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More severe Crohn's disease clinical presentation in an inflammatory bowel disease (ibd) center of emergency department during COVID-19 pandemic

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Abstract. – OBJECTIVE: COVID-19 outbreak and consequential restrictive measures have strongly influenced clinical management of several chronic diseases, causing lengthening of waiting times for visits, follow-up and procedures, particularly conditioning the clinical presentation.

In this short case series study, we aim to demonstrate how COVID-19 pandemic has influenced Crohn's disease (CD) clinical course by increasing the number of patients with more severe symptoms at presentation.

PATIENTS AND METHODS: In our study we observed the clinical presentation of all previously diagnosed, or subsequently confirmed, CD patients who accessed the emergency department and first time visited in our operative gastrointestinal unit from January 2020 to December 2021. The absolute percentage of all symptoms was reported and compared to a CD population admitted to emergency department during a previous two-years period (January 2018 to December 2019). All data were collected from years-related databases based on information contained in medical records. Student *t*-test was used to compare the difference in clinical presentation among the two groups. *p*-values <0.05 were considered statistically significant.

RESULTS: A total of 91 CD patients were first time visited in the two-year period 2020-2021. The median age of patients was 31.7 years (23-35) and 57.8 % (63 out of 109) were female. The most frequent clinical presentations at first medical examination were abdominal pain in 82 patients (90.1%), tiredness/fatigue in 80 patients (87.9%), diarrhoea in 54 patients (59.3%) and abdominal bloating/distension in 61 patients (67.0%). A severe clinical presentation with intestinal obstruction or perforation occurred in 10 (10.9%) and 5 (5.4%) patients, respectively. In the two-year period 2018-2019, a total of 145 CD patients were first time visited; the median age was 32.8 years (25-36) and 61.5% (83 out of 135) were female. At the first medical examination abdominal pain reported in 128 patients (88.3%) and tiredness/fatigue in 125 patients (86.2%) appeared to be the most common symptoms followed by diarrhoea in 85 patients (58.6%) and abdominal bloating/distension in 87 patients (60.0%). No severe presentation symptoms were recorded in 2018-2019 two-years period.

Hence, abdominal pain (*p*=0.035) and tiredness/fatigue (*p*=0.049) were statistically higher in patients observed during two-year period 2020-2021, moreover diarrhoea, abdominal bloating/distension, obstruction and perforation clinical pattern were more frequent indeed, although not reaching the statistical significance.

CONCLUSIONS: Our data suggest a change in clinical presentation of CD patients with an increase of all symptoms including severe presentation, such as intestinal obstruction and/or perforation in 2020/2021 two-year period, likely as direct or indirect consequence of COVID-19 outbreak. Further clinical investigation is needed to confirm this observation.

Booster dose of SARS-CoV-2 mRNA vaccines strengthens the specific immune response of patients with rheumatoid arthritis: a prospective multicenter longitudinal study

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Abstract. – OBJECTIVE: The of the research was to characterize the kinetics of humoral and T-cell responses in rheumatoid arthritis (RA) patients followed up to 4-6 weeks (T3) after the SARS-CoV-2 vaccine booster dose.

PATIENTS AND METHODS: Health care workers (HCWs, n=38) and RA patients (n=52) having completed the mRNA vaccination schedule were enrolled at T3. In each cohort, 25 subjects were also sampled after 5 weeks (T1) and 6 months (T2) from the first vaccine dose. The humoral response was assessed by measuring anti-Region-Binding Domain (RBD) and neutralizing antibodies, whereas the T-cell response was assessed by interferon-(IFN)-γ-release assay (IGRA). By flow cytometry, the T-cell cytokine production and the T and B-cell phenotype were evaluated at T3.

RESULTS: RA patients showed a significant reduction of antibody titers from T1 to T2 and a significant increase at T3. T-cell response by IGRA persisted over time in RA patients, while increased in HCWs. Most RA patients scored positive for anti-RBD, neutralizing antibody and T-cell responses, although the magnitude was lower than HCWs. The spike-specific cytokine response was mainly mediated by $CD4^+$ T cells in both cohorts, and significantly lower with reduced interleukin-2 response and CD4-antigen-responding naïve T cells in RA patients. Unswitched memory B cells were reduced in RA patients compared with HCWs independently of vaccination.

CONCLUSIONS: COVID-19 vaccine booster strengthens the humoral immunity in RA patients. T-cell response by IGRA is stable, although altered when characterized in detail in terms of phenotype and cytokine production.

Peripheral articular manifestations are associated with a reduced quality of life and an impairment of psychological functioning in ibd patients

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Abstract. – OBJECTIVE: Psychological comorbidities are common in IBD patients, with a significant impact on quality of life (QoL). Currently, there are few data concerning the impact of articular manifestations on the psychopathological symptoms in IBD patients. The aim of the present study was to evaluate psychopathology, resilience and QoL in IBD patients with or without articular manifestations.

PATIENTS AND METHODS: Consecutive IBD patients were evaluated. All the patients were screened for articular involvement and IBD disease activity, measured by Mayo score and Harvey-Bradshaw Index. QoL was evaluated by the Inflammatory Bowel Disease Questionnaire (IBDQ) and psychopathology was assessed by self-report questionnaires consisting of the Beck Depression Inventory (BDI) and the Symptom Checklist-90 (SCL-90). Resilience was also measured using Resilience Scale-14 (RS-14). Multivariable analysis evaluated the association between clinical activity and psychopatology scores and level of resilience.

RESULTS: 44 out of the 112 (39.3%) patients included (63 Crohn's disease and 49 ulcerative colitis), presented also arthritis (peripheral: 27; axial: 17). Patients with arthritis showed a significant greater median value of BDI (10.2 *vs.* 12), SCL-90 (47 *vs.* 49.1) e IBDQ (161.1 *vs.* 155.4) compared to those without. Patients with peripheral joint involvement had significantly higher score of all psychopathological scores and IBDQ than those with axial artrhitis (all *p*-values< 0.05), except for social domain of IBDQ. Clinical score for both UC and CD significantly correlated with BDI, IBDQ and SCL-90 (all *p*-values<0.01). The multivariable analysis, identifying the independent variables associated with the resilience, showed a significant inverse association with BDI, SCL-90 e IBDQ scores (all *p*-values<0.01).

CONCLUSIONS: Articular manifestations, in particular peripheral arthritis, are significantly associated with a lower QoL in patients with IBD and an impairment of psychological functioning.

High resilience is a protective factor for the onset of psychopatological symptoms associated with in IBD patients, significantly impacting on QoL perception.

Acute sternocostoclavicular osteochondritis in a patient with Crohn's disease: a diagnostic dilemma between drug-induced extraintestinal manifestations, rare syndromes and infectious complications

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Abstract. – INTRODUCTION: We present the case of a 24 year-old man affected by ileo-colonic Crohn's disease diagnosed in 2018. Given multiple unfavorable prognostic factors at diagnosis, early treatment with biologics was started.

CASE PRESENTATION: After experiencing primary failure to adalimumab and intolerance to infliximab, he was swapped to Vedolizumab which was initiated in 2021 achieving sustained steroid-free remission at 18 months. In August 2022, while still in clinical remission, he was referred to our department complaining persistent chest pain, appeared some weeks before, and fever (up to 39°C) in the previous days. The pain was dull, progressively increasing, exacerbated by extertion, located in the middle of the chest and radiated to the right shoulder and neck. He also complained headache and temporomandibular joint pain and swelling. On examination his right sternocostoclavicular joint was tender. Laboratory test revealed a marked CRP elevation (CRPX30) and inflammatory anaemia (Hb 10.8gr/dl, ferritina 156 ng/ml). Stool pathogens test revealed a positivity for Campilobacter Jejunii and autoantibodies c-ANCA positivity. Ileo-colonscopy revealed severe activity with ulcers in the transverse colon. Chest MR showed hyperintensity of the distal diaphysis of the right clavicle and in the proximal and distal portion of the sternal body. In relation to patient's age, the involved joints and MRI findings SAPHO syndrome (synovitis, acne, pustulosis, hyperostosis, and osteitis) was suspected. After ibuprofene treatment failure systemic steroids and azitromicine were started with rapid clinical improvement. Vedolizumab was withdrawn and shift to ustekinumab was proposed.

CONCLUSIONS: This clinical vignette describes a case of acute sternoclavicular osteochondritis in a young patient with Crohn disease in treatment with Vedolizumab. We would face the problem of differential diagnosis (extraintestinal manifestations induced by Vedolizumab *vs.* infective osteochondritis *vs.* SAPHO) and the importance of a joint gastroenterologist and rheumatologist management.

The role of fatigue in inflammatory bowel disease: the experience of IBD center of University Hospital of Modena

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Abstract. – OBJECTIVE: Fatigue is the subjective feeling of chronic fatigue and exhaustion which affects patients with chronic diseases. It has been seen that this condition may affect IBD patients among twice than general population and involves up to half of those ones with a higher incidence in Crohn's disease (48-62%) than in Ulcerative colitis (42-47%). The evaluation of fatigue is very important from a clinical point of view; indeed, it is a symptom that heavily affects the patients' quality of life, productivity, social and psychophysical well-being. To date, there is neither a standard diagnosis method or a treatment of fatigue. Our aim was to investigate the prevalence and the role of fatigue in IBD patients of University Hospital of Modena, Italy.

MATERIALS AND METHODS: Two fatigue questionaries were administered to IBD patients. 271 patients compiled fatigue severity scale (FSS) and 248 compiled Modified Fatigue Impact Scale (MFIS).

RESULTS: As far as FSS is concerned, 57.2% of patients showed a score > 30, resulting affected by fatigue with a higher prevalence in women compared to men. About 30% of these patients is 40-50 years old. According to the MFIS, fatigue showed the same results for gender and age. Furthermore, MFIS – which evalues three different settings of fatigue – evidence that physical impact of this condition is much more important than cognitive and psychosocial one.

CONCLUSIONS: The study confirms that fatigue affects about 50% of IBD patients. The prevalence among women is higher than men and 45-54 years old patients are the most involved ones. Physical impact of fatigue is the predominant setting compared to cognitive and psychosocial one.

The gastroenterological and rheumatological disease: a double diagnosis in a case report in the University of Modena

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Abstract. – OBJECTIVE: Psoriatic arthritis is a form of long-term inflammatory disease which involves little and big joints asymmetrically. In most cases, but not always, it is associated with skin psoriasis. The arthritis often involves fingers and toes (dactylitis), nails (This may include pits in the nails or changes in nail color) and may be associated to other autoimmune or autoinflammatory disease, as Inflammatory Bowel Disease (Crohn's disease and ulcerative colitis). Crohn's disease may affect any segment of gastrointestinal tract; the symptoms usually include abdominal pain, diarrhea, loss of weight, anemia, arthritis, uveitis, skin rashes and fatigue. The therapy of these two diseases could be both biological and non biological one.

This case report could prove the fact that some biological therapies may unsubscribe autoimmune/autoinflammatory diseases in patients who have a specific background. Moreover, it could demonstrate that, in double diagnosis, we can prescribe therapies which cannot be prescribed in a single rheumatological or gastroenterological setting one.

CASE REPORT: M.D.G, 38 years old. Nothing in past medical and surgery history. Uncle with IBD (Crohn's disease). In 2017 diagnosis of psoriatic arthritis was made, and M.D.G. was treated at first with Methotrexate without success. In 2018 the patients starts with biological therapy (Etanercept); after two months, M.D.G started to have symptoms, such as diarrhea, anemia, abdominal pain. At colonoscopy: Crohn's disease was confirmed by histological exam. The therapy with Etanercept was suspended and the patient began the therapy with Adalimumab at first and Infliximab then, both suspended because of their ineffectiveness. In 2020, shifting to Certolizumab pegol obtained clinical response about gastroenterological and rheumatological symptoms. However, the colonoscopy in 2021 evidenced that Crohn's disease was still active; after two months arthritis reactivated, too. In June 2022, a new flare-up of Crohn's disease was recorded, requiring a new high-dose steroid course. In August 2022, after the tapering of the steroids, the patient started (after the approval by ethics committee) the therapy with a Janus kinase inhibitor (Upadacitinib). Up to date (November 2022) the patient is totally fine, without any rheumatological or gastroenterological symptom.

CONCLUSIONS: This case report proves the fact that a patient with double diagnosis should be always visited by gastroenterologist and rheumatologist at the same time. Etanercept is associated with new cases of IBD in patients with a family history of Chron's disease or ulcerative colitis, as reported in scientific literature. Upadacitinib should be considered in patients who do not responde to biological therapy approved in Italy for IBD (off label), but it can be used in patients with rheumatological condition such as rheumatoid arthritis, psoriasic arthritis, Ankylosing spondylitis. The use of Upadacitinib was subjected to ethics committee because at the time (June 2022) it was not still approved in Italy for psoriasic arthritis.

Explorative survey on the quality of life of patients affected by IBD/ESA

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Abstract. – OBJECTIVE: With this study, we intend to introduce a pilot study regarding the quality of life of patients diagnosed with Inflammatory Bowel Disease (IBD) and Entero-Spondylarthrosis (ESA), a topic which is rarely investigated by psychologists and other professional figures in the field of mental health.

PATIENTS AND METHODS: Due to the increasing studies on self-immune diseases, the quality of life in patients with IBD and ESA seems to be measurable by the level of distress. In order to detect the same measurements on the Italian sample, we aim to recruit at least 250 subjects and administer them a set of questionnaires, focused on the psychological implications associated with typical pathological course of IBD and ESA. The tools employed are the Quality of Life Scale – WHOQOL-BREF, the Depression, Anxiety and Stress Scale 21 – DASS-21, the Rosenberg Self-esteem Scale – RSE, in addition to an original questionnaire related to the subjective experience related to the therapeutic course.

RESULTS: The data analysis will be held with Q-Gis 3.26, an open-source software that includes several levels of analysis through their graphic representation on interactive maps.

CONCLUSIONS: The goal of the study is to obtain an exploratory analysis based on integrated data. The expected results could constitute a statistically informative value, useful for cross-disciplinary teams. At the same time, the interactive maps could provide information for easy access to the medical departments, placing themselves as valuable tool to increase the quality of life of IBD and ESA diagnosed patients.

Clinical efficacy and long-term safety of the adalimumab biosimilar ABP501 in patients with chronic inflammatory bowel diseases: the adaswitch study

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Abstract. – OBJECTIVE: Biosimilars represent a new opportunity for IBD treatment and the economic sustainability of therapies. The aim of the study is to evaluate efficacy and long-term safety of the Adalimumab biosimilar ABP501 in naïve or switched IBD patients.

PATIENTS AND METHODS: A retrospective observational study was conducted on a database, including IBD patients treated with ABP 501, naïve or switched from the originator, at eight IBD centres. We included adult patients with at least one year of follow-up. The primary objective was to assess efficacy (persistence on ABP501 therapy) and safety (rate of adverse events). The categories analysed were: type of IBD, naïve to anti-TNF therapy, switch from anti-TNF originator to biosimilar. Confounding factors analysed in multivariate were: age, sex, smoking, comorbidities, type of IBD, duration of disease, naïve to anti-TNF therapy, switch to ABP 501.

RESULTS: We included 117 patients with IBD: 83 with Crohn's disease (CD, 71% naïve) and 34 with Ulcerative Colitis (UC, 61.8% naïve). ABP 501 showed greater efficacy in maintaining clinical response at 2 years in CD (77.1%) *vs.* UC (64.7%, *p*=0.001) and in antiTNF naïve (78%) *vs.* experienced (72%, *p*=0.0014). There was no difference in the efficacy between ADA-switched and ADA-naïve patients. Nine patients (7.7%) discontinued the drug due to adverse events.

CONCLUSIONS: APB 501 showed a good safety and efficacy profile in maintaining clinical response at 2 years in both treatment-naïve and treatment-shifted IBD patients.

Sarcopenia as a consequence of intestinal and rheumatological diseases in a geriatric population

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Abstract. – OBJECTIVE: Sarcopenia is a frail condition. By frailty we mean a state of increased vulnerability and reduced resilience towards stressful events (trauma/illness, etc.), but by sarcopenia, which is not synonymous with frailty, we mean the progressive and generalized loss of muscle mass and function, with increased risk of adverse phenomena (falls, fractures, worse quality of life and increased mortality). Our aim was to evaluate sarcopenia in relation to the clinical factors that influence its evolution.

PATIENTS AND METHODS: In the period 2020-2021, 126 patients in a geriatric facility, all women, mean age 87.5 years (range 70-103) were carriers of chronic diseases. All were studied using the CIRS index, all were subjected to the Tinetti test for balance and falls, and to the SARC-F questionnaire for muscle mass characteristics.

RESULTS: In the CIRS study there is no statistical significance (*p*=ns). In the Tinetti Test study there is no statistical significance p=ns. Statistical significance was observed in patients with bone disease (*p*=0.003), with metabolic and gastrointestinal disease (*p*=0.0007).

CONCLUSIONS: Sarcopenia is a pejorative element of the organic frailty typical of the elderly. The study shows that the causes related to sarcopenia are the presence of metabolic diseases (diabetes-IBD, etc.) which lead, over time, to a reduction in muscle mass, such as sarcopenic obesity – in the context of excess adiposity. In this context, malnutrition, immobilization and the presence of comorbidities (particularly bone and metabolic, associated in the institutionalized elderly with chronic cardiovascular/brain pathologies) play an important role in the genesis of sarcopenia.

Real word long-term efficacy and safety of vedolizumab in managing ulcerative colitis versus Crohn's disease: results from "LONG VEDO" Italian Multicenter study

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Abstract. – OBJECTIVE: Italian data currently available in long-term managing of ulcerative colitis (UC) and Crohn's disease (CD) patients with vedolizumab (VDZ) are limited. The present study aimed to assess whether there are differences in term of long-term efficacy and safety of VDZ in UC and CD patients.

MATERIALS AND METHODS: Clinical activity was scored according to the Mayo score in UC and to the Harvey-Bradshaw Index (HBI) in CD. The primary endpoints were the achievement and maintenance of clinical remission and safety. Secondary endpoints were clinical response to treatment, achievement of mucosal healing (MH), steroid discontinuation, and treatment optimization.

RESULTS: The study group consisted of 729 patients (475 patients with UC and 254 patients with CD) with a median follow-up of 18 (interquartile range 6-36; mean 23 months with range 2-72) months. Clinical remission was achieved in 407 (85.7%) patients in UC group and in 221 (87.0%) patients in CD group (p=0.622) and clinical response in 432 (90.9%) and in 224 (88.2%) (p=0.237), respectively. Mucosal healing occurred in 42/55 (76.4%) patients in UC group and in 29/36 (80.5%) patients in CD group (p=0.646), steroid discontinuation in 436 (91.8%) and in 232 (91.3%) (p=0.834), and optimization of treatment in 38 (8%) and in 10 (3.93%) (p=0.123).

CONCLUSIONS: VDZ is effective and safe in long-term management of IBD.

Real life comparison of adalimumab biosimilars ABPB501, SB5, GP2017 and MSB11022) in patients with inflammatory bowel diseases undergoing to non-medical switch from adalimumab originator

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Abstract. – OBJECTIVE: Adalimumab (ADA) biosimilars have been included into the therapeutic armamentarium of inflammatory bowel disease (IBD); however, comparative data on the efficacy and safety of the different ADA biosimilars after replacing the ADA originator for a non-medical reason remain scarce. We aimed to compare in a real-life setting the efficacy and safety of four ADA biosimilars SB5, APB501, GP2017, and MSB11022 in IBD patients after replacing the originator for a non-medical reason.

PATIENTS AND METHODS: A multicenter retrospective study was performed on consecutive IBD patients, analyzing clinical, laboratory, and endoscopic data. The primary endpoints of the study were: maintenance of clinical remission and safety of the different biosimilars.

RESULTS: 153 patients were enrolled, 26 with UC and 127 with CD. Clinical remission was maintained in 124 out of 153 (81.0%) patients after a median (IQR) follow-up of 12 (6-24) months, without any significant difference between the four ADA biosimilars. ADA biosimilars dosage was optimized in five patients (3.3%). Loss of remission was significantly higher in UC patients (10/26 patients, 38.5%) than in CD patients (19/127 patients, 14.9 %, $p<0.025$). Adverse events occurred in 12 (7.9%) of patients; the large majority were mild.

CONCLUSIONS: No difference in efficacy and safety was found between ADA biosimilars when used replacing the ADA originator for a non-medical reason. However, in UC patients the replace of ADA originator for this reason should be carefully assessed.

Diagnostic delay and economic burden in IBD: a multicenter italian experience in patients treated with biologics

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Abstract. – INTRODUCTION: Inflammatory bowel diseases (IBDs), Crohn's disease (CD) and Ulcerative colitis (UC), are chronic and immune-mediated diseases with a relapsing-remitting trend. The overall incidence of these diseases is increasing. However, it is estimated that more than one third of patients experienced symptoms for more than one year before diagnosis. Delay in IBD diagnosis has several clinical, therapeutic and economic implications. Early diagnosis and proper treatment are the cornerstones for improving the standard of care for these patients. This study aims to evaluate the diagnostic delay (DD) in patients with IBD and to analyze the clinical burden of the delay in IBD diagnosis in patients treated with biological drugs.

PATIENTS AND METHODS: An observational and retrospective study was performed in IBD patients, regularly followed in four IBD Units. Data regarding delay in IBD diagnosis were assessed through a questionnaire evaluating the disease course. Moreover, data about biologics dispensation were obtained from the medical records in the period 2020-2022.

RESULTS: 135 IBD patients were enrolled (UC 72, CD 63, M 80, F 55). Median age at diagnosis was 32 years (IQR 22-45); 7% of patients were ≤ 16 years old at diagnosis. Median age on erollement was 47 (IQR 4-59): Median DD was 12 months (IQR: 6-24). No significant difference was found in median DD between UC [12 months (IQR: 4.5-12.0)] and CD patients [12 months (IQR: 12-48)]. However, the proportion of patients with a DD >24 months was significantly (p=0.007) higher in CD (21/63 = 33%) than in UC patients (10/72=13%).

After a median disease duration of 10 years (IQR: 4-17), overall, 67 patients (49.7%) were exposed to one biologic agent, 43 patients (31.8%) were exposed to two biologic agents, 25 (18.5%) to three or more biologic agents. 23% of patients (31/135) underwent surgery.

The statistical analysis showed that DD >24 months was not statistically significant associated with history of ≥ 2 biological drugs (*p*=0.51). Conversely, there was association with surgical treatment (*p*=0.004).

***CONCLUSIONS:* The diagnostic delay in IBD represents a challenge with clinical and, therapeutic impact. It is crucial to cooperate with general practitioner and gastroenterologists not dedicated to IBD in order to reduce the diagnostic delay and guarantee an effective, appropriate and early treatment that will improve the patients' quality of life and meanwhile reduce the healthcare system costs.**

Hypertrophic pachymeningitis. Neuro-immuno-rheumatological overlap. A clinical case

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Abstract. – *OBJECTIVE:* Clinical presentation of a patient with ANCA-associated hypertrophic pachymeningitis.

***PATIENTS AND METHODS*: The patient came to the emergency department presenting concomitant convergent strabismus on left eye, horizontal diplopia in the primary position with left lateral rectus muscle deficiency, hypoesthesia in V1, V2, and V3 territory of the left trigeminal nerve, left deviation of the palate, weakness of the right sternocleidomastoid and trapezius muscles, tongue's deviation to the right, dysphagia, and hoarseness. These symptoms justified a hospitalization in neurological department, where the patient was subjected to instrumental investigations, in particular brain MRI, blood tests and CSF analysis. Finally, a targeted antibody dosage confirmed the rheumatological nature.**

***RESULTS*: The brain MRI showed thickening of the dura mater in the posterior cranial fossa and of the two tentorial layers. The haematochemical tests reported ESR (58 mm/h) and CRP 9.95 mg/dL while the CSF showed pleocytosis (63 cells with reference 0-5) of which 70% lymphocytes, an increase in protein (145 with reference 15-45) and 11 oligoclonal bands were found on immunoelectrophoresis. Finally, P-ANCA positivity was confirmed.**

***CONCLUSIONS:* Even if in the context of "limited vasculitis" MPO ANCA positivity is the most common form, PR3 ANCA-positive hypertrophic pachymeningitis is characterized by more severe neurological symptoms and a higher risk of disease progression. As a consequence, this is another demonstration of the multidisciplinary nature of the pathology under examination. It is clear how these two pathogenic subclasses (MPO-ANCA and PR3-ANCA) need further studies with larger cohorts.**

Conflict of Interest
The authors declare they have no conflict of interest.

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