

PREDICTORS OF A FAVOURABLE OUTCOME OF PHYSIOTHERAPY IN FAECAL INCONTINENCE: SECONDARY ANALYSIS OF A RANDOMISED TRIAL

Hypothesis / aims of study

It is unclear which patients with faecal incontinence (FI) are likely to benefit from physiotherapy treatment. Identifying predictors based on pre-treatment assessments is essential to support early clinical decision-making and may lead to more realistic expectations of the outcome, as well as more efficient use of resources and referral. So far, conflicting data has been reported on the predictive value of several demographic, clinical and physiological factors due to heterogeneity of study populations, outcome measures, treatment methods, and definition of favourable outcome. This study aimed to identify patient characteristics predicting a favourable outcome of physiotherapy treatment.

Study design, materials and methods

We report on secondary analyses of data from a randomised controlled trial conducted between August 2006 and May 2009 (1). Eighty consecutive patients with FI, with a mean age of 59.3 (SD ± 11.9), were recruited at the Maastricht University Medical Centre and randomly assigned to receive rectal balloon training as an add-on therapy to pelvic floor muscle training (n=40) or pelvic floor muscle training alone (n=40). Inclusion criteria were: FI complaints lasting at least six months, Vaizey score of at least 12, and failure of medication and dietary adaptations. Treatment groups were combined for prediction modelling. Candidate predictors were obtained from patient demographics, clinical and physical examination, and questionnaires at baseline. Anorectal function was evaluated with the following series of tests: anorectal manometry, rectal capacity measurement, anorectal sensation, anal endosonography, and defecography. In addition, the Vaizey score (primary outcome), the Faecal Incontinence Quality of Life Scale (FIQL) and the nine-point global perceived effect (GPE) score were completed. Evaluation of pelvic floor muscle assessment included the Oxford grading scheme, endurance (submaximum contraction up to 30 seconds), and fatigue (maximum contraction up to five repetitions) of the external anal sphincter and pelvic floor.

In the absence of a test or score that can benchmark favourable treatment of FI, we defined favourable outcome as a combination of: (1) Vaizey score reduction ≥5 points, and (2) 'slightly' to 'very much improved' on the GPE. Missing predictive and outcome variables were completed using the multiple imputation procedure. Predictors derived from univariable logistic regression, using the Akaike Information Criterion (0.157 significance level), were included in the multivariable logistic regression analysis. For the multivariable analyses, a three-stage model was used. The initial prediction model included demographic and medical history variables available at the time the patients first visited the physician. The second model examined the added effect of anorectal functional tests in predicting the outcome of physiotherapy. Finally, the third model included variables available at the time the patient was referred to the physiotherapist. Hence, models 1 and 2 provide physicians with information before referral to physiotherapy, whereas model 3 examines the added effect of variables from physiotherapy diagnostics (including pelvic floor muscle assessment). To evaluate the influence of treatment allocation, we added this variable to the final set of predictors (model 4). A forced entry approach with a significance level of 0.10 was used to build each multivariable model.

Results

The mean baseline Vaizey score changed from 17.8 (SD ± 2.8) to 12.8 (SD ± 5.9) after physiotherapy treatment. Thirty-seven patients (46.3%) had a favourable outcome. Multivariable analysis showed that longer time since FI onset appeared to be associated with an unfavourable outcome (odds ratio [OR], 0.68; 95% confidence interval [CI], 0.47–1.00; P=0.05), whereas the use of constipating medication (OR, 3.79; CI, 0.99–14.51; P=0.05), any obstetric factor (OR, 2.15; CI, 0.94–4.89; P=0.07), and experiencing minor embarrassment (OR, 2.12; CI, 1.10–4.09; P=0.03) predicted a favourable outcome (Table 1).

Table 1. Multivariable logistic regression analyses

	Model 1		Model 2		Model 3		Model 4	
	B (SE)	P	B (SE)	P	B (SE)	P	B (SE)	P
Longer time since onset of FI symptoms (m)	-0.49 (0.22)	0.03	-0.40 (0.19)	0.04	-0.56 (0.23)	0.02	-0.38 (0.19)	0.05
Embarrassment subscale	1.13 (0.50)	0.03	0.67 (0.34)	0.05	0.97 (0.40)	0.02	0.75 (0.34)	0.03
Current constipating medication	1.35 (0.70)	0.05	1.36 (0.69)	0.05	1.33 (0.77)	0.08	1.33 (0.69)	0.05
Any obstetric factor	0.95 (0.45)	0.04	0.93 (0.44)	0.04	0.95 (0.47)	0.04	0.77 (0.42)	0.07
Liquid stool incontinence	-0.46 (0.36)	0.19						
No distinction flatus/faeces	-0.22 (0.16)	0.16						
FIQL total score	-0.21 (0.17)	0.22						
Urge sensation (ml)			-0.01 (0.01)	0.12				
Endurance pelvic floor					-0.05 (0.04)	0.17		
Fatigue pelvic floor					-0.27 (0.23)	0.23		
Group allocation							-0.24 (0.53)	0.65

B (SE), estimate with corresponding standard error; m, months.

Interpretation of results

Our study provides a small subset of factors that independently predict favourable outcome of physiotherapy treatment in patients with moderate to severe FI. These predictors may be relevant in patient counselling and targeting physiotherapy treatment more efficiently, especially as they are available early in the diagnostic process.

Concluding message

Future research is warranted to find out if selecting patients for physiotherapy treatment based on the predictors found in this study may result in better outcomes.

References

1. Bols EM, Berghmans BC, Hendriks EJ, de Bie RA, Melenhorst J, van Gemert WG, et al. A randomized physiotherapy trial in patients with fecal incontinence: design of the PhysioFIT-study. BMC Public Health 2007;7:355

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	The medical ethics committee of the University Hospital Maastricht/Maastricht University
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes