Idiopathic Constipation can be Subdivided in Clinical Subtypes: Data Mining by Cluster Analysis on a Population based Study

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Abstract—The prevalence of non organic constipation differs from country to country and the reliability of the estimate rates is uncertain. Moreover, the clinical relevance of subdividing the heterogeneous functional constipation disorders into pre-defined subgroups is largely unknown.. Aim: to estimate the prevalence of constipation in a population-based sample and determine whether clinical subgroups can be identified. An age and gender stratified sample population from 5 Italian cities was evaluated using a previously validated questionnaire. Data mining by cluster analysis was used to determine constipation subgroups. Results: 1,500 complete interviews were obtained from 2,083 contacted households (72%). Self-reported constipation correlated poorly with symptom-based constipation found in 496 subjects (33.1%). Cluster analysis identified four constipation subgroups which correlated to subgroups identified according to pre-defined symptom criteria. Significant differences in socio-demographics and lifestyle were observed among subgroups.

***Keywords*—**Cluster analysis, constipation, data mining, statistical analysis.

I. Introduction

Constipation is one of the most common chronic digestive complaints in Western populations and affects over 1.4 million people in Italy with an increase in the rate as the population ages [1].

Diet, socio-economic conditions, and geographical location can all influence normal bowel habits and explain the considerable differences in constipation rates from country to country [2].

Furthermore, the reliability of estimates regarding the prevalence of constipation is uncertain since they are calculated in different ways. Most epidemiological studies have been carried out by unreliable approaches such as self-reported constipation [3-5], or have not evaluated a random population sample [3-8], and therefore the results may not be generalizable. Moreover, most people with constipation either do not consult a physician at all, or are treated by general practitioners. [9].

Constipation is a heterogeneous disorder and distinct subgroups have been identified on the basis of patho-physiologic mechanisms [10, 11]. It has been suggested that distinct subgroups of patients can also be identified on the basis of clinical setting [12-14], and specific symptom criteria have been proposed. However, although the symptom-based subgroups display different epidemiological characteristics [14], colonic and rectal symptoms have been found to poorly discriminate among patho-physiological subgroups [15]. Therefore, the reliability of grouping patients with non-organic constipation remains controversial. The distinction among constipation subgroups is important for both research and clinical practice and could have a favorable economic impact related to a more rational use of diagnostic tests and treatment.

We therefore conducted an interview survey of a population-based sample from five Italian cities which was carried out by a group of physicians. Our aims were 1) to estimate the prevalence of constipation, 2) to evaluate whether an objective logical tool such as unsupervised cluster analysis divide is able to group patients on the basis of their clinical pattern alone, and, in that case, 3) whether the clusterized subgroups can fit in to well known symptom-based classifications. As we work in a complete blind way the present study can be regarded as a typical example of knowledge discovery in databases. This has been performed in an interactive/iterative procedure, by which we would like to single out hidden information.

The study was designed according to the suggestions made by a panel of experts who met at Terme di Montecatini (Montecatini Terme, Italy).

II. Materials and Methods

A. Selected Sample Population

Face-to-face interviews were conducted with adults > 18 yrs of age in 5 Italian cities (Genova, Roma, L'Aquila, Firenze, Bologna). Based on the random-walk procedure [16,17], each city was divided into a number of metropolitan and suburban sampling areas (from 15 to 30) and a random sample of telephone numbers was obtained. We made up to

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ten attempts to contact each household to let them know about the nature of the study. After verbal consent, home visits were made by five local physicians who conducted the face-to-face interviews and filled in the previously validated questionnaire as described below. The interviewers attempted to recruit the same quota of males and females and only interviewed the family member who would next celebrate a birthday. Thus, an age-stratified population was recruited. Subjects having undergone abdominal surgery (except appendectomy), or suffering from organic diseases or major psychiatric problems were excluded.

Sequential analysis was used to establish the optimal sample size. Therefore, the study population size was not decided in advance but was established by analysis of the evaluated parameters. After preliminary analysis of the first 1,000 questionnaires, data on 100 subjects at a time were progressively added until the results became stable.

B. Questionnaire

The questionnaire began with several general questions (i.e., age, gender, employment, sports, physical activity) followed by screening questions for constipation (i.e., number of bowel movements, use of medication or food supplements to help with bowel movements, percentage of time that a subject reported straining, incomplete evacuation, or lumpy stool). Questions were asked about various types of problems including a belief of blockage, unsuccessful bowel movements; need to press the lower abdomen. Subjects were also asked about discomfort or pain in the lower abdomen (i.e., occurrence in the last 3 months, average duration, frequency, relief with a bowel movement and association with changes in frequency of bowel movements or consistency of stools). Lastly, symptom questions inquired about bloating or heavy or full feeling, the need to press around the rectum or vagina to have a bowel movement, the average amount of time per movement, and the length of time with constipation-related symptoms. Additional questions were asked about medical care for constipation, family history, whether they had ever told a doctor about constipation, or if they had any other specific medical conditions (i.e. diabetes, thyroid disease, Parkinson's, etc.) and whether they had used medication during the previous 3 months for selected conditions possibly related to constipation. The interview ended with demographic questions.

The reliability of our questionnaire was ascertained before beginning the study. The five physicians who filled in the questionnaires were trained in questionnaire techniques. After agreeing on the meaning of each item, they singly interviewed the same subset of 15 volunteers. A separate subset of 10 patients underwent a test-retest procedure in which the questionnaire was given a second time after an interval ranging from 1 to 3 months. Finally, ten pilot subjects were interviewed in each city to evaluate the comprehensibility.

C. Unsupervised Data Mining with Cluster Analysis

After defining the objectives of the present study, we have worked on the data base to create a suitable set of data on which the automatic data analysis can be performed. Specifically: we recomposed redundant data from the relational tables; after this we have preprocessed data (cleaning up data from spurious data, data normalization, formation of training and test set of data). In the data mining session, we used the k-nearest points cluster analysis to evaluate whether patients with idiopathic constipation can be grouped on the basis of information provided by questionnaire. No data concerning either diagnosis or the number of possible sub-groups that may be present within the population sample are supplied for unsupervised cluster analysis. This method is very rigorous in judging whether the sample can be really sub grouped [18].

D. Statistical Analysis

Sample size population was determined by using sequential analysis. Taking into account the population distribution (in 1991) of each town involved in the study, we evaluated the overall age- and gender-adjusted prevalence rates (per 100) according to the age- and gender distribution of our population study. We calculated the 95% confidence intervals (CI) on the basis of the chi-square distribution.

Logistic regression analysis adjusting for age was performed to evaluate the association between gender and the proportion of subjects with and without a specific feature. Two-tailed chi-square test, and where appropriate, Yates approximation were used. The results of this test were considered statistically relevant if $p < 0.05$.

III. Results

The study was stopped after examining 1500 questionnaires, since the results obtained from the analysis of the first 1000 questionnaires did not change after step by step addition of four more separate blocks of 100 questionnaires each. By the time the study had ended we had contacted 2,083 households. Four hundred seventeen (20%) of them had refused to participate in the study, while 166 (8%) were not eligible for the study or did not complete the interview properly. The subjects we interviewed were socio-demographically similar to the subjects who refused to be interviewed, were not eligible for the study, or gave incomplete responses. Thus, the response bias was unlikely to have affected the results significantly.

A. Prevalence and Features of the Constipated Population

In our population study, the subjects who were actually constipated on the basis of symptoms were 496 (33%).

Self reported constipation was mentioned by 435 (29%) subjects. This population was made up of 252 symptom-based constipated subjects (58%) and by 183 subjects with no symptoms of constipation (42%) (Fig. 1). On the contrary, among subjects with symptoms of constipation, 29% (128) did not report being constipated while 23% (116) did not answer the question. Self reported constipation was significantly more frequent among women (30.9% female, 9.4% male, p<0.01).

Socio-demographic analysis showed that the prevalence rate of constipated subjects was higher in suburban areas versus metropolitan ones (35.8% suburban vs. 29.5% metropolitan). Women were more frequently affected than men, whereas workers less frequently complained of constipation than the unemployed (p<0.05). Educational level, socio-economic status, physical activity, consumption of fruit, vegetables, and mineral water, but not tap water, were all significantly lower in constipated patients.

B. Prevalence and Features of Constipation Subgroups

Unsupervised cluster analysis identified five subgroups of patients on the basis of their symptomatical pattern of symptoms. These cluterized subgroups fit in very well with the symptom-based classification reported in the appendix. The relevant contingency table is shown in Table I.

In the first subgroup, 81.7% of subjects had no symptoms of constipation. In the second subgroup, 78.9% of subjects had symptoms of functional constipation, whereas outlet symptoms were present in subjects included in the third subgroup. Interestingly, the fourth subgroup identified by cluster analysis was made up of a very high percentage (91.9%) of subjects with IBS. The fifth cluster subgroup included subjects with non-specific symptom-based constipation.

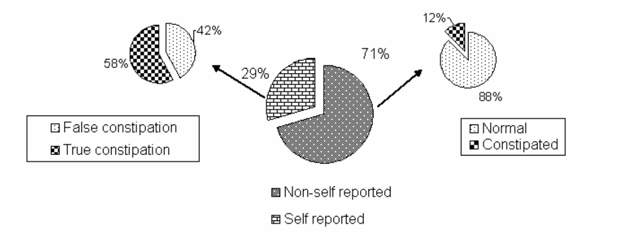

Fig. 1 Self reported constipation compared to symptoms-based constipation

Linear regression analysis showed different socio-demographic features among subgroups. The differences between functional and outlet constipation are reported in Table II (gender distribution), Table III (health habits), Table IV (dietary habits) and Table V (socio-economic features).

Functional constipation was more frequent in suburban areas and in subjects over 50 years of age (p<0.05). Students, ex smokers, abstainers or slight alcohol drinkers (<20-40 g/die) were significantly affected, as were women (p<0.05), especially housewives. There was also a strong correlation with the number of children they had.

The outlet delay subgroup was, on the contrary, more frequent in metropolitan areas (p<0.05), showed no gender differences, and increased after 70 years of age. This subgroup also showed low consumption of fruit, vegetables, and mineral water but not tap water. A high prevalence of tea drinkers was also observed with a significant correlation to the number of cups of tea per day.

IV. Discussion

Our study confirms the high prevalence of constipation (33.1%) in a population-based sample. Interestingly, constipation was more frequent in suburban areas than metropolitan ones. An urban-rural gradient was observed by Johanson et al.[19] who also observed a different geographic distribution of constipation in the United States. We did not come across the latter finding among the five Italian cities, most likely due to fewer geographic differences in our country. In agreement with previous studies [5,8,20,21], women appear to be affected more frequently than men (p<0.05). An increase in constipation was observed after 65 years of age, most likely related to an accumulation of adverse factors including illness and medication affecting gut motility and defecation.

Several environmental factors influence the constipation rate. In addition to the lower socio-economic status previously reported [9,19], our study also showed a relationship between constipation and low educational level, a decrease in physical activity and intake of liquids, and lower consumption of fruit and vegetables. Similar data were also reported by Wong et al. [22] in an elderly Asian community.

As reported by Talley et al [13] and Stewart et al. [14], our findings confirm that self-reported constipation is an inadequate means of measuring constipation symptoms. Therefore, previous epidemiological studies based on this parameter should be evaluated carefully. There were a consistent number of subjects, particularly women, who defined themselves as being constipated or not constipated, regardless of the presence or absence of related symptoms. One explanation could be the lack of a standardized definition of constipation. Thus, constipation may mean different things to different people. This could also explain the differences in the self reported constipation prevalence observed between male and female subjects. Women generally understand the term constipation better than men and the latter may be more likely to deny that they have a medical condition or symptoms related to constipation.

One aim of the present study was to evaluate the possibility of subdividing constipation into clinical subgroups. Therefore, our population study was preliminarily analyzed by cluster analysis. Unsupervised cluster analysis is a classification tool which uses several variables to distinguish whether the data collected from a population study can be grouped into different clusters. Unlike to statistical methods, cluster analysis does not collect one or more variables from groups of subjects established on the basis of some a priori defined criteria. Therefore, the results of unsupervised cluster analysis do not depend on the criteria used for building the subgroups.

Since distinct subgroups of subjects were identified, we then ascertained whether these subgroups could be identified as clinical entities according to predefined symptom criteria. The good correlation shown in Table I suggest that distinct subgroups are clinically significant. This is also supported by the significant differences in epidemiological profiles between subgroups, as shown in tables 2-5 which report the socio-demographic differences between the two main subgroups, i.c., functional and outlet delay constipation.

The present study has a number of strengths. The direct approach by means of the physicians' interviews is a reliable survey method. The subdivision of subjects into pre-defined subgroups was based on clinically relevant previous reports [12-14]. Finally, we adopted a random-selection method that allowed each individual within the five selected cities to have a reasonably equal chance of being chosen for the interview. Therefore, the population we recruited was representative and allowed us to carefully examine variations in the prevalence of socio-demographic features among subgroups.

In conclusion, the different features we observed among the subgroups suggest that functional constipation and outlet delay can be considered two distinct subgroups, relatively independent of each other. Dividing constipation into subgroups is important both for research and clinical practice in order to improve diagnostic criteria and management, as well as for testing newly developed drugs for efficacy in well-defined subgroups. Further studies should be carried out to explore the underlying patho-physiology of the various constipation subgroups and to determine the relationship between each subgroup and the potential risk factors. Better knowledge of these factors might play an important role in the management of these patients.

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TABLE I
RELEVANT CONTINGENCY TABLE ON DISTRIBUTION OF SUBJECTS IN EACH CLUSTER ACCORDING TO THEIR SYMPTOM BASED CONSTIPATION SUBGROUP

Cluster Groups	0	1	2	3	4
Normal	**81.7%** (820)	3.2% (32)	5.6% (56)	3.2% (32)	6.4% (64)
Functional	11.1% (22)	**78.9%** (157)	2.0% (4)	3.5% (7)	4.5% (9)
Outlet	5.4% (8)	3.4% (5)	**79.7%** (118)	2.0% (3)	9.5% (14)
IBS	0% (0)	5.8% (5)	2.3% (2)	**91.9%** (79)	0% (0)

TABLE II
PREVALENCE OF CONSTIPATION SUBGROUPS

	Age-Adjusted Fem.		Age-Adjusted Male		Total	
	Subjects	Prevalence% (95% CI)	Subjects	Prevalence% (95% CI)	Subjects	Prevalence% (95% CI)
Normal	438	57.4 (53-61)*	566	76.9 (74-81)	1004	67.0 (65-72)
Functional	123	16.1 (14-18)*	76	10.3 (9-12)	199	13.3 (12-15)
IBS	65	8.5 (7-10)*	21	2.9 (1-5)	86	5.7 (4-8)
Outlet	90	11.8 (10-14)	58	7.9 (6-10)	148	9.9 (8-12)
Overlapping	48	6.3 (5-7) *	15	2.0 (1-3)	63	4.2 (3-5)

* $p < 0.05$ females vs males

TABLE III
DISTRIBUTION OF HEALTH HABITS AMONG FUNCTIONAL AND OUTLET SUBGROUPS

	Prevalence % (95% CI)		
	Normal	Functional	Outlet
No physical activity	78.5^{+}	16.7 (16 –18) $*^{§}$	4.8 (4 – 6) *
Normal physical activity	82.3^{+}	14.4 (14 –16) $*^{§}$	3.3 (3 – 4) *
Sports	98.3^{+}	1.7 (0 – 4) $*^{§}$	0 (0 – 1) *
No Smokers	84.1	12.4 (12 – 13)	3.5 (3 – 5)
Ex-smoker	78.3	17.4 (17 – 18) *	4.3 (4 – 5)
Smoker	87.8	9.2 (9 – 10)	2.9 (2 – 4)
1-10 Cigarettes / die	80.9	12.7 (12 – 14)	6.4 (6 – 8)
11-20 "	92.0	5.0 (4 – 6)	3.0 (2 – 4)
>20 "	85.2	11.1 (10 – 12)	3.7 (3 – 5)
No Coffee	81.3	14.6 (10 – 17)	4.2 (2 – 6)
1-2 coffee cups / die	85.5	11.6 (10 – 12)	3.0 (2 – 4)
3-4 "	84.7	11.4 (10 – 12)	4.0 (3 – 5)
>4 "	83.3	13.9 (9 - 16)	2.8 (0 – 4)
No Beer	84.0	12.9 (12 – 14)	3.1 (3 – 4)

<500 beer ml / die	90.7	6.7 (6 – 8)	2.7 (2 – 4)
>=500 "	87.5	10.5 (9 – 14)	2.1 (0 – 6)
Slight alcohol drinkers	83.6	12.8 (12 – 14) *	3.6 (3 – 5)
Heavy alcohol drinkers	92.3	5.1 (2 – 7) *	2.6 (1 – 5)
No tea	84.9	12.2 (11 – 13)	2.8 (2 – 4) *
1 tea cup / die	80.6	12.4 (11 – 13)	7.0 (6 – 9) *
>=2 tea cups / die	77.5	7.0 (4 - 10)	8.3 (6 – 9) *

* p <0.05 constipation subgroup vs normal
+ p < 0.05 normal vs constipated patients
§ p < 0.05 functional constipation vs outlet delay subgroups

TABLE IV
DISTRIBUTION OF DIETARY HABITS AMONG FUNCTIONAL AND OUTLET SUBGROUPS

	Prevalence % (95% CI)		
	Normal	Functional	Outlet
No wine	84.6	12.2 (11 – 14)	3.1 (2 – 4)
Light wine drinkers (< 40 g / die)	84.3	12.0 (10 – 13)	3.8 (3 – 5)
Wine drinkers (>= 40 g / die)	80.8	15.4 (13 – 17)	3.8 (2 – 6)
1-500 tap water ml / die	86.2	11.5 (7 – 13)	2.3 (1 – 5)
501-1000 "	84.5	11.6 (10 – 13)	3.9 (1 – 5)
1001-1500 "	96.7	1.7 (1 – 3)	1.7 (1 – 3)
>1500 "	84.4	12.1 (4 – 16)	3.5 (0 – 5)
1-500 mineral water ml /die	67.8+	21.7 (21 – 24) *§	10.5 (9 – 12) *
501-1000 "	83.4	12.9 (11 – 14)	3.7 (3 – 5) *
1001-1500 "	89.7+	7.7 (7 – 9) *§	2.6 (2 – 4) *
>1500 "	90.8+	7.7 (7 – 11) *§	1.5 (1 – 3) *
No bread	83.4	12.9 (12 –15)	3.7 (3 – 4)
<1 bread roll / die	87.7	9.3 (9 – 12)	3.1 (1 – 4)
1 bread roll /die	80.8	17.3 (13 – 21)	1.9 (0 – 3)
>= 2 bread rolls /die	85.7	14.3 (4 – 20)	0 (0 – 1)
No fruit	82.8	10.9 (2 – 16)	6.4 (6 – 9) *
Fruit less 1 time /die	78.0	16.3 (14 – 19)	5.7 (4 – 6) *
Fruit 1 time /die	84.5	11.4 (10 – 12)	4.2 (3 – 4) *
Fruit 2 times /die	86.3	11.6 (10 – 13)	2.2 (2 – 3) *
No vegetables	82.5	8.0 (2 – 18)	9.4 (5 – 11) *
Vegetables less 1 time /die	81.6	13.8 (13 – 15)	4.7 (4 – 6) *
Vegetables 1 time / die	83.3	12.0 (5 – 16)	4.7 (3 – 6) *
Vegetables 2 times / die	86.0	11.8 (10 – 13)	2.2 (1 – 3) *

* p < 0.05 constipation subgroup vs normal
+ p < 0.05 normal vs constipated patients
§ p < 0.05 functional constipation vs outlet delay subgroups

TABLE V
DISTRIBUTION OF SOCIO-ECONOMIC FEATURES AMONG FUNCTIONAL AND OUTLET SUBGROUPS

	Absolute - Prevalence % (95% CI)		
	Normal	Functional	Outlet
Education			
Primary	76.9+	19.2 (18 – 21) *§	3.8 (2 – 5)
Middle school	83.2	12.6 (11 – 13) *	4.2 (3 – 5)
Secondary school	86.2	11.1 (10 – 12) *	2.6 (1 – 3)
University	88.0+	7.7 (7 – 8) *§	4.4 (3 – 5)
Employment status			
Unemployed	80.0	13.3 (10 – 14) *	6.7 (4 – 8)
Student	89.7+	8.4 (6 – 9) *§	1.9 (1 – 4)
Housewife	68.1+	24.5 (22 – 26) *§	7.4 (6 – 9)
Worker	87.2	9.8 (8 – 11) *	3.0 (2 – 4)
Retired	82.1	14.3 (13 - 16) *	3.6 (2 – 5)
Marital status			
Not married	81.1+	15.1 (13 – 17)	3.9 (2 – 5)
Married for 1 - 10 yrs	92.1	5.3 (4 – 8)	2.6 (2 – 4)
11 – 20 yrs	87.0	9.3 (8 – 10)	3.7 (2 – 5)
21-30 yrs	90.3	7.4 (6 – 9)	2.3 (1 – 3)
>30 yrs	83.3+	12.5 (11 – 14)	4.2 (3 – 6)
Number of children			
No Children	88.1+	8.6 (8 – 10)	3.3 (3 – 4)
1 Child	86.9	12.1 (11 – 13)	0.9 (0 – 2)
2 Children	80.4+	17.7 (17 – 19)	1.9 (1 – 3)
3 Children	75.8+	12.1 (11 – 14)	12.1 (10 – 14)
>3 Children	63.0+	33.3 (31 - 35)	3.7 (2 – 5)

* $p < 0.05$ constipation subgroup vs normal
+ $p < 0.05$ normal vs constipated patients
§ $p < 0.05$ functional constipation vs outlet delay subgroups