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Factors Predicting Failure in Anorectal Biofeedback

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Abstract

Anorectal biofeedback is a method used by specialists in gastrointestinal motility to treat disorders of defecation. In the case of the anorectal biofeedback, unlike in biofeedback applications in other medical fields, the signal is represented by the pressure in the anorectal canal. The pressure is assessed by anorectal manometry. Patients are trained to become aware of this signal in an attempt to reeducate them for a correct defecation. Following the variation of the signals, patients can learn how to modulate the anal sphincter pressure and to improve their defecation disorders. Anorectal biofeedback is therefore used for fecal incontinence and for chronic terminal constipation. Despite its potential, the method is not intensively used and many patients ignore it. The specialists' evaluation of the method is controversial: from enthusiastic to deceiving results, different data are available. The aim of this presentation is to analyze factors of success and of failure in the use of anorectal biofeedback in a single center specialized in anorectal manometry and to compare our data with results described by other authors.

Keywords: anorectum, biofeedback, constipation, defecation, feces, incontinence, manometry, stool, therapy

1. Introduction

Biofeedback has its application in gastroenterology as well. According to the definition of biofeedback indicated by Webster Dictionary," the technique of making unconscious or involuntary bodily processes (such as heartbeats or brain waves) perceptible to the senses (as by the use of an oscilloscope) in order to manipulate them by conscious mental control," few people would expect

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the application of feedback in the gastrointestinal tract. If you look to the well-known French dictionary Larousse, one cannot easily understand the use of biofeedback by gastroenterologists:" *Méthode de rééducation utilisant l'action du système nerveux sur les réactions physiologiques* "(*Method for reducation using the action of the nervous system on physiological recations*). To our disappointment, the explicatory dictionary of our tongue mother, Romanian, simply ignores the word biofeedback, maximum it offers is only "feedback." According to these definitions, nonspecialists could believe that biofeedback is something for the patients with disorders of the nervous system. However, the gastrointestinal tract has its own nervous system as well, thus biofeedback should work also for the gastrointestinal system.

Which is the segment of the gastrointestinal tract best suitable for the application of biofeedback? This is the anorectal segment, having important innervation and requiring a perfect correlation between the contraction and relaxation of its different components during defecation [1]. Defecation is a complex function and its deterioration may have very important impact on the quality of life of any patient with defecation disorders [2]. The application of the biofeedback for the correction of defecation disorders caused by the impairment of the anorectal segment of the digestive tract is called anorectal biofeedback.

The physiological signal triggering the biofeedback activity is represented by the pressure of the anorectum in relaxation and contraction. Thus, anorectal biofeedback relies on anorectal manometry. One can claim that anorectal biofeedback represents the field where anorectal manometry evolves from the diagnostic role to the therapeutic role [3]. The clinical conditions where anorectal biofeedback based on anorectal manometry is useful are represented by defecation disorders: anal incontinence and terminal constipation. Both may become severe conditions deteriorating the quality of life [4–7].

The anatomical and physiological background of the normal defecation relies on the integrity of the anorectal structure and function, and these may be influenced by general or systemic conditions or by local changes [8]. The retentions of the fecal bolus are a complex mechanism that involves the two anal sphincters as well as the 90° anorectal flexure. During defecation, the external anal sphincter is relaxing, the puborectal muscle is relaxing as well, and this leads to changes of the anorectal angle to 140°; meanwhile, the abdominal wall muscles contract to increase the intraabdominal pressure. The anal canal is situated in the thickness of the perineum. Posterior to the anus are found in the levator ani muscles and laterally the ischioanal fossa is found. The anatomical relations of the anterior aspect of the anus are different in women and men. In woman, we found the vagina and in men the prostate.

The internal structure of the anal canal is covered by a mucosa formed from simple epithelium. At this level are present the vertical folds that form the anal columns. The inferior third of anal canal is covered by a stratified squamous epithelium that is continuous with the perineal skin. The external anal sphincter is formed from three circular striated muscles the surround the anal canal. The internal anal sphincter lies directly superiorly to the external sphincter. While the control of the external sphincter is voluntary, the internal one is controlled entirely involuntary. The innervations of the sphincter apparatus are realized through fibers from the lumbosacral plexus.

2. Technique of anorectal biofeedback

The performance of anorectal biofeedback requires the availability of a manometry laboratory [1, 9]. **Figure 1** displays a room for gastrointestinal manometry which is useful also for anorectal anometry and biofeedback. The equipment needed for biofeedback is any good system of standard anorectal manometry or of high-resolution manometry (HRM).

We started the procedure with water-perfused systems, using balloons. The balloons were inflated during the procedure and following anorectal manometry, asking the patient to expel the balloon. The patients were also looking to the screen to observe the pressure variations on the screen. **Figure 2** shows the catheter and the balloon used for biofeedback. More recently, after finishing the investigations described here, we started working with a solid-state high-resolution device.

The investigation of the anorectal function in patients with defecation disorders should be carried out in a dedicated room of the laboratory for gastrointestinal motility studies in conditions of



Figure 1. Laboratory for anorectal manometry and biofeedback.



Figure 2. Balloon used for anorectal biofeedback.

comfort (termic and social) respecting patients intimacy. It is advisable to do not accept many trainees during the investigation, as patients could feel stressed and unable to relax the external anal sphincter when asked to do so. One should begin by assessing the anorectal pressures in order to have a correct manometric diagnosis (either incontinence or terminal constipation). During the investigation, the patient is able to look to its own curves of pressure in the anorectal canal, in relaxed condition or in contraction state. Thus, the patient receives the signal offered by the recording of the pressure either by standard manometry or by HRM. The patient becomes aware of the functional deficit of his/her anorectal disorder. The pressure recordings represent in continuation the starting baseline for the exercises to correct these functional disorders [9, 10]. The investigation is carried out by a specialist (can be medical doctor, fellow or technician/nurse), but the biofeedback session should be performed by a very dedicated person, preferably a technician or nurse. The staff should have experience, empathy, patience and tolerance with the patient.

Of course, the patient requires a preliminary preparation for every biofeedback session. This is the same as for anorectal manometric investigation: empty rectum (easy in incontinence, difficult in terminal constipation), emesis should be required at least 60 min before the intervention. All these prerequisites make very much necessary a good collaboration between patient and investigator.

3. Clinical use of anorectal biofeedback

3.1. Anorectal biofeedback in terminal constipation

Chronic constipation is defined as the evacuation of stools from the bowel less frequently than once every 3 days [11]. It also corresponds to the types 1 and 2 of the Bristol Stool Form Scale [12]. Two main factors may cause chronic constipation: slow transportation or difficult evacuation [13]. Therefore, we may encounter two types of constipation: transportation constipation and terminal constipation or dyskesia. Sometimes both factors are contributing to constipation. In this case, we speak of mixed constipation. The indication to use biofeedback in terminal constipation is assessed by the measurement of colonic transit time with radiopaque markers [14]. This is a simple method allowing the estimation of total colonic transit time, as well as of segmental transit times for proximal colon, distal colon and rectosigmoid. A normal transit time of the colon rules out the transportation constipation. It is not uncommon to observe a difference between patients' symptoms and real transit time when assessed by radiopaque markers. This difference might be explained either by over reporting of anxious constipated patients or by variability of transit from day to day in same subject.

Terminal constipation has to be confirmed by anorectal manometry. Anorectal manometry is able to diagnose terminal constipation when rest anal pressures are high or when the anal sphincter does not relax after the dilation of an intrarectal balloon. This is caused by the lack of the inhibitory recto-anal reflex. In some cases, the fecal bolus is not perceived because of altered visceral sensitivity or of the enlargement of the rectal ampulla. If the terminal constipation cannot be managed with normal dietary and pharmacological measures, one should proceed to anorectal biofeedback. The first session starts with the routine anorectal manometry just to identify the pathogenic background and to explain it to the patient. This investigation represents the baseline for consecutive measurements during next sessions. The patient has the possibility to look to the screen of the manometric device and to find out pressure and relaxation alterations.

The sessions are grouped in four steps [15]. During the first step, the patient learns how to try to expel the fecal bolus; during these exercises, the patient tries to relax the anal sphincter to allow to the stool to pass through out. Simultaneously the patient learns how to increase the abdominal pressure. These exercises should be repeated after at least 1 min, several times, for 30 min. If fatigue occurs, the rhythm of exercises should be diminished. During this exercise, one shows to the patient how the correct modality to expel the stool is and is encouraged to continue practicing. In the second step, the patient is helped to become aware of the independence of abdominal and anal contractions. The patient has to contract the anal sphincter without contracting the abdominal muscles and later to contract the abdominal muscles without contracting the anal sphincter. During the third step, the anal relaxation is practiced. After few exercises with the anorectal balloon, the patient is instructed to perform the Valsalva maneuver. The fourth and last step is the forced push to correctly expel the balloon. This movement starts with a diaphragmatic aspiration followed by a respiratory blocking; pushing the balloon has to be energic, progressive and direct. The abdomen of the patient has to become convex. The aim of this maneuver is to obtain three steps elimination of the rectal content: balloon during feedback exercises, feces in real life. The three steps are: anal sphincter relaxation, aspiration of the diaphragm and apnea, correct pushing maintaining the sphincter in relaxed state.

These sessions of anorectal biofeedback should be repeated weekly. Patients can perform also at home these exercises, either without computer, or with transportable biofeedback devices. The length of the therapy is at least 3 months of weekly sessions followed by monthly sessions for another interval of 3–6 months.

3.2. Anorectal biofeedback in fecal incontinence

The fecal incontinence called also anal incontinence is a serious medical condition about which neither doctors nor patients like to discuss [1, 16]. Of organic or functional etiology, this condition is impairing the quality of life very much. Most people do not like to complain of this; therefore, the diagnosis is largely underestimated.

The biofeedback in fecal incontinence is recommended for incontinence caused by the dysfunction of the anal sphincter. In functional incontinence, the results are superior to the organic incontinence; therefore, it should be indicated in functional incontinence, while other conditions present only a relative indication. Incontinence following medullar section, like after traffic accidents, has almost no success at all [3, 17].

The principle of the intervention is to practice a kind of gymnastics for the anal sphincter in order to develop its capacity to retain the fecal material in the rectum. The procedure starts like

for constipation by anorectal manometry. This can be carried out by the traditional standard anorectal manometry or better now by HRM. The investigation allows to estimate the degree of sphincter dysfunction and to measure the baseline values of the anal sphincter. In continuation, the patient is trained to be able produce voluntary contractions and to follow on the screen the change in anal pressure in resting and during these exercises. A therapeutic session may last up to 45 min and should be repeated weekly. Every new session should start by the baseline measurement of the anal sphincter pressure. The recordings of these values may encourage the patient and reinforce him/her. One can also estimate the value of this management for the improvement of symptoms. The patient is asked to perform similar exercises at home daily. There are 6–10 sessions recommended. If no answer is obtained, one should stop this therapeutic approach.

The strategy of approach in anorectal biofeedback for incontinence has three phases. The first step aims to develop the capacity to increase the amplitude of voluntary contractions. The patient follows on the screen his/her own contraction and contractile force. The contractions are repeated at 10 s and should be as strong as possible. Between contractions, pauses of 20 s are necessary. The second phase looks for the progressive extension of perineal muscle contractions. The contraction should be as long as possible, with rest pauses twice as long as the length of the contractions [3]. A third phase may be necessary: the proprioceptive reeducation. This phase means to let the patient progressively eliminate small amounts of air, with the aim to develop contraction reflexes at small volumes. To achieve this aim, the balloon is filled with about 60 ml air and the patient is asked to perform anal contractions when he/she feels distension in the rectum. Next steps are the exercises with decreasing air volumes in the intrarectal balloon, to increase the capacity of discrimination and retention [18]. There are good results with biofeedback, but relapse after the end of therapy is possible. We further describe a single center study to look for success and failure factors in anorectal biofeedback.

4. Original study

Anorectal biofeedback is an established method for the therapy of defecation disorders. However, contradictory data are reported with respect to results and sustainability of the results [18–20]. Given the possibility to work in the busiest center of gastrointestinal motility in our country, we aimed to evaluate the value of the anorectal biofeedback. Impressed by the fact that many patients included in our biofeedback program dropped out, we wanted to look for reasons of failure. Therefore, we analyzed cases of patients submitted to anorectal biofeedback, stratified on presentation and etiology of the medical condition and recorded success or failure, as well as reasons for these outcomes.

4.1. Methods

This was a prospective study conducted in a tertiary medical center with interest in functional and motility disorders; it is the single center in this country performing the anorectal biofeedback. As subjects, we included in this study 20 patients. Eight of them presented with anal incontinence (2 males, 6 females, aged 46-71 years, median 55 years) and twelve patients with terminal constipation (6 males, 6 females, aged 58-78 years, median 67 years). All constipated patients presented only terminal constipation and not transportation constipation. The patients with anal incontinence were functional: 6 cases, or organic: 6 cases (2 after vaginal delivery, 1 after medullar trauma, 2 because of neuropathy). All these patients expressed their informed consent. The study was carried out according to the ethical criteria respected in any human research. They were included after anorectal manometry because conventional therapy was not helpful. Exclusion criteria were represented by the refuse to participate and contraindication to biofeedback. The biofeedback procedure was according to the description of the abovementioned methods. The constipated patients have previously been investigated for colonic transit with radiopaque pellets, and the results were normal in every case. Biofeedback sessions were scheduled twice per week for 2-3 months followed by monthly sessions for another 3-6 months. This rhythm is different from the rhythm described above, but we wanted to have more rapid results and to test the role of such intensive procedure. Patients were advised to repeat daily at home the exercises even in the absence of equipment for biofeedback. Following parameters were investigated (**Table 1**).

All these parameters were evaluated by a qualitative method based on interviews with the patients and using a structured interview appropriate for their understanding.

Descriptive statistics were used according to a commercial package.

4.2. Results

In anal incontinence, the results were favorable in 5/8 cases (60%). Patients were able to better retain the feces and were happy with the quality of life. The rest of three described no improvement. All had organic etiology. In terminal constipation, the outcome was as follows: 5/12 (42%) cases reported positive outcome: normalization or amelioration of bowel movement frequency, while in 7/12 (58%) patients the results were not good.

The patients with incontinence who could follow the biofeedback program till the end had a significant reduction of the number of stools in average from 5 stools/day to 2 stools /day. The result is explained by the reeducation of the anal sphincter. The cases with terminal constipation showed also a change in the bowel movements after the end of the program. Thus, subjects who finished the program and reported improvement showed in average 3 stools per

Table 1. The parameters investigated.

Adherence to the therapeutic program

Factors with positive or negative role in preserving adherence

Duration of intervention

Evolution of symptoms

Quality of life

week, while the patients who did not report any improvement after biofeedback remained with one stool per week.

The adherence to the therapy was also analyzed. It was assessed by recording the presence of the patient to the periodical biofeedback sessions and by interviewing the patients. Thus, it has been observed that among the 10 patients with positive results (5 with terminal constipation, 5 with incontinence), 8 had a perfect adherence, while 2 withdraw with 2, respectively 3 sessions before finishing the program. Those with negative results, in total 10 (7 with constipation, 3 with incontinence) had less subjects who finished the full program. The non-adherent patients presented in three cases terminal constipation and none incontinence. These data show that the adherence to a program of biofeedback in such a sensitive aspect as the defecation is very important for its success. The lack of rapid response may represent the cause of the drop out in several cases.

4.3. Factors influencing the results

We asked the 10 patients who presented favorable outcome on factors who influenced their adherence to therapy and can be determining the success of the biofeedback All mentioned that adherence was considered by them as an important success factor and that they were motivated to attend the biofeedback program. Factors positively associated with adherence to biofeedback therapy and thus with success are displayed in **Table 2**.

Patients who withdraw before the end were less susceptible to indicate positive results. Factors that negatively influenced the success and the adherence to therapy by biofeedback are displayed in **Table 3**.



 Table 3. Factors negatively influencing the outcome of anorectal biofeedback.

4.4. Symptom evolution

The most embarrassing symptoms, that is, the incapacity to defecate, respectively to maintain feces, have been ameliorated after the biofeedback interventions. One can therefore conclude that the anorectal biofeedback is a useful method for treating defection disorders. Our study was a pilot study, including only a limited number of cases. The reason for this is the low frequency of cases accepting anorectal biofeedback and the reduced number of cases with severe conditions resistant to conventional therapy. This represents a limitation for our conclusions. The health-related quality of life has also been investigated, not by specific questionnaires but by qualitative interview. Addressing questions like these: are you happy with this therapy? Did biofeedback help you? Are your family members happy with this method? All 10 subjects with positive outcome answered to these questions in a positive way, emphasizing that positive outcome is associated with better quality of life.

5. Discussions and literature review

The main limit of our study is the reduced number of patients who accepted the program of anorectal biofeedback. On the other hand, we have to accept that the study was performed in the single center of this country performing this kind of management of defecation disorders. The indications for biofeedback are relatively scarce, and for some patients, there are no obvious early results, thus discouraging patients to continue next sessions. A success factor is the motivation of the patient, leading to increased adherence, and not all of possible patients are indeed motivated. Other patients refuse because they would have to travel long distance to the biofeedback laboratory. Our center is also very busy with usual manometric investigations; therefore, time left for biofeedback is reduced also from our side. But even in these conditions, our center is one of the few in East Europe working on anorectal biofeedback. Therapeutic results are important for the patients mainly in functional anal incontinence, but also for terminal constipation. The maintenance of the outcome in terminal constipation after the finishing of the biofeedback sessions is modest, and relapses have been described after the end of the interventions [19].

Better results are observed in the functional anal incontinence and almost nil in organic anal incontinence. About 70% of cases positively respond to biofeedback but there are not predictive criteria to predict well the outcome of anorectal biofeedback in incontinence. Nor in functional incontinence are the results perfect, even if carried out in supervised laboratories. At the end of therapy, relapse can occur in up of one quarter of cases with fecal incontinence. The relationship between the operator and the patient is very important for success of failure, given the very intimate character of this procedure. Lack of appropriate behavior or of empathy will lead to failure. Lack of adherence is another failure factor. Female patients respond better than males, also possibly because the nurses/technicians working in the biofeedback laboratories are of the same gender [20–23]. The complexity of the physiological phenomena involved in defecation renders the therapeutic approach by biofeedback a difficult task. We

consider that not all executor muscles can be involved in exercises. As severe the motor alterations are, as difficult is to expect a favorable outcome.

5.1. The experience of other centers on anorectal biofeedback

In recent years, a number of useful papers have been published on this field, increasing the evidence on the use of anorectal biofeedback for anal incontinence and for terminal constipation. These titles complete the corpus of references accumulated in the last 30 years. A PubMed search using keywords anorectal biofeedback renders more than 400 titles. This shows the interest of the investigators on this topic.

A major paper recently published is the French consensus on therapy of chronic constipation, written by the National Coloproctology Society of France [24]. This working group arrived to a consensus stating that anorectal biofeedback should represent the gold standard for the therapy of anorectal dyssynergia, but only if no response to medical treatment can be observed. This consensus emphasized thus the role of biofeedback treatment of anorectal disorders, situation it as a second line intervention, given the ponderous characteristics of this procedure. In the author's recent review, the shortcoming of HRM in the diagnosis of anorectal disorders is described, while anorectal biofeedback is perceived as a useful tool for terminal constipation caused by dyssynergia. The effect of biofeedback training is explained by central effects. However, baseline manometric data do not predict yet the outcome of biofeedback therapy [25]. Unlike in our study, the author did not consider the role of logistical difficulty cause by distance from the venue of the biofeedback and manometry laboratory.

Another recent work coming from the very active and expert group around Satish Rao [26] evaluated the factors associated with response to biofeedback in anorectal dyssynergia. On a much larger group than our group, containing more than 120 subjects in a post-hoc analysis, the authors showed that anorectal biofeedback improved in more than 60% of the cases the terminal constipation and three quarters of them presented a correction of the dyssynergia. However, there were few predictive factors for success or failure, as either demographic characteristics of the patients or the severity of constipation and manometric baseline data did not differ between the successful and failure cases. Single differences were recorded in respect to satisfaction: lower scores in those who improved and in the used of digital expulsion, maneuver which predicted success. It means that expectancy and difficulty of expulsion are associated with better effect of the biofeedback therapy [26]. Anorectal biofeedback may be performed according to different strategic steps, depending on the experience of each center. But we still need comparative studies to decide which technique is more performing. An attempt to find out which technique is superior was undertaken in a recent study [27]. In St. Marks Hospital, a randomized trial in four groups of anal incontinence was organized. Two groups of patients with incontinence were created according to the living area: urban or rural; each group was further subdivided into two subgroups: one included face-to-face interaction, while the other included telephonic interaction. The therapy lasted 4 months and showed improvement by biofeedback of incontinence, of psychological factors: that is, anxiety and depression, of quality of life, and of manometric data. This study carried out on 350 subjects showed that adding to the procedure of biofeedback an interaction either by face-to-face or by telephone intervention, there is no additional effect on incontinence but patients' satisfaction is higher. Unlike in our area, where living on country side is associated with withdrawing from the biofeedback program because of logistic issues, in this UK study it seems that living in rural area does not influence the outcome of biofeedback. This study is continuing an attempt which was published more than 10 years earlier [28]. In this older study, an attempt to evaluate and validate the interaction with the patient beside the technical procedure only was made. Biofeedback is an effective treatment for patients with fecal incontinence, yet little is known about how it works or the minimum regime necessary to provide clinical benefit. This study compares the effectiveness of a novel protocol of telephone-assisted biofeedback treatment for patients living in rural and remote areas with the standard face-to-face protocol for patients with fecal incontinence. The authors have created a strategy based on the offer of an initial face-to-face assessment before the standard anorectal biofeedback procedure; telephone interview to guide distance living subjects with biofeedback was also used. This strategy was compared with the standard intervention based on manometry, using an ultrasonographic signal for biofeedback. The study included more than 200 participants. More than 70% of them completed the treatment. From these, in more than 50% of cases, the patient rated themselves an improvement; the observers rated in more than three quarters of cases positive results in respect to fecal incontinence and quality of life. Nor in this case was the use of telephone superior to the standard intervention.

All these studies underline the long way from the beginning of the use of biofeedback for fecal incontinence and terminal constipation (dyssynergia). Not more than 10 years ago, systematic reviews of the methods were not able to find relevant and well conducted studies nor definitive conclusions. Thus, the Cochrane Review of 2006 looked for biofeedback interventions on fecal incontinence [29]. The collaborative group was only able to find out 11 eligible studies, including only over 550 subjects. Most trials presented methodological shortcomings, thus having conclusions that could not be accepted without reserves. In no paper could be reported any major improvement of outcome between any biofeedback procedure versus the standard non-biofeedback therapy. The Cochrane group considered the anorectal biofeedback superior to vaginal biofeedback in females with obstetrical history predisposing to incontinence. Thus, the authors concluded that the number of studies (at that time) was insufficient and the quality of most of them not good enough to warrant the use of biofeedback for incontinence. One year later, a British showed a similar reservation versus the biofeedback [30]. In 2012, another Cochrane report [31] dedicated to therapy of fecal incontinence was able to bring much better evidence. This time, the Cochrane collaborative group found 21 eligible studies including more than 1500 subjects. The quality of the studies was better. Some small studies showed the advantage to add exercises or electrostimulation of the sphincter to biofeedback. This time the newer method of sacral nerve stimulation was considered superior to conservative and biofeedback management. The authors were not very happy with the number of studies found, although its number was increased. The effect of biofeedback was inferior to nerve stimulation [31]. Of course, the outcome depends very much on the etiology of incontinence [1].

Anorectal biofeedback has its application also in pediatric patients. There are several papers reporting its effect on children [32–37]. From older studies with less enthusiastic data [33], now we have enough evidence on the benefits of anorectal biofeedback in children with fecal

incontinence or encopresis, or respectively with anismus. The problem of the pediatric investigation is the reduced collaboration with small children. On the other hand, there are devices allowing to perform biofeedback at home.

The role of biofeedback in different applications has been recently emphasized by the fourth edition of the textbook of Schwartz and Andrasik [38].

6. Conclusions

Anorectal biofeedback is a useful method to reeducate the defecation and which is applied in incontinence and terminal constipation. Anorectal biofeedback has positive results in functional anal incontinence and moderate results in terminal chronic constipation. Motivation and high degree of education are factors positively influencing the outcome of anorectal biofeedback. Among failure factors, we should consider the difficulty of some patients to travel long distance to the biofeedback laboratory and unpleasant repeated manipulation of the catheters in the anal canal.

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