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Sensitivity and specificity of multichannel surface electromyography in diagnosing fecal incontinence

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Abstract: Background: Assessment of the neurocontrol of the external anal sphincter has long been restricted to investigating patients by invasive tools. Less invasive techniques have been regarded less suitable for diagnosis.
Objective: The aim was to develop a surface electromyography-based algorithm to facilitate fecal incontinence diagnosis, and to assess its sensitivity and specificity.
Design: Data analysis from a single center prospective study.
Patients: All patients from colorectal surgery office were considered. They underwent a structured interview, a general physical and proctologic examination. Patients with diagnosed fecal incontinence (Fecal Incontinence Severity Index >10) were included into the study group. The control group consisted of healthy volunteers that scored 5 or less and had negative history and physical exam. Both groups underwent the same tests (rectoscopy, anorectal manometry, transanal ultrasonography, multichannel surface electromyography and assessment of anal reflexes).
Methods: EMG results were analyzed to find parameters that would facilitate fecal incontinence diagnosis.
Outcome measures: Sensitivity and specificity of surface electromyography, to diagnose fecal incontinence, were assessed.
Results: A total of 49 patients were included in the study group (mean age ± SD 58.9 ± 13.8). The control group (n = 49) gender matched the study group (mean age ± SD 45.4 ± 15.1). The constructed classifica-

tion tree, based on surface electromyography results, correctly classified 97% of cases. The sensitivity and specificity of this classification tree, to diagnose FI, was 96% and 98% respectively.
L i m i t a t i o n s: The age of women in the control group differs significantly from mean age of other groups.
C o n c l u s i o n s: Surface electromyography is an good tool to facilitate diagnosing of fecal incontinence.

Key words: sEMG, computer-assisted diagnosis, neurogenic, fecal incontinence, external anal sphincter, classification tree.

Introduction

Although no unified definition exists, it is generally accepted that fecal incontinence (FI) can be diagnosed when the leakage of liquid or solid stool exists for more than one month [1]. The prevalence of FI varies depending on the region, population studied and the definition used. It has been reported to be as high as 45% in institutionalized people [2]. Among community dwelling persons, the prevalence of FI varies between 6–24% [3–5]. Unfortunately, the majority of cases remain undiagnosed [1, 5]. Several patomechanisms stand behind FI including parity, dysfunction of the pelvic floor, advance age, cognitive impairment and trauma [1, 2, 5, 6].

FI diagnosis is based on careful history taking, as many patients are reluctant to disclose embarrassing information about themselves [5]. Digital rectal examination is a must in diagnosing FI, as it is both sensitive and specific in identifying dyssynergia [6] and offers essential information about anorectal anatomy. Additional tests include anorectal manometry, transanal ultrasound, pudendal nerve terminal motor latency (PNTML) and electromyography (surface or needle) [1]. A paper by Rao [8] states that the PNTML and translumbar and transsacral motor evoked potentials hold promise to become useful noninvasive objective tests. However, a paper by Hill *et al.* [9] questions the usefulness of PNTML in assessing the innervation of the external anal sphincter (EAS). Among the discussion about current methods of diagnosing FI, a recent review by Halland and Talley [1] states that the clinical role of neurophysiological testing of anorectal function such as needle or surface electromyograms remains unclear. This is true, but primarily due to the fact, that apart from a few studies [10–12], little is known about clinical applications of electromyography. The second reason why EAS electromyography is unpopular is the fact that interpreting its graphic results is difficult, and comparable data is scarce [10–12]. To popularize this method, an automatic algorithm, based on numerical values rather than graphical interpretation, should be developed.

Thus the aim of this study was to develop a surface electromyography (sEMG) based algorithm to diagnose FI, and to assess its sensitivity and specificity.

Materials and methods

Patients

Patients were recruited from among the ones referred to the Outpatient Colorectal Clinic with diagnosis of FI. Each patient included in the study underwent a structured medical interview, a general physical examination and a proctological examination. In addition she or he filled out the fecal incontinence severity index questionnaire (FISI) [13].

Study group

Patients that scored more than 10 points on the FISI underwent further tests that included rectoscopy, anorectal manometry, transanal ultrasonography, multichannel sEMG and assessment of anal reflexes. Based on the outcomes of the above mentioned tests FI was diagnosed, and its etiology established. Patients with fully diagnosed FI were included into the study group.

Study group exclusion criteria were: age below 18 or above 90; pregnancy; lack of consent to participate in the study; not being able to participate in all the necessary test from the study protocol; conditions that influenced the FISI score (other than fecal incontinence, including but not limited to diarrhea or inflammatory bowel disease).

Control group

The control group consisted of healthy volunteers wishing to participate in the study. Each person from the control group underwent the same tests as patients from the study group. To be included in the control group one had to score 5 or less points on the FISI, and have no EAS dysfunction (assessed by transanal ultrasonography and anorectal monometry). Additional control group inclusion criteria included: age between 18 and 85; no anorectal complaints, no history of anorectal surgery; no history of diseases that might impair EAS innervation like diabetes, neuropthies, central nervous system disorders, systemic disorders; for women — no labor induced perineum injuries and not more than one pregnancy; no abnormal findings on the performed tests.

Tests

sEMG — was performed using a prototype EMG-16 multichannel signal enhancer (OT Bioelettronica, Turin, Italy). The frequency used was between 10 to 500 Hz (3 dB). Sampling was set at 2048 samples per second. The transducer used was

NI DAQ_MIO16 E-10 (National Instruments, USA) and attached to a standard PC. Measurements were made using an anorectal probe (diameter 14 mm) with 3 rings of 16 silver bar electrodes each. Each electrode dimensions were 1x9 mm, and the distance between each ring was 8 mm. The measurements were made on the following depths, counting from the internal rim of the anus — from the anal pecten to 9 mm deep; from 18 to 27 mm deep; from 35 to 44 mm deep. After inserting the probe and waiting for 1 minute for the patient to relax, 3 ten second recordings were performed (one on each depth), with the patients' EAS relaxed. Next, the same measurements were repeated with the EAS contracted. The whole procedure was repeated two times. Signal analysis was performed using MathLab. To analyze the amplitude Root Mean Square (RMS) was calculated, according to the following equation:

$$\mathrm{Xrms} = \sqrt{\frac{a_1^2 + a_2^2 + \ldots + a_n^2}{n}}.$$

RMS was calculated for each of the 16 electrode pairs, in each of the 3 rings, both during relaxation and contraction of the anal sphincter. Next mean RMS was calculated for each of the three depths. Median frequency (MF) was calculated similarly to RMS [14].

Anorectal manometry was performed according to the Minimum Standards for Anorectal Manometry [15] of the European Neurogastroenterology and Motility Association. The test was performed using perfusion manometry (Polygraf HR Uro, Synectics Medical, Sweden) with a three-channel manometric probe. Maximal basal pressure (MBP) was defined as the maximal pressure during rest in any part of the anal canal, and was the mean of three measurements. Maximal squeeze pressure (MSP) was defined as the maximal pressure during voluntary sphincter contraction in the same localisation where MBP was previously measured.

Transanal ultrasonography was performed using a Logiq 7 ultrasound machine (General Electric, Great Britain), with a 10–16MHz probe [16].

Statistical analysis

Statistical analysis was performed using Statistica 10 software (StatSoft, Poland). Elements of descriptive statistics were used — mean, standard deviation and percentage distribution. To assess differences between groups the Students' t-test was used. Classification and regression tree (CRT) models was used to create an automatic decision algorithm to diagnose FI. This was done as the number of analyzed parameters by far exceeded the possibilities of conventional statistical analysis. The CRT model assigns patients to one of the groups (control vs. study) based on known factors (RMS and MF). Results were presented as a classification tree. Classification and regression tree models are a well-established way to preform exploratory data analysis. Available statistical software automatically creates and validates (based on specific parameters) several differentiation algorithms. The end results of this process are depicted as decision trees, with a certain number of decision and end nodes. The more nodes, the more complicated and probably also less useful the algorithm.

The significance level was set at $p < 0.05$.

Ethics

All patients gave their informed consent prior to inclusion into the study. The research protocol was approved by the Jagiellonian University Ethics Committee (registry number KBET/27/B/2005). The study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Results

Overall 55 patients were qualified to the study group, but due to artifacts in the sEMG recording, only 49: 39 women (79.6%) and 10 men were finally included in the analysis. Two-hundred-and-thirty-seven (179 women and 58 men) patients were qualified to the control group. From this group 39 women and 10 men were chosen to gender and age-match the study group. The mean age (± SD) of the study group was 58.9 ± 13.8 and of the control group 45.4 ± 15.1. Table 1 presents mean age of different subgroups of patients. The paired t-test showed no significant differences in the mean age of men from the study and the control group ($p = 0.74$). Age of women from the study and control groups differed significantly ($p < 0.001$).

Table 1. Mean ages of different subgroups of patients.

Patient subgroup	Mean age — women	Mean age — men	p-value
Whole group	51.5	54.9	0.39
Study group	60.2	53.8	0.19
Control group	42.7	55.9	0.01

Table 2 presents mean anorectal manometry and FISI values in the study and control groups. As Squeeze Pressure (SP) is a dependent variable (the difference between Maximal Squeeze Pressure (MSP) and Maximal Basal Pressure (MBP)) its p-value is of lesser statistical significance.

Table 2. Mean anorectal manometry and FISI values in the study and control groups.

	Study group n = 49 Mean value (SD)	Control group n = 49 Mean value (SD)	p-value
MBP	45.4 (18.9)	73.2 (16.1)	0.000000
MSP	90.3 (46.8)	131.3 (19.9)	0.000000
SP	44.9 (34.7)	58.1 (20.1)	0.02
FISI	41.8 (11.4)	4.1 (0.3)	0.000000

SD — standard deviation; MBP — maximal basal pressure; MSP — maximal squeeze pressure; SP — squeeze pressure; FISI — fecal incontinence severity index.

Table 3 presents mean results from sEMG testing, both in the study and control groups.

Table 3. Mean results (SD) from sEMG testing, both in the study and control groups.

	Study group n = 49 Mean value (SD)	Control group n = 49 Mean value (SD)	p-value
RMS 1C [μV]	**0.017 (0.014)**	**0.023 (0.015)**	**0.040**
RMS 2C [μV]	0.011 (0.008)	0.014 (0.006)	0.110
RMS 3C [μV]	**0.009 (0.007)**	**0.014 (0.007)**	**0.002**
RMS 1R [μV]	0.012 (0.010)	0.009 (0.007)	0.090
RMS 2R [μV]	**0.008 (0.006)**	**0.006 (0.003)**	**0.030**
RMS 3R [μV]	0.007 (0.004)	0.006 (0.003)	0.780
MF 1C [Hz]	87.739 (14.236)	85.214 (17.650)	0.430
MF 2C [Hz]	85.905 (18.170)	80.221 (24.505)	0.190
MF 3C [Hz]	**89.157 (18.024)**	**79.825 (24.414)**	**0.020**
MF 1R [Hz]	97.680 (21.855)	97.265 (13.629)	0.910
MF 2R [Hz]	97.653 (23.169)	95.987 (14.275)	0.670
MF 3R [Hz]	102.663 (24.640)	93.915 (20.827)	0.060

Hz — Herz; μV — micro Volts; SD — standard deviation; RMS — root mean square; MF — median frequency; R — external anal sphincter relaxed; C — external anal sphincter maximally contracted. Numbers after RMS or MF refer to the depth of the ring that was used to obtain the measurements (1 — closest to the anus; 3 — the deepest ring). Results shown in bold differ statistically between groups.

Diagnosing fecal incontinence using sEMG results and classification tree models

After an automated designing process, the classification tree that showed the best classification properties, had 9 decision nodes and 10 endpoints (Fig. 1). This tree was optimized taking into account the classification costs (number of cases classified incorrectly). When used, this classification tree correctly classified 95 out of 98 cases (97%). Two patients (4.1%) out of the study group were incorrectly classified as not having FI, and one patient (2%) from the control group was classified as having FI. The maximal classification route encompassed 6 nodes. However this was necessary for only 3 patients from the control group and 23 from the study group. To classify the other 46 healthy volunteers and 26 patients from the study group, only a 4-node rout was necessary. The sensitivity and specificity of this classification tree, to diagnose FI, was 96% and 98% respectively.

Classification tree: health status (incontinent vs controls)

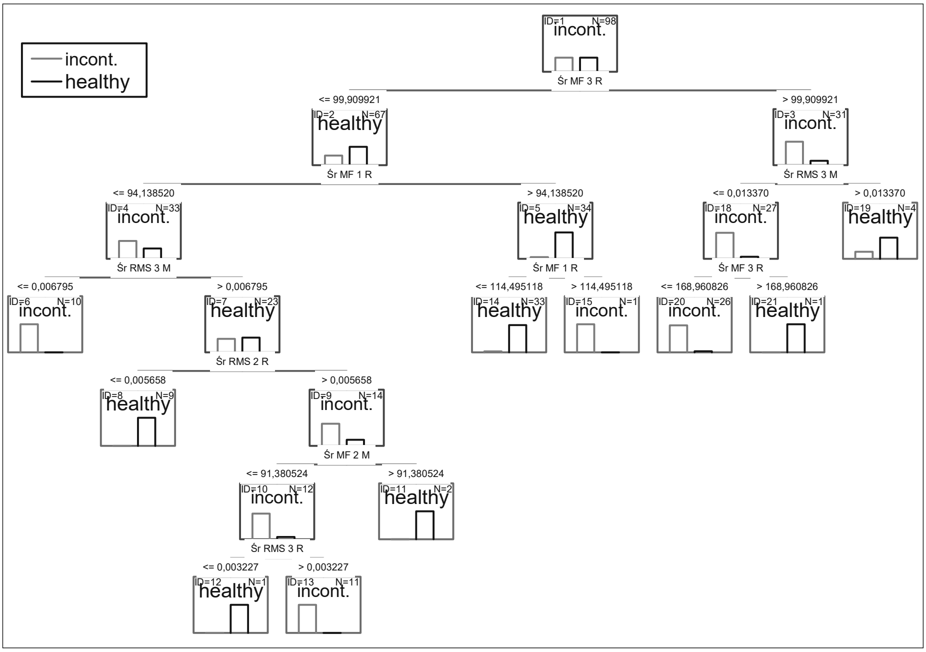

Fig. 1. Classification tree number I [9 decision (non-terminal — blue boxes) nodes and 10 endpoints (terminal nodes — red boxes)].
Tree optimized taking into account minimal classification costs. Bars inside each box depict patients classified into either the control or study group. Green bars depict decisions with the numerical value below and the name of the variable above. Results presented as means. FI — fecal incontinence; RMS — root mean sequence; MF — median frequency; R — external anal sphincter relaxed; C — external anal sphincter maximally contracted. Numbers after RMS or MF refer to the depth of the ring that was used to obtain the measurements (1 — closest to the anus; 3 — the deepest ring).

Discussion

The aim of this study was to develop a surface electromyography-based algorithm to diagnose FI, and to assess its sensitivity and specificity. To the best of the authors knowledge, this is the first study to undertake this subject.

The main finding of our study is the fact that sEMG is in fact an excellent tool for diagnosing FI. When using the right variables in an appropriate algorithm, the sensitivity and specificity of sEMG, in diagnosing FI, becomes extremely high, when compared to other tools used in medical sciences.

The strong points of this study are gender matching of the study and control groups, the right number of patients recruited, sound statistic work-up of data, a detailed diagnosis or rule-out of FI in each qualified patient and the research team experience in sEMG based studies. However this study has some possible limitations. The fact that the age of women in the control group differs significantly from the mean age of other groups, was difficult to be corrected. This occurred due to the fact, that the authors were unable to recruit, into the control group, enough healthy women over 50 years of age. However, after statistical consultation, it was agreed that this difference, taking into account the rest of the group parameters, will not interfere with further analysis. Another limitation is the recruitment pattern. As a 3rd degree referral center our Colorectal Clinic has certainly some bias in patient selection. It may have been reflected in the study population or the severity of FI.

The study group was heterogeneous, including patients with all typical etiologies of FI. From one perspective this could be considered a strong side of the study, better reflecting the diverse patient population. On the other hand this could also be viewed as a weakness influencing the statistical strength of the results.

Up-to-date literature lacks studies assessing the sensitivity and specificity of sEMG in diagnosing FI. This seriously limits the possibilities of this discussion. However, it was the lack of studies to compare our work to, that motivated us to use the classification and regression tree model for statistical evaluation of gathered data and algorithm development. Gardiner *et al.* [17], in their study, developed a computer-aided diagnosis (CAD) system, for diagnosing FI, based on anorectal manometry and PNTML. However, based on doubts whether the PNTML is valid enough to be applied in the FI diagnostic process [9], usefulness of the study by Gardiner *et al.* [17] might be questioned. The major difficulty with PNTML is the principle of measuring conduction velocity as a method of innervation status assessment. It may happen that a significant portion of the pudendal nerve is damaged with no influence on conduction velocity in healthy nerve fibers. On the other hand a minor injury to all fibers may lead to changes in conduction velocity. Moreover artificially evoked electrical stimuli may properly travel via the pudendal nerve producing normal test result. However, physiologically the EAS may not receive any stimulation from higher nerve centers (cortical or spinal injury). EMG measuring electrical activity during rest and voluntary contraction is better for assessment of neuronal activity at the effector (muscle) level.

As it was stated in the introduction of this article, a recent review by Halland and Talley [1] reports that the clinical role of neurophysiological testing of anorectal function such as sEMG remains unclear. This study distinctly shows that sEMG, combined with the appropriate diagnostic algorithm, can be successfully used to diagnose or rule out FI. Its sensitivity and specificity guarantee that it will prove itself in the clinical setting. The developed sEMG-based algorithm forms the base to create a CAD system, that will facilitate the process of FI diagnosis. Authors would suggest that, according to the literature the best way to follow would be to assess muscular injuries with transanal ultrasound, severity of FI with questionnaires and possible defects of innervation with surface, multichannel EMG.

Thus, future research in the field of sEMG-based FI diagnostics, should focus on creating a CAD system to automatize the process of diagnosing of ruling out innervation injury as FI etiology. Large scale field-testing of the developed algorithm could also be performed, to consolidate the use of sEMG in the FI diagnostic process.

Authors fully appreciate that the best tool to diagnose FI is detailed history taking or a simple diary. This study is, however, a first step of our research to develop tools that would help to differentiate not only between the healthy and the incontinent, but to diagnose the etiology of FI with special regard to differentiation between neurogenic and non-neurogenic etiology. At this stage we conclude that the available equipment is precise enough to differentiate between healthy and incontinent patients.

Author contributions

Michał Nowakowski was responsible for study design, performing clinical examinations, data gathering, analysis and interpretation of data and revision of the manuscript.

Krzysztof A. Tomaszewski was responsible for study design, analysis and interpretation of data, writing, revising and editing the manuscript and searching bibliographic databases.

Łukasz Machura was responsible for study design, data acquisition, software development, statistical analysis and review of manuscript in terms of statistical coherence.

Paulina Trybek was responsible for statistical analysis and review of manuscript.

Roman M. Herman was responsible for study design, diagnostic workup of patients and revising the manuscript.

All authors have read and approved the final version of the manuscript.

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Conflict of interest

None declared.

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