A series of severe neurologic complications after bariatric surgery in France: the NEUROBAR Study

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Title

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Running title: Neurological complications after bariatric surgery

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Abstract

Background

Neurological complications following bariatric surgery are rare, but can have dramatic consequences. Little data are available on this topic.

Objectives

The aim of the NEUROlogical complications following BARiatric surgery (NEUROBAR) study was to define, which factors (anthropometric, nutritional, surgical etc.) were frequently associated with neurological complications following bariatric surgery.

Settings

Data were collected by the French Centers of Obesity Care Management hosted in University Hospitals.

Methods

An online standardized questionnaire was designed and submitted to the 37 French Centers of Obesity Management. This questionnaire included items about patient characteristics, bariatric surgery, neurological complications, nutritional status and management. Patients were retrospectively included from January 2010 to November 2018.

Results

Thirteen centers included 38 patients (34 females and 4 males) with neurological complications following bariatric surgery. The two main bariatric procedures were gastric bypass and sleeve gastrectomy. More than half of the patients with neurological complications had a surgical complication following bariatric surgery (53%) and gastrointestinal symptoms including vomiting (53%). Vitamin B deficiencies were frequent (74%) including at least 47% of cases with deficiency in Vitamin B1.

Conclusion

Early identification of patients with surgical complications and gastrointestinal symptoms after bariatric surgery could help prevent neurological complications related to nutritional deficiencies.

Highlights

- We reported 38 cases of neurological complications following bariatric surgery
- Majority of cases had surgical complications
- Majority of cases had postoperative gastrointestinal symptoms including vomiting

Keywords

Bariatric surgery; Nutritional Status; Wernicke Encephalopathy; Thiamine Deficiency; Vitamin B Deficiency

Introduction

Obesity is a major health problem with increasing prevalence [1]. Inducing significant weight loss with medical management remains difficult. In this context, bariatric surgery (BS) is recognized as being the most efficient treatment of severe obesity [2,3]. Most studies in this field have focused on weight loss and resolution of comorbidities. In contrast, the specific area of long-term nutritional consequences of BS has been overlooked [4].

In 2016, more than 50 000 patients underwent a BS in both public and private centers in France with a gradual increase of BS performed every year since 1997 [11]. The increasing number of bariatric procedures in France raises the question of the nutritional long-term follow-up [12]. In this context, French Centers of Obesity Care Management were labeled by the French Health Ministry. They are referral centers for obesity management~~,~~ as well as for BS and their complications.

Neurological diseases are one of the most severe complications of BS related to nutritional impairment. They can have dramatic consequences, including death and permanent disabilities, as we previously reported [5]. Several case reports, but only few case series, with such complications have been published yet [6–8]. The most documented neurological complication after BS is Wernicke encephalopathy. This disease is due to thiamine deficiency and was initially described in subjects with alcoholism [9,10]. The factors associated with such complications remain to be determined.

The NEUROlogical complications following BARiatric surgery (NEUROBAR) study was conducted in France. It aimed to widen current knowledge on severe neurological diseases after BS. It was coordinated by the French Obesity Research Centre of Excellence (FORCE) network, which is a clinical investigation network, labelled by French Clinical Research Infrastructure Network (F-CRIN) in 2014. This network has developed a well-structured national coordination for harmonization and standardization of clinical investigations and data collection.

Materials and Methods

Study description

This was a French national multicentric observational retrospective study. To limit the heterogeneity of practices, only patients who underwent BS after January 2010 and up to November 2018 have been included. Every patient with a neurological complication including encephalopathy or peripheral neuropathy and with a history of BS could be included.

Data collection

Each medical coordinator of the 37 French Centers of Obesity Management received an email explaining the purpose of the NEUROBAR study. Public or private hospitals regularly refer patients with complications after BS to these referral centers. Medical coordinators were asking, if they were aware of patients with neurological complications following BS in their territory. Patients may have been managed inside or outside ~~of~~ their centers. Inclusion of cases was left to the discretion of the medical coordinators. Then, they or their collaborators were provided with a link to an online questionnaire, and, were asked to fulfill one questionnaire for each case. This online questionnaire was defined by 50 items related to 7 categories, namely characteristics, of the case, of the BS, and of the neurological complications, differential diagnosis, factors contributing to the neurological complications, case management, current status of the case (Supplemental data 1). We collected data about diabetes, which is a frequent cause of peripheral neuropathy. We also collected data about psychiatric history including psychotropic drug intake to determine the active psychiatric comorbidities. Indeed, psychiatric diseases could be a factor for poor vitamin adherence after bariatric surgery [13]. We used an

online survey management system, hosted on a secured and authorized system for personal health data collect (Grenoble Hospital). The questionnaire was closed at the end of November 2018. The FORCE network has been strongly involved within the NEUROBAR study.

Ethics and data protection:

The Hospices Civils de Lyon are the sponsor of this retrospective study. None personally identifying information (such as name, day of birth, or social security number...) were collected. Data were collected during routine medical examinations. Patients did not undergo any treatment or examination specifically devised to collect data for this study. Thus, in accordance with the French regulation, the study was approved by the CCTIRS (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé), a French committee dedicated to data protection for biomedical research. Patients were also individually informed that their data would be used for research (MR-003 reference methodology). This study has been registered by the data protection officer (DPO) of the Hospices Civils de Lyon.

Data analysis:

Data analysis was performed using RStudio software version 1.0.136 with occasional reliance on 'prettyR', 'RVAideMemoire'[14]. Owing to the small number of patients, data are presented as median and interquartile range (IQR).

Results

Twenty centers participated in this study and seventeen did not. Three centers had no patient corresponding to the targeted phenotype. Forty-six patients were eligible. Eight patients from six centers declined to take part in the study. Overall, 38 patients from 13 centers were included (Supplemental Table 1).

Subjects characteristics

There were 34 females and 4 males. At the time of the surgery, the median age was 39 [IQR: 26-51years old and the median body mass index (BMI) was 43 [IQR: 39-47] $kg.m^2$. Eight subjects were on psychotropic drugs at the time of surgery and five subjects had diabetes history.

Surgery characteristics

Sleeve gastrectomy and gastric bypass were the two main surgeries (Figure 1A). Among the gastric bypass goup, one-third was anastomosis gastric bypass (OAGB) and two-third were Roux-en-Y gastric bypass (RYGB). Patients were operated in university hospital, private local hospitals or public local hospitals with a fairly similar proportion (Figure 1B). Patients from private or public local hospitals were secondarily referred to French Centers of Obesity Management given the neurological complications. Five patients had a history of two or more previous bariatric surgeries before the neurological event. Only 22 cases (58%) received

vitamin and trace element supplementation with uncertain treatment adherence in ten patients before the neurological complication.

Surgery and gastrointestinal complications

Twenty cases (53%) had both neurological and surgical complications, including six cases of fistula, four cases of anastomotic ulcer of gastric bypass, three cases of stenosis of sleeve gastrectomy and two cases of gastric twist after sleeve gastrectomy.

At least 26 cases had gastrointestinal symptoms (68%). Among them, 77 percent of cases had vomiting, which was the most frequent symptom (Figure 2). In 15 out of the 26 cases (58%), gastrointestinal symptoms were associated with a surgical complication. For 7 out of the 12 patients without gastrointestinal symptoms, limited oral energy intake was reported in the online questionnaire.

Neurological complications after BS

The median duration between the surgical procedure and the onset of the neurological complication event was 6 [IQR: 3-12] months. Ten cases had an encephalopathy, fifteen had a peripheral neuropathy, twelve had both and one case had a pyramidal syndrome.

Every case of encephalopathy had at least one of the three signs of Gayet-Wernicke encephalopathy namely eye signs, cerebellar signs, and either mild memory impairment or an altered mental state in a context of dietary deficiencies. Eighteen out of twenty-two had an imaging examination (Magnetic Resonance Imaging, MRI or computed tomography scan, CT-scan). In the majority of cases, the imaging examination was considered normal. Vitamin B1 deficiency was proven in 14 out of 38 cases (Table 1).

Nutritional status of subjects with neurological complications after BS

At the time of neurological care, nutritional status assessed with BMI, weight loss or albumin level was extremely variable (Figure 3). Twenty-eight cases (74%) had at least one B vitamin deficiency: vitamin B1 deficiency was the most frequent. Deficiencies in trace elements were not rare including deficiency in selenium in 14 cases (Figure 4).

Nutritional care of neurological complications and prognosis

Twenty patients required artificial nutrition, enteral and/or parenteral nutrition. In the majority of cases, patients were supplemented with B vitamins (vitamin B1: 76%, vitamin B6: 68%, vitamin B12 42% vitamin B3 32%). Twelve patients (32 %) underwent a reoperation including three cases of conversion of OAGB to RYGB and two cases of reversal gastric bypass to normal anatomy.

The neurological symptoms were completely resolved in only nine cases. Neurological sequelae included cognitive impairments and symptoms associated with peripheral neuropathy (neuropathic pains, hypoesthesia, cognitive disorders, etc.). Two cases with encephalopathy died with one case directly imputable to the neurological complication of BS.

Discussion

With the increasing development of BS worldwide, nutritionists are facing new challenges related to medical complications of BS [2]. In a recent French series of patients requiring intensive nutrition care after BS, half of the 12 cases displayed neurological disorders, namely encephalopathy or neuropathy, following BS with possible dramatic consequences [5]. Despite the importance of this topic, few studies reported more than 10 cases of neurological complications after BS [6–8]. With the multicentric NEUROBAR study, we aimed to report a French series of patients with severe neurological complications after BS.

The most striking result emerging from the data is that gastrointestinal symptoms (68%) and especially frequent vomiting was a common factor associated with neurological complications in our case series. In contrast, only 7.4 % of patients had often or daily vomiting after BS in a previous study [15]. Our results are consistent with the Oudman et al.'s review showing that vomiting is the most common symptom among patients with Wernicke encephalopathy after BS [10]. Surgical complications are also present in more than half of the patients, which is higher than what is reported [16] and may be involved in decreased food intake. In the NEUROBAR study, 32% of patients underwent a reoperation versus 8% in the systematic review of Gloy et al. [16]. In contrast, some characteristics (sex, age, type of surgery or comorbidities, etc.) are relatively similar in our study compared to a French nationwide study in 2013 [11]. Moreover, the delay between BS and the neurological complication is variable, as well as the nutritional status. Some patients can develop early neurological complications

without large weight loss or decreased albumin level. It suggests that protein-energy malnutrition is not necessarily associated with neurological complications after BS.

Another remarkable result of our series is the high rate of B vitamin deficiencies (74%) and especially vitamin B1 deficiency. Most cases of encephalopathy, described here, displayed symptoms compatible with Wernicke encephalopathy according to the definition in the European Federation of Neurological Societies (EFNS) guidelines [9]. Despite this, brain imaging is often normal. It highlights the difficulty to diagnose Wernicke encephalopathy with atypical presentation in non-alcoholic patients [9]. Moreover, in our study, no deficiency in thiamine was reported in some cases, despite compatible clinical features. It can be explained by a supply in thiamine before any blood analysis or no vitamin B1 blood test, which is not always indicated in the medical records.

We are aware that our research may have some limitations. There are several sources of selection bias: 1) We collected cases only from the 37 French Centers of Obesity Management. 2) Inclusions were left to the discretion of the medical coordinator of every center 3) Sixteen centers did not reply, and some of the patients declined to participate in the study. Thus, our findings might not be transferable to the French population. On a wider level, a study based on Health Insurance Fund for Salaried Workers, which covers a large majority of the French population, would be useful to estimate the prevalence of neurological complication after BS in France. Secondly, it was not possible to determinate odds ratio for risk factors of neurological complications after BS, given the design of our study. We compared our results with previous published results to suggest that some factors can be risk factors. Neurological complications

after BS remain rare, estimated below 5% [8,17], and thus, it is difficult to design prospective studies. Further work based on matched-case control studies could confirm the overrepresentation of surgical complications and gastrointestinal symptoms in patients with neurological complications after BS. Thirdly, we are aware that our research may have limitations related to its retrospective design. To limit the potential bias and to ensure homogeneity, we used a standardized electronic questionnaire with a limited number of questions and we collected data only from 2010. Eventually, we cannot state that all neurological pathologies are directly related to BS. To limit this bias, we included some items in the questionnaire to rule out differential diagnoses, e.g. infections.

We hope that our research will help prevent neurological complications after BS. Regarding our case series, we suggest that every patient with gastrointestinal symptoms, in particular, frequent vomiting, should benefit from a prompt consultation with the surgeon and the nutritionist. It could help identify surgical complications to and may limit neurological complications. Indeed, we found that gastrointestinal symptoms and surgical complications were associated in more than 50% of the cases of severe neurological complications of BS. Moreover, most of the neurological complications were associated with deficiencies in B vitamin and especially in thiamine. We suggest to follow the EFNS guidelines for prevention of Wernicke encephalopathy, namely, parenteral thiamine supplementation for every patient at risk of such complications [9]. Furthermore, deficiencies in trace element were not rare. Our study supports the importance of micronutrient deficiency screening and systematic supplementation.

Conclusions

In conclusion, gastrointestinal symptoms and surgical complications were common in our series. Being aware that such circumstances could be risk factors of neurological complications after BS might help to early set up prevention strategies. B vitamins deficiencies, especially vitamin B1 deficiency, are also frequent in our study.

Conflict of interest: The authors have no conflicts of interest to declare.

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Figure 1. Surgery characteristics of cases with neurological complications after bariatric surgery

1A. Type of bariatric surgery (data available in 34 cases)

1B. Type of hospital for the place of surgery (no available data for 4 cases)

OAGB, one anastomosis gastric bypass

Figure 2.: Gastrointestinal symptoms among subjects with neurological complications after bariatric surgery

Each histogram represents the number of subjects with the symptoms. The sum is greater than 26 because some subjects had several symptoms

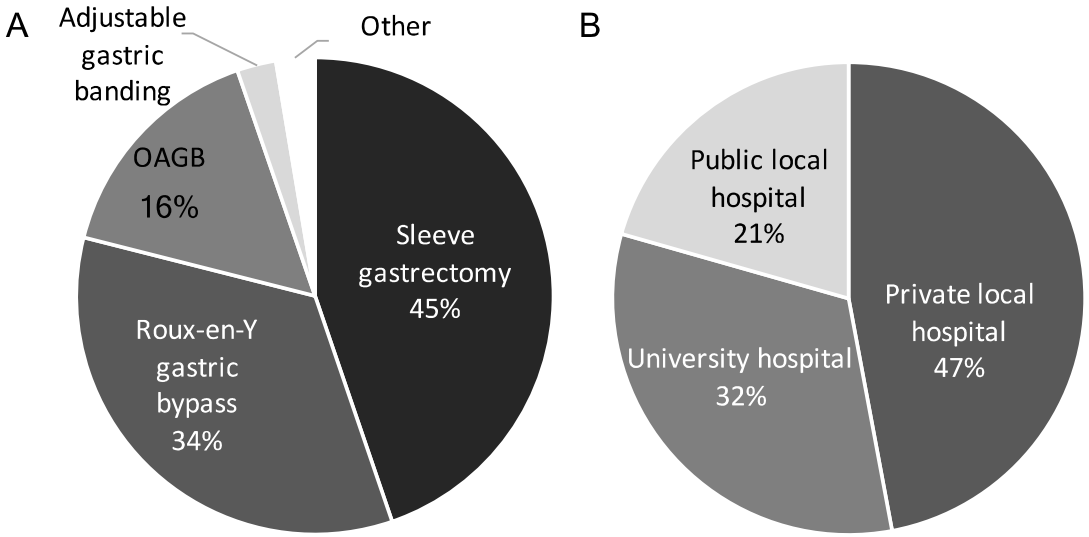
Figure 3. Nutritional status ((A) BMI, (B) percentage of body weight loss defined as total weight loss divided by preoperative weight, (C) Albumin level) at the time of the neurological complication care

Figure 4: Vitamin and trace element deficiencies in cases with neurological complications after bariatric surgery

Each histogram represents the number of cases with deficiency. The sum is greater than 38 because some cases had several deficiencies

	clinical symptoms of encephalopathy			peripheral neuropathy	Imaging examination results (MRI or CT-Scan)	Vitamin deficiency				Vitamin B1 supplémentation	Delay between BS et encephalopathy
Case	eye signs	mild memory impairment or an altered mental state	cerebellar signs			Vitamin B1	Vitamin B6	Vitamin B9	Vitamin B3		
5	N/A	Yes	N/A	MN and SN (LE)	N/A	Yes	N/A	Yes	No	Yes (Oral)	5 months
7	Yes	Yes	N/A	No	Compatible with PRES syndrome	Yes	No	Yes	N/A	Yes (Parenteral)	7 months
12	Yes	Yes	Yes	No	Considered normal	Yes	N/A	No	No	Yes (Parenteral)	5 months
13	Yes	Yes	Yes	No	Considered normal	Yes	N/A	No	N/A	Yes (Parenteral)	N/A
14	No	Yes	Yes	SN (LE & UE)	Considered normal	No	N/A	No	N/A	Yes (Parenteral)	N/A
15	No	Yes	Yes	No	Considered normal	N/A	N/A	N/A	N/A	Yes (Parenteral)	N/A
16	N/A	Yes	Yes	N/A	Compatible with GWE	No (previous supplementation)	No	Yes	N/A	Yes (Parenteral)	N/A
22	Yes	Yes	N/A	N/A	Considered normal	No	Yes	No	No	N/A	12 months
23	Yes	Yes	Yes	N/A	Considered normal	Yes	No	Yes	N/A	Yes (Parenteral)	2 months
24	Yes	Yes	No	MN and SN (LE & UE)	Compatible with GWE	Yes	Yes	No	N/A	Yes (Oral)	N/A
25	Yes	Yes	N/A	MN (LE)	Compatible with GWE	No	No	Yes	Yes	Yes (Parenteral)	3 months
27	Yes	Yes	No	MN (LE)	Compatible with GWE	N/A	No	No	Yes	Yes (Parenteral)	3 months
28	Yes	No	Yes	No	Considered normal	Yes	No	Yes	No	Yes (N/A)	N/A
29	Yes	Yes	Yes	No	Considered normal	Yes	Yes	No	No	Yes (Parenteral)	13 months
30	N/A	Yes	N/A	MN (LE&UE)	Considered normal	No	No	No	No	Yes (Parenteral)	6 months
31	N/A	Yes	N/A	MN and SN (LE)	N/A	Yes	Yes	No	N/A	Yes (Parenteral)	N/A
32	No	Yes	No	MN (UE) and SN (LE&UE)	N/A	No	N/A	N/A	N/A	N/A	N/A
33	N/A	Yes	N/A	No	N/A	No	No	N/A	N/A	N/A	12 months
34	Yes	Yes	Yes	MN (LE&UE)	Disseminate white matter damage	No	No	No	N/A	Yes (Parenteral)	6 months
35	No	Yes	No	MN (LE)	Considered normal	No	No	Yes	N/A	N/A	6 months
37	No	Yes	No	SN (LE)	Considered normal	N/A	N/A	Yes	N/A	Yes (Parenteral)	N/A
38	Yes	No	Yes	MN (LE) and SN (LE&UE)	Compatible with GWE	N/A	Yes	No	N/A	Yes (Parenteral)	10 months

345 Table 1. Characteristics of patients with encephalopathy
MN: motor neuropathy; SN: sensory neuropathy; UE: upper extremities; LE: lower extremities; GWE: Gayet Wernicke encephalopathy
N/A: data not available



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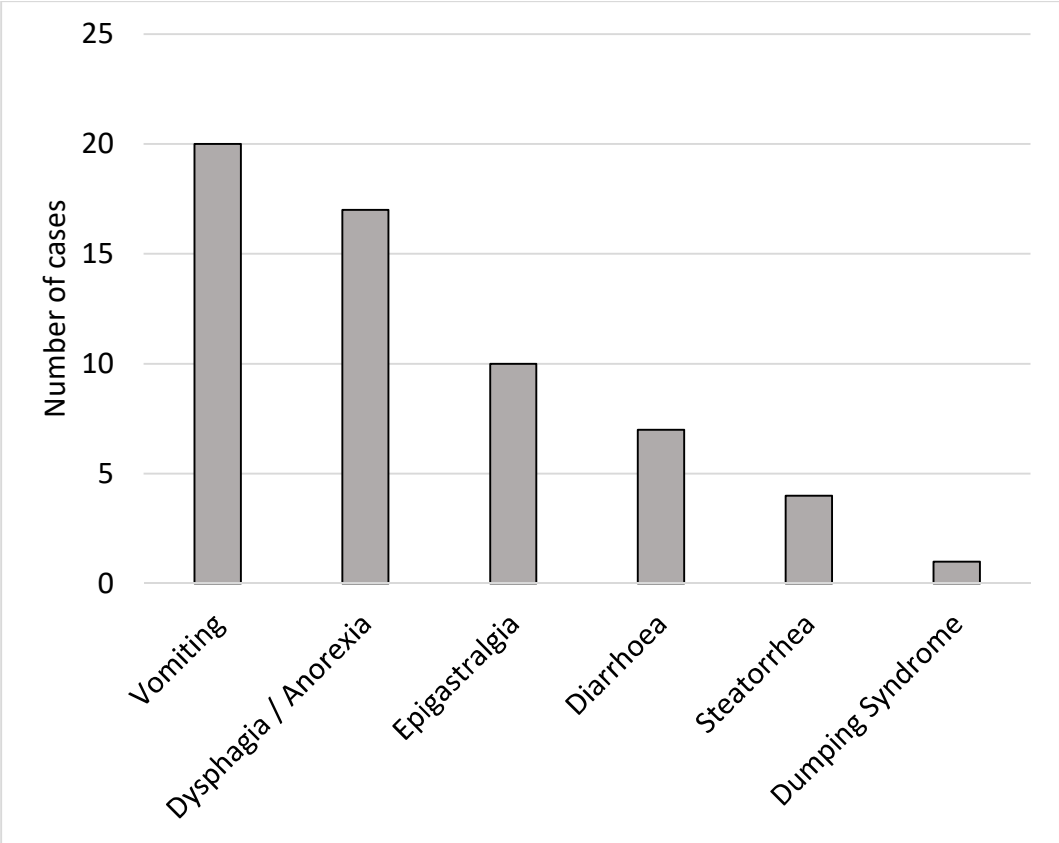
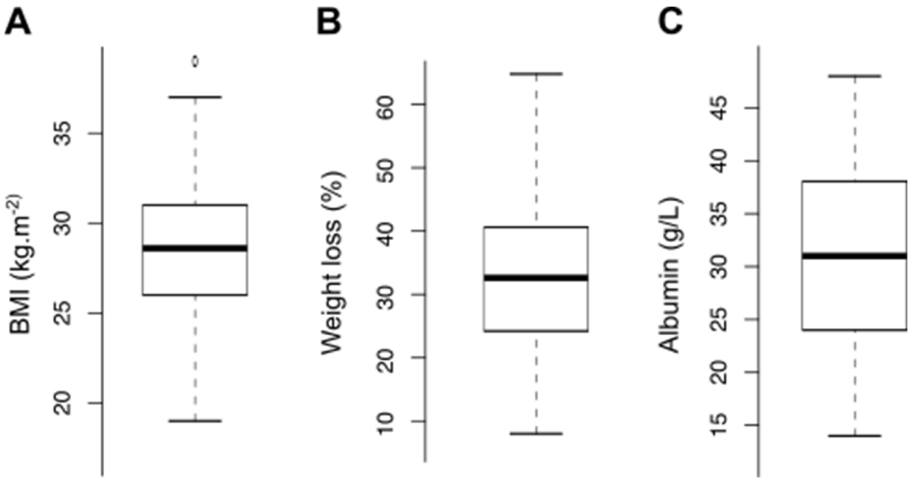


Figure 2.: Gastrointestinal symptoms among subjects with neurological complications after bariatric surgery

Each histogram represents the number of subjects with the symptoms. The sum is greater than 26 because some subjects had several symptoms



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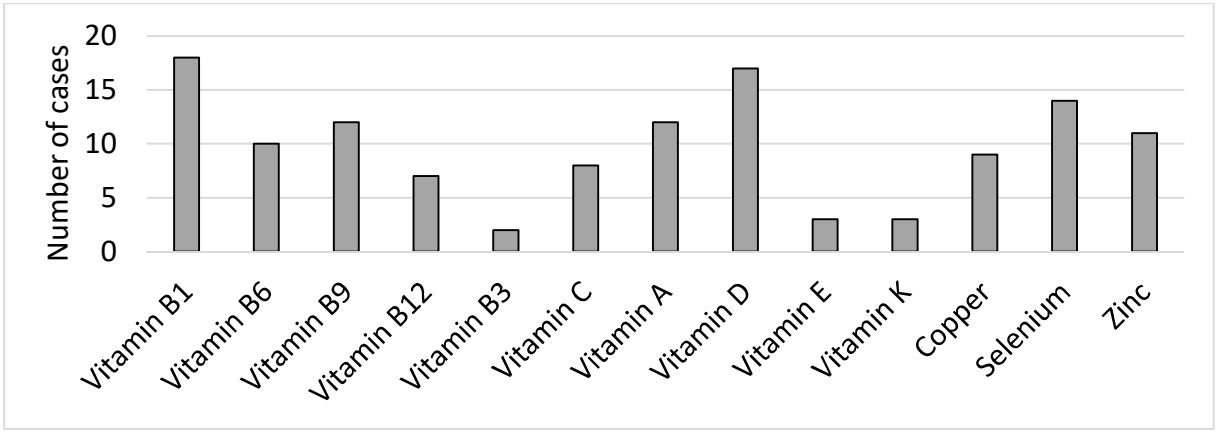

Figure 4: Vitamin and trace element deficiencies in cases with neurological complications after bariatric surgery

Each histogram represents the number of cases with deficiency. The sum is greater than 38 because some cases had several deficiencies