Defining a Clinical Prediction Rule to Diagnose Bacterial Gastroenteritis Requiring Empirical Antibiotics in an Emergency Department Setting: a Retrosepctive Review

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Abstract

BACKGROUND

Gastroenteritis (GE) is a nonspecific term for various pathologic states of the gastrointestinal tract. Infectious agents usually cause acute gastroenteritis. At present, there are no robust decision-making rules that predict bacterial GE and hence dictate when to start antibiotics in patients presenting with acute GE to the ED. We aim to define a clinical prediction rule to diagnose bacterial gastroenteritis requiring empirical antibiotics in an emergency department setting.

METHODS

A 2-year retrospective case review was performed on all cases from July 2015 to June 2017 that presented acutely with infectious GE symptoms to the Emergency Department and then had stool cultures performed. The clinical parameters analysed included patient co-morbid conditions, physical examination findings, historical markers, point of care tests and other laboratory work. We then used multivariate logistic regression analysis on each group (Bacterial culture-positive GE *and* Bacterial culture-negative GE) to elucidate clinical criteria with the highest yield for predicting BGE.

RESULTS

756 patients with a mean age of 52 years, 52% of whom were female, and 48% male, were recruited into the study. Based on the data from these patients, we suggest using a scoring system to delineate the need for empirical antibiotics in patients with suspected bacterial GE based on six clinical and laboratory variables. A score 0-3 points on the suggests low risk (5.8%) of bacterial GE. A score of 4-5 points confers an intermediate risk of 28.5% and a score of 6-8 points confers a high risk of 66.7%. A cut-off of $\geq$5 points may be used to predict culture positive BGE with a 75% sensitivity and 75% specificity. The AUROC for the scoring system (range 0-8) is 0.812$\pm$0.016 (95% CI: 0.780-0.843) p-value <0.001.

CONCLUSION

While this is a pilot study which will require further validation with a larger sample size, our proposed decision-making rule will potentially serve to improve diagnosis of BGE, reduce unnecessary prescribing of antibiotics which will in turn reduce antibiotic associated adverse events and save costs worldwide.

Introduction

Gastroenteritis (GE) represents a nebulous term for a variety of pathologic states of the gastrointestinal tract. It is however commonly used to define an acute infection of the gastrointestinal tract that manifests principally as diarrhea. A universal definition of diarrhea does not exist. Most definitions center upon the frequency, consistency, and water content of stools [1]. It has also been defined as stools that take the shape of their container. Although the primary manifestation is diarrhea, GE may present as a quadrad of signs and symptoms that include nausea and/or vomiting, fever and abdominal pain. [2]

Infectious agents usually cause acute gastroenteritis. These agents cause diarrhea by adherence, mucosal invasion, enterotoxin production, and/or cytotoxin production. Dehydration, fluid loss and electrolyte abnormalities result as a consequence of increased fluid secretion and/or decreased absorption.[2]

Acute gastroenteritis outbreaks are a public health concern throughout the world due to their associated morbidity. Aetiological agents can be viral, bacterial or protozoal. The bacterial agents can be either enteropathogenic, toxigenic or both. While the main goals in management in the emergency department (ED) are symptomatic treatment and hydration, some patients are started on antibiotics for presumptive bacterial gastroenteritis (BGE) whilst only a minority actually receive stool cultures to definitively ascertain the causative agent of their GE. The American College of Gastroenterology (ACG) guidelines recommend stool cultures in presence of severe diarrhoea (defined as greater than 6 times in a 24-hour period), temperature > 38.5^{o}C (taken orally), passage of bloody stools, persistent diarrhea which was defined as greater than 3 days duration [3]. However, there are no robust decision-making rules that predict bacterial GE which dictate when to start antibiotics in patients presenting with acute GE to the ED, although a few have been proposed for example by Cadwgan et al (2000) [4]. We aim to derive a clinical prediction rule based on both historical and laboratory markers to help predict BGE.

Methodology

Intuitively, BGE could be defined if any of the following criteria were satisfied:

1) Moderate to severe functional disease with temperature of > 38.3^{o}C (> 101^{o}F) and > 3 days duration of symptoms

Disease severity being defined as

Severe - total disability due to diarrhea;

Moderate - able to function but with forced change in activities due to illness.

2) Traveller’s diarrhoea

3) Dysentery defined as passage of blood (in the absence of hemorrhoids) with watery stools

4) Patients presenting with watery diarrhea and having positive stool cultures for bacteria [1].

We collated all patients presenting to the ED of an acute care hospital in Singapore with symptoms consistent with gastroenteritis who then had stool cultures performed and subdivided them into 2 groups:

A. Those with bacterial culture-positive GE (BGE) and

B. Those with bacterial culture-negative GE (NBGE).

We appreciate that the diagnostic yield of stool cultures is low, with Slutsker et al[5] finding only 5.6% of cultures producing bacterial isolates and other studies demonstrating yields as low as 1.5%[6]. Hence, instead of subdividing our patients into bacterial gastroenteritis and non-bacterial gastroenteritis, we used stool cultures to define bacterial culture-positive gastroenteritis (patients with GE with positive stool cultures) and those with bacterial culture-negative gastroenteritis (patients with GE with stool cultures negative for bacteria).

We then performed a multivariate logistic regression analysis to derive a clinical decision-making rule that will aid physicians in ambulatory settings, such as ED physicians, in regard to diagnosing BGE and thus aid antibiotic prescribing practices.

A 2 year retrospective case review was performed on all patients from July 2015 to June 2017 who presented acutely with infectious GE symptoms to the ED of an acute care hospital in Singapore and then had stool cultures performed. These cases were collated and the presenting history (with cardinal presenting symptoms that include vomiting, diarrhea, abdominal pain and fever) and examination was reviewed by an independent ED specialist/gastroenterologist to ensure congruity with the final appended diagnosis of Gastroenteritis. If incongruent with the initial diagnosis of GE, the patient was excluded from our study.

The data was gathered from the review of electronic medical records (EPIC electronic case database) of the selected patients based on a specific proforma and entered into an Excel spreadsheet. The clinical parameters analyzed included patient co-morbid conditions, physical examination findings, historical markers, point of care tests and other laboratory work. We then used multivariate logistic regression analysis on each group (Bacterial culture-positive GE *and* Bacterial culture-negative GE) to elucidate clinical criteria with the highest yield for predicting BGE. The ultimate objective was to incorporate these high yield criteria into a clinical prediction score or rule which will be able to aid physicians in ambulatory settings, such as ED physicians, in regard to diagnosing BGE and thus aid antibiotic prescribing practices.

Exclusion criteria were previous recent antibiotic use, urinary tract infection (UTI) symptoms, prolonged recent inpatient stay, chronic episodes of diarrhea such as seen in irritable bowel syndrome, gastrointestinal neoplasias or bleeding and diarrhea related to inflammatory bowel disease such as Crohn's or ulcerative colitis and the incongruence of clinical notes with diagnosis of GE. (See Fig. 1). Ethics approval from the National Health Group Domain Specific Review Board was obtained for the collection and analysis of data.

Results

Seven hundred fifty-six patients with a mean age of 52 years, 52% of whom were female, and 48% male, were recruited into the study. A vast majority (99.9%) reported diarrhea as the main symptom, with 77.5% reporting watery type of stools. The subjects had a median number of 7 episodes of diarrhea per day. Other main symptoms were abdominal pain reported by 67.2%, while 64.1% and 61% had vomiting and nausea respectively. A majority of the subjects were BGE negative on stool culture (*n = 611, 80.8%*).

The subjects had a median temperature of 37.2 ^{o}C with about half (49.1%) reporting to have had fever subjectively prior to coming to the ED. Median C-reactive protein was 51.9 with a range of 12.9-140.5 mmol/L. Serum sodium median was 136 mmol/L (range of 133 mmol/L -138mmol/L). Neutrophil count median was 8.7 (x 10^{9}/L /L) with a range of 5.3–12.3 9(x 10^{9}/L /L).

STATISTICAL ANALYSIS

Categorical variables were reported as proportions and were compared using the Chi-square and Fisher's Exact test, if the expected count was less than 5. Normally distributed continuous variables were reported as means (standard deviation, SD) and were compared using the Student T test and ANOVA. Non-parametric data were reported as medians (interquartile range, IQR) and compared using the Mann-Whitney U test. To determine factors independently associated with positive BGE, variables with $p < 0.2$ on univariate analysis were entered into a multivariable logistic regression model. Hosmer Lemeshow test was performed for model calibration to assess agreement between predicted and observed probabilities. All tests were two sided and statistical significance was set at $P < 0.05$. All statistical analysis was conducted using SPSS statistical package (version 23.0 SPSS Inc., Chicago, Illinois, USA). Tables 1 to 3 show the characteristics and laboratory results of included patients.

Table 1
Baseline Demographics, Characteristics, Co-morbidities and Risk factors

	All Patients (n = 756)	BGE Negative (n = 611)	BGE Positive (n = 145)	p-value
Age (Years) [mean ± SD]	52.11 ± 20.06	52.48 ± 19.81	50.58 ± 21.09	0.306
Female [n (%)]	396 (52.5%)	323 (53.0%)	73 (50.3%)	0.572
Diarrhoea [n (%)]	749 (99.9%)	605 (100.0%)	144 (99.3%)	0.153
Blood in Stool [n (%)]	21 (2.8%)	20 (3.3%)	1 (0.7%)	0.103
Mucous with Stool [n (%)]	26 (3.4%)	22 (3.6%)	4 (2.8%)	0.801
Nausea [n (%)]	460 (61.0%)	365 (59.9%)	95 (65.5%)	0.215
Vomiting [n (%)]	484 (64.1%)	398 (65.2%)	86 (59.3%)	0.180
Abdominal Pain [n (%)]	501 (67.2%)	402 (66.7%)	99 (69.7%)	0.486
Fever [n (%)]	368 (49.1%)	268 (44.3%)	100 (69.0%)	< 0.001*
Myalgia [n (%)]	42 (7.4%)	34 (7.2%)	8 (8.1%)	0.765
Travel History [n (%)]	112 (15.6%)	93 (16.0%)	19 (13.9%)	0.540
Sick Contacts with Gastroenteritis [n (%)]	105 (14.5%)	83 (14.2%)	22 (15.7%)	0.639
Recent Gatherings with Communal Eating [n (%)]	58 (8.1%)	43 (7.4%)	15 (10.8%)	0.187
Febrile [n (%)]	291 (38.8%)	220 (36.4%)	71 (49.0%)	0.005*
Presence for Signs of Dehydration [n (%)]	385 (54.5%)	310 (54.0%)	75 (56.8%)	0.559
Abdominal Tenderness [n (%)]	240 (31.8%)	190 (31.1%)	50 (34.5%)	0.438
Number of Episode (per day) [median (IQR)]	7.0 (4.0–10.0)	7.0 (4.0–10.0)	8.0 (5.0–10.0)	0.209
Duration (days) [median (IQR)]	2.0 (1.0–3.0)	2.0 (1.0–3.0)	2.0 (1.3-3.0)	0.136
Number of Vomiting Episodes [median (IQR)]	5.0 (3.0–10.0)	5.0 (3.0–10.0)	5.0 (3.0–10.0)	0.753

*p-value < 0.05

Table 2
Vital Signs and laboratory parameters

	All Patients (n = 756)	BGE Negative (n = 611)	BGE Positive (n = 145)	p-value
Heart Rate (BPM) [mean ± SD]	90.03 ± 19.52	90.03 ± 19.84	90.03 ± 18.21	0.999
Systolic Blood Pressure (mmHg) [mean ± SD]	124.08 ± 22.63	124.27 ± 22.67	123.28 ± 22.55	0.635
Diastolic Blood Pressure (mmHg) [mean ± SD]	72.48 ± 13.70	72.33 ± 13.49	73.11 ± 14.59	0.537
Mean Arterial Pressure (mmHg) [mean ± SD]	89.68 ± 14.62	89.64 ± 14.49	89.83 ± 15.22	0.889
Haemotocrit (%) [mean ± SD]	40.78 ± 6.88	40.50 ± 6.84	41.96 ± 6.97	0.023*
Haemoglobin (g/L) [mean ± SD]	13.66 ± 3.01	13.57 ± 2.96	14.04 ± 3.19	0.092
Temperature (^{o}C) [median (IQR)]	37.2 (36.6–38.1)	37.1 (36.6–38.0)	37.3 (36.7–38.4)	0.013*
White Blood Cells Count (x10^{9}/L) [median (IQR)]	10.9 (7.4–14.4)	11.2 (7.8–14.6)	9.3 (6.4–14.0)	0.003*
Neutrophil Count (x10^{9}/L) [median (IQR)]	8.7 (5.3–12.3)	9.1 (5.5–12.4)	7.4 (4.7–12.1)	0.017*
C-Reactive Protein (mg/L) [median (IQR)]	51.9 (12.9-140.5)	44.4 (10.7-132.4)	95.1 (27.3-149.4)	0.008*
Serum Urea (mmol/L) [median (IQR)]	5.6 (3.9–8.6)	5.5 (3.9–8.5)	5.8 (3.8–10.1)	0.760
Serum Creatinine (µmol/L) [median (IQR)]	84.0 (63.0-127.0)	82.0 (63.0-122.5)	94 (65.0-149.0)	0.085
Serum Sodium (mmol/L) [median (IQR)]	136.0 (133.0-138.0)	136.0 (134.0-139.0)	135.0 (131.0-138.0)	0.001*
Serum Potassium (mEq/L) [median (IQR)]	3.9 (3.5–4.2)	3.9 (3.5–4.2)	3.8 (3.5–4.2)	0.157
Serum Bicarbonate (mEq/L) [median (IQR)]	20.0 (18.0–22.0)	20.0 (18.0–22.0)	19.0 (17.5–22.0)	0.278
Serum Lactate (mmol/L) [median (IQR)]	1.9 (1.4–2.9)	1.9 (1.4–2.9)	1.7 (1.2–2.7)	0.257

IQR – Interquartile range *p-value < 0.05

	All Patients (n = 756)	BGE Negative (n = 611)	BGE Positive (n = 145)	p-value
Anion Gap (mEq/L) [median (IQR)]	15.7 (14.1–18.0)	15.7 (14.0–18.0)	15.9 (14.5–18.2)	0.294
Serum Chloride (mmol/L) [median (IQR)]	104.0 (101.0-107.0)	104.0 (101.5–107.0)	103.0 (99.0-106.5)	0.005*
IQR – Interquartile range *p-value < 0.05				

Table 3
Diagnostics Findings

	All Patients (n = 756)	BGE Negative (n = 611)	BGE Positive (n = 145)	p-value
Nature of Stool being watery [n (%)]	586 (77.5%)	458 (75.0%)	128 (88.3%)	0.001*
Digital Rectal Examination Blood in Stool [n (%)]	446 (59.0%)	358 (58.6%)	88 (60.7%)	0.644
Positive Blood Culture Results [n (%)]	475 (62.8%)	387 (63.3%)	88 (60.7%)	0.553
Positive Stool Culture Results [n (%)]	147 (19.4%)	2 (0.3%)	145 (100.0%)	< 0.001*
Positive Findings in AXR or CT report [n(%)]	652 (86.2%)	521 (85.3%)	131 (90.3%)	0.111
*p-value < 0.05				

A non-parametric test was performed for laboratory result and proportional chi-square test for the categorical variables with p-value < 0.1 deemed to be significant.

The following variables are significant at P < 0.1:

- Serum Sodium
- Serum Chloride
- C-Reactive Protein
- Haemoglobin
- Haematocrit
- Neutrophil Count

- White Blood Cell Count
- Objective fever
- Subjective feeling of being febrile
- Watery Stool

The sensitivity of at least 0.7 was used to determine the cut-off of each continuous variable. However, due to the small sample size of BGE positive from stool result (n = 61), six were identified as the variables of interest in the study.

The six variables are as follow with their cut-off values:

- Serum Sodium (< 135 mmol/L) -1 point
- C-Reactive Protein
- 10 mg/L to 16.5 mg/L -1 point
- 16.6 mg/L – 24.9 mg/L – 2 points
- > 25 mg/L – 3 points
- Neutrophil count (> 8 X 10^9/L) – 1point
- Objective fever (Yes) – 1 point
- Subjective feeling of being febrile (Yes) – 1 point
- Watery Stool (Yes) – 1 point

Discussion

The pathogenesis of GE is usually multi-factorial but often occurs when microbial virulence overwhelms normal host defenses. The acidity of the stomach and colon is an effective antimicrobial defense. When this normal acidity is disrupted, for example, in achlohyric states (ie, caused by antacids, histamine-2 blockers, gastric surgery, decreased colonic anaerobic flora), this defense is significantly weakened. The host's capacity to mount an effective defense may be compromised by a large inoculum of offending viruses, bacteria or protozoa. An alteration of normal bowel flora can create a biologic void that is filled by pathogens. This occurs most commonly after antibiotic administration. Hypomotility states may result in colonization by pathogens, especially in the proximal small bowel, where motility is the major mechanism in the removal of organisms. Hypomotility may be induced by anti-peristaltic agents or anomalous anatomy and is common in patient with co-morbidities such as diabetes mellitus or scleroderma. In addition, immunocompromised hosts are more susceptible to infection by a wide variety of pathogens. [2]

Diarrhea is one of the most common reasons patients seek medical care. In the developed world, it is one of the most common reasons for time off work, while in the developing world, it is a leading cause of mortality. According to a publication by Wilkoswo et al, an estimated 179 million cases of acute gastroenteritis occur every year in the United States. Of these patients, the vast majority (80–85%) do not

seek medical attention, and only a minority (1–2%) require hospital admission[7]. If allowed to reach epidemic proportions, diarrheal illnesses can quickly overwhelm health care systems.

The burden of disease is often under-reported in adults. Each year, gastroenteritis in adults accounts for 8 million doctor visits and 250,000 hospitalizations and often occur in the setting of localized outbreaks. Furthermore, traveler's diarrhea affects 20–50% of people traveling from industrialized to developing countries [8, 9, 10, 11]

Appropriate management of GE requires extensive history and assessment, an accurate diagnosis and then appropriate, general supportive treatment that is often aetiology specific. Patient history and examination alone have been found to be notoriously poor at differentiating BGE from NBGE [12]. However, epidemiological studies have noted that the prevalence of BGE is approximately one third that of NBGE. [1, 8]

With the data in Table 4, we suggest using a scoring system to delineate the need for empirical antibiotics in patients with suspected bacterial GE.

Table 4
Recommended scoring system for bacterial gastroenteritis

Variables	*Range*	*Points*
Serum Sodium	< 135 mmol/L	*1*
C-Reactive Protein	10mg/L -16.5mg/L	*1*
	16.6mg/L -24.9mg/L	*2*
	> 25mg/L	*3*
Neutrophil	> 8.0 $X10^9$/L	*1*
Temperature	> 37.5^oC	*1*
Febrile	Yes	*1*
Watery Stool	Yes	*1*
Total	≥ 5 points determine the high possibility of positive BGE	8

Based on the rate of BGE associated with each score as shown in Fig. 2., a score 0–3 points suggests low risk (5.8%) of bacterial GE. A score of 4–5 points confers an intermediate risk of 28.5% and a score of 6–8 points confers a high risk of 66.7%. A cut-off of > 5 points may be used to predict culture positive BGE with a 75% sensitivity and 75% specificity. The AUROC for the scoring system (range 0–8) is 0.812 + 0.016 (95% CI: 0.780–0.843) p-value < 0.001.

The most common antibiotic prescribed for BGE in adults is a 3-day course of Ciprofloxacin which costs approximately S$ 6 per course. The financial magnitude of the problem is thus potentially astounding. Assuming that 20% of BGE presenting to ambulatory settings received antibiotics world-wide based on physician judgement but that a decision making rule would allow for a more accurate identification of BGE thus halving antibiotic prescriptions to 10% of all BGE patients this would result in savings of $1.2 million worldwide (assuming above mentioned incidence of 8 million doctor visits per year). Economics aside, another important benefit would be to save these select patients (NBGE) from the adverse effects that are the inevitable concomitance of needless antibiotic administration.

While this is a pilot study which will require further validation with a larger sample size, our proposed decision-making rule will potentially serve to improve diagnosis of BGE, reduce unnecessary prescribing of antibiotics which will in turn reduce antibiotic associated adverse events and save costs worldwide.

Abbreviations

GE = Gastroenteritis

ED = Emergency Department

BGE = Bacterial Gastroenteritis

NBGE = Non Bacterial Gastroenteritis

ACG = American College of Gastroenteritis

UTI = Urinary Tract Infection

AUROC = Area under the Receiver Operating Characteristic Curve

SD = Standard Deviation

IQR = Inter-quartile Range

Declarations

Ethics approval and Consent to Participate

Ethical approval was obtained by the Domain Specific Review Board of the National Health Group for the use of patient's data.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

Not applicable

Authors contributions

ACP is the project mentor who wrote the protocol and obtained ethics approval as well as collected data. SMS, MPD assisted with the data analysis and data collection sheet. OWJD did the statistical analysis. MPD and SMS wrote the manuscript and this were read and approved by all authors.

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Not applicable

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Figures

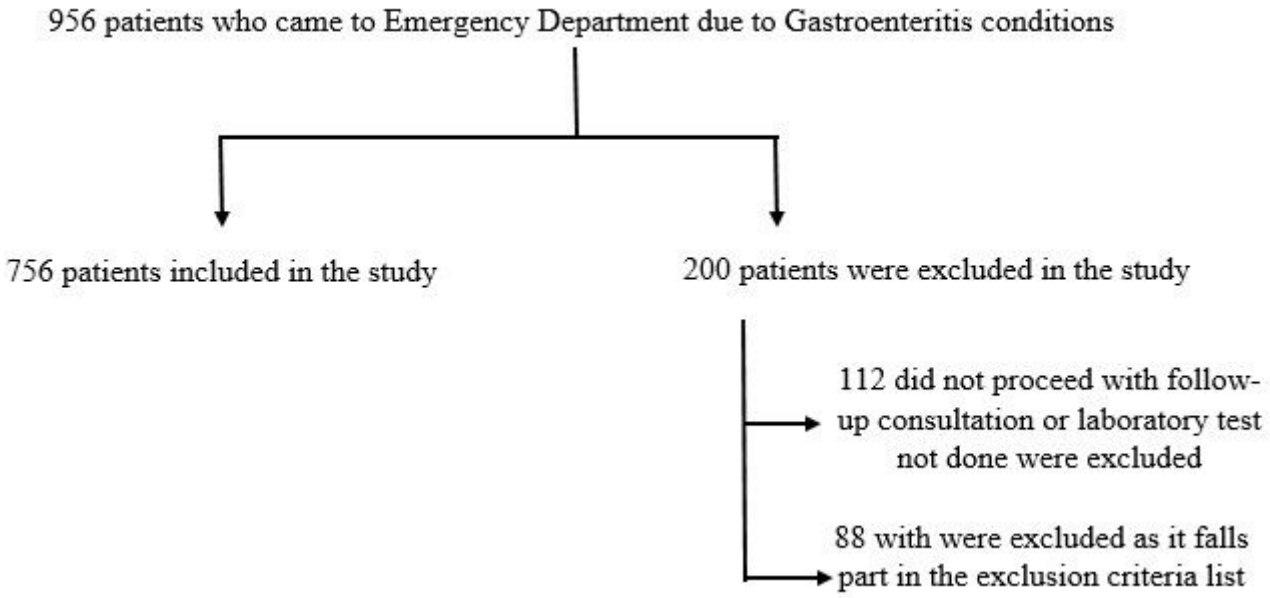
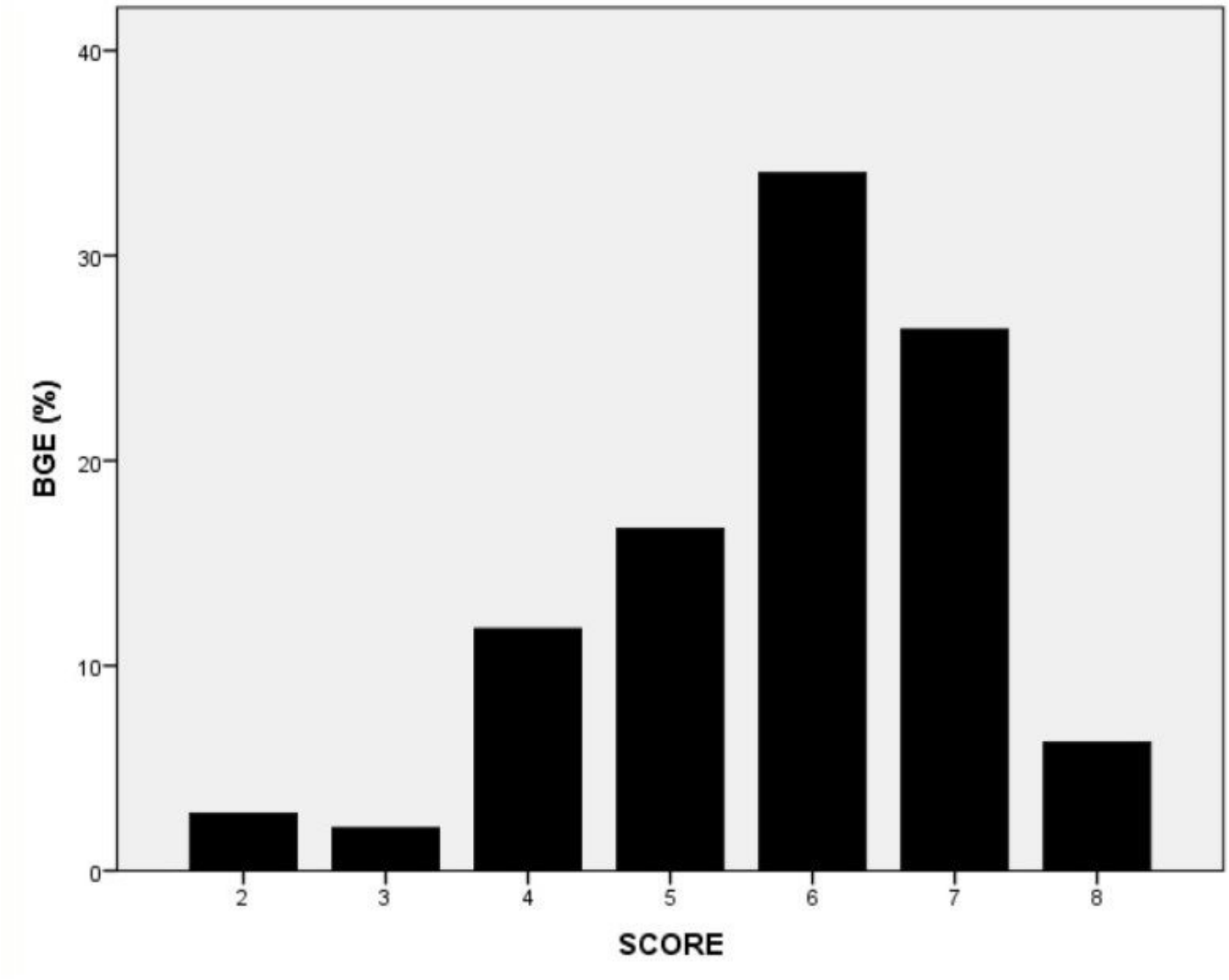


Figure 1

Flow chart of study participants.

Figure 2



Rate of BGE versus score in 756 participants.