Internacionalni medicinski časopis iz oblasti biomedicinskih nauka International medical journal in the field of biomedical sciences
Medicinska reč **Medical Word**

APSTRAKT 3P 2025; 6(1): 4–5 ABSTRACT 3P

Bezbedna primena lekova i uloga zdravstvenih radnika u sistemu farmakovigilance

Safe Application of Medicines and the Role of Healthcare Workers in the Pharmacovigilance System

Desanka Nikolić

Apotekarska ustanova Niš Pharmacy Institution Niš

Apstrakt

Novi lekovi su široko zastupljeni u modernoj medicini. Međutim, uprkos svim njihovim prednostima, učestalost neželjenih reakcija na lekove stalno se povećava. Poslednjih nekoliko decenija brojne studijepokazale su visoku učestalost morbiditeta i mortaliteta uzrokovanih lekovima. U nekim zemljama neželjene reakcije na lekove spadaju među 10 vodećih uzroka smrtnosti. Procenjuje se da su neželjene reakcije četvrti, peti i šesti najčešći uzrok mortaliteta u SAD-u, a broj pacijenata koji imaju posledice neželjenih dejstava je još veći. Pored toga, kada je pacijentu propisano više od jednog leka, povećava se i rizik od neželjenih interakcija. Izbor najboljeg i najbezbedijeg leka za svakog pacijenta je izazov za lekare koji propisuju lekove.

U cilju sprečavanja ili smanjenja štete po pacijente, mehanizmi procene i praćenja bezbednosti lekova u kliničkoj praksi su od vitalnog značaja. U praksi to znači da postoji dobro organizovan sistem farmakovigilance. Farmakovigilanca je termin koji se koristi za opisivanje procesa praćenje i procenu neželjenih reakcija i ključna je komponenta efikasnog sistema praćenja lekova u kliničkoj praksi. Naime, broj neželjenih reakcija na lekove i smrtnih ishoda koji su posledica istih, moguće je smanjiti ranim otkrivanjem problema vezanih za bezbednost primene leka, kao i boljim izborom i racionalnijim propisivanjem lekova od strane zdravstvenih radnika.

Začetak razvoja farmakovigilance vezuje se za tzv.„talidomidsku katastrofu". Talidomid se u ranim šezdesetim godinama prošlog veka propisivao trudnicama za smanjenje jutarnje mučnine. Međutim, njegova primena je izazvala 10.000–15.000 slučajeva teške deformacije udova (fokomelije) kod dece čije su majke uzimale ovaj lek. Prošlo je mnogo decenija od stavljanja u promet do otkrivanja štetnih efekata aspirina na gastrointestinalni trakt i gotovo isto toliko do prepoznavanja renalne toksičnosti fenacetina pri produženoj primeni. Da aminopirin može da prouzrokuje agranulocitozu, postalo je jasno tek nakon 35 godina, a nekoliko godina je prošlo do uspostavljanja jasne uzročno-posledične povezanosti između primene talidomida i razvoja fokomelije.

Većina novih lekova koji su dostupni na tržištu ispitana je na bezbednost i efikasnost u kratkom vremenskom periodu, na ograničenom broju pažljivo odabranih ispitanika. U većini slučajeva taj broj se kreće do 500, a retko više od 5000 ispitanika koji su uzimali lek pre njegovog zvaničnog puštanja u promet. Svaki lek koji je na tržištu manje od pet godina smatra se novim lekom. Zbog toga je neophodno da se novi lekovi prate nakon registracije i puštanja u promet. Generalno, više informacija je potrebno o efikasnosti i bezbednosti hronične upotrebe, posebno

Abstract

New drugs are more widespread in modern medicine. However, despite all their advantages, the frequency of adverse drug reactions is constantly increasing. Over the past few decades, numerous studies have shown a high incidence of drug-related morbidity and mortality. In some countries, adverse drug reactions are among the 10 leading causes of death. Adverse reactions are estimated to be the 4th-6th most common cause of mortality in the US, and the number of patients who suffer from adverse effects is even higher. In addition, when a patient is prescribed more than one drug, the risk of adverse interactions increases. Choosing the best and safest drug for each patient is a challenge for prescribers.

To prevent or reduce harm to patients, mechanisms for evaluating and monitoring drug safety in clinical practice are of vital importance. In practice, this means that there is a well-organized system of pharmacovigilance. Pharmacovigilance is a term used to describe the process of monitoring and evaluating adverse reactions and is a key component of an effective drug monitoring system in clinical practice. Namely, the number of adverse reactions to drugs and the resulting deaths can be reduced by early detection of problems related to the safety of drug application, as well as by careful selection and more rational prescribing of drugs by health workers.

The beginning of the development of pharmacovigilance is related to the so-called "thalidomide disaster". In the early 1960s, thalidomide was prescribed to pregnant women to reduce morning sickness. However, its use has caused 10,000-15,000 cases of severe limb deformation (phocomelia) in children whose mothers took this drug. It took many decades from its commercialization to the discovery of the harmful effects of aspirin on the gastrointestinal tract, and almost as long to the recognition of the renal toxicity of phenacetin with its prolonged use. That aminopyrine can cause agranulocytosis became clear only after 35 years, and several years passed before establishing a clear cause-and-effect relationship between the use of thalidomide and the development of phocomelia.

Most new drugs available on the market have been tested for safety and efficacy in a short period of time, on a limited number of carefully selected subjects. In most cases, that number ranges up to 500, and rarely more than 5,000 respondents who took the drug before its official release. Any drug that has been on the market for less than five years is considered a new drug. This is why it is necessary to monitor new drugs after registration and marketing. In general, more information is needed for the use of drugs in certain patient populations, such as children,

u kombinaciji sa drugim lekovima, u određenim populacijama pacijenata, kao što su deca, trudnice i starije osobe. Iskustvo je pokazalo da su potrebne godine da bi se otkrili mnogi neželjeni efekti, interakcije (sa hranom ili drugim lekovima) i faktori rizika.

Zadatak farmakovigilance je da poboljša bezbednosni profil lekova i pomogne u izbegavanju daljih katastrofa. Osnovni cilj ovog rada je razvoj svesti zdravstvenih radnika o značaju praćenja bezbednosti lekova i prijavljivanja neželjenih reakcija na lekove.

pregnant women, and the elderly, about the efficacy and safety of chronic use, especially in combination with other drugs. Experience has shown that it takes years to discover many side effects, interactions (with food or other drugs) and risk factors.

The task of pharmacovigilance is to improve the safety profile of medicines and help avoid further disasters. The main goal of this work is to develop the awareness of health workers about the importance of monitoring the safety of medicines and reporting adverse reactions to medicines.