

# GEORGIAN MEDICAL NEWS

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ISSN 1512-0112

No 5 (302) Май 2020

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ТБИЛИСИ - NEW YORK



ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии  
საქართველოს სამედიცინო სიახლენი

# GEORGIAN MEDICAL NEWS

**No 5 (302) 2020**

Published in cooperation with and under the patronage  
of the Tbilisi State Medical University

Издается в сотрудничестве и под патронажем  
Тбилисского государственного медицинского университета

გამოიცემა თბილისის სახელმწიფო სამედიცინო უნივერსიტეტთან  
თანამშრომლობითა და მისი პატრონაჟით

**ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ  
ТБИЛИСИ - НЬЮ-ЙОРК**

**GMN: Georgian Medical News** is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board and The International Academy of Sciences, Education, Industry and Arts (U.S.A.) since 1994. **GMN** carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

**GMN** is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

**GMN: Медицинские новости Грузии** - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией и Международной академией наук, образования, искусств и естествознания (IASEIA) США с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения.

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**GMN: Georgian Medical News** – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

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**Версия:** печатная. **Цена:** свободная.

**Условия подписки:** подписка принимается на 6 и 12 месяцев.

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Monthly Georgia-US joint scientific journal published both in electronic and paper formats of the Agency of Medical Information of the Georgian Association of Business Press; Georgian Academy of Medical Sciences; International Academy of Sciences, Education, Industry and Arts (USA).

Published since 1994. Distributed in NIS, EU and USA.

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3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

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2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალებების შედეგების ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფხიხლებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემაში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.



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## EVALUATION OF THE EFFICACY OF ATYPICAL ANTIPSYCHOTIC DRUGS AND PSYCHOTHERAPY IN PATIENTS WITH PARANOID SCHIZOPHRENIA BASED ON THE DURATION OF REMISSION

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Schizophrenia is still to be a major psychiatric problems, taking into account that schizophrenia disease rate makes up 0.068%, and disorders of schizophrenia spectrum and schizophrenia itself makes up the significant part of psychiatry pathology - 17,3% and 12,9% correspondingly [1 2,10,13]. An important element of the history of psychopharmacology has become its complex cooperation with psychotherapeutic and social rehabilitation methods of influence in treatment of mental illnesses [3,7-9,11,14-16]. The aim of psychosocial rehabilitation is reaching an independent functional patient in the society, delay of neurocognitive deficiency, prevention of recurrent exacerbations and re-hospitalizations, developing of effective disease control strategies and improving the quality of life of the patient and his/her environment [4-6,12,17].

The purpose of the study is to analyse duration of remission as a criterion for the effectiveness of prescribing atypical antipsychotic drugs and psychotherapy to patients with paranoid schizophrenia.

**Material and methods.** The study included patients admitted to treatment at the 2nd and 7th department of Vinnytsia Regional Acad. O.I. Yushchenko Psychoneurological Hospital. Patients were observed throughout the inpatient phase of treatment and, subsequently, within a year after discharge, or, in case of exacerbation of the disease, until the time of hospitalization to the psychiatric hospital. The study was conducted in a randomized, non-blinded, controlled manner. The patients in all clinical groups have been prescribed the antipsychotics registered and authorized in Ukraine. The antipsychotics have been administered as a monotherapy in the average therapeutic doses. The therapeutic schemes and the drugs used within them were in line with clinical guidelines and standards for treatment of schizophrenia, as well as with local protocols. All patients provided informed written consent to participate in the study.

The total number of patients examined was 164 patients, of which 91 were women and 73 men, the average age of patients was  $29.25 \pm 13.5$  years, the number of patients diagnosed with "paranoid schizophrenia" was 118, with the diagnosis of "acute polymorphic psychotic disorder with symptoms of schizophrenia" - 46 patients who were diagnosed with "paranoid schizophrenia" at the readmission, the average duration of the disease was  $2.7 \pm 2.1$  years. Each treatment group included patients with first-time diagnosed schizophrenia (patients who had a clear-cut exacerbation of schizophrenia

when enrolled in the study) and patients with recurrent episodes of disease (patients who had 2 or more cases of schizophrenia exacerbations during their lifetime year).

There were 4 groups of patients, depending on the received antipsychotic and psychotherapy: the study group No. 1 (SG No. 1) included patients receiving antipsychotic therapy with atypical antipsychotic drugs (risperidone, aripiprazole, amisulpride, sertindole; quetiapine), the study group No. 2 (SG+PC) included patients receiving antipsychotic treatment with atypical antipsychotic drugs and psychotherapeutic correction in the form of group psychotherapy using transactional analysis; the control group No. 1 (CG No. 1) included patients receiving antipsychotic therapy with typical antipsychotic drugs (chlorpromazine, levomepromazine, fluphenazine, flupentixol, zuclopentixol, butyrophenone, trifluoperazine, thioridazine); the control group No. 2 (CG+PC) included patients receiving antipsychotic treatment with typical antipsychotic drugs and psychotherapeutic correction in the form of group psychotherapy using transactional analysis. The clinical groups were divided into 4 groups and cohorts 1 and 2 (patients who remained in the study throughout the observation period and patients who left the study at different dates until the end of the study). The statistical tobit model made it possible to objectify the efficiency combination results of antipsychotic drugs and psychotherapy and DR by schizophrenia patients and was used to test the power of hypotheses, that is, the ability of this model to detect existing differences in the efficiency of the compared treatment methods (Rosenbaum and Rubin, 1983; Wooldridge, J.M., 2012).

**Results and discussion.** The criterion for the treatment efficacy was the period between regular hospitalizations that is the duration of remission (DR). DR is equivalent to the risk of rehospitalization that has been considered as evidence of the failure of treatment completion. On the other hand, one can expect a link between a longer hospital stay and a reduced risk of readmission, as long-term hospitalization could be considered to improve treatment adherence. Such a possible relation has formed a separate hypothesis. Evidence of the reliability of the DR criterion for treatment efficacy is the distribution of DR values among patients with re-hospitalization observed during the follow-up period. In table 1 there is a clear dynamic of the proportion of patients until hospitalization during the observation period with the highest hospitalization rate within the first 100 days.

Table 1. Dynamics of patient drop-out during follow-up, number of patients in cohorts at the time of examination

| Antipsychotic drugs | Psychotherapeutic correction (PC) | Observation time, months |     |     |     |
|---------------------|-----------------------------------|--------------------------|-----|-----|-----|
|                     |                                   | 1                        | 3   | 6   | 12  |
| Typical             | -                                 | 57                       | 57  | 30  | 24  |
|                     | +                                 | 25                       | 25  | 15  | 14  |
|                     | Total                             | 82                       | 82  | 45  | 38  |
| Atypical            | -                                 | 41                       | 40  | 36  | 31  |
|                     | +                                 | 41                       | 41  | 41  | 39  |
|                     | Total                             | 82                       | 81  | 77  | 70  |
| Total               |                                   | 164                      | 163 | 122 | 108 |

Evidence of the prior test power is a clear predominance of re-hospitalization cases by the persons treated with typical antipsychotic drugs (44 cases - 54%) compared with those treated with atypical ones (12-15%). Instead, there was a clear predominance of cases of long-term remission by the patients with atypical antipsychotic drugs treatment (70 cases - 86%) compared with those treated with typical ones (38 - 46%) among 108 total number of patients.

The statistical rationale for testing the effectiveness of a rehabilitation program belongs to the segment of data analysis techniques under the general name "Average treatment effect" (ATE). One of the main problems is the shift in performance evaluation due to the violation of randomization of the program purpose, in particular the self-selection effect. The general "outline" of the techniques is to take into account directly unobserved heterogeneity, which, in particular, leads to biased efficacy testing when it is related to test parameters, such as placement of patients in the main and control cohorts.

We used one of the ATE estimator techniques, which uses the proposition of the "redundancy" of the vector  $w$  in the presence of covariate  $x$ . This technique was chosen due to the lack of reliable instrumental variables. In fact, the techniques are connected to solving the problem of missed variables using proxy variables, and under special conditions are simplified to OLS regression with many control cohorts (Wooldridge, J.M. (2012).

Analytical techniques in this category are based on the proposals of Rosenbaum and Rubin (1983), which is known as ignoring the variable purpose of the program (ignorability of treatment) for the observed covariates  $x$ . The main parameter of ATE testing is the coefficient "beta". It's identification from the offsets due to the violation of the program randomization is provided by the inclusion of the component  $b_{Treatment} * Treatment * b_j$ . This component corresponds to the control function.  $b_j$  expresses the individual effect of the patient, which is

decentralized by assigning the function of generating its a priori values to the normal law with zero mean ( $b [j] \sim \text{dnorm}(0, \tau)$ ).

In fact, the individual effect of the patient absorbs all possible fixed effects, ie both observed covariates and unobserved signs (US), thus being a powerful proxy variable for unbiased testing of the effect of DR. The insignificance of the coefficient "bTreatmentb" indicates the absence of shifts in the assessment of ATE due to the violation of appointments randomization. We used a modification of credibility function (CF) fragments according to Clayton (Aitkin and Clayton, 1980; Orbe and Nunez-Anton, 2006) using the generation of facts of re-hospitalizations from the Poisson distribution. MCMC algorithms are a powerful modern driver for the implementation of hierarchical mixed models, to which our model structure belongs. We chose the most proven and powerful Gibbs sampler. The first frailty model included all the observed characteristics of the patient along with the frailty component, which described the directly unexamined characteristics. We used the Geweke's Z and Heidelberg-Welch halfwidth tests (H-W) to diagnose convergence.

The Hooke test is based on comparing the average values of the series of initial 10% and the last 50% of the parameters generated in a single chain of estimates. Estimates of the variances of the mean values are estimates of the spectral density of the corresponding series. The operational test is the classic Z - test of comparison of sample means. Values of  $|Z| > 2$  indicate a significant difference between the means, and, consequently, the lack of convergence. The Heidelberg-Welch test works on a similar principle. Its operational statistics are also Z - test, but the latter is based on half the length (hl) of the intercentile (0.5 and 0.95 centiles) interval of the a posteriori distribution of parameter estimates. If the ratio of hl to the average value of the parameter exceeds 0.1, convergence is not achieved. From Table 2 it follows that convergence is not achieved only for sigma individual effects.

Table 2. Centers of a posteriori distributions of estimates of the basic frailty model parameters with convergence tests of parameters on Markov chains

| Model parameters      | Centile values |         | Convergence tests |            |           |
|-----------------------|----------------|---------|-------------------|------------|-----------|
|                       | 0,05           | Median  | 0,95              | Geweke's Z | H-W hl    |
| Significant effects   |                |         |                   |            |           |
| bTreatment            | -3,344         | -2,103  | -1,192            | -1,97      | 0,000017  |
| bTreatPC              | -2,675         | -0,9694 | -0,5894           | -0,31      | 0,000020  |
| bLOS                  | -0,0708        | -0,0588 | -0,0384           | 0,96       | 0,000017  |
| bDrop                 | 1,096          | 1,188   | 1,299             | -0,12      | 0,001220  |
| bGender               | -2,101         | -1,175  | -0,4953           | 0,78       | 0,000035  |
| bType                 | 0,3109         | 0,9287  | 1,613             | -0,96      | 0,000011  |
| bDisability           | -1,12          | -0,5227 | -0,0110           | 1,08       | 0,007660  |
| bHeredity             | -0,0517        | 0,6001  | 1,571             | -0,20      | 0,000015  |
| bIncidence            | 0,297          | 1,404   | 2,327             | -0,25      | 0,000022  |
| a0                    | 3,8485         | 7,1215  | 12,170            | -0,02      | 0,177000  |
| sigma                 | 0,0529         | 0,0854  | 0,1793            | -0,18      | 0,036400* |
| Insignificant effects |                |         |                   |            |           |
| bTreatb               | -0,875         | 0,123   | 1,865             | 0,93       | 0,000753  |
| bAge                  | -0,0257        | 0,0233  | 0,0469            | -1,44      | 0,000157  |
| bComp0                | -0,0399        | -0,0021 | 0,0429            | -1,94      | 0,000267  |
| bCompD                | -0,0926        | 0,0256  | 0,1168            | -1,69      | 0,000134  |
| bPC                   | -0,7038        | 0,0930  | 0,7851            | -1,54      | 0,000139  |

\* - convergence has not been achieved

When evaluating the  $b_{\text{Treatment}}$  parameter, the effect of atypical antipsychotic drugs with a median value of ATE -2,103 [-3,344; -1,192] appeared to be true-to-fact. The relative risk made up 0.122. The risk of subsequent hospitalization as a result of prescribing of atypical antipsychotic drugs on average decreased by  $(1-0,122) = 100 \cdot 87.8\%$  compared to prescription of typical ones. Thus, it is reliably confirmed that prescription of atypical antipsychotic drugs significantly increases DR compared to prescription of typical antipsychotic drugs.

When evaluating  $b_{\text{TreatPC}}$  parameter, ATE was found to be reliable with accompanying PC treatment with atypical antipsychotics with a median value of -0.9694 [-2.675; 0,5894]. The relative risk was 0.379. The risk of the subsequent hospitalization due to the accompanying of prescription of atypical PC antipsychotics was on average decreased by  $(1-0,379)62.1 = 100 \cdot 62.1\%$  compared to such prescription, but without PC accompanying. Thus, a significant increase of DR by accompanying of atypical antipsychotics PC was proved compared to prescriptions of atypical antipsychotics without PC accompanying).

When evaluating the  $b_{\text{Treatb}}$  parameter, no significant effect was found [-0.875; 1,865] and unbiased evaluation of ATE effect. Therefore, distribution of the patients to therapeutic cohorts was of random character.

BLOS model parameter evaluations [-0.0708; -0,0384], which indicates the effect of duration of psychotherapy accompanying, showed a significant reduction in the risk of re-hospitalization at the optimal duration of psychotherapy, and the risk of subsequent hospitalization with each additional day of psychotherapeutic accompanying during the first 100 days of the observation period with the highest risk of re-hospitalization as a result of relapse from the time of discharge from the hospital decreased on average by 6%. Due to incomplete full-fledged psychotherapy accompanying, the risk of subsequent hospitalization significantly increased in 3.28 times. Thus, it was proved that the optimal duration of psychotherapy accompanying for the patient causes a significant reduction in the risk of relapse. This result can be used as evidence of the need for psychotherapeutic accompanying for the patient at both the hospital and post-hospital stages.

Survival curves (dynamics of the proportion of patients until subsequent hospitalization due to exacerbation of the disease), along with risk modification evaluations, allow to more clearly demonstrate the additional effectiveness of prescription of atypical antipsychotics and PC accompanying compared to prescription of typical antipsychotics. According to the seven-parameter Cox model two curves were constructed that showed the dynamics of proportion of the individuals until subsequent hospitalization in the primary and control cohorts. Performance parameters for atypical antipsychotics and PC accompanying prescription have proven to be reliable. The integral difference of DR per patient made up 140 days. This is the additional number of days of DR before the next hospitalization which is provided by the prescription of atypical antipsychotics and PC accompanying compared to prescription of typical antipsychotics.

Traditionally, the treatment results described in the outpatient card are used. However, it is impossible to avoid two problems:

a) objectivity of the assessment outcome; b) their transient nature. The hospital discharge supposes a stable mental state. At the time of discharge, psychiatrists assess the patient's current condition that may be a temporary improvement, but not a full recovery. The prospective efficiency assessments, such as mortality, disability, exacerbations, look more appropriate. There are three problems in applying the first two medical cases as criteria

for the efficiency of the patient care at hospital: a) the need for a large number of observation units; b) presence of competitive risks; c) comorbid disorders.

The first problem is obvious, its overcoming takes us beyond a certain medical institution, and thus concretizing and meaningfulness of the observation disappear. Competitive risks are traditionally associated with mortality and lethality, but disability can also occur due to a different reason than the previous hospitalization, which significantly shifts the efficiency test. Comorbid disorders imply the need for screening of lethal cases according to the reasons and inclusion only of the risks related or mediated by the previous hospitalization with regulation of the risk competition. As to disability, it is possible even in case of the patient's condition relief and is associated even more with the loss of working capacity and daily activity. Considering that determination of the disability degree is a long process that removes the possible link with the last episode of hospitalization, as well as the objectivity of the medical and social expert commission as to the appointment of a disability group, comorbid disorders lead to serious violations of the test validation.

Exacerbation due to the disease that led to previous hospitalization is a valid criterion, however impractical. Not all the exacerbations induce the patient to seek for medical help; also, some of the outpatient referrals are performed for the dispensary, consultation, other reason under the disguise of an exacerbation. In addition, the fact even of a verified exacerbation itself does not give us a "sensitive key" to the efficiency of the previous inpatient treatment, as an exacerbation can occur immediately after discharge or over a long period with a completely different interpretation. In view of the above, we chose the period duration between regular hospitalizations, that is, the duration of remission (DR) as a criterion for the treatment efficiency.

Thus, DR is a sensitive index of the prescription efficiency. Thus, the efficiency testing according to the experimental frame is a difficult problem, in particular because of the effect bias of the treatment program prescription, and due to the large number of factors which levels are not controlled in the study or even unknown. The main point is to solve the problem of the statistical identification of the treatment program effect, statistical substantiation of the base model based on the chosen approach of the treatment effect identification of the survival curve construction models, that help to evaluate the treatment program effects better.

The following hypotheses were the main for testing:

1. Prescription of atypical antipsychotics significantly increases the DR compared with the appointment of typical antipsychotics.

2. Accompanying of the prescription of atypical antipsychotics with psychotherapeutic consulting (PC) significantly increases the DR compared with the prescriptions of atypical antipsychotics without psychotherapeutic accompanying.

3. The selection of patients to the cohort by prescriptions was randomized.

4. The longer stay of the patient at hospital for completion of the psychotherapy causes significant reduction of the re-hospitalization risk.

The most important parameters were  $b_{\text{Treatment}}$ ,  $b_{\text{TreatPC}}$ , which evaluated the average treatment effect (ATE) of atypical antipsychotics and their DR accompanying, as well as  $b_{\text{Treatb}}$ , which corrected and evaluated the bias in the ATE evaluation due to the heterogeneity of the control and main cohorts.



One of the most important reasons for the formation of unstable remissions is the lack of coverage of all the psychopathological manifestations with therapeutic accompanying, when only the symptoms of the psychotic level are reduced, and the neurotic level remains practically unchanged. The common psychosocial factors that reduce compliance to psychotherapy include the following: the presence of negative symptoms, cognitive disorders in the patient; the use of typical antipsychotics, which do not significantly affect the deficiency symptomatology, complicate the stage of the initial contact with the patient and worsen his susceptibility to psychotherapy; side effects of the drug therapy followed by further violation of therapeutic recommendations by the patient; lack of understanding of the disease nature by the patient and his family; psychological problems of the family members and, as a consequence, impaired social adaptation of the patient. An important factor of the psychotherapeutic effect can include a dysfunctional family structure when the parental figures have opposite positions that creates constant contradictions between them, or inconsistent in their decisions or expectations about the child. This can be a trigger point for the disease re-exacerbation when the patient returns to the family after the inpatient treatment.

The antipsychotic therapy was aimed at manifestations of the psychotic level, and the psychotherapy - at secondary psychogenic symptoms of the neurotic level. Considering the significant role of negative sociogenic factors, among the psychotherapeutic accompanying tasks there was their reduction or, at least, weakening together with the complex therapy with antipsychotics, contributing to the formation of an adequate idea of the disease, cognitive "stimulation" and social activation of patients, personality restructuring, change of the system of mutual relations with the people around and formation of adequate forms of psychological protection with further integration of the new experience into the patients' family structure.

*Scientific novelty.* In the course of the research, from the point of view of the systemic approach, the dynamics of the psychopathological picture was studied during the exacerbation phases and one year of remission in the patients with schizophrenia against the complex use of antipsychotics and group psychotherapy using a transactional analysis. Based on the analysis of the remission duration, the efficiency of the combination of antipsychotics and group psychotherapy using the transactional analysis in the patients with schizophrenia was studied and evaluated for the first time to optimize their treatment and rehabilitation methods. The results of the combined treatment of patients with schizophrenia were objectified for the first time by testing the efficiency of the proposed hypotheses when using the Tobit model for identification of the existing differences in the efficiency of the compared treatment methods.

*The practical significance of the obtained results.* The complex use of atypical antipsychotics and group psychotherapy using the transactional analysis allows to increase the efficiency of schizophrenia treatment both at the stage of exacerbation and at the stage of the process stabilization and remission formation. This effect is manifested in the improvement of the clinical and psychopathological picture of the patients' condition, in the indicators of their cognitive functioning and susceptibility to the psycho-corrective work. The complex use of atypical antipsychotics and group psychotherapy using the transactional analysis allows to reduce the duration of the

inpatient stage of treatment of the patients with schizophrenia and to improve the state of social functioning of the patients. The combined therapy helps to achieve higher quality remission states and creates the tendency for more prolonged remission of the patients.

Summarizing the above-stated information, it can be noted that the use of the combination of psychopharmacological treatment with atypical antipsychotics and group psychotherapy allowed to influence the disease manifestations on the whole, which was reflected in the duration of remission in SG No. 2. Therefore, preconditions for a better adaptation and re-socialization of the patients with schizophrenia are formed.

#### **Conclusions and prospects of further studies**

1. There was a clear dynamic of a part of the patients for re-hospitalization during the observation period with the highest rate of hospitalizations during the first 100 days. The evidence of the prior test efficiency is a clear predominance of re-hospitalization cases among the patients treated with typical neuroleptics (44 cases) compared with such among the patients who were treated with atypical ones (12). Instead, there was a clear predominance of the long-term remission in people treated with atypical antipsychotics (70 cases) compared with those who were treated with typical ones (38) among 108 total number of patients.

2. The risk of the subsequent hospitalization due to the prescription of atypical antipsychotics decreases by 87.8% on the average compared to the prescription of typical ones, that is, prescription of atypical antipsychotics significantly increases the DR compared with the prescription of neuroleptics.

3. The risk of the subsequent hospitalization as a result of accompanying the prescription of atypical antipsychotics of the PC decreases by 62.1% on the average compared with the same prescription but without the PC accompanying.

4. The risk of the subsequent hospitalization with each additional day of hospital stay decreases by 6% on the average. Thus, the longer stay of the patient at hospital leads to a significant reduction of the re-hospitalization risk due to the longer accompanying of the patient with psychotherapeutical consultancy.

5. At the early completion of the inpatient phase of treatment, the subsequent hospitalization risk significantly increases by a factor of 3.28.

6. The continuous course of the disease causes a significantly higher risk of re-hospitalization by a factor of 2.53. Survival curves allow, along with the risk modification estimates, to demonstrate the additional efficiency of prescribing atypical neuroleptics and PC accompanying more clearly compared with the prescription of typical antipsychotics. The integral difference of the DR per patient was 140 days. This is the additional number of DR days before the next hospitalization which is provided by the prescription of atypical neuroleptics and PC accompanying compared with the prescription of typical ones. The values of the DR in case of prescription of atypical neuroleptics and PC accompanying are significantly higher than in case of prescription of typical ones.

7. The data obtained during the study on the improvement of treatment efficacy, the achievement of optimal outcome at inpatient stage, prevention of the relapses, rehospitalization and hospitalism and social restructuring of personality substantiate the reasonability of the group psychotherapy and the use of the transactional analysis together with atypical antipsychotics for reaching and maintaining of remissions at the initial stage of schizophrenia.



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## SUMMARY

### EVALUATION OF THE EFFICACY OF ATYPICAL ANTIPSYCHOTIC DRUGS AND PSYCHOTHERAPY IN PATIENTS WITH PARANOID SCHIZOPHRENIA BASED ON THE DURATION OF REMISSION

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Duration of remission (DR) is the equivalent of the risk of re-hospitalization, which is considered as evidence of unsuccessful completion of the prescribed treatment. The evidence of DR informativeness as a criterion for effectiveness of prescriptions is distribution of DR values among patients with re-hospitalization during the observation period.

The aim of the study is to analyse the duration of remission as a criterion for the effectiveness of prescribing atypical antipsychotic drugs and psychotherapy for patients with paranoid schizophrenia.

4 groups of patients were formed: the study group No. 1 includes patients who received atypical antipsychotic drugs; the study group No. 2 includes patients who received atypical antipsychotic drugs and psychotherapeutic correction (PC); the control group No. 1 includes patients receiving typical antipsychotic drugs; the control group No. 2 includes patients who received typical antipsychotic drugs and PC. The total number of examined patients was 164 people, the average age was 29.25±13.5 years, the number of patients with a diagnosis of paranoid schizophrenia was 118, with a diagnosis of acute polymorphic psychotic disorder with symptoms of schizophrenia - 46. The average duration of the disease was 2.7±2.1 years. The statistical tobit model made it possible to objectify the results of the effectiveness of the combination of antipsychotic drugs, psychotherapy, and DR by the studied patients. We used the tobit model to test the power of hypotheses, i.e., the possibility of this model to determine the existing differences in the effectiveness of the compared treatment methods (Rosenbaum and Rubin, 1983; Wooldridge, J.M., 2012).

The effectiveness of the treatment was evaluated by indicators of duration of the remission period by the patients and the risk of re-hospitalization due to disease relapse. We observed a clear dynamic of some patients to re-hospitalization during the observation period with the highest hospitalization rates in the first 100 days. Evidence of the tests powers was a clear prevalence of cases of re-hospitalization by the patients taking typical antipsychotic drugs (44 cases) compared with those among patients receiving atypical ones (12). There was a clear predominance of cases of prolonged remission by the patients who took atypical antipsychotic drugs (70) compared with those who received typical ones (38) among 108 of censored ones. It was determined that patients who took typical and atypical antipsychotic drugs entered remission with the same period, but its quality was different. It was found that the indices of DR by prescription of atypical antipsychotic drugs and PC were significantly higher compared with those of typical antipsychotic drugs - the integral difference in DR per patient was 140 days. The risk of re-hospitalization due to prescription of atypical antipsychotic drugs decreases on average by 87.8% compared with prescription of

the typical ones, that is, prescription of atypical antipsychotic drugs significantly increases DR compared with prescription of typical antipsychotic drugs.

**Key words:** paranoid schizophrenia, remission, atypical antipsychotic drugs, psychotherapy.

## РЕЗЮМЕ

### ОЦЕНКА ЭФФЕКТИВНОСТИ ПРИМЕНЕНИЯ АТИПИЧЕСКИХ АНТИПСИХОТИКОВ И ПСИХОТЕРАПИИ У ПАЦИЕНТОВ С ПАРАНОИДНОЙ ШИЗОФРЕНИЕЙ В ЗАВИСИМОСТИ ОТ ДЛИТЕЛЬНОСТИ РЕМИССИИ

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Длительность ремиссии (ДР) является показателем риска регоспитализации и считается индикатором неудачного завершения назначенного лечения. Доказательством информативности ДР как критерия эффективности назначений является распределение значений ДР среди пациентов с регоспитализацией на протяжении периода наблюдения.

Цель исследования – анализ длительности ремиссии как критерия эффективности назначения атипичных антипсихотиков и психотерапии пациентам с параноидной шизофренией.

Пациенты были распределены на 4 группы: в I группу исследования вошли пациенты, получавшие атипичные антипсихотики; во II группу исследования - пациенты, получавшие атипичные антипсихотики и психотерапевтическую коррекцию (ПК); в I группу контроля - пациенты, получавшие типичные антипсихотики; во II группу контроля - пациенты, получавшие типичные антипсихотики и ПК. Общее количество обследованных больных составило 164 человека, средний возраст -  $29,25 \pm 13,5$  лет, количество пациентов с диагнозом «параноидная шизофрения» - 118, с диагнозом «острое полиморфное психотическое расстройство с симптомами шизофрении» - 46. Средняя длительность болезни составила  $2,7 \pm 2,1$  года. Статистическая тобит модель позволила объективизировать результаты эффективности комбинации антипсихотиков, психотерапии и ДР у исследуемых больных. Тобит модель использована для тестирования мощности гипотез, т.е. возможности данной модели определить в эффективности сравниваемых методов лечения.

Оценку эффективности проведенного лечения осуществляли с учетом показателей длительности периода ремиссий у пациентов и риска регоспитализации вследствие релапса заболевания. Наблюдали четкую динамику части пациентов к регоспитализации на протяжении периода наблюдения с наивысшими показателями госпитализаций в первые 100 дней. Доказательством мощности тестов было явное превалирование случаев регоспитализации у больных, принимающих типичные антипсихотики ( $n=44$ ) сравнительно с пациентами, получавшими атипичные ( $n=12$ ). Наблюдалось явное преобладание случаев длительной ремиссии у пациентов, принимающих атипичные антипсихотики ( $n=70$ ) в сравнении с больными, получающими типичные ( $n=38$ ) из 108 цензурированных. Определено,

что больные, которые принимали типичные и атипичные антипсихотики, вступали в ремиссию с одинаковым промежутком времени, однако качество ремиссии отличалось. Установлено, что показатели ДР при назначении атипичных антипсихотиков и ПК оказались значительно выше в сравнении с таковыми типичных антипсихотиков - интегральная разница ДР на пациента составила 140 дней. Риск регоспитализации вследствие назначения атипичных антипсихотиков, в среднем, уменьшился на 87,8% в сравнении с применением типичных, т.е. назначение атипичных антипсихотиков достоверно увеличивает показатели ДР.

## რეზიუმე

ატიპობრივი ანტიფსიქოზური საშუალებების და ფსიქოთერაპიის დანიშნვის ეფექტურობის შეფასება რემისიის ხანგრძლივობის გათვალისწინებით პაციენტებში პარანოიდული შიზოფრენიით

ო.მრუგი, ს.რიმშა, ვ.მრუგი

ვინიცას ნ. პიროგოვის სახელობის ეროვნული სამედიცინო უნივერსიტეტი, ფსიქიატრიისა და ნარკოლოგიის კათედრა, ფსიქოთერაპიის კურსით, მიკრობიოლოგიის, ვირუსოლოგიისა და იმუნოლოგიის კათედრა, უკრაინა

რემისიის ხანგრძლივობა წარმოადგენს რეკონსტიტუციის რისკის მაჩვენებელს, რაც მკურნალობის წარმატებული დასრულების ინდიკატორადაა მიჩნეული. რემისიის ხანგრძლივობის ინფორმაციულობის, როგორც დანიშნულების ეფექტურობის კრიტერიუმის, დადასტურებას წარმოადგენს მისი მნიშვნელობების განაწილება რეკონსტიტუციის საჭიროების მქონე პაციენტებში დაკვირვების პერიოდში.

კვლევის მიზანს წარმოადგენდა რემისიის ხანგრძლივობის, როგორც ატიპობრივი ანტიფსიქოზური საშუალებების და ფსიქოთერაპიის დანიშნვის ეფექტურობის კრიტერიუმის, ანალიზი პაციენტებში პარანოიდული შიზოფრენიით.

პაციენტები დაიყო 4 ჯგუფად: I ჯგუფში გაერთიანდნენ პაციენტები, რომლებიც იღებდნენ ატიპობრივ ანტიფსიქოზურ საშუალებებს, II ჯგუფში - პაციენტები, რომლებიც იღებდნენ ატიპობრივ ანტიფსიქოზურ საშუალებებს და ფსიქოთერაპიულ კორექციას; I საკონტროლო ჯგუფი შეადგინა პაციენტებმა, რომლებიც იღებდნენ ტიპობრივ ანტიფსიქოზურ საშუალებებს, II საკონტროლო ჯგუფი კი - ტიპობრივ ანტიფსიქოზურ საშუალებებს და ფსიქოთერაპიულ კორექციას. გამოკვლევული პაციენტების საერთო რაოდენობა - 164, საშუალო ასაკი -  $29,25 \pm 13,5$  წელი; პაციენტები დიაგნოზით “პარანოიდული შიზოფრენია” - 118, დიაგნოზით “მწვავე პოლიმორფული ფსიქოზური აშლილობა შიზოფრენიის სიმტომებით” - 46. დაავადების საშუალო ხანგრძლივობამ შეადგინა  $2,7 \pm 2,1$  წელი.

სტატისტიკურმა ტობიტ-მოდელმა შესაძლებელი გახადა ანტიფსიქოზური საშუალებების, ფსიქოთერაპიის და სხვ. კომბინაციის ეფექტურობის შედეგების ობიექტივიზაცია გამოკვლევულ პაციენტებში. ავტორების მიერ გამოყენებულია ტობიტ-მოდელი პიპოტეზების სიმძლავრის ტესტირებისათვის, ანუ ამ მოდელით განსაზღვრულია მკურნალობის შესაძარებელ მეთოდებს შორის არსებული განსხვავებები.

ჩატარებული მკურნალობის ეფექტურობა შეფასდა პაციენტებში რემისიის პერიოდის ხანგრძლივობის და რეკონსტიტუციის რისკის მიხედვით დაავადების რელაქსის შედეგად. პაციენტების ნაწილში სახეზეა რეკონსტიტუციის მკაფიო დინამიკა დაკვირვების პერიოდში, მაქსიმალური მაჩვენებლით პირველი 100 დღის განმავლობაში.

ტესტების სიმძლავრის მტკიცებულებას წარმოადგენდა რეკონსტიტუციის აშკარა პრევალირება პაციენტებში, რომლებიც იღებდნენ ტიპობრივ ანტიფსიქოზურ საშუალებებს (44 შემთხვევა), იმ პაციენტებთან შედარებით, რომლებიც იღებდნენ ატიპობრივ ანტიფსიქოზურ საშუალებებს (12 შემთხვევა). ცენტრირებულ 108 პაციენტს შორის ავტორები მიუთითებენ ხანგრძლივი რემისიის შემთხვევების სიჭარბეზე პაციენტებში, რომლებიც იღებდნენ ატიპობრივ ანტიფსიქოზურ საშუალებებს (70 შემთხვევა), იმ ჯგუფთან შედარებით, რომელიც იღებდა ტიპობრივს

(38 შემთხვევა). განსაზღვრულია, რომ პაციენტები, რომლებიც იღებდნენ ტიპობრივ და ატიპობრივ ანტიფსიქოზურ საშუალებებს რემისიაში შედიოდნენ დროის ერთნაირ მონაკვეთში, მაგრამ რემისიის ხარისხი განსხვავებული იყო. დადგინდია, რომ რემისიის ხანგრძლივობა ატიპობრივი ანტიფსიქოზური საშუალებების და ფსიქოთერაპიის დანიშვნის დროს მნიშვნელოვნად მეტია, ვიდრე ეს მაჩვენებელი ტიპობრივი ანტიფსიქოზური საშუალებების მიღების შემთხვევაში; ინტეგრალურმა განსხვავებამ რემისიის ხანგრძლივობისათვის შეადგინა 140 დღე. რეკონსტიტუციის რისკი ატიპობრივი ანტიფსიქოზური საშუალებების დანიშვნის შემთხვევაში, საშუალოდ, შემცირდა 87,8%-ით, ტიპობრივის დანიშვნასთან შედარებით. ამრიგად, ატიპობრივი ანტიფსიქოზური საშუალებების დანიშვნა, ტიპობრივთან შედარებით, სარწმუნოდ ზრდის რემისიის ხანგრძლივობას.

## SEPSIS: IMPORTANCE OF ETHNIC PROPERTIES AND PHENOTYPES (REVIEW)

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Sepsis is a common, heterogeneous clinical syndrome. According to the new definition, this is a life-threatening organ dysfunction caused by dysregulated host response to infection. Sepsis incidence and septicemia-related deaths over the last decades is rising worldwide [18]. This trend is expected to continue due to aging of the population, increasing burden of chronic health conditions, and increased use of immunosuppressive therapy, transplantation, chemotherapy, and invasive procedures [10]. Although its outcomes have improved during last decades, mortality remains high – about 30% [28-31]. Multiple factors can affect the outcome of sepsis: infectious agent, site of infection, organ dysfunction, comorbidities, age, sex, social, ethnic, race factors [1,18-20,28,29]. There are different scoring systems for prediction of sepsis outcome but in some cases we can see that patient, whose outcome must be pure is recovering but other patient, whose outcome predicted excellent is dying [45]. According to clinical findings is difficult to explain such paradox. Some authors suggesting that racial, ethnic, genetic factors not only influencing on sepsis clinic, but can serve as predictive factors for outcome [4,9,13,15-20]. In this review we are focusing on the importance of ethnic and phenotype properties on sepsis, its treatment and outcome.

*Ethnic and racial disparities in sepsis outcome.* Most studies about the patient depended factors of sepsis outcome are focusing primarily for age and sex [10,18,45]. The effect of other patient and hospital characteristics on disparities in sepsis mortality is not yet well-known. However, it had been reported that wide racial variation exists in the incidence of septicemia, with rates among nonwhites almost double those of whites [18,19]. These observations persisted after adjusting for preexisting chronic

illness and source of infection. On the same time, these differences can be related with socioeconomic status, tobacco smoking, statin therapy, region of residence as well as to pre-hospital and in-hospital care, because black and Hispanic patients live in geographically segregated regions of USA [5-8,12,21-25].

Barnato AE. et al [18] studied outcome of sepsis in 6 states of USA with population about 78 mln. Interestingly, that he largest racial group was white (66.2%), followed by Hispanic (19.7%) and black (14.1%). The mean age was much lower in blacks and Hispanics compared with whites (mean age: 31.8 and 29.4 vs. 39.5 yr,  $P<0.0001$ ). In this region of USA during 2001, 282,292 hospitalized patients met to criteria for severe sepsis, most common infection was pneumonia, bloodstream and genitourinary tract infections. Blacks had the highest rate of severe sepsis (6.08 per 1,000), followed by Hispanics (4.06 per 1,000) and whites (3.58 per 1,000). Black patients, and to a lesser degree Hispanics, were more likely to receive treatment in large, urban teaching hospitals than whites. According to the study, overall mortality for blacks was higher than for whites, due both to greater incidence and higher case fatality. One of the explanations, given from authors is that blacks being treated at large, urban teaching hospitals and hospitals with poorer quality processes and outcomes of care [6,21,22]. Other factors are not excluded too, such as tobacco use, pharmaceutical use, health care resources, social factors but the greater adjusted incidence among blacks and the lower incidence among Hispanics could be due to differences in the underlying biologic response to infection and injury. From authors opinion one possible explanation is different genetic susceptibility to sepsis between blacks and whites. Individuals of European and African ancestry likely