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immunoplus

magazine for patients with primary immunodeficiencies

Future of the treament of immuno-deficiency

Antibody transfusions, bone marrow transplants, gene therapy: which of these methods give patients a chance to cure them completely of immunodeficiencies?

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PI gets much more coverage in media

Photo: Tadeusz Żalik

Adrian Górecki along with Prof. Danuta Kowalczyk and Prof. Maciej Siedlar at the press conference

On 21 May 2014, the University Children's Hospital of Cracow held a press conference about primary immunodeficiencies. PI were discusses by Prof. Danuta Kowalczyk and Prof. Maciej Siedlar as well as patients representing Immunoprotect, Adrian Górecki and Aleksander Żalik.

As a result, the Polish TV Cracow Branch aired a material about saving 65 patients diagnosed in Cracow owing to the financial support of our association and the American Jeffrey Modell Foundation. Shortly after, we got a lot of publicity in the Poland-wide television: the PI topic appeared in the Teleexpress news programme. People could read about our achievements in such newspapers as Gazeta Krakowska or Dziennik Polski. Numerous publications appeared in the Internet as well.

Every subsequent material in media offers to many patients a great opportunity for an early diagnosis. Katowice-based Guarana PR deserves words of recognition for helping the association to organise that conference free of charge.

Adrian Juszkiewicz

Busy quarter at the association

Within the recent quarter, our association have organised several events. We trained general practitioners from the Podlaskie Province; we organised meetings for patients in such cities as Łódź, Gdańsk, Warsaw and Bydgoszcz.

The Łódź meeting which we held as part of the social campaign, "Choose Immunity: Start with the Diagnosis", gathered the roomful of participants. While the parents listened to lectures, their children were playing at robotics classes in a separate room. This year, patients and their parents may extend their knowledge in the diseases accompanying PI at all of our meetings. What's more, we try to put an emphasis on informing them about available welfare benefits.

Photo: Zuzanna Kwiatkowska

At the meeting for patients in Łódź

An important element of such meetings is a discussion and the mutual exchange of experiences. After summer holidays, we are planning to organise workshops for patients and physicians in several places such as Poznań, Lublin, Cracow and Olsztyn.

In September, Kruszwica will host a football tournament for small patients, accompanied with lectures on going in for sports by PI patients. At each of these events, we will talk about the documentary, "This Might Be Your Story" which premièred in late June.

You can find up-to-date information on our website www. immunoprotect.pl.

Adrian Juszkiewicz

Another training for volunteers

Our association builds its structures in further provinces: we have representatives engaged in as many as 10 provinces already. Despite coming from all over Poland, our regional coordinators meet regularly to consult the current activity of the association and extend their knowledge.

This happened at the May two-day training for provincial coordinators in Warsaw as well. Beside lectures on the treatment and diagnostics of PI and on the arcana of the effective organisation management, the participants received comprehensive knowledge in self-presentation, effective relations with media or motivation. Further training is planned in the second half of October.

Photo: Zuzanna Kwiatkowska

Training is a forum for the exchange of experiences

Any persons interested in taking part in the training and any activities for PI patients, please contact Kamila Rzepka, kamila.rzepka@immunoprotect. pl to leave your contact details.

You can get more information by phone +48 731 083 308 from 6 pm to 9 pm. We publish a list of regional coordinators on the last page of the magazine.

AJ

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Magazine for patients with primary immunodeficiencies

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CSL Behring

EDITORIAL

We create the quarterly for you

Dear Readers, we are placing in your hands the first issue of the only printed magazine in the world for patients with primary immunodeficiencies. This exceptional magazine is to serve all those who are in any way connected with the subject of immunodeficiencies, patients, their families, physicians, nurses and medical students. "ImmunoPlus" quarterly will be available in all hospital wards treating PI in Poland, for both children and adults.

The patient magazine is a milestone in the development of the development. For seven years now "Immunoprotect" has supported patients suffering from PI. We assist in many fields: we educate patients, parents and general practitioners; we campaign to inform the public that immunodeficiencies exist; and finally we fund genetic diagnostics: thanks to us several little patients were diagnosed at the University Children's Hospital of Cracow.

On 28 June, at the convention of the Polish Society of Experimental and Clinical Immunology in Wrocław, two important events took place; this quarterly and a documentary on PI were premièred. Yes! We were first in the world to produce a feature-length documentary about a life with primary immunodeficiencies (more importantly, simultaneously in two languages, Polish and English). We are one of the most quickly developing primary immunodeficiency patient associations in the world. We take an active part in international projects, primarily assisting other organisations in Central and Eastern Europe with our knowledge and experience.

This issue contains information about a hot topic: we are considering whether PI patients may normally go on holiday. We hope that an interview with immunologist Dr Hanna Suchanek and the story of patient Małgorzata Łukasiewicz will allow you to find an answer to that question. The cover story makes us wonder about the future of treating PI, from the gene therapy to new methods of administering antibodies.

The latter is the topic of the text by Dr Małgorzata Pac from the Warsaw Child Health Centre who writes about the rapid-push method. We are giving some thought to whether PI patients may pursue their passions. Furthermore, it is worth reading the text on difficult professional choices made by PI patients. Finally, a few words about another disease which requires a constant administration of subcutaneous drugs, diabetes.

We encourage you to be co-authors of this title and send your stories, opinions or comments to the editorial office addresses, both the e-mail address (redakcja@ immunoprotect.pl) as well as itsa postal address.

Enjoy your reading.

Adrian Górecki

Editor-in-chief of "ImmunoPlus", Chairperson of the "Immunoprotect" association, patient with Bruton type agammaglobulinemia

SURVEY

Can PI patients pursue their passions?

Collected by Jacek Pietrusiński-Wesołowski

Gabriela Jastrzębska

My 17-year-old son Oskar loves playing football and is a sports school student. He was diagnosed with common variable immunodeficiency (CVID). When the disease first started, he had ear problems, upper respiratory tract inflammations and monthly antibiotic therapies and, as a result, he had to leave school and his football practice. He couldn't - like any other child - go to the swimming-pool, which was one of a sports school student's duty.

After the diagnosis and the first intravenous immunoglobulin infusions, the symptoms started to subside. Since subcutaneous substitutions were introduced, my son hasn't had any limitations any more. He feels much better and can spend his week very actively but for the days he allows for the therapy only.

Ewa Kapuścińska

My passions are work and travelling. Fortunately, I manage to normally fulfil myself professionally despite the disease, common variable immunodeficiency.

As far as travelling is concerned, it's restricted chiefly to Poland as I have many concerns and doubts connected with foreign travels, therefore to some extent I can't keep to my plans completely.

On the other hand, I love reading, listening to the music or watch some ambitious film. I use the time when I infuse immunoglobulins under the skin, that is, four hours a week, to catch up with reading newly released books or films. Considering this, I can even perversely say that immunodeficiency helps me to pursue my passions.

Joanna Kołodziejczyk, MD, PhD

It all depends on the person and what their passion is. The course of primary immunodeficiencies may vary considerably.

It all depends on when it was diagnosed, whether the diagnosis was very delayed, whether complications developed, what the type of the disease it is and what its sequelae are. Given recurring infections occurring in the course of PI, particularly in both upper and lower respiratory tracts, serious complications may develop such as bronchiectasis and obstructive bronchial disease which can significantly reduce the lung ventilation efficiency.

In such situations, passions involving intensive physical effort or difficult conditions such as mountaineering or other extreme conditions will certainly be contraindicated. However, moderate physical exercise within the patient's capabilities, e.g. riding a bike, jogging or walking in nature, could even be a positive factor. During physical effort, endorphins having a beneficial effect on feeling well are released and give the feeling of happiness, even have painkilling properties. Travelling is possible as well. There are not any contraindications to travelling by plane; the patients can take their drugs and pump with them.

Definitely, it's easier in the subcutaneous immunoglobulin treatment; you can go for longer and you are not bound by hospital visit dates. You should very carefully choose countries which pose a great risk of infections with local bacteria, viruses or parasites, or require additional vaccinations since the usual set won't protect patients with primary immunodeficiencies. It's also important to accept patient's own limitations.

PI patient goes to work

A choice of a proper career path is a serious problem faced by many PI patients. Some of them try to work full time, others cannot cope without allowances, and still others are successful running their own businesses. How does your disease affect your work and how do you choose so that your condition does not deteriorate?

Adrian Górecki
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It's 6.30 am. The alarm clock rings. Marcin, Bruton type agammaglobulinemia patient, opens his eyes. It's not easy for him: first he has to cleanse them of an excessive purulent discharge which is the result of a recurrence of conjunctivitis. When he's finally managed this, there is a host of activities which are to make Marcin better: coughing up of bronchial secretion, nebulisation, sinus rinsing. Marcin has quick breakfast and runs to catch the bus to take him to work. Marcin rushes into his office a few minutes late. In his office, Marcin's furious boss is already waiting for him and in a moment in simple soldierly words will express his disapproval of Marcin's health condition. 'Since you have that your HIV, you are to take a holiday leave and not to swindle a sick leave', yells his superior. Marcin goes to his desk and makes his coffee. He starts work. After ten hours (he's supposed to work eight hours but his boss told him to stay and finish an important project threatening him with his bonus cut) Marcin goes out of the office. Tired out, he gets on the bus and goes back home where he falls on his bed and can't stand up out of exhaustion. Destroyed by chronic diseases, his lungs make themselves felt: secretion soars, acute inflammation develops and he begins to cough up blood. Contacting the crowds on the bus, Marcin caught another sinus infection. He's forced to go on a sick leave again. After a few days his boss calls telling him that he doesn't have to come to work anymore. He's fired. Third time this year.

Are you ill? Forget a full-time job

Such stories have become the daily bread of many patients with primary immunodeficiencies. Obviously, this is not so in every case but we may take it as a rule that they have problems with finding and keeping a job. The patients may not always count on their employer's understanding. Even if initially it is not a problem to the boss, with time many trips to hospital or sick leaves may exhaust his patience. Even more so if their performance drops significantly during the exacerbation of chronic disease symptoms. Then such patients most often lose their jobs. There are also such situations where that all of a sudden the patients are fit for work.

It happens mainly because in the meantime they started work somewhere (it is possible according to the regulations of the Social Insurance Institution). 'I had a problem with getting the disability pension again', says Aleksander, patient with IgG subclass deficiency from Upper Silesia. 'However, no one noticed that I used to work in one place a few months at the most because it always ended with my dismissal due to PI', he explains. Thus, the patients with immunodeficiencies are left without the State support and without any chance for work.

Frequently, such cases end in court where above all they put forward the argument of the need for treatment for life. 'After all, one will not be cured of immunedeficiency; it might only be worse with time. Such decisions made by the Social Insurance Institution are completely incomprehensible to me', complains Aleksander.

Eight hour intense work can be too much for a PI patient

adult patients who were diagnosed with immunodeficiency (most often it is CVID) are not able to go on working in their field. Then, it is necessary to change the job. 'I was ill all the time; I couldn't work normally. I had to switch sectors', says Marek, CVID patient from Greater Poland. 'I was diagnosed with immunodeficiency when I was adult. I worked in the building sector then and unfortunately it often involved huge physical effort', he explains. 'As a result, I opened my own photographer's shop. Thus today I can live more or less comfortably on my own', he explains.

Miraculous recovery in the Social Insurance Institution

Achieving independent life by the PI patients is not made easier by the Social Insurance Institution. Frequently, the patients get a decision of permanent incapacity, which entitles them to receive social pension. However, the Social Insurance Institution every now and then reviews such decisions. Then it turns out

Solution: own business?

Undoubtedly, most successful are persons running their businesses. 'Running my own company offers me an opportunity of adjusting work time on my own', says Jacek, patient with hypogammaglobulinemia from Warmia. 'If I feel worse, I can stay at home. Sometimes I can stay in bed for all that day', explains Jacek. 'I make up for the lost time when I'm in good shape. Such a system allows me to perform work whose important component involves constant travelling by car across Poland', says Jacek.

Obviously, not everyone has a predisposition or capability to start work on one's own. However, it seems that such a method of making a living is most advantageous in many respects. An equally good solution is remote work, i.e. performed at home. It may be carried out in many professions; for instance, giving legal advice over the Internet or performing many tasks in widely understood computer science becomes more and more popular.

Let us talk with children

It is important for parents with PI children to start talking with children early about their plans for the future. A person with immunodeficiency will not be able to cope with the requirements of heavy physical labour or professional sports. It is not recommended either to stay constantly in places full of people (e.g. teachers) or intense contact with customers (e.g. attending customers in a fast food restaurant). 'When a child approaches approximately the age of 14-15, we ask their preferences for their career choice', says Prof. Anna Pituch-Noworolska, Immunologist from the University Children's Hospital of Cracow. 'If children say they want to be computer specialists, then everything is OK', she explains. 'However, if they plan to be fire-fighters or miners, then we talk to parents explaining to them the threats caused by such a choice', explains Prof. Pituch-Noworolska. As in every sphere of life, it is here as well that the ability of reaching a compromise plays a great role. It it worth finding common points between the child's aspirations and limitations posed by primary immunodeficiency. Thus, work will become pleasure in the future and the disease will have a little effect on his/her everyday life.

There is a chance for a home treatment for adult patients

Predominantly, an immunodeficiency therapy involves antibody transfusion. Generally, the access to the most modern subcutaneous methods of administration at home has so far been offered to children only. It is supposed to change next year

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Photo: Zuzanna Kwiatkowska

A home therapy makes the patient's life much easier. On transfusion, the patients can use a laptop computer for instance

The therapy with subcutaneous products offers almost only benefits, both for the patient and for the hospital and as a consequence for the State too.

Asked for the advantages of the subcutaneous methods of immunoglobulin administration, Prof. Sylwia Kołtan from the Paediatrics, Haematology and Oncology Clinic, Collegium Medicum, in Bydgoszcz discusses primarily the comfort for the patients who can freely administer antibodies on their own at home, which reduces the hospital admissions from 12 to 4 in a year. 'In addition, the subcutaneous therapy is cheaper for the hospital', explains Prof. Kołtan. 'It saves on the nurses' work and low consumption of small medical equipment. The need to treat quite frequent complications, sometimes very dangerous, is avoided', she says. The only additional cost to a medical institution in this PI treatment method is for providing a special infusion pump which introduces subcutaneous drugs. Most often, the pump costs around PLN 4,000. However, the service life of this equipment is very long, even over 10 years, which ultimately reduces onerousness of such an investment for the hospital.

Better results, fewer infections

The patients undergoing the subcutaneous therapy avoid school, university or work absences. Such patients can freely work so they do not use any disability allowances or pensions. That is what is known as social costs which are much lower than in a conventional intravenous therapy. 'It is a saving which in Polish conditions is taken into account in all calculations very rarely', says Prof. Kołtan. It is a very safe method which may be used almost by every patient. General symptoms occur extremely rarely. However, we very often observe localised reactions which more reflect the skin reaction to the drug than they may indeed be regarded as an undesirable reaction. They do not require any treatment; they subside spontaneously within several hours after the drug was administered. What is more, subcutaneous transfusions do not require intravenous cannulation (i.v. line placement), which tends to be frequently an enormous problem, particularly in small children. 'The cons of this therapy may be a fear of pain or of pricking oneself', says Ewa, PI patient from Rypin, Kuyavian-Pomeranian Province. 'However, it is only a minor flaw in the context of the benefits of the subcutaneous administration', she assures.

Thanks to this therapy, Ewa can live an active life; she is an English teacher in a secondary school and an "Immunoprotect" association volunteer. The onerousness of the subcutaneous methods is also the need to take immunoglobulins more often, 2 to 4 times a month. 'From the medical point of view, the most vital advantage is the therapy ensuring similar and sometimes even higher anti-infection efficacy than in intravenous transfusions. All this owing to stable IgG levels reached in the subcutaneous therapy', says Prof. Kołtan. Although there are not any problems with the PI therapy in children, it is basically inaccessible for adults. When becoming 18, the patients often have to return to intravenous transfusions, which for many is a life drama. 'The absence of a drug programme for adults is absolutely incomprehensible for me. It is as if the National Health Fund expected that there would be a sudden recovery at the age of 18!' says outraged Prof. Kołtan.

Programme the next year already?

Therefore, a system solution of the absence of home therapy for adults would be a special therapeutic programme. It is not only a guarantee for patients but also certainty for the hospital that does not have to worry about the reimbursement for the patient treatment cost. Currently, the PI patients are often a reason for financial trouble for the health centre since the existing regulations demand funding the adult treatment under the general contract the centre has. For 7 years now, the "Immunoprotect" association has taken attempts to lobby for creating such a programme. Last year, the light at the end of the tunnel appeared. Owing to the actions of the association and initiative by Prof. Maciej Siedlar, National Consultant for Clinical Immunology, a draft programme was developed. Unofficially, there are voices saying that it may become effective even in January 2015. 'A draft drug programme for adult patients was accepted by the Ministry and along with reimbursement applications sent to the Agency for Health Technology Assessment in Poland (AHTAPol)', says Krzysztof Bąk, Ministry of Health spokesperson. It means that the first stage of the entire procedure is already behind us. 'The assessment of the drug programme application is ongoing. Its recommendation is to be expected in July', confirms Katarzyna Jagodzińska-Kalinowska, AHTAPol spokesperson.

Everything seems to be on the right track, however having learnt our lesson in the previous years, we will continue to watch carefully actions by officials. We hope that our matter will not become bogged down somewhere in the bureaucratic machine and it will have a quick and positive solution.

Immunodeficiency treatment: what future is ahead of us?

The progress in medicine does not pass by the therapies used in the treatment of primary immunodeficiencies. From the patients' perspective, it is important to know not only about available treatment methods but also about any new possibilities which may in the future lead to curing them of PI completely

Dorota Marynowicz
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On getting their diagnosis, the patients suffering from primary immunodeficiencies feel a deep relief that the nightmare of persisting infections is ending. On the other hand however, they face a great unknown. A host of new questions pops up like those concerning the quality of everyday life, the future of the career and family life and the access to the treatment. Today, we have the therapy ensured and know what to expect. But can we foresee how primary immunodeficiencies will be treated in the future?

Immunoglobulins still at the top

The history of the immunoglobulin administration dates back to WWII. For the first time, the immunoglobulin preparations were applied as a preventive and therapeutic measure in American soldiers, counting on their anti-infective effect. The use of this form of drugs was possible owing to the blood plasma fractionation method that had been developed. A few years later, gamma globulins appeared in the treatment of primary immunodeficiencies. In 1952, military paediatrics doctor Ogden Bruton developed the method for an intramuscular application of immunoglobulins in the therapy of a child with an undetectable serum immunoglobulin levels. Since then, the immunoglobulin treatment in primary immunodeficiencies has been constantly developed. 'The therapy involving immunoglobulin transfusions is the most efficient medication used since the 1950s in the treatment of the largest patient group with PI, a deficiency related with the defective antibody synthesis,' believes Prof. Ewa Bernatowska, Manager of the Immunology Clinic at the Warsaw Child Health Centre and also Regional Consultant for Clinical Immunology in Masovian Province. Preparations used today are much safer and much more effective and their application from the patient's point of view becomes easier and more comfortable. However, it has not always been so simple. The first immunoglobulin preparations were administered into the muscle and injections caused great pain.

Photo: CSL Behring

The manufacture of immunoglobulin preparations is a complicated and demanding process

A single dose was quite limited thus the attempts to administer the preparations into the vein started. Unfortunately, patients experienced anaphylactic shocks. Works to modify the drug began. 'An immunoglobulin particle was "cut" to pieces so as to avoid anaphylactic reactions. However, they had one flaw: the antibody pieces were indeed biologically active but they could only survive in blood for 3-5 days. Further chemical modification allowed for preserving the entire antibody particle but they did not have all of the bactericidal properties distinct for natural antibodies', says Prof. Bernatowska. The gamma globulin preparations are developed in terms of the safety of their use. Pharmaceutical companies continue to improve their methods for pathogen inactivation in plasma obtained from donors. For around 15 years now, we have had preparations that satisfy most stringent safety standards.

Various routes of administration

Not only the drug itself changes, its route of administration changes as well. Today, we have a subcutaneous administration. Such a route "exempts" the patient from frequent hospital visits. Instead of monthly visits for intravenous transfusions, the patient comes to the hospital quarterly to take the drugs.

Subcutaneous preparations offered the patients one more possibility: the chance for a home therapy. The patients choose by themselves the time and place of the drug application. They treat themselves in the privacy of their homes, around their families, and not in a hospital room. It is a huge change in the approach to the treatment. Common access to the therapy involving a subcutaneous gamma globulin preparation is a huge change in the lives of adult PI patients. Every stay in hospital to have the intravenous transfusion is de facto a day off at work. Within a year, 12 days disappear all too easily that could have been devoted to the career. The subcutaneous application of gamma globulins gives the patient a greater flexibility on the job market. These days, it is a vital argument. All the time, works are ongoing to extend the time between drug applications. 'In a moment, the patients are going to get a new proposal: the drug administration in a subcutaneous transfusion once a month and not as previously once a week', says Prof. Bernatowska. Despite all the progress, one thing has not changed: the plasma donor may not be skipped over. If the patient is to be efficiently protected from the whole spectrum of bacteria and viruses, it is necessary to have access to natural antibodies.

The drug that today protects the patient is collected from the plasma of 1,000 donors. There is nothing that can replace them. And this will certainly not change in the nearest future.

Secrets of the gene chain

The breakthrough in the treatment of numerous gene-related diseases is sought in the gene therapy. 'The treatment involves interacting with the patient's genetic material. **c.o.p. 7**

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Damaged genes may become replaced with properly functioning genes introduced to the patient's cells, which restores the proper cell function', explains Prof. Bernatowska. It so happened that the first genetic disease where the gene therapy was used was severe complex immunodeficiency.

The attempt was made in 1990 in the US replacing the bone marrow transplant applied so far. T lymphocytes were isolated from peripheral blood and the gene coding human adenosine deaminase was introduced using retroviral vectors. Over the years, the treatment method was improved administering the missing gene to the bone marrow stem cell, which took up the production function of the fully efficient cells.

However, it turned out that the method entailed the risk of tumour growth. Oncological lesions are caused by what is known as a viral vector which is responsible for introducing the correct genetic code to the bone marrow stem cells.

Therefore today works on the gene therapy focus on searching for new vectors which would not result in neoplastic lesions. The aim is to find precise methods for delivering genes to the patient's target cells. Thus, the future of the gene therapy will concentrate on improving its safety.

'Currently, the gene therapy is undertaken in cases where a compatible bone marrow donor cannot be found. The attempts to reconstitute the bone marrow are made even in the womb, e.g. in the Wiskott-Aldrich syndrome. The gene therapy is used also in adult patients with chronic granulomatous disease', says Prof. Bernatowska.

Cured to the marrow

'Bone marrow transplantation is a procedure involving the administration to the patient a preparation with blood-forming stem cells which are able to reconstruct the patient's blood-forming system. PI makes use of allogeneic transplants, from the family or unrelated donor', explains Prof. Bernatowska.

The first attempts to treat with the bone marrow transplant were made as early as in the 1960s in patients with severe complex immunodeficiency. Since then, this treatment form has been developing continuously. The method for preparing the patients for transplants has improved; less aggressive conditioning methods have been introduced. These actions have resulted in the survival rate of the bone marrow transplant patients in some PI types reaching almost 100%. Furthermore, the number of PI types treated with this method has increased. The picture of the bone marrow transplant therapy in Poland seems to be optimistic. 'There are not any queues and the patient's parents have a choice: they can choose to have the therapy in one of the six hospitals, near the place where they live.

All the patients are registered in Medigen where bone marrow donor bases are searched through in terms of the HLA-DR gene compatibility. Umbilical blood is taken into account. We have access to all of the bone marrow donor bases in the world. An average waiting time is around 4 months', explains Prof. Bernatowska.

What does the future hold?

The progress in the PI treatment in the next years will focus on improving today's therapies and promoting them in all the patient groups suffering from PI. Let us hope that in Poland the gamma globulin subcutaneous therapy will be popular among adult patient groups who so far have not had their own drug programme.

- Also, we pin our hopes on the development of very efficient biological drugs. Even today, they are used in the treatment of autoimmune diseases which frequently are concomitant with PI, and in the treatment of genetic autoinflammatory diseases', says Prof. Bernatowska.

The progress in the PI treatment is going on before our eyes. We are dealing with much safer treatment methods and much modern drugs. The knowledge of PI is becoming more and more propagated. The patient's dependency on permanent hospital stays is becoming reduced. All this provides us with an opportunity for a normal, happy and above all healthy life.

Most important is to understand the patient

Sheila A. Burke of CSL Behring discusses the future of the immunoglobulin treatment

Noted down by Dorota Marynowicz

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The world immunoglobulin market sees a strong competition and at present its worth is estimated to be around USD 7 billion. It is expected that the market will grow together with the growing number of patients diagnosed with diseases which can be treated with immunoglobulins.

The success in this area depends on various factors which include carrying out world-class research and production capacities; safe, high-quality, consistently developed and improved efficient drugs; proper strategies; and a deep concern for the health and well-being of the patients, their families and health care professionals.

Not only immunodeficiencies

Available drugs include advanced immunoglobulin preparations for intravenous (IVIg) or subcutaneous (SCIg) administration for the treatment of primary immunodeficiencies and secondary immunological disorders. Offered in Poland, ready for intravenous administration, 10% IVIg solution is indicated as an immune-modulatory drug in the treatment of such diseases as immune thrombocytopenic purpura, Kawasaki disease, Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy (CIDP). In addition, we work on extending the indications for our drugs to include neurological diseases.

Over the years, we became convinced that the basic element in supporting the patients and their facilities in day-to-day challenges posed by a chronic disease was to understand their needs, concerns and personal experiences. Showing our understanding, we can be certain that the therapies we are developing and provide to the patients are the proper ones and that they are the response to the changing expectations of patients and health care professionals.

Photo: own files

Subcutaneous antibodies is independence'- says Burke

As many patients as requirements

The patients require a larger number of options as far as the possibilities of independent immunoglobulin administration are concerned.

More frequently, they express their wish for the drug to be administered at higher concentrations so that the time needed for its administration is reduced.

We know that some patients pay a lot of attention to having longer breaks between the administrations, such as fortnightly; for other patients it is important to have the immunoglobulin administration more often than once a week.

Such wide possibilities of the immunoglobulin application, both intravenous and subcutaneous, may allow the patients to have more comfort, more control of their own treatment and higher quality of life. Many patients are pleased about such independence.

Let us travel reasonably

Certainly, many of us ask the question whether we, PI patients, can go on for a summer holiday like others. Can we go climbing, getting a sun tan and swimming in a sea? We have tried to answer these and some other questions in our interview with Hanna Suchanek, PhD, MD, Clinical Immunologist from the University Clinical Centre in Gdańsk

Interviewed by Wojciech Jałoszyński
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It's summer, holiday season and many of our friends go on holiday to leave their everyday routine. Can we afford holiday as well?

The PI patients may go on holiday just like they may work, study, take care of children, take up sports or go to the cinema. All these activities are possible in the patients with defective antibody production and these are patients that definitely prevail among adult patients. A holiday trip is possible after the patient first makes sure that the blood antibody level is protective and stable.

We need to remember that the protective level is not a specific and equal serum IgG level for all the patients. Talking with the patient, I establish whether with the specific blood immunoglobulin level there are infections and if yes what they are. A properly treated patient, i.e. receiving the proper immunoglobulin dose, either intravenously or subcutaneously, should be free from infections. Another factor assessing the efficacy of the substitution is the stability of the IgG level within the last 3 months for example.

A constant stable serum antibody level can be reached decidedly easier through the subcutaneous route. Furthermore, a young man leaving for holiday should have other drugs necessary to treat disorders concomitant with immunodeficiencies, e.g. antiasthmatic drugs or drugs with a positive effect on the alimentary tract function. Don't be scared by this small travel first aid kit.

Where to go best: to the mountains or to the sea? Are there any places that we should especially avoid?

It'd be nice for the PI patients to go on holiday where they want.

However, the choice of the place is decided by their general condition, ability to take physical effort and here I would recommend consulting the patient's attending physician. I would advise the patients with concomitant chronic lung disease against having holiday that demands great physical effort.

Well, OK, and if we've gone on holiday to the sea, then I can't imagine such holiday without swimming in the sea and lying on the beach. Can we use such forms of relaxation?

Yes, of course, within reason, in terms of lying on the sun.

And what if we want to go somewhere further like Egypt?

A further travel, for example to Egypt and to other countries of Africa, Middle East, Far East or South America requires taking some precautions, mainly due to diarrhoea commonly occurring in such regions. Therefore, you need to avoid raw food, seafood, ice cubes and ice cream.

Moreover, PI patients shouldn't plan their holiday to countries where protective vaccination with any vaccine is required. The holiday plan should take into account holiday duration; in the case of the patients treated with subcutaneous immunoglobulins, it's necessary to think about the need to administer the drug while on holiday and the conditions of keeping the drug at a proper temperature.

Photo: own files

When travelling, we have to remember that we are ill but it should not take away joy at our holiday

It'd be best to discuss all of the holiday details with the physician beforehand or to receive information at health centres which deal with travel medicine.

If you travel by plane, I encourage you to check whether the carrier requires a physician's confirmation of the necessity to carry specific drugs.

What steps should we take before going on holiday?

Before a longer trip, e.g. a 14-day one (especially abroad), it's recommended to have the patient condition examination by a physician, to receive a programme of subcutaneous immunoglobulin treatment, if any, and information on how the drug needs to be kept.

The physician should inform the patient about the need to have antibiotic prophylaxis. The attending physician should also draw up a declaration to describe the patient's disease, best in English. Before leaving, the patient should also take out relevant tourist and health insurance.

To sum up, I think we can with calmness wish you all to have a nice holiday.

Absolutely! Enjoy your holiday reasonably.

DOSSIER

Hanna Suchanek, PhD, MD, Specialist in Internal Diseases and Clinical Immunology at the Internal Diseases, Connective Tissue Diseases and Geriatrics Clinics of the University Clinical Centre in Gdańsk, dealing with PI patients on a daily basis.

COMMENTARY

When I was a boy of several years and summer holiday was approaching, my parents cudgelled their brains whether they could take me for holiday. It was the mid-1990s and almost nobody knew about primary immunodeficiencies. There was no Internet or specialist press and the access to professional literature was limited. The general practitioner categorically advised against the holiday and the attending physician warningly gave my Dad and Mum his consent together with a long list of orders. And so almost groping in the dark I was given the chance to discover the world. Thanks to proper rules that I have followed, today I'm able to travel to many places in Europe and not only. The therapy as well—owing to the subcutaneous method—doesn't have to be a problem for persons suffering from primary immunodeficiencies who want to explore the world. **WJ**

I'm infected with... travels!

We hear a lot that the PI patients can't travel. Let's check the story of Małgosia Łukasiewcz, CVID patient from Lower Silesia whose travel achievements wouldn't be the reason to be ashamed of for Wojciech Cejrowski himself

Małgorzata Łukasiewicz
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Photo: own files

Primary immunodeficiency doesn't have to entail giving up a passion for travelling

I've always travelled, on my own (across Western Europe), with my family (e.g. Lithuania, Latvia, Belarus, Ukraine and Russia) and with my friends (such as the post-war expedition to Bosnia and Herzegovina, Croatia and former Yugoslavia) and I was most confident while travelling when I was still ill not so often.

With a syringe on the plane

In 2000, my condition suddenly started to deteriorate until I was diagnosed with CVID in 2003 and started on the intravenous immunoglobulin therapy. I still haven't abandoned travelling then and it remained to be a great fun, thus I decided to continue my passion as long as possible.

And although I don't deny that the awareness of a serious disease and resultant complications caused changes in how I plan my travels: today, additionally taking account of the dates when the transfusions have to take place, I can invariably see a lot of pros of this situation. So far, I've tried to fit in two monthly drug doses and in the subcutaneous therapy which I've used successfully for over 5 years, I take with me abroad (for longer trips) my volumetric pump with all the necessary instrumentation and ampoules. Wanting to have them within reach, while planning a flight I remember to try to get a proper medical certificate confirming the necessity to take the drug.

Firstly: the doctor's recommendations

Travelling is for me not only an exciting adventure but also the chance to taste world's delicious culinary trends, therefore beside the proper clothes protecting against excessive sun and unexpected cold air as well as insects and venomous creatures, I try to adhere to, depending on the existing conditions, at least the basic hygiene rules such as washing hands and not only.

Furthermore, I drink water from secure sources and don't eat meals made of raw and unprocessed products. And thus I admit that there were exceptions from these rules tasting wonderfully such as gorging on sweet lychee fruit in Morocco, munching water lily fruit and drinking a refreshing coconut milk in India or savouring fresh juicy pineapple, rambutan and controversial durian in Sri Lanka. It's good to be prepared for any health problems, mainly stomach trouble, which I experienced, therefore, I am stressing: it's important to have regular tests, take prescribed drugs and listen to our body needs and consult the trips we plan with immunologists.

Personally, I gladly make use of that, asking for advice when buying a few necessary medicines such as tablets and energising preparations or those eliminating respiratory or alimentary tract problems, protective or disinfecting/soothing ointments and vaccination that I needed for instance for a three--week travel to India and Nepal. And I don't think that somehow reasonable travel belittles accompanying positive feelings.

Being a PI patient, I just look before I leap such as while trekking to Annapurna in the Himalayas (one of the first eight-thousanders that was climbed by a man) planned by me and my husband. Taking into account doctor's suggestions (warnings even!) concerning the fact that I was expected to be at large heights and that related respiratory complications could occur, we decided to replace this doubtful pleasure into two other adventures, a flight over the Crown of the Himalaya and mountain river rafting. Our experiences were exciting!

Travelling: a way to live my life

Travelling that I like is not only large--scale touring trips but the stationary ones chosen primarily by our 14-year old daughter. Human life is a constant journey and opens up a plethora of opportunities for it that's why I'm going to my walking, bike, car, lake, sea and mountain trips equally readily.

It's enough to have a little perseverance and strength in your joints and then I recommend(!) going for example to a late summer expedition to the Mountaineers' Cabin (Izera Pass) for delicious omelette with fresh bilberries or plenty of canoeing, or breath-taking gliding.

Travelling gives me the possibility to develop my passions, learning and observing the diversity of the world as well as people and animals living in it and to constantly expand my photo base by recording in my photos places and/or people that make up unique picture stories later on. I'm very interested in travel festivals with my favourite being the Three Elements. Furthermore, I collect various bits and pieces/souvenirs from my travels, colourful masks, dishes or other knick--knacks and jewellery, particularly my favourite earrings.

Seeing my booty always gives me a great joy making me feel good, which is also important in overcoming diseases, and gives me strength and ideas for new challengers.

Infected with an adventure

I can't wait my holiday leave! The nearest of the major trips we've planned will be a two-week exploration of Spain and Portugal and in late winter of 2014/2015 for me and my husband there's a non-commercial expedition with a few other people through the wilderness of Georgia (currently at the stage of hunting with my friends for cheap airline tickets).

Famous Polish traveller Ryszard Kapuściński said, "Indeed, there exists something like a contagion of travel, and the disease is essentially incurable". This is the only contagion that I wish to myself and to you alike.

Rapid-push administration: facts and myths

It is being increasingly recognised across the PI patient circles that there is a rapid-push method in which the patients themselves administer subcutaneous antibodies without the infusion pump

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Primary antibody immunodeficiencies are the largest group in all primary immunodeficiencies. Their prominent feature is a reduced serum antibody level and susceptibility to recurring life-threatening infections. The treatment of choice is substitution with gamma globulin preparations, usually for life. Since the treatment was introduced in the 1950s, the technology of preparation manufacturing, posology and routes of administration have changed.

Intravenous infusions of antibody preparations prevail in many countries in Europe and America; in Scandinavia they were almost completely replaced with infusions of subcutaneous preparations. Within the recent years, the rapid-push method has become more and more popular in the US and Canada; it involves the direct subcutaneous administration of a gamma globulin preparation without the infusion pump. The therapy principles remain the same (dose, infusion frequency). The exception is that the preparation is given directly from the syringe through a drain and a subcutaneous needle. The infusion rate is faster, 1-2 ml/min, which reduces considerably its duration, even to 9-20 minutes.

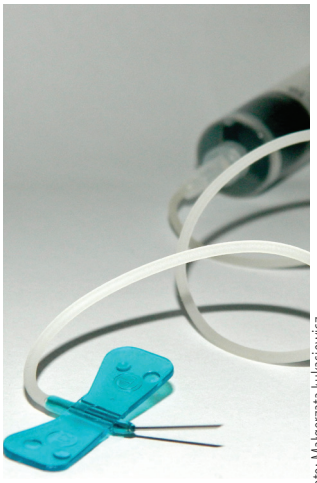

Photo: Małgorzata Łukasiewicz

The rapid-push method has many followers in the US and Canada

An average dose volume administered to one injection site is from 5 to 30 ml, depending on age, weight and individual tolerance. It is recommended to have 1-2 injections per infusion to the same sites as in SCIG (abdomen, thighs and arms). Side effects observed during the administration of immunoglobulin preparations using the rapid-push method are comparable to the side effects observed when the preparation is given using the pump, and they are localised, with mild intensity, and self-limiting.

The argument for the rapid-push method is its convenience. The method eliminates the necessity to have additional specialist equipment (the pump). For frequent travellers, this reduces the size and weight of the luggage.

The rapid-push method is a convenient method alternative to the infusion pump, accepted by the patient, and offering a quick drug administration. It has been successfully used in the US and Canada, although so far it has not gain popularity in Europe and is not commonly used by the patients in Poland.

European-quality hospital

Wrocław can boast a modern European-quality hospital. It is in that hospital in the Immunology and Paediatrics that little patients with primary immunodeficiencies are treated. Let us see closer the hospital profile

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The Jerzy Gromkowski Regional Specialist Hospital in Wrocław was set up in 1998 after several Wrocław-based medical institutions combined into one and currently - as a complex of buildings and facilities that underwent complete modernisation - is one of the most modern hospitals in Lower Silesia and in Poland, for years taking up top places in the rankings of the best Polish hospitals. With its solutions, highly qualified personnel and state-of-the-art apparatuses, the patients have ensured a high standard of treatment.

Its modern kitchen and meal distribution system guarantee hygienic, aesthetic and timely serving of meals in hermetically sealed containers (that is known as the tray food serving system) following the diets strictly indicated to every patient.

The hospital buildings have innovative sanitary solutions ensuring epidemiological safety and convenience for people using it. The hospital is 100% computerised. The medical documentation and data are created, filed and sent electronically.

In addition, the hospital has a modern pneumatic post system which allows the employees to efficiently send and receive material for testing and test results and any other documents needed at the moment to the doctors or other authorised hospital employees. It eliminates problems of covering quite a good distance between individual hospital buildings. Beside numerous awards for adult patients, the hospital has specialist children wards. The Janusz Korczak Paediatric Pavilion, floor 3, building A3, houses a newly created Clinical Immunology and Paediatrics Ward.

CLINICAL IMMUNOLOGY AND PAEDIATRICS WARD IN NUMBERS

Beds: 27 (including 3 private rooms and 2-3 patient rooms)

PI patients: 35-40 (including around 16 subcutaneous patients; 19-24 intravenous patients and 5 adult patients continuing their therapies)

Bone marrow transplants: they are not done; if necessary, the patients are referred to haematology and transplantation centres. Within the last 1.5 year, three such patients were referred to the Wrocław hospital: one with Nijmegen breakage syndrome, one with ataxia telangiectasia and one with SCID; two of the procedures were successful and the diagnosis process of the third one is pending.

Genetic diagnostics: the patients are referred to different hospitals in Poland and abroad, within the last 0.5 year around seven persons and currently one PI patient; after domestic tests the material was sent to Stockholm (the treatment is pending, currently there is no final diagnosis).

We are optimistic about the future

We are talking with Aleksandra Lewandowicz-Uszyńska, PhD, MD, Head of the Clinical Immunology and Paediatrics Ward at the Jerzy Gromkowski Hospital in Wrocław, about the treatment of immunodeficiencies in Lower Silesia and some other things

Interviewed by Małgorzata Łukasiewicz
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Doctor Uszyńska, last year, it was 10 years since I first had come to you to diagnose my child in primary immunodeficiencies. How the PI patient therapy has changed over time?

The progress in the PI therapy is substantial, particularly for children. Most importantly, not only the awareness of physicians, especially paediatricians, has improved but also that of the patients who now know that there is a branch of medicine dealing with primary immunodeficiencies. Unfortunately, we can still complain about that part of medicine that deals with PI in adults where the disease is diagnosed too rarely. The situation still is that these diseases are diagnosed in adults by paediatricians and that in Poland there are still blank pages in terms of access to hospitals which could deal with the diagnostics and treatment of adult patients with primary immunodeficiency diseases. However, comforting are the perspectives on implementing a separately funded therapeutic programme for adults, which will be an enormous progress in the therapy of the patients diagnosed with PI after the age of 18.

What is therefore your opinion of the functioning of the current Clinical Immunology and Paediatrics Ward where we are now?

For two years, we have been dealing in our ward with the full diagnostics and treatment of disorders originating in immunodeficiencies. Predominantly, the patients are children with primary humoral and cellular immune deficiencies, immunological defects which are the consequence of other chronic diseases and children with recurring infections. We refer them to other hospitals in Poland in order to exclude immune disorders. We are the only ward of such a type in Lower Silesia. Both the hospital and our ward are very modern, which allows us to create very comfortable conditions for the patients' stay and treatment.

A modern ward, that is,…

For example, one of the rooms located near the nurses station is separated especially for the patients receiving immunoglobulin preparations where they do not have any contact with other patients reducing the risk of transmitting a trivial infection for one person and a severe condition for another one, thus we improve their safety. Beside typical 2-3 rooms, the wards have three complex immunological rooms: these are private rooms with a decontamination area and en suite bathroom (that also has specialist disinfecting equipment) for the patients with severe immunodeficiencies who if necessary should be completely isolated so that they won't have any contact with the external world. Every patient room has a system of bactericidal lamps which can work in the patient's presence as they suck in the air and disinfect it inside the lamp, which ensures continuous sterility of the rooms and prevents the spreading of airborne infections. Apart from that, we have the decontamination system in place: it's a certain type of gas sterilisation of the rooms where beside typical disinfectants it effectively removes particularly onerous pathogens from various possible and difficult-to-reach surfaces in the rooms.

Thus, I take care and encourage hospital authorities so that the PI patients have the world-class diagnostics ensured, which is why the hospital acquired other most modern diagnostic equipment. At present, the hospital is in the process of testing and buying for us a specialist machine to perform immediate tests and obtain quick screening results which will be placed in the emergency room. With only a droplet of blood, the machine will help us to know the CRP level in the person tested and whether or not the person is infected with Streptococcus. As a result, it'll become a kind of microdiagnostics useful both for physicians and friendly for little patients. In addition to medical care for our little patients, the ward offers all the facilities for the children's parents and carers. They can stay and sleep with children in their rooms using the additional beds we prepared especially for them and beside the modern hospital kitchen there is a special social room (ward kitchen) with the equipment necessary to prepare meals within the hospital where they can eat as well.

Photo: Małgorzata Łukasiewicz

Both the hospital and our ward are very modern, which allows us to make very comfortable conditions for the patients' stay and treatment' - says Dr Uszyńska

You are Chairperson of the Organising Committee for the 15th Convention of the Polish Society of Experimental and Clinical Immunology in Wrocław which will be held on 26-28 June 2014. Tell us more about what you consider as possibilities for the development of the therapy in connection with the progress of research?

It's a great event both in Poland and in the world. We'll have big names, greatest authorities from all major hospitals in Poland such as clinical immunology, haematology, oncology and rheumatology, the cream of Polish immunology which in fact is an interdisciplinary area. The PI patients are not only the ones with infections but also with autoimmune disorders, thus there's always an increased risk of tumour to develop in them. Since the range of related disorders expands and the progress in this area is for them very important, we'll have specialists from foreign hospitals as well, from all around the world, the US, Sweden, the Netherlands and Germany. Moreover, we'll learn how the treatment and patient care look in the Czech Republic and Slovakia.

What other information will the convention participants learn?

The convention will hold sessions devoted to immunodeficiencies in children and adults. On the last day of the convention, there'll be a session devoted to the problems of the deficiencies from the perspective of Regional Consultants: what they did, what we expect and what we fight for so as to improve the life for the patients as well as the quality of work for the physicians. This will be accompanied by a film devoted to the PI patients, their experiences and problems entitled "This May Be Your Story". As a matter of fact, immunology concerns every medical speciality as every one of them relies on it. Thus, we're talking not only about primary immunodeficiencies but also about infections, wound healing, nutrition, in particular about nutritional treatment, and even about its effect on the immune system. Therefore, I'd like to draw the participants' attention at the convention to the sessions on organ transplants or the transplantation of bone marrow and stem cells which after all for some of the patients are the only chance to lead more or less normal life. As you can see, immunology is a discipline that develops dynamically and is ubiquitous, thus one needs to be open and reach for modern diagnostic and therapeutic methods as it opens up the path in this branch of medicine to completely new realities.

We often have to prick ourselves as well

Not only primary immunodeficiencies can be treated with self-administered subcutaneous therapy. Also patients suffering from type 1 diabetes give themselves their drug, insulin. We are discussing this disorder with Aleksandra Świerzy, diabetic patient

Interviewed by Adrian Górecki
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Diabetes: what kind of a disease is this?

Actually, we have to start by saying that diabetes and diabetes is not always the same. There is insulin-dependent type 1 diabetes and type 2 diabetes known as adult-onset diabetes. Type 1 diabetes is autoimmune disease. Its cause is the destruction by the patient's immune system the pancreatic beta cells that produce insulin.

This leads to the necessity to deliver it to the body from external sources since insulin is a hormone key which allows for absorbing carbohydrates to the body cells and thus for their proper function. In the absence of insulin, carbohydrates delivered to the body can't enter the cell which starves and they remain in excess in the blood; therefore, an untreated patient feels generally tired, has eye problems, and feels increased thirst and nausea.

The patients with type 1 diabetes also have, just like the PI patients, to take subcutaneous drugs. What kind of a drug is it and how is it given?

The patients with type 1 diabetes have to supplement insulin in the body by taking it subcutaneously. Currently, there are several types of insulin therapy, just like there are many insulin types. However, we have to notice what leap has been made within the last 20 years. At present, obviously in cooperation with their attending physicians the patients can choose by themselves such a model of insulin therapy that suits best their lifestyle, needs and financial situation. In fact, we can say that there are two basic treatment models, the multiple daily injections system or the insulin pump. Both models are to imitate as much as possible the functioning of the healthy pancreas.

It's much easier using the insulin pump since it offers the possibility to set the insulin dose flexibly. Having consulted the physician, the patient can set the base dose in the pump which is the foundation of the daily insulin demand. Beside the base dose, it's necessary to administer meal-related boluses.

These are insulin doses adjusted to the size and type of the meal the patient has. The multiple daily injections system involves supplying the body with insulin through injections that depend on the insulin type: once a day in long-acting insulin (which is an equivalent for the "base" in the pump), and with each subsequent meal another insulin administration, and thus another injection, is necessary.

How does the disease affect your daily life?

It's very much dependent on the stage my therapy is in. Unfortunately, the more you get into it, the more complicated it becomes.

Diabetes is a disease requiring a considerable involvement on a daily basis and not always there are favourable conditions for that: I tend to notice decreasing concentration, weakness and a general poorer form in the periods of worse glycaemic control. Once I almost lost contact with the reality; fortunately, my long habits I had established for many years prevailed. I try not to provoke such situations as I'm aware that this disease, usually little burdensome, can make my life difficult. Nevertheless, I'm convinced that out of the huge number of ills that man can have my disorder isn't so bad.

Photo: private files

Diabetes is a disease that requires a considerable dedication every day - says Aleksandra Świerzy

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