Srpsko lekarsko društvo
Serbian Medical Society

Sekcija za kliničku farmakologiju „dr Srđan Đani Marković"
Section of Clinical Pharmacology „dr Srđan Đani Marković"

Organizuju nacionalni kongres
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XV NEDELJA BOLNIČKE KLINIČKE FARMAKOLOGIJE

XV WEEK OF THE HOSPITAL CLINICAL PHARMACOLOGY

23. - 24. decembar 2023.
December 23th - 24th, 2023

ZBORNIK SAŽETAKA
BOOK OF ABSTRACTS
Beograd, 23. - 24. decembar 2023.

Izdavač
Sekcija za kliničku farmakologiju Srpskog lekarskog društva „dr Srđan Đani Marković", Džordža Vašingtona 19, Beograd, 2023

Za izdavača
Prof. dr Boris Milijašević

Glavni i odgovorni urednik
Prim. dr Dragana A. Kastratović - Maca

Urednici:
Prof. dr Boris Milijašević
Dr Srđan Z. Marković - Đani

Grafičko-tehničko uređenje
Prof. dr Boris Milijašević

Štampa
Sekcija za kliničku farmakologiju Srpskog lekarskog društva „dr Srđan Đani Marković", Džordža Vašlngtona 19, Beograd, 2023

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PROGRAM
PROGRAMME

XV NEDELJA BOLNIČKE KLINIČKE FARMAKOLOGIJE
XV WEEK OF THE HOSPITAL CLINICAL PHARMACOLOGYS

SUBOTA, 23. decembar 2023. / SATURDAY, 23th December 2023

10:00-10:30 **Petnaest godina rada Sekcije za kliničku farmakologiju „dr Srđan Đani Marković" Srpskog lekarskog društva**
Fifteen years of activity of the Section for Clinical Pharmacology „dr Srdjan Djani Marković" of the Serbian Medical Society
Dragana Maca A. Kastratović, Srdjan Djani Z. Marković, Slobodan M. Janković, Boris Ž. Milijašević, Radmila M. Veličković-Radovanović, Momir M. Mikov, Mira H. Vuković, Viktorija M. Dragojević-Simić, Branka M. Terzić, Biljana P. Radojević, Zoran M. Todorović, Aleksandar L. Rašković, Ivana Miličević, Snežana Panić, Olga J. Horvat, Dejana T. Ružić-Zečević, Ivana P. Timotijević-Marković

10:30-11:00 **Stiven – Džonsonov sindrom i toksična epidermalna nekroliza**
Stevens-Johnson syndrome and toxic epidermal necrolysis
Slobodan M. Janković

11:00-11:30 **Zdravi dobrovoljci u kliničkim studijama**
Healthy volunteers in clinical studies
Zoran M. Todorović

11:30-12:00 **Deprivacija empatije kao ekvivalent depresije**
Deprivation of empathy as the equivalent of depression
Ivana P. Timotijević, Mirjana M. Todorović, Katarina B. Crnić

12:00-12:30 **Novine u farmakoterapiji arterijske hipertenzije**
New drug targets for hypertension
Radmila M. Veličković-Radovanović

12:30-13:00 **Mogućnosti farmakoterapije negativnih simptoma shizofrenije**
Possibilities of pharmacotherapy of negative symptoms of schizophrenia
Žana B. Stanković

13:00-13:30 **Značaj transdermalnih formulacija opioidnih analgetika u farmakoterapiji bola**
Significance of transdermal formulations of opioid analgesics in pain pharmacotherapy
Dane A. Krtinić, Dragana S. Stokanović, Gorana G. Nedin Ranković, Ivan Z. Petković, Ana S. Cvetanović, Irena K. Conić, Aleksandar D. Stojanov, Hristina M. Jovanović, Hristina S. Trajković, Milan V. Čevrljaković

13:30-14:00 **Izazovi za primenu NOAK-a**
Challenges for NOACs use
Gorana Nedin-Ranković, Dane Krtinić, Dragana Stokanović, Hristina Trajković, Hristina Jovanović, Tomislav Kostić, Slobodan M. Janković

14:00-14:30 **Prednosti i nedostaci upotrebe biosimilara**
Advantages and disadvantages of biosimilars use
Dragana S. Stokanović, Valentina N. Nikolić, Gorana G. Nedin-Ranković, Dane A. Krtinić, Hristina M. Jovanović, Hristina S. Trajković

14:30-15:00 **Zajednička karika kliničke transfuziologije i kliničke farmakologije-patient blood management**
The point of intersection between clinical transfusiology and clinical pharmacology-patient blood management
Ljubinka I. Nikolić, Ljiljana M. Zdelar-Stojanović, Dragana N. Bakić-Oršit, Marija G. Matić, Dušanka M. Rajković, Ana D. Petrović

15:00-15:30 **Psihoterapija kao epigenetski "lek" - značaj i mogućnosti kombinovanja psihoterapije i psihofarmakoterapije**
Psychotherapy as an epigenetic "drug" - importance and possibilities of combining psychotherapy and psychopharmacotherapy
Isidora N. Samojlik, Ivana Vidaković

15:30-16:00 **Povezanost upotrebe antibiotika i infekcija izazvanih uzročnikom *Clostridioides difficile* koje su nastale u bolnici tercijernog nivoa zdravstvene zaštite**
Association between antibiotic use and hospital-onset *Clostridioides difficile* Infection in Tertiary Hospital
Viktorija M. Dragojević Simić, Nemanja K. Rančić, Vesna M. Begović Kuprešanin, Vesna D. Šuljagić

16:00-16:30 **Mesto antipsihotika III generacije u tretmanu mladih zavisnika**
III generation antipsychotics in the treatment of young addicts
Katarina B. Crnić, Mirjana M. Todorović, Ivana P. Timotijević

16:30-17:00 **Povezanost serumskih koncentracija vitamina D3 sa depresijom kod pacijenata sa sarkoidozom**
Association of serum vitamin D3 concentrations with depression in patients with sarcoidosis
Mira H. Vuković, Branislav S. Gvozdenović

17:00-17:30 **Primena 2D EPR imidžinga za ispitivanje transporta nesteroidnih antiinflamatornih lekova intergrisanih u lipozome kroz kožu**
2D EPR imagingfor assessingthe topial delivery of liposome-integrated nonsteroidal anti-inflammatory drugs
Đura J. Nakarada, Srđan Z. Marković, Dragana A. Kastratović, Miloš D. Mojović

17:30-18:00 **Značaj prikupljanja neželjenih dejstava novih lekova**
The importance of collecting adverse effects of new drugs
Dragana A. Kastratović, Srdjan Z. Marković, Miloš M. Mojović, Djura J. Nakarada

NEDELJA, 24. decembar 2023. / SUNDAY, 24th December 2023

10:00-10:30 **Faktori povezani sa kontrolom krvnog pritiska u sredinama sa različitim nivoima zdravstvene zaštite u Srbiji**
Identifying factors associated with blood pressure control in settings with different level of healtcare in Serbia
Olga J Horvat, Tinde I Halgato

10:30-11:00 **Nove psihoaktivne supstance u Vojvodini**
New psychoactive substances in Vojvodina
Mijatović Jovin Vesna, Živanović Dejan, Miljković Ana, Kelečević Igor

11:00-11:30 **Kognitivni simptomi u depresiji i sch - novi terapijski izazovi**
Cognitive symptoms in depression and sch - therapeutic challenges
Mirjana M. Todorović, Ivana P. Timotijević-Marković, Katarina B. Crnić

11:30-12:00 **Potrošnja hipolipemika u Srbiji u periodu 2011-2020. godine**
Consumption of hypolipidemic drugs in serbia in 2011-2020
Boris Ž. Milijašević, Jovana R. Lajčak, Nataša Z. Tomić, Dragana S. Milijašević, Radmila N. Popović, Zdenko S. Tomić

12:00-12:30 **Poređenje parametara terapijskog monitoringa takrolimusa u populaciji pacijenata sa transplantiranim bubregom u zavisnosti da li uzimaju lek jednom ili dva puta na dan**
The comparison of tacrolimus therapeutic monitoring parameters in renal transplant recipients depending od the frequency of oral intake of drug: once or twice daily
Nemanja K. Rančić, Neven N. Vavić, Katarina S. Obrenčević, Milorad M. Radojević, Jelena V. Tadić, Viktorija M. Dragojević Simić

12:30-13:00 **Farmakološki efekti ekstrakta rogača kod laboratorijskih životinja sa indukovanim metaboličkim sindromom**
Pharmacological effects of carob extract in laboratory animals with induced metabolic syndrome
Aleksandar L. Rašković, Nikola B. Martić, Nebojša P. Stilinović, Ana D. Tomas Petrović, Bojana Andrejić Višnjić, Milana Bosanac, Jana Zahorec, Branimir Pavlić, Dragana Šoronja Simović, Zita Šereš

16:30-17:00 **Diskusija i zaključci**
Discussion and Conclusions
Dragana A. Maca Kastratović, Slobodan M. Janković, Viktorija M. Dragojević Simić, Aleksandar L. Rašković, Radmila M. Veličković Radovanović, Boris Ž. Milijašević

POSTERI
POSTER SESSION

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Determination of the anaerobic threshold by the direct and indirect measurement of AT with and without prior administration of the warm up protocol in female athletes
Ivana B. Mladenović Ćirić

Poster 2 **Pregled prijavljenih neželjenih događaja nakon imunizacije vakcinama protiv bolesti COVID-19 tokom 2021. i 2022. godine**
Overview of reported adverse events after immunization with vaccines against the disease COVID-19 in 2021 and 2022
Hristina S. Trajković, Dragana S. Stokanović, Gorana G. Nedin-Ranković, Dane A. Krtinić, Hristina M. Jovanović, Stefan S. Stojanović, Nikola Z. Stojanović, Jelena N. Stanković, Aleksandar G. Marković

Poster 3 **Problem polifarmacije kod pacijenata starijeg životnog doba**
The problem of polypharmacy in elderly patients
Ana L. Zubić, Milica M. Paut Kusturica, Nebojša P. Stilinović, Nebojša M. Pavlović, Ana D. Tomas Petrović

Poster 4 **Aktuelnosti u polifarmaciji i depreskripciji**
Current conceptsin polypharmacy and deprescribing
Ana L. Zubić, Milica M. Paut Kusturica, Nebojša P. Stilinović, Nebojša M. Pavlović, Ana D. Tomas Petrović

Poster 5 **Slučaj anafilaktičkog šoka nakon ujeda pčela**
A case of anaphylactic shock due to a bee sting
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Poster 6 **Adherencija i savremeni pristup tretmanu dijabetesa melitusa tipa 2**
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Poster 7 **Farmakokinetika nifedipina formulisanog kao čvrsta disperzija sa polivinilpirolidonom**
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Poster 8 **Efekti COVID-19 na pacijente sa dijabetesom u Srbiji: studija preseka**
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Poster 11 **Potrošnja preparata gvožđa u terapiji sideropenijske anemije**
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ZBORNIK SAŽETAKA

BOOK OF ABSTRACTS

HOSPITAL PHARMACOLOGY
International Multidisciplinary Journal

Petnaest godina rada Sekcije za kliničku farmakologiju „dr Srđan Đani Marković" Srpskog lekarskog društva

Dragana Maca A. Kastratović[1a], Srdjan Z. Marković[1a], Slobodan M. Janković[1b], Boris Ž. Milijašević[1c], Radmila M. Veličković-Radovanović[1d], Momir M. Mikov[1c], Mira H. Vuković[1e], Branka M. Terzić[1a], Viktorija M. Dragojević-Simić[1a], Biljana P. Radojević[1a], Zoran M. Todorović[1a], Aleksandar L. Rašković[1c], Ivana Miličević[1f], Snežana Panić[1g], Olga J. Horvat[1c], Dejana T. Ružić-Zečević[1b], Ivana P. Timotijević-Marković[1a]

[1] Sekcija za Kliničku farmakologiju „dr Srđan Đani Marković" Srpskog lekarskog društva: [a]Beograd, [b]Kragujevac, [c]Novi Sad, [d]Niš, [e]Valjevo, [f]Užice, [g]Kruševac

Sekcija za kliničku farmakologiju Srpskog lekarskog društva (SKFSLD) osnovana je 19. Februara 2009, sa ciljem da implementira i unapredi bolničku primenu znanja kliničke farmakologije u sve medicinske oblasti.

Na predlog Predsedništva i Naučnog odbora SKFSLD uz jednoglasnu podrsku Predsedništva SLD ustanovljena je godisnja nagrada za primenjenu bolničku farmakologiju „dr Srđan Đani Marković". Nagrada je jednoglasnom odlukom Predsedništva i Naučnog odbora SKFSLD dodeljena za 2020 Dr Srdjanu Djaniju Markoviću - našem Sekretaru, istraživaču lekaru, ECRIN correspodentu i monitoru, idejnom ocu i članu Uređivačkog odbora stručno - naučnog časopisa Hospital Pharmacology – International Multidisciplinary Journal. Za 2021 godinu godisnja nagrada za primenjenu bolničku farmakologiju „dr Srđan Đani Marković" je jednoglasnom odlukom Predsedništva i Naučnog odbora SKFSLD dodeljena prof prim dr Slobodanu Jankoviću – našem Predsedniku naučnog odbora SKFSLD, članu Uređivačkog stručno - naučnog časopisa Hospital Pharmacology – International Multidisciplinary Journal, osnivač i rukovodilac bolničke kliničke farmakologije kliničkog centra Kragujevac, rukovodiocu i istraživaču u više od 100 međunarodnih i nacionalnih naučnih projekata, autoru više od 600 naučnih radova i visokog ranga citiranosti, mentoru velikog broja doktorskih disertacija. Za 2022 godinu nagrada za primenjenu bolničku farmakologiju „dr Srđan Đani Marković" je jednoglasnom odlukom Predsedništva i Naučnog odbora SKFSLD dodeljena prof dr Borisu Milijaševiću – našem sekretaru Sekcije, izvršnom uredniku stručno-naučnog časopisa Hospital Pharmacology – International Multidisciplinary Journal, rukovodiocu i istraživaču u projektima farmakoekonomije i farmakogenetike, kolegi koji postojano doprinosi razvoju bolničke kliničke farmakologije kroz izuzetan pedagoški rad sa studentima.

Tokom ovih 14 godina članovi SKF "Dr Srdjan Đani Marković" radili su veoma vredno kroz:

1. Kontinuiranu medicinsku edukaciju. Kursevi su akreditvani kao Prva kategorija kod Zdravstvenog saveta Srbije, sto je slušaocima donelo maksimalan broj poena u Lekarskoj komori Srbije za licencu za rad. Kursevi su namenjeni lekarima, farmaceutima, ekolozima, biohemičarima, tehničarima.
2. Simpozijume Nedelja Bolnićke kliničke farmakologije I-XIV. Tema Simpozijuma je Integracija nauke i prakse, učesnici izlažu svoje radove kroz usmene prezentacije, postere, okrugle stolove, komercijalna predavanja, 2020-22 on line. Svake godine učestvuje oko 100 lekara svih medicinskih specijalnosti, farmaceuta, biohemičara. Gosti predavači bile su kolege iz Francuske, USA, Nemačke, Grčke, Bugarske, Austrije.
3. Predavanja po pozivu u saradnji sa Akademijom medicinskih nauka, održali su: Prof Dr David T. W. Wong (USA), Primarius Dragana Maca Kastratović, Prof Dr Edoardo Spina (Italy), Prof Dr Jacques Demotes Mainard (France), Prof Pharm Christine Kubiak (France), Emil Miltchev Gatchev (Bulgaria), Vangelis G. Manolopoulos (Greece), Markus Zeitlinger (Austria), itd. Tokom 2022 nije bilo predavanja po pozivu iz inostranstva. Predavači po pozivu iz Republike Srbije su redovni učesnici Simpozijuma NBKF.
4. Naučno-stručni časopis pokrenuli smo 2014 na predlog Dr Srdjana Djanija Markovića, kao online, open access, free full text Hospital Pharmacology International Multidisciplinary Journal, dostupan na

http://www.hophonline.org.
5. Uspesi. Tokom ovih 10 godina svi lekari SKFSLD postizali su značajne uspehe na radnim mestima, kroz doktorske disertacije, akademske/profesionalne pozicije. Profesori Momir Mikov, Radmila Veličković-Radivojević, Ivana Timotijević-Marković, Mihajlo Jakovljević primljeni su u AMNSLD. Profesor Primarijus Slobodan Jankovic postao je clan Akademije medicinskih nauka BIH. Nagradu za izuzetna ostvarenja u bolničkoj farmakologiji dobili su Dr Srdjan Djani Marković za 2020, Prof Prim dr Slobodan Janković za 2021 godinu.
6. The Pharmacology International, časopis IUPHAR-a, više puta je objavljivao tekstove o radu SKFSLD.
7. Ostvarenje razvoja kliničke farmakologije i dalje će ići kroz KME, podršku mlađim lekarima da uče kliničku farmakologiju i primene znanja u bolnicama. Podstičemo kolege da svoje stručno-naučne rezultate publikuju u stručno-naučnom časopisu Hospital Pharmacology – International Multidisciplinary Journal. Starije kolege razvijaće i nadalje nacionalnu i međunarodnu saradnju u oblasti primenjene nauke, sa naglaskom na uključivanje mlađih kolega u multidisciplinarne timove.

Fifteen years of activity of the Section for Clinical Pharmacology „dr Srdjan Djani Marković" of the Serbian Medical Society

Dragana Maca A. Kastratović[1a], Srdjan Z. Marković[1a], Slobodan M. Janković[1b], Boris Ž. Milijašević[1c], Radmila M. Veličković-Radovanović[1d], Momir M. Mikov[1c], Mira H. Vuković[1e], Branka M. Terzić[1a], Viktorija M. Dragojević-Simić[1a], Biljana P. Radojević[1a], Zoran M. Todorović[1a], Aleksandar L. Rašković[1c], Ivana Miličević[1f], Snežana Panić[1g], Olga J. Horvat[1c], Dejana T. Ružić-Zečević[1b], Ivana P. Timotijević-Marković[1a]

[1] Section for Clinical Pharmacology „dr Srđan Đani Marković" of the Serbian Medical Society: [a]Belgrade, [b]Kragujevac, [c]Novi Sad, [d]Niš, [e]Valjevo, [f]Užice, [g]Kruševac

The Section for Clinical Pharmacology "Dr Srdjan Djani Marković" of the Serbian Medical Association was established on February 19, 2009, with the aim of implementing and improving the hospital application of knowledge of clinical pharmacology in all medical fields.

At the suggestion of the Presidency and the Scientific Committee of the CCPSMS, with the unanimous support of the Presidency of the SMS, the annual award for applied hospital pharmacology „dr Srdjan Djani Marković" was established. The award was given by a unanimous decision of the Presidency and the Scientific Committee of SCPSMS for 2020 to Dr Srdjan Djani Markovic - our Secretary, researcher, doctor, ECRIN correspondent and monitor, the father of the launch and a member of the Editorial Board of the scientific journal Hospital Pharmacology - International Multidisciplinary Journal (www.hophonline.org). For the year 2021, the annual award "Dr Srdjan Djani Marković" was awarded by a unanimous decision of the Presidency and the Scientific Board of the SKFSLD to Prof. Dr. Slobodan Janković - our President of the Scientific Board, a member of the editorial professional and scientific journal Hospital Pharmacology - International Multidisciplinary Journal, founder and head of Cenre for hospital clinical pharmacology of the University Clinical Center Kragujevac, principal investigator and researcher in more than 100 international and national scientific projects, author of more than 600 scientific papers with high citation rank, mentor of a large number of doctoral dissertations. For the year 2022, the award for Applied Hospital Pharmacology "Dr. Srđan Đani Marković" was awarded by a unanimous decision of the Presidency and the Scientific Board of SKFSLD to Prof. Borisu Milijašević MD, executive editor of the scientific journal Hospital Pharmacology - International Multidisciplinary Journal, manager and researcher in pharmacoeconomics and pharmacogenetics projects, a colleague who constantly contributes to the development of hospital clinical pharmacology through exceptional pedagogical work with students.

During these 14 years, the members of SCPSMA have worked very hard through:

1. Continuous medical education. The courses were accredited as the first category with the Health Council of Serbia, which brought the students the maximum number of points in the Medical Chamber of Serbia for a work license. The courses are intended for doctors, pharmacists, biochemists, technicians.
2. Symposiums Week of Hospital Clinical Pharmacology I-XIV. The topic of the Symposium is the inte gration of Science and Practice, participants present their works through oral presentations, posters, round tables, commercial lectures, 2020 on line. About 100 doctors of all medical specialties, pharmacists and biochemists participate every year. Guest lecturers were colleagues from France, USA, Germany, Greece, Bulgaria, Austria.
3. Lectures by invitation in cooperation with the Academy of Medical Sciences, were held by: Prof. Dr. David TW Wong (USA), Primarius Dragana Maca Kastratović, Prof. Dr. Edoardo Spina (Italy), Prof. Dr. Jacques Demotes Mainard (France), Prof. Pharm Christine Kubiak (France), Emil Miltchev Gatchev (Bulgaria), Vangelis G. Manolopoulos (Greece), Markus Zeitlinger (Austria), etc. During 2022, there were no lectures by invitation from abroad. Lecturers invited from the Republic of Serbia are participants

in the Symposium.
4. Based on the idea of Dr Srdjan Djani Markovic the scientific-professional journal SCPSMS was launched in 2014, as an online, open access, free full text Hospital Pharmacology International Multidisciplinary Journal, available at http://www.hophonline.org.
5. Successes. During these 10 years, all SCPSMA physicians have achieved significant success in the workplace, through doctoral dissertations, academic / professional positions. Professors Momir Mikov, Radmila Veličković Radivojević, Ivana Timotijević Marković, Mihajlo Jakovljević were admitted to the AMNSLD. Professor Primarius Slobodan Jankovic became a member of the Academy of Medical Sciences of BiH. The award for outstanding achievements in hospital pharmacology was awarded to Dr Srdjan Djani Marković for 2020, Prof. Prim. Dr Slobodan Janković for 2021.
6. The Pharmacology International, a journal of IUPHAR, has repeatedly published articles on the work of SCP "Dr Srdjan Djani Marković" Serbian Medical Society.
7. The realization of the development of clinical pharmacology will continue to go through KME, supporting junior doctors to learn clinical pharmacology and applying knowledge in hospitals. We encourage colleagues to publish their professional-scientific results in the professional-scientific journal Hospital Pharmacology - International Multidisciplinary Journal. Senior colleagues will continue to develop national and international cooperation in the field of applied science, with an emphasis on the inclusion of younger colleagues in multidisciplinary teams.

Antibiotska terapija bolničke pneumonije izazvane multirezistentnim uzročnicima

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Stiven-Džonsonov sindrom (engl. Stevens-Johnson syndrome - SJS) i toksična epidermalna nekroliza (TEN) su teške mukokutane reakcije, najčešće izazvane lekovima, koje karakteriše velika nekroza i odvajanje epidermisa. Slučajevi sa manje od 10 procenata zahvaćenosti kože klasifikuju se kao Stiven-Džonsonov sindrom; oni sa 30 ili više procenata uključenosti se klasifikuju kao TEN, a slučajevi sa 10 do 30 procenata uključenosti smatraju se preklapanjem Stiven-Džonsonovog sindroma i TEN. Incidencija je oko 2 slučaja na 1,000,000 stanovnika, a mortalitet je veoma visok: SJS oko 4.8%, a TEN oko 14.8%

Najčešći lekovi – uzročnici su: aromatični antiepileptici (karbamazepin, lamotrigin, fenitoin, fenobarbital), valproat, alopurinol, NSAIL, antibiotici (kotrimoksazol, aminopenicilini, tetraciklini, cefalosporini), pembrolizumab i nivolumab. Pre promena na koži pacijenti par dana osećaju slabost, imaju znake respiratorne infekcije i povišenu temperature. Na koži najpre nastaje crvenilo u obliku nepotpune mete, sa bledilom u sredini, da bi se zatim pojavile bule koje prskaju i zaostaju erozije prvo na grudnom košu, pa onda na ekstremitetima. Na sluzokožama se javljaju erozije. SJS/TEN spada u kasnu preosetljivost, glavnu ulogu imaju T-lilmfociti. Specifična terapija za sada ne postoji; koriste se kortikosteroidi, kombinacija kortikosteroida sa imunoglobulinima, ciklosporin, plazmafereza, etarnecept i infliksimab, ali nema dokaza da je takva terapija efikasna.

Antibiotic therapy of hospital pneumonia caused by multidrug-resistant bacteria

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Stevens-Johnson syndrome (Stevens-Johnson syndrome - SJS) and toxic epidermal necrolysis (TEN) are severe mucocutaneous reactions, most often caused by drugs, characterized by extensive necrosis and detachment of the epidermis. Cases with less than 10 percent skin involvement are classified as Stevens-Johnson syndrome; those with 30 percent or more involvement are classified as TEN, and cases with 10 to 30 percent involvement are considered overlapping Stevens-Johnson syndrome and TEN. The incidence is about 2 cases per 1,000,000 inhabitants, and the mortality is very high: SJS about 4.8%, and TEN about 14.8%

The most common causative drugs are: aromatic antiepileptics (carbamazepine, lamotrigine, phenytoin, phenobarbital), valproate, allopurinol, NSAIDs, antibiotics (cotrimoxazole, aminopenicillins, tetracyclines, cephalosporins), pembrolizumab and nivolumab. Before the changes on the skin, patients feel weak for a few days, have signs of respiratory infection and elevated temperature. Redness first appears on the skin in the form of an incomplete target, with pallor in the middle, then blisters appear that splash and erosions remain, first on the chest, and then on the extremities. Erosions appear on the mucous membranes. SJS/TEN belongs to delayed hypersensitivity, the main role is played by T-lymphocytes. Specific therapy does not exist for now; corticosteroids, a combination of corticosteroids with immunoglobulins, cyclosporine, plasmapheresis, etanercept and infliximab are all used, but there is no evidence that such therapy is effective.

Zdravi dobrovoljci u kliničkim studijama

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Prva primena novih terapijskih sredstava na ljudima sprovodi se na malom broju ispitanika, obično zdravih dobrovoljaca. Zadatak takvih studija je prvenstveno da se ispita koliko je lek pogodan za kliničku primenu bez stavljanja u kontekst specifične indikacije. Sprovodi se procena podnošljivosti, kliničke farmakokinetike i farmakodinamije, obično na odeljenjima kliničke farmakologije koja su opremljena odgovarajućim brojem postelja, imaju posebno edukovani kadar i povezane su sa jedinicama intenzivnog lečenja. Rane studije na zdravim dobrovoljcima mogu se podeliti na ispitivanja faze 0 i 1. Definicija zdravog dobrovoljca uzima u obzir zdravstveni status (odsustvo poznatog oboljenja koje je u vezi sa planiranom studijom), morfološke karakteristike i mentalnu sposobnost da potpiše informisani pristanak. Takođe, definisani su i kriterijumi za obustavu studije na zdravim dobrovoljcima i publikovane odgovarajuće smernice (EMEA/CHMP/SWP/28367/07 Rev. 1, 20 July 2017). Potencijalna šteta za zdrave dobrovoljce koji učestvuju u ranoj fazi kliničkog razvoja leka može da bude u vidu fizičkog oštećenja (subjektivnog ili objektivnog) i ostalih vidova štete (etički, psihološki, socijalni, ekonomski, pravni i vid ugrožavanja familije ispitanika, recimo kao rezultat genetskih testiranja). Validnost takvih studija se obezbeđuje promovisanjem 4R principa.

Healthy volunteers in clinical studies

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The first-in-human studies are conducted on a few subjects, usually healthy volunteers. Such studies aim to examine how suitable the drug is for clinical use without putting it in the context of a specific indication. Assessment of tolerability, clinical pharmacokinetics, and pharmacodynamics is carried out, usually in departments of clinical pharmacology that are equipped with an appropriate number of beds, have specially trained staff, and are connected to intensive care units. Early studies on healthy volunteers can be divided into phase 0 and 1 trials. The definition of a healthy volunteer considers health status (absence of known disease related to the planned study), morphological characteristics, and mental capacity to sign an informed consent. Also, the criteria for stopping the study on healthy volunteers were defined, and the corresponding guidelines were published (EMEA/CHMP/SWP/28367/07 Rev. 1, 20 July 2017). Potential harm to healthy volunteers who participate in the early phase of clinical drug development can be in the form of physical harm (subjective or objective) and other types of harm (ethical, psychological, social, economic, legal, and threat to the family members, for example as a result of genetic testing). The validity of such studies is ensured by promoting the 4Rs.

Deprivacija empatije kao ekvivalent depresije

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Emotivna ekspresija u zdravlju i bolesti uslovljena je mrežom složenih faktora psihološkog i biološkog razvoja. Ne može se negirati dinamična povezanost feed-back mehanizama psiholoških ekspresija i biološke osnove.

Empatija prestavlja posebno intrigativan fenomen koji od nedavno ima značajno mesto u sagledavanju psihijatrijskih fenomena, dijagnostici I lečenju.

Bihevioralne manifestacije, u kontinuumu od funkcionalnosti do patologije i psihopatološke simptomatologije, imaju osnova u strukturama CNS (reinforsment, pozitivna/negativna uslovljavanja), transmiterskim sistemima, receptorskoj dinamici (stimulacija/blokada) na pre i post sinaptičkoj membrani do delikatnih, kaskadnih intraneuronskih prcesa.

Do skora se funkcija ne samo serotonina nego i ostalih transmitera posmatrala kroz definisane uloge neurona u određenim strukturama koje su bile odgovorne za afektivne ili kognitivne poremećaje. Istovremeno, procesi u CNS posredno se prelamaju na somatske implikacije u zdravlju i bolesti.

Složenost funkcionisanja ključnih struktura kao što su amigdala, prefrontalni korteks i hipokampus čija se uloga menja zavisno od spoljašnjih impulsa (input) koji se primaju i od impulsa koji se odašilju ka releventnim oblastima telesnih struktura, predstavlja drugi važan aspekt ekspresije u svim modalitetima psihijatrije. To podrazumeva da transmiteri i posebno serotonin imaju mnogo šire dejstvo koje se ispoljava ne samo u ključnim strukturama CNS već dinmikom složenih mehanizama.

Empatija opšte prisutno ljudsko iskustvu ukoliko je deprivirana brojnim uzrocima često je uzrok ali i evidentni pokazatelj depresivne dekompenzacije.

Deprivation of empathy as the equivalent of depression

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Emotional expression in health and illness is conditioned by a network of complex factors psychological and biological development. The dynamic connection cannot be denied bz the feed-back mechanisms of psychological expressions and biological basis.

Empathy represents a particularly intriguing phenomenon that has recently had a significant place in observation of psychiatric phenomena, diagnosis and treatment.

Behavioral manifestations, in the continuum from functionality to pathology and psychopathological symptomatology, have a basis in CNS structures (reinforcement, positive/negative conditioning), transmitter systems, receptor dynamics (stimulation/blockade) on the pre- and post-synaptic membrane to delicate, cascading ones intraneuronal processes. Until recently, the function of not only serotonin but also other transmitters was observed through defined roles of neurons in certain structures that were responsible for affective or cognitive disorders. At the same time, the processes in the CNS are indirectly reflected on somatic implications in health and disease.

The complexity of the functioning of key structures such as the amygdala, prefrontal cortex and the hippocampus, whose role changes depending on the external impulses (input) that are received i from the impulses that are transmitted to the relevant areas of the body structures, represents the second an important aspect of expression in all modalities of psychiatry. This implies that the transmitters and serotonin in particular have a much broader effect that manifests itself not only in the key ones structures of the CNS, but the dynamics of complex mechanisms.

Empathy, generally present in the human experience, if it is deprived due to numerous causes is the cause but also an evident indicator of depressive decompensation.

Novine u farmakoterapiji arterijske hipertenzije

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Arterijska hipertenzija je glavni faktor nastanka kardiovaskularnih oboljenja (KVO) i hronične bolesti bubrega (HBB). Uprkos mnoštvu dostupnih terapijskih opcija značajan procenat pacijenata ne postiže ciljne vrednosti krvnog pritiska. Terapija neregulisane hipertenzije može se delimično unaprediti razvojem novih lekova koji poboljšavaju ishode lečenja i sprečavaju nastanak komplikacija. Meta analiza 45 placebo kontrolisanih studija je pokazala da sGLT2 inhibitori smanjuju srednji arterijski i noćni krvni pritisak i doprinose usporavanju progresije srčane i HBB. Antagonisti endotelinskih receptora (darusentan, aprocitentan) značajno smanjuju krvni pritisak u toku 24h. Novi nesteroidni. selektivni antagonisti aldosterona (finerenon, esakseron) su pored antihipertenzivnog dejstva efikasni u prevenciji endotelne disfunkcije i vaskularne rezistencije. Finerenon smanjuje rizik od bubrežne slabosti, usporava progresiju HBB, KV smrti, nefatalnog srčanog udara i hospitalizacije od srčane insuficijencije kod pacijenata sa HBB i dijabetesom tipa 2. Esakseren značajno smanjuje krvni pritisak i albuminuriju kod bolesnika sa dijabetesom i HBB. Upotrebom sGLT2 i novim nesteroidnim, antagonistima aldosterona započeta je nova era u farmakološkom lečenju dijabetesne bolesti bubrega, čime se usporava progresija HBB i smanjuje KV morbiditet i smrtnost. Veliki broj studija je potvrdio da regulisanje crevne mikrobiote pacijenata može biti efikasna strategija za lečenje hipertenzije.

U budućnosti se očekuje primena novih klasa antihipertenzivnih lekova (inhibitori vazopeptidaza, nesteroidni, selektivni inhibitori sinteze aldosterona i novi MRA, agonisti natriuretskog peptida A i vazoaktivnog intestinalnog peptidnog receptora, inhibitori aminopeptidaze A) u cilju optimalne regulacije krvnog pritiska i prevencije komplikacija arterijske hipertenzije.

New drug targets for hypertension

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Hypertension is a major contributing factor for cardiovascular disease (CVD) and chronic kidney disease (CKD) worldwide, that can increase the risks of comorbidities. However, in the population of resistant hypertension, blood pressure (BP) is difficult to control effectively. New therapeutic targets and treatments are needed to uncovered and exploited to control hypertension and its comorbidities. There is now a new era in the pharmacological treatment of hypertension. In the past, classical drug targets, such as the aldosterone receptor, aldosterone synthase, and ACE2/angiotensin 1–7/Mas receptor axis, have been investigated. A landmark trials consistently showed the benefits of SGLT-2 inhibitors on kidney and cardiovascular outcomes in CKD patients, irrespective of the presence or absence of Type 2 diabetes (T2D). Finerenone is a novel, selective, nonsteroidal mineralocorticoid receptor antagonist (MRA) that safely and effectively improved cardiorenal outcomes. The new nonsteroidal MRAs esaxerenone is able to effectively reduce BP, and finerenone has a protective effect on cardiovascular and kidney function in patients with T2DM and CKD. Therefore, nonsteroidal MRAs may be a novel and optimal option of guide line-compliant therapy for these patients. Recently, vaccines and drugs targeting the gastrointestinal microbiome, which represent drug classes, have also been investigated for the management of blood pressure.

Mogućnosti farmakoterapije negativnih simptoma shizofrenije

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Shizofrenija (SCH) je neurodegenerativni poremećaj koji se javlja kod oko 1% opšte populacije. Klinička slika SCH obuhvata pozitivne simptome (PS) (halucinacije, deluzije), kognitivne simptome i negativne simptome (NS) (zaravnjenost afekta, alogija, avolicija, asocijalnost, anhedonija).

NS se dele na primarne (PNS)("simptomi deficita") i sekundarne negativne simptome (SNS), koji su povezani sa terapijom antipsihoticima (sedacija, ekstrapiramidni sindrom), psihijatrijskim faktorima (PS, anksioznost, depresija, sloupotreba psihoaktivnih supstanci), emocionalnom deprivacijom i somatskim komorbiditetom.

Perzistentni negativni simptomi (PNS) (alternativni pristup u kontekstu kliničkih studija) obuhvataju PNS i SNS (one koji su rezistentni na uobičajene tretmane za SNS). Pacijenti sa NS imaju lošiji odgovor na terapiju, kao i tok i ishod bolesti.

Atipični antipsihotici (AA) su efikasniji od antipsihotika prve generacije u terapiji kognitivnih i NS SCH, a imaju i povoljniji profil podnošljivosti. AA se znatno razlikuju prema profilu neželjenih efekata (akatizija, sedacija, dobijanje na težini, elevacija prolaktina, produženje QTC).

Prema rezultatima kliničkih studija, antipsihotici koji su pokazali efikasnost u lečenju NS SCH su amisulprid (vezuje se selektivno za D2 i D3 receptore u limbičkom sistemu; niske doze blokiraju presinaptičke D2 i D3 autoreceptore pospešujući dopaminergički prenos, dok veće doze blokiraju postsinaptičke receptore, inhibirajući dopaminergičku hiperaktivnost), brekspiprazol (u poređenju sa aripiprazolom ima manju aktivnost na D2 receptorima, jači antagonizam za 5HT2A receptore i afinitet za transporter norepinefrina), cariprazin (D2 i D3 parcijalni agonist), asenapin (visok afinitet i specifičnost brojnih dopaminskih, serotoninskih, noradrenalinskih i histaminskih podtipova receptora), pimavanserin (5HT2A inverzni agonist/antagonist i manje potentni inverzni agonist/antagonist 5HT2C receptora i sigma 1 receptora), roluperidon (antagonist 5HT2A, sigma 2 i alfa 1A receptora).

Potrebno je usavršiti psihometrijske instrumente za merenje NS, ispitati efikasnost lekova sa novim mehanizmom dejstva i prediktore odgovora na terapiju. Neophodna je primena individualizovanog pristupa tretmanu, kao i racionalne polifarmakoterapije.

Possibilities of pharmacotherapy of negative symptoms of schizophrenia

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Schizophrenia (SCH) is a neurodegenerative disorder that occurs in about 1% of the general population. The clinical picture of SCH includes positive symptoms (PS) (hallucinations, delusions), cognitive symptoms and negative symptoms (NS) (affect flatness, alogia, avolition, asociality, anhedonia).

NS are divided into primary (PNS) ("deficit symptoms") and secondary negative symptoms (SNS), which are associated with antipsychotic therapy (sedation, extrapyramidal syndrome), psychiatric factors (PS, anxiety, depression, psychoactive substance abuse), emotional deprivation and somatic comorbidity.

Persistent negative symptoms (an alternative approach in the context of clinical trials) include PNS and SNS (those resistant to conventional treatments for SNS). Patients with NS have a worse response to therapy, as well as the course and outcome of the disease.

Atypical antipsychotics (AA) are more effective than first-generation antipsychotics in the treatment of cognitive and NS of SCH, and have a more favorable profile of tolerability. AA varies considerably according to the profile of unwanted effects (akathisia, sedation, weight gain, prolactin elevation, QTC prolongation).

According to the results of clinical studies, antipsychotics which demonstrated efficacy in the treatment of NS of SCH are amisulpride (binds selectively to D2 and D3 receptors in the limbic system; low doses block presynaptic D2 and D3 autoreceptors enhancing dopaminergic transmission, whereas higher doses block postsynaptic receptors, thus inhibiting dopaminergic hyperactivity), brexpiprazole (compared to aripiprazole has lower activity at the D2 receptors, stronger antagonism at 5HT2A receptors and affinity for norepinephrine transporter), cariprazine (D2 and D3 partial agonist), asenapine (high affinity and specificity to numerous dopamine, serotonin, noradrenaline and histamine receptor subtypes), pimavanserin (5HT2A inverse agonist/antagonist and less potent inverse agonist/antagonist at 5HT2C reeptors and sigma 1 receptors), roluperidone (5HT2A, sigma-2 and alpha 1A receptor antagonist).

It is necessary to improve psychometric instruments for measuring NS, examine the effectiveness of drugs with a new mechanism of action and predictors of response to therapy, use of individualized approach to treatment, as well as rational polypharmacotherapy.

Značaj transdermalnih formulacija opioidnih analgetika u farmakoterapiji bola

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Transdermalne formulacije zauzimaju bitno mesto u opioidnoj farmakoterapiji bola, naročito kod onkoloških pacijenata u terminalnim fazama bolesti. Takodje, specifične populacije pacijenata zahtevaju ovakav terapijski pristup opioidoterapije. Ove farmaceutske formulacije su prilagodjene i bezbedne za pacijente u malignoj kaheksiji i sa nemogućnošću gutanja, za pacijente koji boluju od hronične bubrežne i hepatične insuficijencije kao i u pedijatrijskoj populaciji pacijenata. U svetu postoje dve formulacije liposolubilnih opijata u obliku transdermalnih formulacija, a to su fentanil i buprenorfin. U Srbiji su registrovani fentanilski transdermalni farmaceutski oblici. Većina fentanilskih transdermalnih flastera su tipa matriksa I sadrže polimerni matriks sa fentanilom, adheziv, potporni sloj i zaštitni film. Kod transdermalnih flastera matriksnog tipa fentanil je dispergovan u hidrofilnom ili lipofilnom polimeru ili adhezivu, koji kontroliše njegovo oslobađanje. Transdermalni flasteri mogu da imaju rezervoar polučvrste konzistencije koji sa jedne strane ima poroznu membranu koja kontroliše oslobađanje i difuziju lekovite supstance iz celokupne formulacije. Brzina oslobađanja opioida iz rezervoara zavisi od: poroznosti, permeabilnosti i debljine membrane, i eventualno sastava i debljine sloja adheziva. Transdermalni flasteri matriksnog tipa su jednostavnijeg dizajna i obično su tanji od onih sa rezervoarom, pa su estetski prihvatljiviji, ali je izbor adheziva izuzetno komplikovan, budući da ovaj sloj mora da obezbedi kontrolisano oslobađanje lekovite supstance i prijanjanje za kožu. Koža ispod sistema resorbuje fentanil i depo fentanila se koncentriše u gornjim slojevima kože. Terapijska koncentracija fentanila se dostiže posle 12 - 24 sata i održava tokom 72 sata. Primenom fentanila u ovom farmaceutskom obliku nije moguće brzo titriranje doze, pa nisu pogodni za ublažavanje akutnog bola već hroničnog bola. Doziranje treba individualno prilagoditi na osnovu opšteg stanja pacijenta i treba koristiti najnižu efektivnu dozu. Transdermalni put primene opioida se ne preporučuje kod pacijenata koji su „opioid naive“, dakle ovaj način administracije opioida nije prvi farmakoterapijski izbor.

Significance of transdermal formulations of opioid analgesics in pain pharmacotherapy

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Transdermal formulations occupy an important place in opioid pain pharmacotherapy, especially in oncology patients in the terminal stages of the disease. Also, specific patient populations require this therapeutic approach of opioid therapy. These pharmaceutical formulations are adapted and safe for patients with malignant cachexia and with the inability to swallow, for patients suffering from chronic renal and hepatic insufficiency as well as in the pediatric patient population. In the world, there are two formulations of liposoluble opiates in the form of transdermal formulations, fentanyl and buprenorphine. Fentanyl transdermal pharmaceutical forms are registered in Serbia. Most fentanyl transdermal patches are of the matrix type and contain a polymer matrix with fentanyl, an adhesive, a support layer and a protective film. In matrix-type transdermal patches, fentanyl is dispersed in a hydrophilic or lipophilic polymer or adhesive, which controls its release. Transdermal patches can have a reservoir of semi-solid consistency that has a porous membrane on one side that controls the release and diffusion of the medicinal substance from the entire formulation. The rate of opioid release from the reservoir depends on: porosity, permeability and thickness of the membrane, and possibly the composition and thickness of the adhesive layer. Matrix-type transdermal patches have a simpler design and are usually thinner than those with a reservoir, so they are more aesthetically acceptable, but the choice of adhesive is extremely complicated, since this layer must ensure the controlled release of the medicinal substance and adhesion to the skin. The skin under the system resorbs fentanyl and the depot of fentanyl is concentrated in the upper layers of the skin. The therapeutic concentration of fentanyl is reached after 12 - 24 hours and is reflected for 72 hours. With the use of fentanyl in this pharmaceutical form, it is not possible to quickly titrate the dose, so they are not suitable for alleviating acute pain but chronic pain. Dosage should be individually adjusted based on the general condition of the patient and the lowest effective dose should be used. The transdermal route of opioid administration is not recommended in patients who are opioid naïve, so this method of opioid administration is not the first pharmacotherapeutic choice.

Izazovi za primenu NOAK-a

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Uvođenje novih oralnih antikoagulanasa (NOAK) u kliničku praksu predstavlja revoluciju upravljanja antikoagulantnom terapijom. Oni su postepeno postali preferirani lekovi za prevenciju moždanog udara kod pacijenata sa atrijalnom fibrilacijom (AF) i za prevenciju i lečenje venskog tromboembolizma (VTE), a lista indikacija se proširuje. Međutim, uprkos obećavajućim prednostima, postoje faktori koji mogu da utiču na njihovu efikasnost i bezbednost. Prisustvo komorbiditeta svakako predstavlja jedan od tih faktora, uključujući oštećenu funkciju bubrega, koja može da utiče na klirens NOAK-a i može dovesti do povećanog rizika od krvarenja, i oštećenu funkciju jetre. Takođe, nekontrolisano primenjivanje antikoagulantne terapije može ugroziti adherencu, o čemu treba posebno voditi računa kod specifičnih populacija kao što su npr. starije osobe. Ne treba zaboraviti ni pacijente sa ekstremnom telesnom težinom (< 60 kg i > 150 kg), za koje postoje ograničeni podaci kada je u pitanju bezbednost primene NOAK-a, jer su oni uglavnom isključeni iz kliničkih studija, tako da izbor optimalne doze kod njih predstavlja pravi izazov. I na kraju, jedan od ključnih ograničavajućih faktora za masovnu upotrebu NOAK-a je svakako cena. Uvođenje NOAK-a u mnogome pojednostavljuje antikoagulantnu terapiju. Sa sve većom sigurnošću, oni polako zamenjuju varfarin za sve više indikacija, međutim i dalje postoje brojni izazovi sa kojima se susreću kliničari prilikom njihove primene.

Challenges for NOACs use

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The introduction of new anticoagulant drugs (NOAC) into clinical practice represents a revolution in the management of anticoagulant therapy. They have gradually become the preffered drugs for the prevention of stroke in patients with atrial fibrillation (AF) and venous tromboembolism (VTE) prophylaxis and treatment, and the list of other indications is expanding. Howere, despite their promising benefits, there are many factors that can affect their effectiveness and safety. The presence of comorbidities is certainly one of those factors, including impaired renal function, which can affect the clearance of NOACs and may lead to an increased risk of bleeding, and impaired liver function. Also, unmonitored anticoagulant therapy can compromise the adherence to treatment, which should be taken into account in specific populations such as the elderly. We should also not forget patients with extreme body weight (< 60 kg i > 150 kg), for whom there are limited data when it comes to the safety of NOAC administration, because they are mostly excluded from clinical trials, so selecting the optimal dose of NOACs may be challenging in these individuals. And finally, one of the key limiting factors for the massive use of NOACs is certainly the cost. The introdaction of NOACs greatly simplifies anticoagulant therapy. With increasing safety, they are slowly replacing warfarin for more and more indications, however there are still numerous challenges faced by clinicians during their application.

Prednosti i nedostaci upotrebe biosimilara

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Biosimilari su biološki lekovi slični originalnom biološkom leku, odnosno lekovi istog kvaliteta, bezbednosti i efikasnosti. Stoga, sa kliničkog aspekta oni se ne razlikuju značajno u odnosu na referentni lek. Međutim, s obzirom na kompleksnost biotehnološkog procesa proizvodnje, neohodno je dokazati njihovu ekvivalentnost, ali kliničke studije nisu potrebne. Upravo to čini da biosimilari brže dospevaju na tržište i po nižoj ceni. Time bi biološki lekovi bili dostupniji pacijentima, uz manje sveukupne troškove lečenja.

Odnos lekara prema propisivanju biosimilara je vrlo raznolik, a naročito među lekarima različitih specijalnosti. Oko jedne trećine lekara nikada ne bi propisala biosimilar umesto originalnog leka, dok bi trećina uvek izabrala biosmilar ukoliko je dostupan. Najveća zabrinutost se odnosi na bezbednost, odnosnu višu incidencu neželjenih lekova, uglavnom usled nepoznavanja ili nepoverenja u informacije o biosimilarima. Osim toga, njihova očekivanja su da bi biosimilari trebalo da budu čak i za 50% jeftiniji da bi bili široko prihvaćeni. Najveće nepoverenje vlada među dermatolozima i reumatolozima koji smatraju da su njihovi pacijenti previše osetljiva populacija da bi propisali lek za koji nema direktnih dokaza o bezbednosti i efikasnosti.

S obzirom da je glavna prednost biosimilara niža cena, neophodna je bolja edukacija lekara. Intenzivna farmakovigilanca biosimilara, farmakoekonomska istraživanja, kao i uporedna klinička ispitivanja bi mogla značajno doprineti rastu poverenja lekara u ove lekove i porastu njihovog udela u propisivanju.

Ključne reči: biološki lekovi, biosimilari

Advantages and disadvantages of biosimilars use

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Biosimilars are biological drugs similar to the original biologic drug, or drugs with the comparable quality, safety and efficacy. Therefore, from the clinicians' point of view, they do not differ significantly from the reference drug. Due to the complexity of biotechnological manufacturing process, the equivalence needs to be proved, but clinical trials are not necessary. Consequently, biosimilars reach the market more quickly and have the lower price. That could make biological drugs more available to the patients, and the overall treatment costs lower.

The physicians' attitude towards biosimilars is highly variable, especially among those of different specialities. About one third of the physicians would never prescribe a biosimilar instead of the original drug, while a third would always choose a biosimilar if available. The greatest concern is over the safety, meaning the possible higher incidence of side effects, mainly because of the lack of knowledge or the distrust in the information on the biosimilars. Besides, their expectations are that biosimilars should be even 50% less costly, so they could be widely accepted. The highest distrust is among dermatologists and rheumatologists who consider their patients to be extremely sensitive populations for the use of a drug without direct proofs of safety and effectiveness.

Since the main advantage of the biosimilars is their lower price, better education of the physicians is necessary. Intensive pharmacovigilance, pharmacoeconomic studies, as well as comparative clinical trials could help increase the physicians trust in these drugs and increase the rate of their prescribing.

Key words: biological drugs, biosimilars

Zajednička karika kliničke transfuziologije i kliničke farmakologije - patient blood management

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Termin engl. *patient blood management* (PBM), prvi put je upotrebljen 2005. godine od strane prof Džejmsa Isbistera, australijskog hematologa, koji je shvatio da fokus transfuzijske medicine treba da se preusmeri sa krvnih produkata na pacijente. PBM je multimodalni, multidisciplinarni pristup, usresređen na pacijenta,a usvojen da bi se smanjila upotreba alogenih komponenti krvi, sve u svrhu poboljšanja kliničkog ishoda pacijenata. PBM ima tri glavna cilja (postulata): 1) povecanje mase eritrocita, upotrebom farmaceutskih agenasa, kao što su agensi stimulacije eritropoeze (ESA), suplementima gvožđa i vitamina i planiranje operacije prema optimalnim vrednostima hemoglobin; 2) smanjenje gubitaka krvi primenom poštednih hirurških i anestetičkih tehnika, primenom traneksamične kiseline (TXA) i spasavanje autologne krvi; i 3) povećati toleranciju anemije maksimalnom plućnom i srčanom potporom, optimizacijom ventilacije, oksigenacije i upotrebom restriktivnog transfuzijkog praga. Da bi se krvarenje stavilo pod kontrolu, pacijentu primeniti intravensko gvožđe za lečenje srednjih i teških anemija (Hb 60-90 g/L). Intravensko gvožđe se pokazalo efikasnim kod krvarenja, u kombinaciji sa drugim hirurškim i medicinskim tretmanima (TXA) i doprinelo smanjenju gubitaka krvi i potrebe za alogenim transfuzijama. Hirurški protokoli, pored ostalog, moraju sadržati i procedure za hitno trebovanje O i K negativne krvi. U bolničkim bankama krvi su, prema transfuziološkim principima, uvek dostupne O- i K- jedinice krvi. Nažalost, O- i K- krv nije uvek kompatibilna kod svih pacijenata. U ovoj situaciji, neophodno je izvršiti proširenu fenotipizaciju eritrocita za Rh (CcDEe), Dufy (Fya,Fyb), MNSs, Kidd (Jka,Jkb) sistem krvnih grupa. Proširena fenotipizacija eritrocita je potreba za pacijente koji su kandidati za terapiju monoklonskim antitelima (CD20, C38, CD47, Mabtera, Dorzalex) i transplantaciju, za pacijente sa antitelima na eritrocite i za trudnice koje su kandidati za intrauterine transfuziju. Davanje kompatibilne tipizirane krvi prema fenotipu pacijenta, ne znači davanje iste krvne grupe, već krvne grupe sa minimalnim rizikom od senzibilizacije i neželjenih reakcija za određenog pacijenta. Ovo je prava personalizovana terapija. U eri smanjenja troškova i pritiska da se smanje testovi i procedure koje nisu korisne za pacijenta, PBM je važno dostignuće. Štaviše, standardizacijom nege i redukcijom nepotrebnog testiranja i troškova, ova promena je praktično u skladu sa kampanjom Choosing Wisely. Izbegavati transfuzije kad god je to moguće; koristiti sve vrste autolognih transfuzija kad kliničko stanje pacijenta to dozvoljava; optimizirati hirurške i anesteziološke tehnike. Obavezna transvuzija na vrednostima Hb<60g/L, i uvek koristiti deleukocitovane komponente. Koristiti farmakoterapiju ESA (Fe, B12, Folna kiselina, EPO), za korekciju anemije; Koristiti farmakološke agense za kontrolu krvarenja(Traneksamičnu kiselinu, Dezmopresin, PCC).

The point of intersection between clinical transfusiology and clinical pharmacology - patient blood management

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The term patient blood management (PBM) was first used in 2005 by Professor James Isbister, an Australian hematologist, who realized that the focus of transfusion medicine should be changed from blood products to the patients. PBM is a multimodal, multidisciplinary patient-centered approach adopted to minimize the use of allogeneic blood components with the aim of improving clinical outcomes of patients. PBM has three main objectives (pillars): 1) improving red cell mass, including pharmacological correction such as erythropoiesis-stimulating agents (ESA) and iron and vitamin supplements and time surgery with optimization of Hb; 2) minimizing blood loss by optimizing surgical and anesthetic techniques, treatment with tranexamic acid (TXA) and autologous blood salvage; and 3) optimizing the tolerance of anemia by promoting maximum pulmonary and cardiac function, optimize ventilation, optimize oxygenation and the use of a restrictive transfusion threshold. Once the hemorrhagic episode is controlled, patient should receive intravenous iron for the treatment of moderate-to-severe anemia (Hb 60-90 g/L). IV iron has proved to be effective in hemorrhage, in association with other surgical and medical therapies (TXA) in reducing blood loss and the need for allogeneic blood transfusions. Surgical management protocols must include the immediate issue of group O, RhD-negative and K-negative RBC units. In blood banks, by blood bank policy, is O ccddee K- RBC always available. Unfortunately, O- K- blood is not compatible in all patients. In this situation, it is essential to perform extended erythrocyte phenotyping for Rh (CcDEe), Dufy (Fya,Fyb) , MNSs, Kidd (Jka,Jkb) blood group system. Extended erythrocyte phenotyping is needed for: patients who are candidates for monoclonal antibody therapy (CD20, C38, CD47, Mabtera, Dorzalex) and kidney transplantation, for patients with RBC antibodies, and for pregnant women who are candidates for Intra Uterine Transfusion. Administration of Compatible phenotyped blood according to patient pfenotype doesn't mean the same blood group, but Blood Group with minimal risk of sensitization and adverse reactions for particular patient. This is a real Personalized Therapy. In an era of cost reduction and pressure to reduce tests and procedures that are not beneficial to patient care, PBM is an important approach. Furthermore, by standardizing care and reducing unnecessary testing and costs, this change in practice are according to the goals of campaign Choosing Wisely. Avoid transfusion whenever is possible; Use all types of autologous transfusion when the patient's clinical condition allows; Optimize surgical and anesthetic techniques. Mandatory transfuse at Hb level <60 g/L, and always use leukodepleted blood components. Use pharmacological ESA (Fe, B12, Folic acid, EPO), to correct anemia; Use pharmacological agents to control bleeding (Tranexamic acid, Desmopresin, PCC).

Psihoterapija kao epigenetski “lek” - značaj i mogućnosti kombinovanja psihoterapije i psihofarmakoterapije

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TI psihoterapija i medikamentozna terapija su efikasni u lečenju širokog spektra psihijatrijskih poremećaja i često se kombinuju. Ni jedno ni drugo nije *panacea*, svaki terapijski pristup ima svoje koristi, a kombinacija često poboljšava efekat bilo koje od njih same.

Iako farmakoterapija i psihoterapija u svojim postavkama i terapijskom pristupu potiču iz različitih izvora i različito definišu pojmove zdravlja i bolesti, njihovo (holističko) povezivanje daje značajan doprinos prevazilaženju dihotomnog razmišljanja odn. pristupa: psihoterapija vs. medikacija (terapija lekovima).

Uspešna psihoterapija može aktivirati epigenetičke mehanizme u moždanim strukturamada bi se smanjili psihijatrijski simptomi, baš kao što se smatra da čini efikasna terapija lekovima. S obzirom na ograničenja i neželjena dejstva psihotropnih lekova, kao i usporavanje tempa inovacija u psihofarmakologiji, jedan od najperspektivnijih terapijskih napredaka, koji daje mogućnost da nas izvuče izvan trenutnog platoa farmakoterapije, je kombinovanje lekova sa psihoterapijom.

Psihoterapija pomaže u mobilizaciji aktivnog učešća pacijenta u životnim odlukama i procesima, korišćenje psihoterapijskih intervencija je u cilju ozdravljenja, a lekovi pomažu u povećanju uključenosti pacijenata u psihoterapijskom procesu.Tako, u psihoterapijskom procesu, lekovi mogu olakšati kontakt pacijenta i terapeuta, dok psihoterapijapodržava efikasan put u oporavka pacijenata nakon epizoda bolesti, podržavajući njegovu stabilnost i odlažući ponovnu pojavu poremećaja.To predstavlja značajnu potencijalnu dobit za pacijenta kada postane funkcionalan,utičući na kvalitet života i potencijalno smanjenje stope hospitalizacije ili polifarmacije.

Psychotherapy as an epigenetic “drug” - importance and possibilities of combining psychotherapy and psychopharmacotherapy

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Both psychotherapy and pharmacotherapy are effective in treating a wide range of psychiatric disorders and are often combined. None of them is a *panacea*, each therapeutic approach has its own benefits, and the combination often improves the effect of either alone.

Although pharmacotherapy and psychotherapy in their settings and therapeutic approach come from different sources and define the concepts of health and disease differently, their (holistic) connection makes a significant contribution to overcoming dichotomous thinking and approaches: psychotherapy vs. medication (drug therapy).

Successful psychotherapy can activate epigenetic mechanisms in brain structures to reduce psychiatric symptoms, just as effective drug therapy is thought to do. Considering the limitations and side effects of psychotropic drugs, as well as the slowing pace of innovation in psychopharmacology, one of the most promising therapeutic advances, which gives the possibility to get us beyond the current plateau of pharmacotherapy, is combining drug treatment with psychotherapy.

Psychotherapy helps in mobilizing the patient’s active participation in life decisions and processes, the use of psychotherapy interventions contribute in healing course, and drugs help in increasing the patient’s involvement in the psychotherapy process. Thus, in the psychotherapy process, drugs can facilitate the contact between the patient and the therapist, while psychotherapy supports an effective path in the patient’s recovery after episodes of illness, supporting its stability and postponing the relapseof the disorder. This represents a significant potential gain for the patient once functional, affecting quality of life and potentially reducing the rate of hospitalization or polypharmacy.

Povezanost upotrebe antibiotika i infekcija izazvanih uzročnikom *Clostridioides difficile* koje su nastale u bolnici tercijernog nivoa zdravstvene zaštite

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Clostridioides difficile infekcija (CDI) je česta infekcija koja počinje u bolnici (PB) i vodeći je uzrok infektivnih dijareja kod hospitalizovanih pacijenata. Rizični faktori koji su mnogobrojni uključuju i prethodno izlaganje antibioticima, kao što su cefalosporini, karbapenemi, klindamicin i fluorohinoloni. Antibiotici su za svrhu analize bili podeljeni, prema Listi SZO, na one koji treba da su uvek dostupni, koji se primenjuju sa posebnim oprezom i na rezervne antibiotike. Prema riziku da izazovu CDI podeljeni su na visokorizične antibiotike, srednje rizične i antibiotike čija primena je povezana sa niskim rizikom za ove infekcije. Cilj ispitivanja je bio da se dovede u vezu upotreba antibiotika i gustina incidencije CDI. Rezultati su pokazali da se u toku celog višegodišnjeg perioda posmatranja incidenca PB-CDI nije povećavala, kao i ukupna potrošnja antibiotika. Međutim, potrošnja srednje-rizičnih antibiotika, kao što su penicilini, aminoglikozidi i makrolidi, je pokayala značajno negativnu korelaciju sa učestalošću PB-CDI. Takođe, upotreba rezervne grupe antibiotika je imala statistički značajan trend povećanja. Stoga su potrebne dalje mere u cilju racionalnijeg propisivanja antibiotika u našoj ustanovi.

Association between antibiotic use and hospital-onset *Clostridioides difficile* Infection in Tertiary Hospital

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Clostridioides difficile infection (CDI) is a common healthcare-associated (HA) infection and the leading cause of infectious diarrhoea in hospitalised patients. Risk factors for CDI, among others, include previous exposure to antibiotics (especially fluoroquinolones, cephalosporins, carbapenems and clindamycin). In order to perform analysis, we accepted WHO AWaRe classification of antibiotics devided into three groups: Access, Watch, and Reserve. We also divided antibiotics into three groups based on their risk of causing CDI in patients: high-risk antibiotics (cephalosporins, fluoroquinolones, clindamycin, and carbapenems), medium-risk antibiotics (penicillins, macrolides, aminoglycosides, sulfonamides, and trimetoprime) and low-risk antibiotics (tetracyclines). In this study, our aim was to corelate antibiotic use and the incidence density of HO-CDI. IIt was found that the incidence of HO-CDI did not increase, as well as the total consumption of antibiotics during the whole study period. In our tertiary hospital, consumption of medium-risk antibiotics had a significantly negative correlation with the rate of HO-CDI. The utilization of the Reserve group of antibiotics showed a statistically significant increasing trend. Therefore, more rational prescribing of antibiotics in our hospital is needed in the future.

Mesto antipsihotika III generacije u tretmanu mladih zavisnika

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Zloupotreba PAS i mentalno zdravlje mladih privlače pažnju stručne javnosti, posebno zbog porasta konzumacije PAS medju mladima zadnih decenija, kako u svetu, tako i kod nas. Istraživanja su ukazala da su najčešće korišćene droge u adiolescentnoj populaciji marihuana i alkohol, zatim amfetaminske droge, a naročito tkz "nove droge"-sintetičke droge, često nedovoljno poznatog sastava, sa ozbiljnim ili fatalnim neželjenim efektima. Adolescenti su vulnerabilna populacija, bilo zbog naslednih faktora, bilo zbog nedovoljno razvijenih "copping" mehanizama za brojne stresogene činioce iz spoljašnje sredine, što često dovodi do razvoja negativnih emocija i stanja, psihičkih poremećaja, gde je zloupotreba PAS simptom adolescentne krize ili uvod u teže poremećaje. Apstinencijalni simptomi su često udruženi sa komorbididetnim poremećajima-psihozom, anksioznošću, depresijom, auto i hetero agresivnim ponašanjima. Sve ovo dovodi do polimorfnih kliničkih slika, koje zahtevaju i farmakoterapijski pristup. Primena psihijatrijskih lekova u adolescentnoj populaciji zahteva oprez u izboru i doziranju, kao i intenzivno praćenje. Antipsihotici, imaju svoje mesto u tretmanu i primenjuju se za psihotične simptome, psihotičnu anksioznost, psihomotorni nemir, suicidalnost, impulsivne acting-out-e. Atipični antipsihotici su prema istraživanjima efikasniji i bolje podnošljivi. Koriste se najčešće olanzapin, quetiapin, risperidon, aripiprazol i u poslednje vreme cariprazin. Cariprazin je Dopamin parcijalni agonist, a deluje i na serotinergičke 1A i 2A receptore, a delotvoran je ne samo u tretmanu shizofrenije i BAP, veći u tretmanu teraporezistentne depresije, poremećaja ponašanja kod dece i omladine, poremećajima kontrole impulsa. U našoj praksi se pokazao koristan u tretmanu psihotičnih simptoma, anksioznosti i depresije koji nisu odgovorili na tretman anksioliticima i antidepresivima, kao i impilsivnih i agresivnih ponašanja. Pored delovanja na kliničku sliku, poboljšava i socijalnu funkcionalnost i saradljivost u daljem psihosocijalnom tretmanu.

III generation antipsychotics in the treatment of young addicts

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The abuse of PAS and the mental health of young people attract the attention of the professional public, especially due to the increase in the consumption of PAS among young people in recent decades, both in the world and in our country. Research has shown that the most commonly used drugs in the adolescent population are marijuana and alcohol, followed by amphetamine drugs, and especially the so-called "new drugs" - synthetic drugs, often of insufficiently known composition, with serious or fatal side effects. Adolescents are a vulnerable population, either due to hereditary factors, or due to insufficiently developed "copping" mechanisms for numerous stressors from the external environment, which often leads to the development of negative emotions and conditions, psychological disorders, where PAS abuse is a symptom of an adolescent crisis or a prelude to more difficult disorders. Withdrawal symptoms are often associated with comorbid disorders - psychosis, anxiety, depression, auto and hetero aggressive behaviors. All this leads to polymorphic clinical pictures, which also require a pharmacotherapeutic approach. The use of psychiatric drugs in the adolescent population requires caution in the selection and dosage, as well as intensive monitoring. Antipsychotics have their place in treatment and are used for psychotic symptoms, psychotic anxiety, psychomotor restlessness, suicidality, and impulsive acting-outs. According to research, atypical antipsychotics are more effective and better tolerated. The most commonly used are olanzapine, quetiapine, risperidone, aripiprazole, and recently cariprazine. Cariprazine is a dopamine partial agonist, and it acts on serotinergic 1A and 2A receptors, and is effective not only in the treatment of schizophrenia and BAP, but also in the treatment of therapy-resistant depression, behavioral disorders in children and youth, and impulse control disorders. In our practice, it has proven useful in the treatment of psychotic symptoms, anxiety and depression that have not responded to treatment with anxiolytics and antidepressants, as well as impulsive and aggressive behaviors. In addition to the effect on the clinical picture, it also improves social functionality and cooperation in further psychosocial treatment.

Povezanost serumskih koncentracija vitamina D3 sa depresijom kod pacijenata sa sarkoidozom

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Uvod: Sarkoidoza je retko autoimuno, zapaljensko oboljenje sa kliničkim manifestacijama na plućima i/ili drugim organima. Sarkoidoza je veoma često udružena sa povišenom depresijom. Sa druge strane, niski nivoi vitamina D3 u serumu, povezani su, kako sa stepenom težine sarkoidoze, tako i sa nivoom depresivnosti pacijenata sa sarkoidozom.

CIlj: U našoj studiji ispitali smo povezanost nivoa depresivnosti sa različitim koncentracijama vitamina D3 u serumu.

Metod: U studiji preseka gde je 254 pacijenata konsekutivno uključeno na Klinici za pulmologiju Kliničkog centra Srbije, evidentirani su sledeći pokazatelji: starost, pol, tok i oblik ispoljavanja sarkoidoze, pojava pridruženih oboljenja (dijabetes, zapaljenje štitaste žlezde, hipertenzija, aritmija, koronarna bolest), rendgenski stadijum i terapija. Nivo depresivnosti kod svih pacijenata meren je skalom depresije centra za epidemiološke studije (CES-D), gde su vrednosti CES-D ≥16 označene kao vrednosti sa značajnom povišenom depresivnošću. Svim pacijentima izmeren je serumski nivo vitamina D3. Studije preseka izvedene su prema tri nivoa vitamina D3 u serumu (<20 ng/mL, <30 ng/mL i <50 ng/mL).

Rezultati: Serumski vitamin D3 <20 ng/mL bio je povezani sa starošću iznad 60 godina (r=0.159; p=0.015), kao i sa CES-D ≥16 (r=0.171; p=0.007), dok je serumski vitamin D3 <30 ng/mL pozitivno korelisao sa zapaljenjem štitaste žlezde (r=0.206; p=0.001) i rendgenskim stadijumom oboljenja na plućima (r=0.185; p=0.04). Serumski vitamin D3 <50 ng/mL nije pokazao značajnu povezanost ni sa jednom ispitivanom varijablom.

Zaključak: Kod pacijenata sa sarkoidozom, serumski vitamin D3 <30 ng/mL značajno je povezan sa stepenom obuhvaćenosti pluća granulomatoznim promenama ili zapaljenjem štitaste žlezde, dok se povišena depresivnost značajno može povezati sa serumskim nivoima vitamina D3 koji su niži od 20 ng/mL.

Association of serum vitamin D3 concentrations with depression in patients with sarcoidosis

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Introduction: Sarcoidosis is a rare autoimmune, inflammatory disease with clinical manifestations in the lungs and/or other organs. Sarcoidosis is very often associated with increased depression. On the other hand, low levels of vitamin D3 in the serum are associated with both the severity of sarcoidosis and the level of depression in patients with sarcoidosis.

Objective: In our study, we examined the association of depression with different concentrations of vitamin D3 in the serum.

Method: In a cross-sectional study where 254 patients were consecutively included at the Pulmonology Clinic of The Clinical Center of Serbia, the following indicators were recorded: age, sex, course, and form of manifestation of sarcoidosis, occurrence of associated diseases (diabetes, inflammation of the thyroid gland, hypertension, arrhythmia, coronary disease), X-ray stage and therapy. The level of depression in all patients was measured by the Center for Epidemiological Studies Depression Scale (CES-D), where CES-D values ≥16 are marked as values with significantly elevated depression. Serum levels of vitamin D3 were measured in all patients. Cross-sectional studies were performed according to three serum vitamin D3 levels (<20 ng/mL, <30 ng/mL, and <50 ng/mL).

Results: Serum vitamin D3 <20 ng/mL was associated with age over 60 years (r=0.159; p=0.015), as well as with CES-D ≥16 (r=0.171; p=0.007), while serum vitamin D3 <30 ng/mL positively correlated with inflammation of the thyroid gland (r=0.206; p=0.001) and X-ray stage of lung disease (r=0.185; p=0.04). Serum vitamin D3 <50 ng/mL did not significantly correlate with any of the investigated variables.

Conclusion: In patients with sarcoidosis, serum vitamin D3 <30 ng/mL is significantly associated with the degree of lung involvement by granulomatous changes or thyroid inflammation, while increased depression can be significantly associated with serum vitamin D3 levels lower than 20 ng/mL.

Primena 2D EPR imidžinga za ispitivanje transporta nesteroidnih antiinflamatornih lekova intergrisanih u lipozome kroz kožu

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Nesteroidni antiinflamatorni lekovi (NSAIL),kao što su ibuprofen, diklofenak, ketoprofen, indometacin i drugi, se danas uveliko koriste protiv inflamacije, bolova i povišene temperature. Međutim, iako oni mogu veoma efikasni u svom delovanju, postoji niz potencijalnih neželjenih efekata koji se posebno mogu ispoljiti ukoliko se ovi lekovi koriste u većim dozama. Jedan od načina na koji se može povećati efikasnost isporuke ovih lekova je njihova integracija u lipozome, pri čemu se otvara mogućnost njihove kontrolisane i ciljane isporuke, uz mogućnost dobijanja istog antiinflamatornog efekta upotrebom smanjene koncentracije leka. Cilj ove studije bio je ispitati mogućnost primene tehnike 2D Imidžinga Elektronskom Paramagnetnom Rezonancijom (2D EPRI) za praćenje prodiranja lipozoma koji sadrže NSAIL u duboke slojeve kože. Kako bi lipozome bilo moguće detektovati ovom rezonantnom tehnikom, spinski su obeleženi pomoću 16-doksilstearinske kiseline.Eksperimetalno je potvrđeno da je 2D EPRI veoma efikasna tehnika za praćenje prostorne raspodele lipozoma u tkivu (koži), i da se potencijalno može upotrebiti i u farmaceutskim studijama.Koliko je autorima poznato, ovo je prvi rad u kome je 2D EPRI tehnika upotrebljena za praćenje raspodele lipozoma koji sadrže nesteroidne antiinflamatorne lekove kroz kožu.

Ključne reči: Lipozomi, nesteroidni antiinflamatorni lekovi (NSAIL), 2D Imidžing Elektronskom Paramagnetnom Rezonancijom (2D EPRI), lipozomska enkapsulacija, prodornost lekova kroz kožu

2D EPR imaging for assessingthe topial delivery of liposome-integrated nonsteroidal anti-inflammatory drugs

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Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, diclofenac, ketoprofen, indomethacin, and others, are widely used today against inflammation, pain, and elevated temperature. However, even though they can be very effective in their action, there is a range of potential side effects that can particularly manifest when these drugs are used in higher doses. One way to increase the efficiency of NSAIDs delivery is their integration into liposomes, which opens the possibility of controlled and targeted delivery, with the potential to achieve the same anti-inflammatory effect using a reduced drug concentration. The aim of this study was to investigate the possibility of applying the 2D Electron Paramagnetic Resonance Imaging (2D EPRI) technique to monitor the penetration of liposomes containing NSAIDs into the deep layers of the skin. To able to detect liposomes using this resonant technique, they were spin-labeled with 16-doxylstearic acid. It has been experimentally confirmed that 2D EPRI is a highly effective technique for monitoring the spatial distribution of liposomes in tissue (skin) and has the potential to be used in pharmaceutical studies. As far as the authors are aware, this is the first study in which the 2D EPRI technique has been used to track the distribution of liposomes containing nonsteroidal anti-inflammatory drugs through the skin.

Keywords: Liposomes, nonsteroidal anti-inflammatory drugs (NSAIDs), 2D Electron Paramagnetic Resonance Imaging (2D EPRI), liposomal encapsulation, topical drug transport.

Znacaj prikupljanja nezeljenih dejstava novih lekova

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Ovu oblast kliničke farmakologije zakonski regulise Pravilnik o načinu prijavljivanja, prikupljanja i praćenja neželjenih reakcija na lekove ("Sl. Glasnik RS", br. 64/2011, 75/2017, 82/2017 - ispr. i 107/2023). Novi lek, u smislu ovog pravilnika, je lek koji je u upotrebi manje od pet godina, odnosno lek koji je u dužoj upotrebi ali sa novim načinom primene ili novom indikacijom.Zdravstveni radnici koji su u kontaktu sa lekom i pacijentom, odnosno korisnikom leka, sve sumnje na neželjene reakcije na lekove koji se nalaze u prometu u Republici Srbiji pismeno prijavljuju regionalnom centru za farmakovigilancu ili Agenciji.Pored neželjenih reakcija na lek, zdravstveni radnik prijavljuje regionalnom centru za farmakovigilancu ili Agenciji, sve sumnje na medicinske greške, predoziranje, zavisnost, zloupotrebu i neodobrenu primenu leka, izostanak terapijske efikasnosti leka i klinički značajne interakcije.Zdravstveni radnik prijavljuje neželjene reakcije na lek dostavljanjem obrasca neposredno, poštom, elektronskim putem ili faksom . Izuzetno, zdravstveni radnik može telefonom da obavesti regionalni centar za farmakovigilancu, odnosno Agenciju, u slučaju ozbiljne ili neočekivane neželjene reakcije na lek, a posle telefonskog obaveštavanja, dostavlja prijavu zdravstvenog radnika.

Lekari u svom radu radije koriste lekove koji su dugo u upotrebi jer sa istim imaju i lično iskustvo. Zbog toga novi lekovi i novi oblici lekova imaju sigurniju praktičnu budućnost.

Lek ulazi u kliničku upotrebu kada se registruje, a to je nakon zaršene treće (registracione) faze kliničkog ispitivanja. Bez obzira na regularno obavljenu proceduru puštanja leka u promet njegova bezbednost se procenjuje tek nakon toga. Dakle, prijavu sumnji na ND lekova ne samo da treba stimulisati, nego treba kažnjavati izostanak iste. S obzirom da sumnju na ND leka može prijaviti svako, jednostvna kontrola bi pokazala koliko puta sami pacijenti prijavljuju, a lekar izostaje, i obrnuto. Analiza prijave je obaveza tima eksperata u agenciji, ali je blagovremenom reakcijom lokalnih timova u bolnicama moguće odmah pomoći opomenom tj informacijom na lokalnom bolničkom nivou a u agenciji uslovnim povlačenjem leka. Primenom novih oblika lekova je sve lakše i brze i bezbednije za pacijenta kao i za lekara.

Savesno prikupljanje, analiza i primena znanja stečenog iz neželjenih dejstava lekaru i pacijentu obezbedjuje najviši nivo zaštite u procesu lečenja i očuvanja zdravlja. Razvoj novih oblika lekova, posebno kao nadgradnja već postojećih lekova jeste siguran put u razvoju bezbedne i efikasne farmakoterapije. Razvoj novih oblika lekova je moguć jedino u multidisciplinarnim timovima sa visokim naučnim standardima. Ovo podrazumeva poštovanje regulative , kao i aktivan stav prema kontroli u primeni iste, uz poštovanje etičkih principa. Uvremenjenu informisanost i primenu znanja stečenih prikupljanjem neželjenih dejstava lekova razumemo i prihvatamo kao odbranu poštene struke i nauke. Vreme će pokazati šta je bila istina u ovoj oblasti. Obećavamo da ćemo sa vama podeliti istinu koju razumemo kao ljubav.

The importance of collecting adverse effects of new drugs

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This field of clinical pharmacology is legally regulated by the Rulebook on the method of reporting, collecting and monitoring adverse reactions to drugs ("Official Gazette of RS", no. 64/2011, 75/2017, 82/2017 - corrected and 107/2023). A new drug, as defined by this regulation, is a drug that has been in use for less than five years, that is, a drug that has been in use for a longer time but with a new method of administration or a new indication. Healthcare workers who are in contact with the drug and the patient, that is, the user of the drug, report all suspected adverse reactions to drugs in circulation in the Republic of Serbia in writing to the regional center for pharmacovigilance or the Agency. In addition to adverse reactions to the drug, the health worker reports to the regional center for pharmacovigilance or the Agency, all suspicions of medical errors, overdose, addiction, misuse and unapproved use of the drug, lack of therapeutic efficacy of the drug and clinically significant interactions. A healthcare worker reports adverse drug reactions by submitting the form directly, by post, electronically or by fax. Exceptionally, a healthcare worker can notify the regional center for pharmacovigilance, i.e. the Agency, by telephone in case of a serious or unexpected adverse reaction to the drug, and submit the healthcare worker's report following the telephone notification.

In their work, doctors prefer to use drugs that have been in use for a long time because they have personal experience with them. Therefore, new drugs and new forms of drugs have a more secure practical future.

The drug enters clinical use when it is registered, and that is after the third (registration) phase of the clinical trial has been completed. Regardless of the regularly performed procedure for releasing the medicine into the market, its safety is assessed only after that. Therefore, the reporting of suspected AEs of drugs should not only be stimulated, but the absence of the same should be punished. Given that anyone can report a suspected AE of a drug, a simple control would show how many times the patients themselves report, and the doctor is absent, and vice versa. The analysis of the application is the responsibility of the team of experts in the Agency, but with the timely reaction of the local teams in the hospitals, it is possible to immediately help with a warning or information at the local hospital level, while the Agency orders a conditional withdrawal of the drug. With the use of new forms of medicine, everything is easier, faster and safer for the patient as well as for the doctor.

Conscientious collection, analysis and application of knowledge gained from reporting adverse effects provides the doctor and the patient with the highest level of protection in the process of treatment and preservation of health. The development of new forms of drugs, especially as an extension of already existing drugs, guarantees the development of safe and effective pharmacotherapy. The development of new forms of medicines is possible only in multidisciplinary teams with high scientific standards. This implies respect for regulations, as well as an active attitude towards control in their application, with respect for ethical principles. We understand and accept the up-to-date information and application of knowledge gained by collecting adverse drug effects as a defense of honest profession and science. Time will tell what the truth was in this area.We promise to share with you the truth meaning that we understand it as love.

Faktori povezani sa kontrolom krvnog pritiska u sredinama sa različitim nivoima zdravstvene zaštite u Srbiji

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Cilj istraživanja je odreditii faktore koji utiču na kontrolu krvnog pritiska kod ambulantnih pacijenata sa hipertenzijom u zavisnosti od nivoa zdravstvene zaštite.

Materijali i metode: Istraživanja je sprovedena na dva mesta sa različitim nivoima zdravstvene zaštite (primarna zdravstvena zaštita (PZZ) i sekundarna zdravsrvena zaštita (SZZ)). Tokom istraživanja su prikupljeni podaci vezani za socio-demografske karakteristike, za antihipertenzivnu terapiju, statusa kontrola krvnog pritiska pacijenata i određen je znanje o hipertenziji.

Rezultati: Većina ispitanika (74,9%) imala je loše kontrolisan krvni pritisak. Veći broj pacijenata iz sredine sa PZZ bila je na monoterapiji dok su pacijenti iz sredine sa SZZ najčešće uzimali tri ili više antihipertenziva. Ispitanici iz sredine sa SZZ pokazali su pokazali znatno niži rezultat znanja (medijana znanja 9, 2–15) u poređenju sa ispitanicima iz sredine sa PZZ (medijana znanja 11, 4–15, p=0,001). Udeo ispitanika sa adekvatnim znanje o hipertenziji bio je značajno veći u grupi sa dobrom kontrolom krvnog pritiska (26% i 9,2%, respektivno). Statistički značajni faktori su povezani sa lošom kontrolom krvnog pritiska su znanje o hipertenziji (p<0001), broj lekova (p<0001) i komplikacije hipertenzije (p=0004).

Zaključci: Loša kontrola krvnog pritiska je uobičajena kod ambulantnih pacijenata, bez obzira na dostupnost različitih nivoa zdravstvene zaštite. Naša studija bi mogla da posluži kao osnova za ciljane intervencije za poboljšanje upravljanja hipertenzijom.

Identifying factors associated with blood pressure control in settings with different level of healtcare in Serbia

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The aim of this study is to determine the factors that influence the control of blood pressure in outpatients with hypertension, depending on the level of healthcare.

Materials and methods: Research was conducted in two study sites with different levels of healthcare (primary healthcare (PHC) and secondary level of healthcare (SHC)). During the research, data related to socio-demographic characteristics, antihypertensive therapy, status of blood pressure control of patients were collected and knowledge about hypertension was determined, too.

Results: Majority of the respondents (74.9%) had poorly controlled blood pressure. Larger number of patients at PHC site was mananged with monotherapy while at the SHC majority received three or more antihypertensive drugs. Respondents from SHC showed a significantly lower knowledge score (9, 2–15) compared with the respondents from PHC (11, 4–15, p=0.001). The share of respondents with adequate knowledge on hypertension was significantly higher in the group with good blood pressure control (26% and 9.2%, respectively). Statistically significant factors associated with poor blood pressure control were knowledge (p<0001), number of drugs (p<0001) and complications (p=0004).

Conclusions: Poor blood pressure control is common among outpatients, irrespective of different levels of healthcare. Our study could serve as a basis for targeted interventions to improve hypertension management in Serbia.

Nove psihoaktivne supstance u Vojvodini

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Termin „nove psihoaktivne supstance“ (NPAS) odnosi se na psihotropne supstance koje se u poslednje vreme zloupotrebljavaju, a nisu obuhvaćene Konvencijom o narkoticima iz 1961. godine i Konvencijom o psihotropnim supstancama iz 1971. godine, ali mogu predstavljati pretnju po javno zdravlje uporedivu sa pretnjom koju predstavljaju klasične kontrolisane psihoaktivne supstance. U protekloj dekadi zabeležen je značajan i neprestani porast dostupnosti i upotrebe NPAS širom sveta, što je ove supstance učinilo globalnim fenomenom. NPAS se mogu klasifikovati na osnovu psihotropnog efekta na stimulanse, empatogene/entaktogene ili halucinogene. Sa druge strane, mogu se klasifikovati u odnosu na hemijsku strukturu kao: fenetilamini, amfetamini, katinoni, piperazini, piperidini, aminoindani, benzofurani i triptamini. Posebnu grupu čine sintetski kanabinoidi, koji obuhvataju veliki broj supstanci različitog hemijskog sastava, a koje deluju na nivou kanabinoidnih receptora. Sve je veći broj kliničkih dokaza o potencijalnim štetnim akutnim i hroničnih efektima povezanim sa upotrebom NPAS. Zabeležena je i pojava smrtnih slučajeva kao posledica njihove upotrebe. Osim toga, raste zabrinutost zbog nastupanja akutnih i hroničnih psihopatoloških manifestacija povezanih sa konzumacijom različitih NPAS. Upravo iz razloga što nedostaju informacije zasnovane na dokazima o NPAS, mnoge od ovih supstanci su i dalje nepoznate zdravstvenim radnicima. NPAS nisu prepoznate od strane nadležnih instanci kao realan problem jer zakonodavac ne može da sustigne tempo kojim se na tržištu javljaju novi oblici istih, i potrebni su širi napori zajednice kako bi se zaštitile najosetljivije grupe stanovništva.

New psychoactive substances in Vojvodina

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The term “new psychoactive substances” (NPAS) refers to recently abused psychotropic substances that are not covered by the 1961 Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances, but may pose a threat to public health comparable to the threat posed by classic controlled psychoactive substances. The past decade has shown a significant and continuous increase in the availability and use of NPAS worldwide, making these substances a global phenomenon. NPAS can be classified based on their psychotropic effect on stimulants, empathogenic/entactogenic or hallucinogenic. On the other hand, they can be classified according to their chemical structure as: phenethylamines, amphetamines, cathinones, piperazines, piperidines, aminoindanes, benzofurans and tryptamines. A special group consists of synthetic cannabinoids, which include a large number of substances of different chemical composition, which act at the level of cannabinoid receptors. There is a growing body of clinical evidence of potential adverse acute and chronic effects associated with the use of NPAS. The occurrence of deaths as a consequence of their use has also been recorded. In addition, there is growing concern about the onset of acute and chronic psychopathological manifestations associated with the consumption of various NPAS. Precisely because of the lack of evidence-based information on NPAS, many of these substances are still unknown to health professionals. NPAS are not recognized by the competent authorities as a real problem because the legislator cannot catch up with the pace at which new forms of them appear on the market, and wider community efforts are needed to protect the most sensitive groups of the population.

Kognitivni simptomi u depresiji i sch - novi terapijski izazovi

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Prema izveštajima WHO depresija pogađa 300 miliona ljudi širom sveta i vodeći je uzrok radne nesposobnosti, a povezano sa prisustvom kognitivnih simptoma u depresiji, pored klastera emocinalnih i fizičkih simptoma. Kognitivni simptomi u depresiji najčešće zahvataju oblasti pažnje, memorije i učenja, kao i egzekutivne funkcije i psihomotoriku, što se značajno odražava na funkcionalnost. Kognitivni poremećaj u depresiji često ne odgovara na uobičajenu terapiju amtidepresivima, ili ometa postizanje remisije. U poslednje vreme istraživanja sugeriraju formiranje nove podvrste depresivnog poremećaja, sa poremećajem kognicije, koji uključuje dodatne dijagnostičke metode i drugačiji terapijski pristup.Novije studije usmerene na istraživanje efekta antidepresiva na kognitivne simptome u depresiji su ukazale da SSRI, SNRI i bupropion imaju efekta, preko delovanja na serotonergičke, norepinefrinske i dopaminergičke projekcije CNS, koje povezuju regione za kontrolu emocija i kognitivnih procesa. Pokazalo se u više studija da vortioxetin, antidepresiv multimodalnog mehanizma delovanja, ima značajno bolje delovanje na učenje, memoriju i egzekutivne funkcije u poređenju sa placebom ili drugim antidepresivima. U toku su istraživanja delovanja psihostimulansa, kao dodatne terapije-methylphenidat i modafinil, kao i memantina,inhibitora cholinesteraze, poznat iz tretmana Alzcheimer-ove demencije. Shizofrenija se smatra najtežim psihijatrijskim poremećajem, upravo zbog oštećenja kognitivnih procesa, koji dominiraju kod većine pacijenata. Glutaminergička teorija u sch ukazuje da je disbalans glutamatergičke transmisije direktno odgovoran za negativne i kognitivne simptome, te antipsihotici, delujući na dopaminsku neurotransmisiju nemaju uticaj na njih. U toku su brojna istraživanja, usmerena na nove supstance, sa agonističkim i modulatornim delovanjem na NMDA receptore, direktno ili preko glycin transportera, kao model novog terapijskog pristupa.

Cognitive symptoms in depression and sch - therapeutic challenges

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According to WHO reports, depression affects 300 million people worldwide and is the leading cause of work incapacity, and is associated with the presence of cognitive symptoms in depression, in addition to a cluster of emotional and physical symptoms. Cognitive symptoms in depression most often affect the areas of attention, memory and learning, as well as executive functions and psychomotor skills, which significantly affects functionality. Cognitive impairment in depression often does not respond to the usual treatment with antidepressants, or interferes with the achievement of remission. Recently, research has suggested the formation of a new subtype of depressive disorder, with cognitive disorder, which includes additional diagnostic methods and a different therapeutic approach. to the serotonergic, norepinephrine and dopaminergic projections of the CNS, which connect regions for the control of emotions and cognitive processes. Vortioxetine, an antidepressant with a multimodal mechanism of action, has been shown in multiple studies to have significantly better effects on learning, memory, and executive functions compared to placebo or other antidepressants. Research into the action of psychostimulants, as additional therapy - methylphenidate and modafinil, as well as memantine, a cholinesterase inhibitor, known from the treatment of Alzheimer's dementia - is underway. Schizophrenia is considered the most severe psychiatric disorder, precisely because of the impairment of cognitive processes, which dominate in most patients. The glutaminergic theory in sch indicates that the imbalance of glutamatergic transmission is directly responsible for negative and cognitive symptoms, and antipsychotics, acting on dopamine neurotransmission, have no effect on them. Numerous researches are underway, focused on new substances, with agonistic and modulatory action on NMDA receptors, directly or via the glycine transporter, as a model of a new therapeutic approach.

Potrošnja hipolipemika u Srbiji u periodu 2011-2020. godine

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Uvod: Hipolipemici su lekovi koji se koriste za regulaciju različitih klasa lipida u krvi i za cilj imaju primarnu i sekundarnu prevenciju kardiovaskularnih događaja. Ovo su visokoefikasni lekovi koji su široko korišćeni u populaciji i čija upotreba je često dugoročna.

Cilj: Cilj rada bio je da se analizira količina i struktura potrošenih hipolipemika u Republici Srbiji tokom 10 godina i da se utvrdi da li postoji korelacija između cene i potrošnje ovih lekova.

Materijal i metode U našem istraživanju koristili smo metodologiju Upotreba lekova 90% i ATC/DDD metodologiju. Cene lekova po DDD su predstavljene u evrima (€). Povezanost potrošnje i cene lekova ispitana je linearnom regresijom na nivou statističke značajnosti od 0,05.

Rezultati: Potrošnja hipolipemika u Srbiji je u porastu, ali je ona i dalje značajno manja od potrošnje u Norveškoj i Finskoj. U Srbiji postoji negativna korelacija između potrošnje i cene lekova.

Zaključak: Upotrebu hipolipemika treba povećati u cilju primarne prevencije kardiovaskularnih događaja. Trenutna upotreba lekova je ograničena na neizlečive slučajeve bolesti i sekundarnu prevenciju, te je potrebno promeniti ograničenja RFZO na ove lekove.

Ključne reči: hipolipemici; kardiovaskularni sistem; hiperlipidemija

Consumption of hypolipidemic drugs in serbia in 2011-2020

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Introduction: Hypolipidemic drugs are used for regulating various classes of lipids in blood and their purpose is to provide primary and secondary prevention of cardiovascular events. These are highly efficient drugs that have wide usage in population, and their use is often long- term.

The aim: The aim of this study was to analyze the amount and structure of hypolipidemics consumed in the Republic of Serbia during 10 years and to determine whether there is a correlation between the price and consumption of these drugs.

Material and methods: In our investigation we used drug utilization 90% and ATC/DDD methodology. Prices of drugs per DDD are presented in euros (€).The relation between drug consumption and price was examined by linear regression at the level of statistical significance of 0.05.

Results: Hypolipidemics consumption in the Serbia is increasing, but it is stil significantly lower than in Norway and Finland. In Serbia, there is a negative corelation between consumption and price of the drugs.

Conclusion: Consumption of hypolipidemics should be increased for purposes of primary prevention of cardiovascular events. Current consumption of the drugs is limited for treatment of incurable cases of the desease and secondary prevention, and therefore the restrictions of the RFZO should be changed.

Key words: hypolipidemics; cardiovascular system; hyperlipidemia

Poređenje parametara terapijskog monitoringa takrolimusa u populaciji pacijenata sa transplantiranim bubregom u zavisnosti da li uzimaju lek jednom ili dva puta na dan

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Takrolimus je lek koji predstavlja kamen temeljac u prevenciji odbacivanja grafta nakon transplantacije bubrega. Nakon dugogodišnje upotrebe farmaceutske formulacije ovog leka koja se primenjuje na 12 sati, usledila je nova era primene takrolimusa sa produženim oslobađanjem, koji se primenjuje jednom dnevno. Cilj ovog rada je bio da se uporede parametri terapijskog monitoringa takrolimusa kod pacijenata sa transplantiranim bubregom na imunosupresivnoj terapiji ovim lekom jednom ili dva puta na dan. Urađeno je praćenje 60 pacijenata godinu dana pre i godinu dana nakon konverzije u Klinici za nefrologiju. Praćeni su sledeći parametri: nivo takrolimusa u krvi, dnevna doza takrolimusa, dnevna doza takrolimusa po kg telesne mase i odnos koncentracije i doze takrolimusa izražene po kg telesne mase (pokazatelj bioraspoloživosti). Konverzija je rađena uglavnom u odnosu 1:1. Ukupna dnevna doza takrolimusa koji se uzima dva puta na dan neposredno pre konverzije je bila statistički značajno manja u odnosu na dozu godinu dana nakon konverzije na formulaciju takrolimusa koja se primenjuje jednom dnevno, gde je bila u proseku- 3,45 vs. 3,88 mg (p=0,002). U koncentraciji takrolimusa u krvi nije nađena značajna razlika između ove dve formulacije leka. Takođe, značajna razlika nije pokazana ni u odnosu koncentracije i doze, pa je ovaj pokazatelj bioraspoloživosti bio neznačajno veći kod formulacije dva puta na dan u odnosu na formulaciju jednom na dan. S obzirom na dobijene rezultate može se zaključiti da se obe formulacije leka mogu podjednako preporučivati i dalje koristiti kao prva linija imunosupresivne terapije kod pacijenata sa transplantiranim bubregom, ali zbog bolje komplijantnosti koja je pokazana u svim studijama ipak se daje prednost formulaciji jednom na dan.

The comparison of tacrolimus therapeutic monitoring parameters in renal transplant recipients depending od the frequency of oral intake of drug: once or twice daily

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Tacrolimus is an immunosuppressive drug that that still represents a cornerstone in the prevention of graft rejection after kidney transplantation. The aim of this work was to compare the parameters of tacrolimus (TAC) therapeutic monitoring in kidney transplant patients on immunosuppressive therapy taking it once or twice a day. Sixty patients were followed up one year before and one year after conversion from the 12-hours pharmaceutical formulation of this drug to extended-release TAC, which was administered once daily at the Nephrology Clinic of the Military Medical Academy. The conversion was done mostly in a 1:1 ratio. The following parameters were monitored: TAC blood level (Cmin), daily dose of TAC (D), daily dose of TAC per kg of body weight (D/kg), and ratio of blood concentration and dose of TAC expressed per kg of body weight (Cmin/D/kg) (bioavailability indicator). The total daily dose of twice-daily TAC immediately before conversion was statistically significantly lower than the drug dose one year after conversion to once-daily TAC formulation, with averaged values of 3.45 vs. 3.88 mg, respectively ($p=0.002$). There were no statistically significant differences between other parameters: D, D/kg, and Cmin/D/kg. Since there were no significant differences between formulations concerning their bioavailability, both formulations can be equally recommended for further treatnement as the first-line immunosuppressive therapy in kidney transplant recipients. However, due to the better compliance shown in most of the performed studies, the once-daily TAC formulation has the advantage at the moment.

Farmakološki efekti ekstrakta rogača kod laboratorijskih životinja sa indukovanim metaboličkim sindromom

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Uvod: Metabolički sindrompredstavlja jedan od najčešćih poremećaja u opštoj populaciji i jedan je od najvažnijih faktora rizika za razvoj i komplikacije bolesti krvnih sudova. Plod rogača karakteriše visok sadržaj fenolnih komponenti, dominantno fenolnih kiselina, flavonoida i galotanina. Ova jedinjenja se nalaze u slobodnom, vezanom ili kondenzovanom obliku u plodu rogača.

Cilj: Cilj rada je bio ispitivanje uticaja ekstrakta rogača na parametre metaboličkog sindroma kod pacova.

Materijal i metode: Ispitivanje je sprovedeno na laboratorijskim pacovima soja Wistar koji su bili izloženi hraniobogaćenoj holesterolom i vodi za piće sa dodatkom 10% glukoze. Životinje su uz kalorijski obogaćenu hranu bile tretirane fiziološkim rastvorom,ekstraktom rogača, simvastatinom i kombinacijom ekstrakta rogača i simvastatinau trajanju od28 dana.Žrtvovanje je sprovedeno u opštoj anesteziji, a u dobijenom serumu su ispitivaniparametri, pokazatelji funkcije jetre, markeri funkcije masnog tkiva i određivan je lipidni status.

Rezultati: Životinje tretirane ekstraktom rogača imale su statistički manje prosečne telesne mase u odnosu na životinje koje su dobijale samo fiziološki ratvor, dok je unos hrane i vode bio veći u odnosu na ostale grupe.Koncentracije ukupnog i LDL holesterola bile su niže kod životinja tretiranih ekstraktom rogača i kombinacijom ekstrakta rogača i simvastatina u odnosu na kontrolnu grupu, dok je nivo HDL holesterola bio viši u odnosu na životinje tretirane fiziološkim rastvorom. Koncentracije leptina i adiponektina bile su najniže u grupama koje su uz simvastatin bile tretirane i ekstraktom rogača.

Zaključak: Ekstrakt rogača ima potencijalno povoljan uticaj na parametre metaboličkog sindroma kod laboratorijskih životinja, a dobijeni rezultati predstavljaju značajnu osnovu za dalja ispitivanja.

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Pharmacological effects of carob extract in laboratory animals with induced metabolic syndrome

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Introduction: Metabolic syndrome is one of the most common disorders in the general population and is one of the most important risk factors for the development and complications of blood vessel disease. Carob fruit is characterized by a high content of phenolic components, predominantly phenolic acids, flavonoids and gallotannins. These compounds are found in free, bound or condensed form in carob fruit.

Objective: The objective was to investigate the influence of carob extract on the parameters of metabolic syndrome in rats.

Material and methods: The study was conducted on laboratory Wistar rats that were exposed to cholesterol-enriched food and drinking water supplemented with 10% glucose. Animals were treated with saline solution, carob extract, simvastatin and a combination of carob extract and simvastatin for 28 days along with calorically enriched food. Sacrifice was performed under general anesthesia, and parameters, indicators of liver function, markers of adipose tissue function, and lipid status were determined in the obtained serum.

Results: Animals treated with carob extract had a statistically lower average body weight compared to animals that received only physiological solution, while food and water intake was higher compared to the other groups. Concentrations of total and LDL cholesterol were lower in animals treated with carob extract and the combination of carob extract and simvastatin compared to the control group, while the level of HDL cholesterol was higher compared to animals treated with saline solution. The concentrations of leptin and adiponectin were the lowest in the groups treated with simvastatin and carob extract.

Conclusion: Carob extract has a potentially beneficial effect on the parameters of the metabolic syndrome in laboratory animals, and the obtained results represent a significant basis for further research.

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Određivanje anaerobnog praga direktnom i indirektnom metodom sa i bez prethodno sprovedenim protokolom zagrevanja kod sportistkinja

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Ovo istraživanje imalo je za cilj da prikaže mogućnosti određivanja anaerobnog praga direktnom (merenjem laktata u krvi) i indirektnom metodonm (Conkoni test) sa i bez prethodno sprovedenim protokolom zagrevanja kod sportstkinja.

Ispitivanje je sprovedeno na 25 ispitanica ženskog pola koje su podeljene u dve grupe: I 15 utreniranih ispitanica koje su pre ispitivanja sprovele protokol zagrevanja, II 10 utreniranih ispitanica koje pre ispitivanja nisu sprovele protokol zagrevanja.

Rezultati prezentovani u ovom radu pokazuju da se AT, koji je određivan direktnim merenjem laktata u krvi formira na nižim vrednostima HR u odnosu na indirektni metodu primenom Conconi testa. Statistički signifikantno ($p < 0,001$) AT formira se na všim vrednostima srčane frekfence kod utreniranih ispitanica koje su sprovele protokol zagrevanja u odnosu na one koje nisu sprovele protokol zagrevanja pre početka testa opterećenja.

Metoda direktnog određivanja AT merenjem laktata u krvi je najtačnija i najpouzdanija metoda. Ona može i treba da se primenjuje u trenažnom procesu pri proceni stepena utreniranosti sportista. Indirektna metoda određivanja AT (Konkonijev test) nije validna za precizno određivanje anaerobnog praga kod ove grupe ispitanika. Međutim zbog svoje neinvazivnosi, jednostavnosti i praktičnosti Konkoni test je odličan orjentir praćenja trenažnog procesa i prevencije stanja preopterećenja kod sportista.kl

Ključne reči: anaerobni prag, laktati, žene, sport.

Determination of the anaerobic threshold by the direct and indirect measurement of AT with and without prior administration of the warm up protocol in female athletes

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This research aimed at pointing out the determination of the anaerobic threshold by the direct (level of lactate at blood semple) and indirect measurement (Conconi test) of AT with and without prior administration of the warm up protocol in female athletes.

Resesearch sample was drawn from 25 female athletes subjects divided into two groups:15 well- trained subjects prior subjected to the warm up protocol, 10 well trained subjects, who were not prior subjected to the warm up protocol.

Results obtained and presented in this paper show that AT, determined by the direct blood lactate measurement, present at lower valuees of HR than at the indirect method by using Conconi test. Statistically significant ($p < 0,001$) AT is formed at higher values of the heart rate (HR) in well- trained subjects who had warm up protocol before the workload test compared with those who didn’t have warm up protocol.

The method of direct AT determination by blood lactate measurement is the most accurate and reliable method. It can and should be applied in the training process when assessing the level of training of athletes. The indirect method of determining AT (Conconi’s test) is not valid for the precise determination of the anaerobic threshold in this group of subjects. However, due to its non-invasiveness, simplicity and practicality, the Conkoni test is an excellent benchmark for monitoring the training process and preventing the condition of overload in athletes.

Key words: anaerobic threshold, lactates, women, sport.

Pregled prijavljenih neželjenih događaja nakon imunizacije vakcinama protiv bolesti COVID-19 tokom 2021. i 2022. godine

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Imunizacija stanovništva u Srbiji protiv bolesti COVID-19 počinje 19.01.2021. godine. Tokom 2021. i 2022. godine prijavljeni su neželjeni događaji nakon imunizacije (NDNI) Agenciji za lekove i medicinska sredstva (ALIMS). Cilj ovog istraživanja je upoređivanje prijavljenih NDNI tokom 2021. i 2022. godine i njihovih karakteristika. Podaci koji su korišćeni preuzeti su iz Godišnjeg izveštaja ALIMS-a o prijavljivanju neželjenih reakcija na lekove u Republici Srbiji za 2021. i 2022. godinu. Upoređivanjem podataka dobili smo da je ukupan broj prijavljenih slučajeva tokom 2022. godine za 85.25% manji nego 2021. godine. Tokom 2021. godine najveći broj prijava došao je od strane zdravstvenih radnika (756), a tokom 2022. godine od strane nosioca dozvole (141). Tokom obe godine zastupljenije su prijave kod osoba ženskog pola, a najzastupljenije su u starosnoj grupi od 18 do 44 godine. U 2021. godini je u okviru 1316 slučajeva zabeleženo 3375 NDNI, a tokom 2022. godine zabeleženo je 557 NDNI u okviru 194 slučaja. Najzastupljeniji NDNI vakcinama protiv COVID-19 prema SOC kategoriji u toku obe godine su opšti poremećaji i reakcije na mestu primene. Prijavljeni NDNI nisu zahtevali regulatorne mere. Manji broj prijava tokom 2022. godine se može objasniti smanjenim trendom vakcinacije u odnosu na 2021. godinu.

Overview of reported adverse events after immunization with vaccines against the disease COVID-19 in 2021 and 2022

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Immunization of the population in Serbia against the disease COVID-19 begins on January 19, 2021. During 2021 and 2022, adverse events following immunization were reported to the Agency for Medicines and Medical Devices (ALIMS). This research aims to compare the reported adverse events following immunization during 2021 and 2022 and their characteristics. The data used were taken from the Annual Report of ALIMS on reporting adverse drug reactions in the Republic of Serbia for 2021 and 2022. By comparing the data, we found that the total number of reported cases in 2022 is 85.25% lower than in 2021. During 2021, the largest number of applications came from healthcare workers (756), and during 2022, from license holders (141). During both years, more applications were made by women, who are most represented in the age group from 18 to 44 years old. In 2021, 3375 adverse events following immunization were recorded within 1316 cases, and in 2022, 557 adverse events following immunization were recorded within 194 cases. The most common adverse events following immunization with vaccines against COVID-19 according to the SOC category in both years are general disorders and reactions at the site of administration. The reported adverse events following immunization did not require regulatory measures. The reduced vaccination trend can explain the lower number of applications in 2022 compared to 2021.

Problem polifarmacije kod pacijenata starijeg životnog doba

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Uvod: Mnoge države danas predstavljaju veoma stara društva, čiji dug život je često povezan sa udruženim bolestima s kojima se starije osobe bore, gde će se velika većina susresti sa upotrebom velikog broja lekova kao jednim od najčešćih i najvažnijih načina lečenja.

Cilj: Ciljevi ovog rada su određivanje učestalosti fenomena polifarmacije u starijoj odrasloj populaciji na lokalnom nivou i razvijanje i validiranje upitnika o uverenjima o depreskripciji.

Materijal i metode: Istraživanje je sprovedeno putem direktnih kontakata, društvenih mreža, kao i na javnim mestima u Novom Sadu na slučajnom uzorku od 100 pacijenata starosti preko 65 godina sa minimalno jednim lekom u svakodnevnoj upotrebi. U istraživanju je korišćen standardizovani upitnik "Revised Patients' AttitudesTowards Deprescribing (rPATD) Questionnaire".

Rezultati: Polifarmacija je identifikovana kod 54% ispitanih pacijenata starijih od 65 godina. Učestalost polifarmacije je bila statistički značajno veća kod pacijenata sa završenom osnovnom školom i niskim primanjima, kod kojih su uočene i barijere za smanjenje broja lekova Vrednosti indeksa komorbiditeta bile su više kod pacijenata sa polifarmacijom. Pacijenti sa polifarmacijom su lošije ocenili svoje zdravstveno stanje i kvalitet života, gde bi veći broj voleo da im se smanji broj lekova, osećaju da uzimaju previše lekova i na njih daju previše novca.

Zaključak: Polifarmacija je učestala kod starijih pacijenata, negativno je povezana sa samoocenom zdravstvenog stanja i kvaliteta života. Postoji spremnost ispitanika za smanjenje broja lekova koji koriste, ali određeni pacijenti mogu imati otpor prema ovoj praksi, što je neophodno razmotriti pre potencijalnog revidiranja terapije.

Ključne reči: polifarmacija; stariji pacijenti; depreskripcija; *Beers* kriterijum; STOPP/START kriterijum

The problem of polypharmacy in elderly patients

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Introduction: Numerous nations today have elderly populations in general, where long life is often associated with co-morbidities that the elderly suffer with, and where the most individuals will experience daily intake of a wide range of medications as one of the most common and significant ways of treatment.

Objective: The goals of this manuscript are to determine the frequency of the phenomenon of polypharmacy in the older adult population at the local level and to develop and validate a questionnaire on beliefs about deprescribing.

Material and methods: The research was conducted through direct contacts, social networks, as well as in public places in Novi Sad on a random sample of 100 patients over the age of 65 with at least one drug in daily use. The standardized questionnaire "Revised Patients' Attitudes Towards Deprescribing (rPATD) Questionnaire" was used in the research.

Results: Polypharmacy was detected in 54% of patients over the age of 65. Polypharmacy was statistically considerably more common in patients who graduated from elementary school and had weak income, who accordingly have challenges reducing the number of prescriptions. Patients with polypharmacy had higher comorbidity index values, considered their health and quality of life to be progressively challenging, with a greater number wishing to minimize the number of medications they take and spending too much money on them.

Conclusion: Polypharmacy is frequent in elderly patients, it is negatively related to self-assessment of health status and quality of life. There is a willingness of respondents to reduce the number of drugs they use, but certain patients may have resistance to this practice, which is necessary to consider before potentially revising therapy.

Keywords: polypharmacy; elderly patients; deprescription; Beers category; STOPP/START category

Aktuelnosti u polifarmaciji i depreskripciji

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U današnjem svetu moderne zdravstvene zaštite upravljanje lekovima postaje sve izazovnije, a polifarmacija, termin koji označava istovremenu upotrebu više lekova, je sve češća. Ovaj rad ispituje složen koncept polifarmacije, kao i razvoj sistema za depreskripciju, nudeći uvid u to kako bi zdravstveni radnici mogli da učestvuju u optimizaciji nege pacijenata. Takođe, proučavamo prepreke, ali i benefite depreskripcije, kao i značaj zajedničkog donošenja odluka između zdravstvenih radnika i pacijenata.

Polifarmacija se smatra neizbežnom posledicom kod lečenja hroničnih zdravstvenih oboljenja, zbog čega je danas značajan problem, jer učestalo dovodi do ispoljavanja neželjenih reakcija lekova, interakcija lekova i smanjenog pridržavanja pravilne upotrebe prepisanih lekova.Depreskripcija, kao relativno nov pojam, podrazumeva sistematsko smanjenje upotrebe nepotrebnih ili potencijalno štetnih lekova koje pacijenti sa prisutnom polifarmacijom koriste.

Naše istraživanje ima za cilj da promoviše pristup kontrolisanja lekova koji se izdaju na recept, koji je zasnovan na dokazima međusobnog odnosa terapeutskih prednosti i mogućih neželjenih reakcija različitih lekova. Dodatno,u radu se ističe značaj redovnih evaluacija lekova, uzimajući u obzir potrebe i mišljenje pacijenata, kao i uloge medicinskih stručnjaka kao edukatora i podrške.

Ova studija naglašava značaj medicinskih stručnjaka i farmaceuta u pružanju povratnih informacija o problemu polifarmacije i depreskripcije, udružujući se međusobnoi omogućavajući prilagođeno lečenje pacijenata lekovima koji se izdaju na recept, kao i prilikom postizanja sveobuhvatnog smanjenja štetnog uticaja polifarmacije implementiranjem depreskripcije.

Current conceptsin polypharmacy and deprescribing

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In the world of modern healthcare, the management of medication treatments has become increasingly complex, with polypharmacy—a term describing usage of multiple medications at the same time—increasingly common. This paper explores the dynamic context of polypharmacy and the developing deprescribing system, offering insights into how healthcare professionals can optimize patient care. Here we study the obstacles and benefits of deprescribing, as well as the significance of shared decision-making between healthcare professionals and patients.

Polypharmacy used to be considered as an unavoidable consequence in treatment of chronic medical conditions. Nowadays, it is recognized as a significant concern due to its potential for adverse drug reactions, drug interactions, and decreased medication adherence. Deprescribing, a relatively novel concept, emphasizes the systematic and patient-centered reduction of unnecessary or potentially harmful medications.

Our research would like to promote a patient-centric, evidence-based approach to controlling prescription medications through reviewing the balance between the therapeutic advantages and possible risks of various medications. It emphasizes the significance of regular drugs evaluations, considering the patient's needs and preferences, and the role of medical professionals as educators and supporters.

Finally, the current study emphasizes the essential part of medical professionals and pharmacists in addressing the complexity of polypharmacy and deprescribing, teaming up to ensure that prescription treatments are optimized, impact is reduced, and overall patient well-being is improved.

Slučaj anafilaktičkog šoka nakon ujeda pčela

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SAnafilaktički šok je jedno od najurgentnijih stanja u medicini. Najčešće se javlja nakon parenteralne upotrebe pojedinih lekova (penicilinski antibiotici, lokalni anestetici, vitaminski preparati), ali po intezitetu ne zaostaje ni anafilaktički šok nakon ujeda pojedinih insekata.

Predstavljamo slučaj 43 godine starog pacijenta, muškog pola, koga su sa groblja privatnim vozilom doneli u SHMP, nakon što su ga izujedale pčele. Pacijent je bio somnolentan, hipotenzivan 70/40 mmHg, tahikardan 170/min, dispnoičan, tahipnoičan 23/min, saturacije SPO2 89%, Glasgow koma skor 11, sa brojnim urtikama po koži glave, vrata, grudnog koša i ekstremiteta, otečenog lica, jezika, usana, uz prisutan stridor i auskultatorno vizing difuzno obostrano. Po postavljenoj dijagnozi anafilaktičkog šoka nakon obezbeđenja disajnog puta i aplikacije kiseonika preko nazalne maske 5 l/min, venske linije i postavljanja pacijenta u Trendelburgov položaj, odmah je aplikovan intravenski adrenalin 1mg, nakon toga antihistaminik hloropiramin (Synopen) 20mg intravenski i na kraju kortikosteroid metilprednizolon-natrijum-sukcinat (Lemod-Solu) 80mg intravenski. U 500 ml 0,9%NaCl aplikovan je teofilin-etilendiamin (Aminofilin) i pantoprazol (Controloc) po jedna ampula. Pacijent je sa stabilnim vitalnim parametrima nakon primenjene farmakoterapije hospitalizovan radi daljeg posmatranja i tretmana. Ovakvi kritični pacijenti se veoma uspešno ovim farmakoterapijskim pristupom stabilizuju na terenu i medikamentozni postupci su usmereni ka redukciji promena pod uticajem histamina. Od suštinskog značaja je redosled medikamentoznog postupka, adrenalin koriguje lezije koje izaziva histamin, sinopen sprečava dejstvo već oslobođenog histamina, kortikosteroidi sprečavaju degranulaciju mastocita i bazofila i dalje oslobađanje histamina.

A case of anaphylactic shock due to a bee sting

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Anaphylactic shock is one of the most urgent conditions in medicine. It most often occurs after the parenteral use of certain medications (penicillin antibiotics, local anesthetics, vitamin preparations), but in terms of intensity, anaphylactic shock after the sting of certain insects is not far behind.

We present the case of a 43-year-old male patient who was brought from the cemetery to the SHMP by private vehicle after being stung by bees. The patient was somnolent, hypotensive 70/40 mmHg, tachycardic 170/min, dyspnoic, tachypnoic 23/min, SpO2 saturation 89%, Glasgow coma score 11, with urticaria on the scalp, neck, chest and extremities, with swollen face, tongue and lips, with stridor and auscultatory registrated wheezing diffuse bilaterally. After the diagnosis of anaphylactic shock was made, airway was provided and oxygen was applied through a nasal mask 5l/min, intravenous line was provided and patient was placed in the Trendelburg position, intravenous adrenaline 1mg was immediately administered, then the antihistamine chloropyramine (Synopen) 20mg intravenously and finally corticosteroid methylprednisolone sodium succinate (Lemod-Solu) 80mg intravenously. One ampoule each of theophylline- ethylenediamine (Aminophylline) and pantoprazole (Controloc) was applied in 500 ml of 0.9% NaCl. After administrated pharmacotherapy patient was hospitalized with stable vital parameters for further observation and treatment. These critical patients are very successfully stabilized in the field with this pharmacotherapeutic approach and medical procedures are aimed at reducing the changes caused by histamine. The order of applying medications is essential, adrenaline corrects lesions caused by histamine, sinopen prevents the action of already released histamine, corticosteroids prevent degranulation of mast cells and basophils and further release of histamine.

Adherencija i savremeni pristup tretmanu dijabetesa melitusa tipa 2

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Uvod: Pored promene stila života, tretman dijabetesa melitusa tipa 2 podrazumeva i rano uvođenje farmakološke terapije.

Cilj: Glavni cilj ovog rada je bio da predstavi aktuelni pristup lečenju ove hronične, progresivne bolesti i da ukaže na važnost adherencije u ishodu lečenja.

Metod: Analiza i sinteza rezultata dosadašnjih istraživanja. Ključni nalazi: Tretman dijabetesa melitusa tipa 2 treba da sprovodi tim stručnjaka u saradnji sa pacijentom, koji ima centralnu ulogu u lečenju, sa svim svojim karakteristikama i preferencijama. Edukacija i uključivanje pacijenta u lečenje, podstičući brigu o sebi su ključni. Zdrav način života (medicinska nutritivna terapija, fizička aktivnost, kontrola telesne mase) je i dalje temelj lečenja, ako to nije dovoljno pristupa se ranom uvođenju farmakoterapije. Razvijeni su lekovi za snižavanje glikemije sa kardiorenalnom protekcijom kao što su inhibitori natrijum-glukoznog kotransportera tipa 2 i agonisti receptora glukagonu sličnog peptida 1, kao i lekovi koji povoljno utiču na nealkoholnu masnu bolest jetre i nealkoholni statohepatitis, kao što je pioglitazon. Pridržavanje dogovorenom režimu lečenja od strane pacijenta je na žalost često loše. Faktori koji su povezani sa lošom adherencijom su različiti i često višestruki kod određenog pacijenta.

Diskusija: Od lekova sa kardiorenalnom protekcijom mnogi pacijenti mogu imati benefit, ipak, zbog još uvek visoke cene, metformin ostaje lek prvog izbora za većinu pacijenata. Loša adherencija prema terapijskom planu je povezana sa lošom kontrolom glikemije, sa povećanjem rizika od komplikacija dijabetesa, sa povećanjem kardiovaskularnog rizika, sa povećanim mortalitetom, povećanjem broja bolničkih lečenja i povećanjem troškova zdravstvene zaštite. Pored smanjenja kompleksnosti medikamentozne terapije i boljeg informisanja pacijenta, bolja edukacija i motivacija bi mogli da utiču na bolju adherenciju. Poboljšana komunikacija između pacijenta i lekara i smanjenje troškova lečenja bi takođe mogli da imaju pozitivan uticaj.

Zaključak: Razvoj farmakoterapije pruža sve veće mogućnosti u lečenju dijabetesa melitusa tipa 2 i pridruženih bolesti. Od novih medikamenata mnogi pacijenti mogu imati benefite. Delovanjem na poznate faktore loše adherencije, kao i sa daljim istraživanjem nepoznatih, moglo bi se uticati na bolji ishod lečenja i smanjenje troškova zdravstvene zaštite.

Ključne reči: dijabetes melitus tip 2, antidijabetici, adherencija, komplijansa

Adherence and the contemporary approach to treating type 2 diabetes mellitus

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Introduction: In addition to lifestyle changes, the treatment of type 2 diabetes mellitus also implies early introduction of pharmacological therapy.

Aim: The main goal of this paper was to present the contemporary approach to treating this chronic, progressive disease and to indicate the importance of adherence in treatment outcomes.

Methods: Analysis and synthesis of the results of previous research. Key findings: The treatment of type 2 diabetes mellitus should be conducted by a team of experts in collaboration with the patient, who plays a central role in the treatment, with all their characteristics and preferences. Education and involving the patient in treatment, encouraging self-care, are crucial. A healthy lifestyle (medical nutritional therapy, physical activity, weight control) remains the foundation of the treatment, and if that is not sufficient, early pharmacotherapy is initiated. Medications have been developed to lower blood sugar level with cardiorenal protection, such as sodium-glucose cotransporter-2 inhibitors and glucagon-like peptide 1 receptor agonists, as well as drugs that have a favourable impact on non-alcoholic fatty liver disease and non-alcoholic steatohepatitis, such as pioglitazone. Unfortunately, patient adherence to the agreed treatment regimen is often poor. Factors associated with poor adherence are diverse and often multiple in a particular patient.

Discussion: Many patients may benefit from cardiorenal-protective glucose-lowering medications; however, due to their still high cost, metformin remains the drug of first choice for most patients. Poor adherence to the therapeutic plan is associated with poor glycaemic control, increased risk of disease complications, increased cardiovascular risk, increased mortality, hospitalizations, and healthcare costs. In addition to reducing the complexity of drug therapy and better informing the patient, improved education and motivation could lead to better adherence. Enhanced communication between the patient and the physician and reduced treatment costs could also have a positive impact.

Conclusion: The development of pharmacotherapy provides increasing possibilities for the treatment of type 2 diabetes mellitus and associated diseases. Many patients may benefit from the new medications. By addressing known factors of poor adherence, as well as further researching unknown factors, a better treatment outcome and reduced healthcare costs could be achieved.

Keywords: type 2 diabetes mellitus, antidiabetic drugs, adherence, compliance

Farmakokinetika nifedipina formulisanog kao čvrsta disperzija sa polivinilpirolidonom

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Čvrste disperzije su se pokazale kao dobra strategija za prevazilaženje niske rastvorljivosti lekova i posledično male brzine rastvaranja i bioraspoloživosti. Na tržištu već postoje autorizovane formulacije, ali se metode dobijanja i sastav čvrstih disperzija i dalje istražuju. Industrijska primenljivost i ekološka prihvatljivost karakterišu metodu superkritičnog fluida (MSF) koja bi mogla biti pogodna za formulisanje čvrstih disperzija.

Cilj ovog rada bio je da se ispita farmakokinetika nifedipina iz prethodno izrađenih i karakterisanih čvrstih disperzija nifedipina sa polivinilpriolidonom (PVP).Odabir formulacija je urađen primenom kategorijskog dizajna, uzimajući u obrzir rezultate in vitro karakterizacije (protočnost, higroskopnost, rastvorljivost, brzina rastvaranja).

Farmakokinetika je ispitana na životinjskom modelu (muški zdravi pacovi soja Wistar). Formirane su tri grupe sa po šest životinja. Životinjama je prvo peroralno aplikovan nifedipin, odnosno odabrana formulacija čvrste disperzije nifedipina (4 mg/kg), a nakon wash out perioda iste životinje su istu dozu iste formulacije dobile intravenski. Tečna hromatografija sa masenom spektrometrijom je primenjena za određivanje koncentracije nifedipina u odabranim vremenskim tačkama. Farmakokinetički parametri su izračunati primenom nekompartmanskog modela (WinNonlin v. 8.3). Statistički test jednofaktorska analiza varijanse je upotrebljena u analizi podataka.

Primenom eksperimentalnog dizajna odabrane su dve formulacije čvrstih disperziha za farmakokinetička ispitivanja: F1 (metoda nidinga, nifedipin:PVP K30 1:1 (m/m)) i F2 (MSF, nifedipin: PVP K30 1:5 (m/m)). Farmakokinetički profil je više izmenjen kod formulacije F2 nego kod formulacije F1, u odnosu na čist nifedipin. Formulacija F1 je imala statistički značajno povećanje AUC i smanjenje klirensa, a ostali parametri su ostali nepromenjeni. Formulacija F2 je imala statistički značajno drugačije farmakokinetičke parametre (osim λ_z i $t_{1/2}$) u odnosu na formulaciju F1 i čist nifedipin. Relativna bioraspoloživost formulacije F6 je bila 5,2 puta veća u odnosu na bioraspoloživost čistog nifedipina.

Tokom odabira formulacija za farmakokinetičko ispitivanje uzet je u obzir širi opseg rezultata in vitro ispitivanja, ali je in vivo studija pokazala da je udeo polimera ključan za povećanje bioraspoloživosti. Dalja optimizacija procesa dobijanja i drugih farmaceutsko-tehnoloških postupaka formulacije F2 potencijalno bi omogućila dobijanje finalnog proizvoda nifedipina sa optimizovanom farmakokinetikom.

Ključne reči: nifedipin, polivinilpirolidon, farmakokinetika, kategorijski dizajn, pacovi

Pharmacokinetics of nifedipine formulated as solid dispersions with polyvinylpyrrolidone

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Solid dispersions have proven to be a good strategy to overcome low drug solubility and consequently low dissolution rate and bioavailability. There are already authorized formulations on the market, but the methods of obtaining and the composition of solid dispersions are still being investigated. Industrial applicability and environmental acceptability characterize the supercritical fluid technology (SFT) that could be suitable for formulating solid dispersions.

The aim of this work was to investigate the pharmacokinetics of nifedipine from previously prepared and characterized solid dispersions of nifedipine with polyvinylpriolidone (PVP). The selection of formulations was made by using a multilevel categorical design, taking into account the results of in vitro characterization (flowability, hygroscopicity, solubility, dissolution rate).

Pharmacokinetics were investigated in an animal model (male healthy Wistar rats). Three groups with six animals each were formed. Firstly, nifedipine or selected solid dispersion formulations were administered to animals perorally(4 mg/kg), and after the wash out period the same animals received the same dose of the same formulation intravenously. Liquid chromatography with mass spectrometry was applied to determine the concentration of nifedipine at selected time points. Pharmacokinetic parameters were calculated using a non-compartmental model (WinNonlin v. 8.3). Statistical test one-factor analysis of variance was used in data analysis.

Using the experimental design, two formulations of solid dispersions were selected for pharmacokinetic studies: F1 (kneading method, nifedipine:PVP K30 1:1 (w/w)) and F2 (SFT, nifedipine:PVP K30 1:5 (w/w)). The pharmacokinetic profile was more altered with formulation F2 than with formulation F1, relative to pure nifedipine. Formulation F1 had a statistically significant increase in AUC and decrease in clearance, while other parameters remained unchanged. Formulation F2 had statistically significantly different pharmacokinetic parameters (except λ_z and $t_{1/2}$) compared to formulation F1 and pure nifedipine. The relative bioavailability of formulation F6 was 5.2 times higher than the bioavailability of pure nifedipine.

During the selection of formulations for the pharmacokinetic study, a wider range of in vitro studies results took into account, but the in vivo study showed that the proportion of polymer was crucial for increasing bioavailability. Further optimization of the production process and other pharmaceutical-technological procedures of the F2 formulation would potentially enable obtaining the final product of nifedipine with optimized pharmacokinetics.

Key words: nifedipine, polyvinylpyrrolidone, pharmacokinetics, multilevel categorical design, rats

Efekti COVID-19 na pacijente sa dijabetesom u Srbiji: studija preseka

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Dijabetes (diabetes mellitus - DM) predstavlja značajan izazov za javno zdravlje u Srbiji i širom sveta, a o potencijalno povećanoj ranjivosti pacijenata sa DM tokom pandemije koronavirusa se često diskutuje.

Kako bi se ispitali neki od efekata COVID-19 na pacijente sa DM u Srbiji, sprovedena je onlajn opservaciona studija preseka u februaru 2022. godine. U studiji je učestvovalo 422 odraslih pacijenata sa dijabetesom tipa 1 i tipa 2 koji žive u Srbiji.

Od ukupnog broja ispitanika, oko pola je imalo COVID-19 (54,0%). Ukupno, 37,2% se osećalo uznemirenim zbog COVID-19 (odgovarajući sa "da, donekle" ili "da, veoma" na 5-stepenoj Likertovoj skali). Žene su se osećale više uznemirenim od muškaraca ($p < 0,001$). Nije bilo statistički značajne razlike u samoprocenjenoj uznemirenosti između različitih starosnih grupa. Mnogi učesnici (43,1%) su izjavili da nisu obavili neophodne medicinske preglede tokom 2021. godine kao proteklih godina. Većina je prijavila uskraćenost za neku od usluga zdravstvenog sistema (76,9%), tačnije nemogućnost zakazivanja pregleda kod lekara specijaliste (46,4%), odložen/otkazan pregled lekara specijaliste (29,9%), nemogućnost zakazivanja pregleda kod lekara opšte prakse (23,2%), odloženu/otkazanu hiruršku intervenciju (6,2%) i ostalo (7,1%).

Unapređena i pristupačnija psihološka podrška pacijentima sa DM u Srbiji bi bila korisna. Premeštanje specijalista unutar zdravstvenog sistema u kriznim situacijama kao što su pandemije trebalo bi pažljivo planirati kako ne bi poremetilo korišćenje usluga zdravstvenog sistema za hronične pacijente poput onih sa dijabetesom.

Ključne reči: upravljanje dijabetesom, korona virus, COVID, anksioznost

Effect of COVID-19 on diabetes patients in Serbia: a cross-sectional survey

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Diabetes mellitus (DM) is a significant public health challenge in Serbia and worldwide, with the potentially increased vulnerability of DM patients during the coronavirus pandemic being often discussed.

In order to analyse some of the effects of COVID-19 on DM patients in Serbia, an online, observational, cross-sectional survey was conducted in February 2022. It included 422 adult diabetes type 1 and type 2 patients residing in Serbia.

Around half of the respondents had COVID-19 (54.0%). In total, 37.2% felt anxious about COVID-19 (answering either with “yes, somewhat” or “yes, very” on the 5-point Likert Scale). Women felt more anxious than men ($p < 0.001$). There was no statistically significant difference in self-perceived anxiety between different age groups. Many participants (43.1%) stated they did not undergo the necessary medical examinations during 2021 as in previous years. The majority reported experiencing a lack of access to medical care within the healthcare system (76.9%), precisely due to the system’s failure to schedule an examination by a specialist (46.4%), delayed/cancelled examination by a specialist (29.9%), and the system’s inability to schedule an examination by a general practitioner (23.2%), delayed/cancelled surgery (6.2%) and other (7.1%).

Improved and more accessible psychological support for DM patients in Serbia would be beneficial. Relocation of specialists within the healthcare system in cases of emergency such as the pandemic, should be carefully planned in order not to disrupt the utilisation of services for chronic patients such as those with diabetes.

Key words: diabetes management, corona virus, COVID, anxiety

Acne vulgaris u populaciji studenata medicine u Novom Sadu: studija preseka

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Acne vulgaris je polietiološka kožna bolest koja se javlja na seboreičnim područjima kože. Cilj studije bio je utvrditi prevalencu akni u populaciji studenata medicine na Medicinskom fakultetu Univerziteta u Novom Sadu, proceniti njihovo znanje, analizirati faktore rizika i proceniti kvalitet života zahvaćenih studenata.

Sprovedena je studija preseka na uzorku od 200 studenata medicine na Medicinskom fakultetu Univerziteta u Novom Sadu, koristeći onlajn anketu. Studenti su podeljeni u dve grupe: od prve do četvrte godine studija i od pete do šeste godine studija. Za procenu kvaliteta života korišćen je upitnik Cardiff Acne Disability Index. Acne vulgaris je imalo 30% ispitanika, od kojih je 85% bilo ženskog pola. Od zahvaćenih ispitanika, 70% je koristilo neki oblik terapije, pri čemu je 52,4% bilo propisano od strane dermatovenerologa. Samo 20% studenata je bilo sigurno u svoje znanje o aknama, od čega su 60% bili studenti pete i šeste godine studija. Rezultati su pokazali statistički značajnu razliku ($p < 0,05$) između pojave akni i faktora nasleđivanja, kao i između pojave akni i konzumiranja masne hrane ili grickalica. Za većinu studenata, akne su predstavljale blagi do umereni problem, dok su studentima ženskog pola predstavljale veći problem. Ograničenje studije proizilazilo je iz nedostatka lekarskog pregleda studenata, što je uticalo na potencijalnu relevantnost rezultata.

Ova studija ističe potrebu da se prioritet stavi na edukaciju o aknama tokom pretkliničkih godina studija medicine na Medicinskom fakultetu u Novom Sadu. Važno je sprečiti zablude studenata i širenje netačnih informacija, jer to može značajno uticati pacijente u opštoj populaciji.

Ključne reči: studentska populacija, znanje, kvalitet života

Acne vulgaris in the population of medical students in Novi Sad: a cross-sectional survey

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Acne vulgaris is a polyetiological dermatosis that appears on the seborrheic areas of the skin. The aim of the study was to determine the prevalence of acne vulgaris in the population of medical students in Novi Sad, assess their knowledge, analyse risk factors, and assess the quality of life of affected students.

A cross-sectional study was applied to a sample of medical students at the Faculty of Medicine, University of Novi Sad, by conducting an online survey. Students were divided into two groups: 1st to 4th-year students and 5th to 6th-year students. The Cardiff Acne Disability Index questionnaire was used to assess the quality of life. Acne vulgaris affected 30% of respondents, of which 85% were female. Of the affected respondents, 70% used some form of therapy, with 52.4% prescribed by a dermatovenereologist. Only 20% of students were confident in their knowledge about acne, whereas 60% were 5th or 6th-year students. The results indicated a statistically significant difference ($p < 0.05$) between the prevalence of acne vulgaris and the hereditary factors, as well as between the prevalence of acne vulgaris and the consumption of fatty foods or snacks. For most students, acne represented a mild to moderate problem, and it represented a bigger problem for female students. The study's limitation stemmed from the absence of student examinations, impacting the potential relevance of the results.

This study underscores the need to prioritise education on acne vulgaris during the preclinical years of medical studies at the Faculty of Medicine in Novi Sad. Addressing student misconceptions and misinformation dissemination is crucial, as it can significantly impact patient care within the general population.

Key words: student population, knowledge, quality of life

Antiobiotska terapija u komplikovanoj pneumoniji – koja kombinacija daje najbolji rezultat?

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U poslednjih nekoliko decenija opao je broj vanbolnički stečenih pneumonija, ali one i dalje ostaju vodeći uzrok morbiditeta u dečijem uzrastu. Komplikacije kao što su pleuralni izliv/pleuralni empijem, nekrotizirajuća pneumonija i plućni apsces i dalje su izazovi. Prezentujemo vam slučaj pneumonije koja je zakomplikovana razvojem plućnog apcesa.

Jednogodišnje dete je primljeno u bolnicu sa visokom temperaturom (40°C), slabošću, neproduktivnim kašaljem, teškom dispneomi povećanom nazalnom kongestijom. Inicijani tretman je uključivao dva antibiotika: klaritromicin (125 mg/5ml) u dozi od 3 ml dvaput dnevno i cefpodoksim (40 mg/5 ml) u dozi od 5 ml svakih 12 sati u vidu peroralne suspenzije. Nakon porasta u vrednostima CRP (249 mg/L), antibiotska terapija je zamenjena sa drugom intravenoznom kombinacijom - cefalosporin treće generacije ceftazidim u dozi od 500 mg svakih 8 sati, zajedno sa klindamicinom u dozi od 100 mg svakih 6 sati. Tok lečenja pneumonije je zakomplikovan razvojem plućnog apscesa. Uvedena je trojna antiobiotska terapije intravenskim putem koju su činili vankomicin, meropenem i metronidazol u trajanju od najmanje tri nedelje koji su u bili u skladu sa vodičima za tretiranje plućnih apcesa.Trajanje antibiotske terapije zavisiod kliničkog i radiološkog odgovora na primenjenu kombinaciju, i po potrebi ona se menja i koriguje do izlečenja. Odabrani antibiotici su pokrivali širok spektar gram-pozitivnih i gram-negativnih bakterija.

Bez obzira na primenu standardne antibiotske terapije, odgovor organizma je uvek individualan. Kombinacija koja je dovela do saniranja apscesa je uključivala vankomicin, meropenem i metronidazol.

Ključne reči: antibiotska terapija, zamena terapije, komplikovana pneumonija i plućni apces

Antibiotic therapy in complicated pneumnonia – what combination gives best results?

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Although community-acquired pneumonia (CAP) mortality in well-developed countries decreased significantly in the last decades, it remains one of the leading causes of morbidity in childhood. However, local CAP complications such as parapneumonic effusion (PPE)/pleural empyema (PE), necrotizing pneumonia (NP) and lung abscess are still challenging issues. We are presenting specific case who developred lung abscess as complication of pneumonia.

A 1-year-old child was admitted to hospital with the symptoms of high (elevated) body temperature (400C), fatigue, non-productive cough, severe dyspnea and increased nasal congestion. Initial treatment included two antibiotics: clarithromycin (125 mg/5ml) at a dose of 3 ml twice a day and cefpodoxime (40 mg/5 ml) at a dose of 5 ml every twelve hours in the form of a peroral suspension. After increase in CRP values (249 mg/L), a double antibiotic therapy is switched with another combination (intravenous therapy with cephalosporin of the third generation of ceftazidime at a dose of 500 mg was included every eight hours, together with clindamycin at a dose of 100 mg every six hours. The clinical course of pneumonia was complicated with development of lung abscess. Triple intravenous antibiotic therapy with vancomycin, meropenem and metronidazole over a period of at least three weeks and in accordance with guidelines for treating abscess was involved.The duration of antibiotic therapy depends on the clinical and radiographic response of the patient. The chosen antibiotics have to cover a wide specter of Gram-positive and Gram-negative bacteria.

In spite of the standard antibiotic therapy (treatment), the response of the organism is always individual. The combination of antibiotics that led to recovery included meropenem, vancomycin and metronidazole.

Keywords: antiobiotic therapy, switch therapy, complicated pneumonia, lung abscess

Potrošnja preparata gvožđa u terapiji sideropenijske anemije

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Uvod: Sideropenijska anemija predstavlja najčešći oblik anemije i uzrokovana je deficitom gvožđa u organizmu. Njeno lečenje podrazumeva supstituciju gvožđa, koja se može postići primenom oralnih i parenteralnih preparata gvožđa.

Cilj: Analiza upotrebe oralnih preparata gvožđa u Republici Srbiji u periodu od 2009. do 2020. godine, uz poređenje sa potrošnjom istih lekova u Republici Hrvatskoj i Republici Finskoj za navedeni vremenski period.

Materijal i metode: Podacima o potrošnji lekova u navedenim država pristupljeno je na osnovu zvaničnih publikacija nacionalnih agencija za lekove. Upotrebom metodologije DDD po ATC klasifikaciji izračunata je potrošnja lekova, dok je uz pomoć izraza DDD/1000 stanovnika na dan omogućen je uvid u broj stanovnika (1000) koji je koristio određeni lek. Farmakoekonomski aspekt potrošnje oralnih preparata gvožđa sagledan je uz pomoć određivanja cena lekova na veliko po 1 definisanoj dnevnoj dozi u eurima (cena/1DDD €).

Rezultati: Tokom perioda posmatranja od 12 godina, u navedenim državama u upotrebi su bili različiti oralni preparati gvožđa. U Republici Srbiji i Republici Hrvatskoj, najčešće upotrebljavan bio je preparat gvožđe (II)-fumarata, čiji su troškovi istovremno bili među najnižima. U Republici Finskoj najveća potrošnja zabeležena je za preparat gvožđe (II)-glicin sulfata, uz istovremeno skoro najveće troškove za pomenuti preparat. Takođe, troškovi upotrebe preparata gvožđe (III)-hidroksid polimaltoznog kompleksa bili su među najvećim u sve tri zemlje.

Zaključak: Republika Srbija i Republika Hrvatska imaju slične karakteristike po pitanju potrošnje i troškova upotrebe oralnih preparata gvožđa, dok Republika Finska ima drugačiju distribuciju potrošnje i troškova.

Ključne reči: sideropenijska anemija, oralni preparati gvožđa, troškovi lečenja

Consumption of iron supplements in the therapy of sideropenic anemia

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Introduction: Sideropenic anemia is the most common form of anemia and is caused by iron deficiency in the body. Its treatment involves iron substitution, which can be achieved by using oral and parenteral iron supplements.

Goal: Analysis of the use of oral iron supplements in the Republic of Serbia in the period from 2009 to 2020, with a comparison with the consumption of the same drugs in the Republic of Croatia and the Republic of Finland for the specified time period.

Material and methods: Data on drug consumption in the mentioned countries were accessed based on the official publications of the national drug agencies. Using the DDD methodology according to the ATC classification, the consumption of drugs was calculated, while with the help of the expression DDD/1000 inhabitants per day, it was possible to see the number of inhabitants (1000) who used a certain drug. The pharmacoeconomic aspect of the consumption of oral iron supplements was analyzed with the help of determining the wholesale prices of drugs per 1 defined daily dose in euros (price/1DDD €).

Results: During the 12-year observation period, different oral iron supplements were in use in the countries listed. In the Republic of Serbia and the Republic of Croatia, the supplements of iron (II)-fumarate was most often used, the costs of which were also among the lowest. In the Republic of Finland, the highest consumption was recorded for the supplements of iron (II)-glycine sulfate, with almost the highest costs for the aforementioned supplements. Also, the costs of using iron (III)-hydroxide polymaltose complex supplements were among the highest in all three countries.

Conclusion: The Republic of Serbia and the Republic of Croatia have similar characteristics in terms of consumption and costs of using oral iron supplements, while the Republic of Finland has a different distribution of consumption and costs.

Keywords: sideropenic anemia, oral iron supplements, cost of treatment