggered biofeedback training (EMG-BF) to a type of multimodal treatment that they call triple-target treatment (TTT or 3T), consisting of EMG-BF combined with amplitude-modulated medium-frequency anal electrostimulation (AM-MF).

This large multicenter trial included nearly 160 patients, and the results were evaluated with an intention-to-treat analysis. After nine months of follow-up, far more 3T patients than EMG-BF patients had markedly better anal continence than at the start. The trial met with criticism (4), however, because only 62

of the 158 patients (39%) actually received treatment as planned for the full nine months—43 in the 3T group and 19 in the EMG-BF group. The trial was thus much less informative than it otherwise might have been; the main thing that it demonstrated was the practical difficulty of carrying out highly demanding investigations of competing treatments for anal incontinence.

The three goals (targets) to which the term 3T refers are:

- coordination training with EMG-BF to normalize "corrupt" motor activity in the central nervous system,
- conditioning of the puborectalis muscle, and
- stimulation of the slow fibers of the internal anal sphincter.

Medium-frequency electrostimulation (AM-MF) exerts its effect through summation of action potentials. It is less painful than low-frequency stimulation (LFS), because it requires a less intense current. In LFS, the current must be intense enough to stimulate slow muscle fibers as well; many patients find such high currents unpleasant or painful.

Alternative therapeutic approaches

The latter consideration led to the hypothesis that Thilo Schwandner, Claudia Hemmelmann, and colleagues tested in their second multicenter, randomized trial, as reported in the current issue of the *Deutsches Ärzteblatt International* (5). This trial, on a smaller scale than the first one, included 80 patients, who were to be treated for six months. Nearly all of them were treated for the entire six months, as planned. This second trial compared 3T with low-frequency stimulation.

None of the patients treated with LFS gained any improvement of fecal continence, while 28% of the of 3T patients had some improvement of continence, and more than half of them were fully continent after six months of treatment.

This trial, too, can be criticized for the short duration of treatment and follow-up, yet one should bear in mind that, for practical reasons, a longer trial would not have been feasible with the desired statistical power.

The design of the trial can be criticized, too: 3T was compared to LFS alone, rather than LFS combined with biofeedback. For this very reason, however, the trial was able to show that LFS by itself, a treatment currently listed as reimbursable in the Medical Aids

Klinik für Allgemein- und Viszeralchirurgie, Georg-August-Universität, Göttingen: Prof. Dr. med. Heinz Becker

Praxis für Koloproktologie und chirurgische Endoskopie, Göttingen: PD Dr. med. Samel

Directory (*Hilfsmittelverzeichnis*) of the GKV, appears to have no effect and ought to be abandoned. This finding is one of the authors' two valuable achievements; the other one is that they have provided good evidence for the efficacy of an alternative treatment, 3T, while considering and discussing the relevant pathophysiological issues in detail.

Conflict of interest statement

The authors declare that no conflict of interest exists.

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Corresponding author

Prof. Dr. med. Heinz Becker
Klinik für Allgemein- und Viszeralchirurgie
Georg-August-Universität Göttingen
Robert-Koch-Str. 40
D-37099 Göttingen, Germany
hbecker@chirurgie-goettingen.de

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