**REVIEW**

**By Prof. Dr. Hristo Tsekov Tsekov, Head of the Clinic of Neurosurgery, Acibadem City Clinic UMHAT Tokuda Hospital, EAD, Sofia**

**Subject: Dissertation of Dr. Evgeni N. Vlaev, orthopedist at the Clinic of Orthopedics at Tokuda Hospital, Sofia on "Surgical treatment of scoliosis in childhood - methods for evaluation and analysis of results"**

Dr. E. Vlaev was born in 1971, graduated from high school teaching English in St. Zagora, and in the same city he completed his higher education with a master's degree in 1995. He works as a pediatrician in Chirpan, as a military doctor in the Lyubimets unit, as a doctor in the SNMP - Stara Zagora. During the period 1998-2006 he was an assistant, senior assistant and chief assistant in the Department of Anesthesiology, General and Emergency Medicine at the Medical Faculty at the Thracian University in St. Zagora. Since 2006 he has been a doctor at the Clinic of Orthopedics and Traumatology at Acibadem City Clinic UMHAT Tokuda Hospital, Sofia. He has participated in several international conferences at home and abroad, attended many short courses and qualifications, mainly in Europe and Asia. He is a member of the BMA. Filed in the Mountain Rescue Service, he participated in the 18th National Arctic Expedition on Livingston Island.

Presents a dissertation on the topic: "Surgical treatment of scoliosis in childhood - methods for evaluation and analysis of results."

To be admitted to the forthcoming defense, the requirements and deadlines required by the Law on the Development of the Academic Staff in the Republic of Bulgaria and the Regulations of Tokuda Hospital - Sofia have been met. A dissertation, an abstract and three full-text publications related to the dissertation are presented. The following are presented in full text: Surgical treatment of neuromuscular scoliosis in children. A.Ivanov, V.Yablanski, E.Vlaev Medical Review LII, 4, 53-56 (2016), Surgical treatment of scoliosis in children V.Yablanski, A.Ivanov, E.Vlaev, V.Stefanov, B.Kamenova , Г.Симеонов. Orthopedics and Traumatology 53.2, 95-99 (2016) and official note for a peer-reviewed article in Medical Magazine, ISSN, 1314-9709 for May 2022.

The dissertation treats a socially significant problem, such as the surgical treatment of scoliosis in childhood. Its frequency is on average about 3% of the population, and in a significant percentage of children it progresses, causing a high degree of disability, which requires surgical treatment. Surgical treatment has no alternative in progressive and non-conservative cases. Indicated - surgical treatment is usually not carried out in a timely manner, but is expected due to a number of considerations of parents and largely due to the frequent mismatch between the expected effect of surgical treatment and actual results, mostly nuanced by subjective experiences of patients and relatives.

The aim of this dissertation is to find a balance between the type and degree of scoliosis on the one hand and the result obtained on the other (objective and subjective), and when discussing postoperative results with the patient and his relatives it is necessary to have a significant the expected and achieved results, which is a significant problem in such complex interventions as spinal corrections. This problem arises from the desire of the surgeon - orthopedist to achieve the maximum in the correction of scoliosis, which allows him the appropriate intraoperative environment, but this will not always correlate with the obtained postoperative result, i.e. to assess at what stage the correction should be terminated, regardless of the fact that the situation allows resp. tempting. In order to achieve the much-needed balance, appropriate tasks and analysis of the operated group of patients have been set.

The dissertation itself is written on 138 standard typewritten pages, structured as follows: introduction - 3 pages, literature review - 23 pages with conclusions from the literature review of one page, research methodology - 12 pages, research results - 55 pages, discussion of the results - 21 pages, conclusions and recommendations - 1 page, literature review - 9 pages. It is illustrated with 89 figures, 14 tables, and the figures include many graphic images.

Regarding the title of the dissertation "Surgical treatment of scoliosis in children - methods for evaluation and analysis of results" it would seem more logical as "Methods for evaluation and analysis of results in surgical treatment of scoliosis in children", as in my opinion, in the dissertation the emphasis is on the analysis of the results, and not on the operative technique itself. The literary review is up-to-date, extensive, engaged with the topic, with discussion, although not in detail, but it results in well-formulated goals and objectives. The analyzed literature sources are 135, 11 of which are in Cyrillic, citing only Bulgarian authors, which promotes and evaluates the efforts of Bulgarian authors and which honors the author of the dissertation. A thorough analysis of all possible methods for monitoring the disease - preoperative and postoperative, in addition to standardized radiographic parameters are analyzed and data from the patient and his parents providing comprehensive information about the health, mental and emotional state of the patient. the information is to obtain information about the wishes and expectations of the patient and his relatives about the effect of the intervention, as well as to measure its effectiveness.

The questionnaires and tests adopted in practice, analyzed in detail by the author and compared in various literature sources with the results of imaging studies help to study which of the elements forming spinal deformity are directly related to complaints and visible condition of the patient and thus form the idea of the intervention itself, so that the patient's expectations are closest to the real result.

The author considers the SRS22r questionnaire to be the most comprehensive, which is specific for children with spinal deformities and has proven to be the most effective assessment tool for them. The results obtained with the help of this questionnaire are accepted as a criterion in deciding on the specific treatment, follow-up of the patient and evaluation of the results of the treatment. The comparative analysis of the SRS22r questionnaire with other similar ones is extremely valuable: ODI and SF-36.

The purpose of the present dissertation derives from the analysis of the literature: To study the possibilities for qualitative / subjective / evaluation of the results of surgical treatment of children with scoliosis and to implement it as a modern approach in developing protocols for clinical evaluation of surgical treatment.

To achieve this goal, specific tasks have been set:

1. To collect and analyze the results of surgical treatment of scoliosis in a sufficient number of children with various forms of scoliosis, allowing statistically reliable data.

2. To make a comparative analysis of the objective clinical and X-ray data before and after their surgical treatment.

3. To explore the possibilities for assessing patient satisfaction before and after surgical treatment by applying a specific questionnaire to measure the patient's subjective self-esteem and the impact of surgery on his lifestyle. To analyze the data obtained before and after surgical treatment.

4. To study the available relationships between objective clinical and X-ray data and the subjective perception of patients in the evaluation of surgical treatment of scoliosis and to analyze the results obtained.

5. To analyze the results of the study and to make recommendations that will lead to the creation of protocols for preoperative planning and postoperative follow-up of patients.

6. To prove the effectiveness of the specific questionnaire SRS22r as a tool for qualitative assessment of the results of surgical treatment of scoliosis and to introduce it as a necessary element in the protocols for preoperative preparation of patients and postoperative follow-up.

The study included a group of 101 children with scoliotic spinal deformity operated on in Tokuda Hospital - Sofia with direct participation of dr. Vlaev for the period 2014 - 2019. The number allows conclusions to be drawn with static reliability. In addition to the standard anamnesis, clinical examination, specific examination, all patients are examined with modern diagnostic techniques: radiography, CT, MRI. All patients completed a SRS22r form - a questionnaire - a questionnaire including 22 questions related to quality of life in 5 areas: function, pain, self-esteem, mental health, satisfaction. Based on all data and measurements, the nature of spinal deformity / congenital scoliosis, neuromuscular scoliosis, scoliosis in neurofibromatosis, scoliosis in genetic syndromes, infantile scoliosis, juvenile scoliosis, adolescent idiopathic operative scoliosis, and operative access, size of fusion and instrumentation, density of instrumentation, type of synthesis, need for osteotomies and tocoplastics.

Postoperatively, after the complete recovery of the child, the same form is filled in again, and children must meet the following criteria when included in the study: patients under 18 years of age, available scoliotic deformity, surgical treatment including posterior spinodesis. Thus, 86 children with SRS22r test and 101 children with X-ray examinations and clinical examinations were included in the study. The material is sufficient and allows quality static processing, which the dissertation has benefited from, presenting everything in graphs, tables, diagrams, figures. Modern methods have been used to assess the patient's condition before and postoperatively, including objective examination, subjective complaints, imaging, functional assessment. Such a comprehensive assessment has been made for both different age groups and different forms of scoliosis, which makes the results of this study extremely valuable.

Statistical processing includes variational analysis of quantitative variables / mean, standard deviation, standard error, 95% confidence interval of the mean, minimum and maximum /, frequency analysis of qualitative variables (nominal and rank), graphical images. As methods for testing hypotheses are applied:

1. Parametric methods

1.1 T-test for two independent samples (IndependentSamplesT-Test) - check for equality of two averages in normal distribution.

1.2 One-way variance analysis (OnewayANOVA - independent samples) - check for equality of more than two averages using PostHocTests for multiple comparisons with Bonferoni correction.

2. Non-parametric methods

2.1 Chi-square test or Fisher's exact test - search for a relationship between two qualitative variables.

2.2 Mann-Witney method - comparison of two groups of one quantitative variable when the distribution is not normal.

2.3 Kruskal-Wallis Test - comparison of more than two independent groups in terms of the characteristics of a quantitative variable that does not have a normal distribution.

2.4. Kolmogorov-Smirnov and Shapiro-Wilk methods - check for normality of the distribution of a quantitative variable.

2.5. Wilcoxon Signed Ranks Test - Comparison of nominal or rank variables in 2 dependent samples.

The critical significance level used is α = 0.05. The corresponding null hypothesis is rejected when the P-value is less than α. In multiple comparisons, the Bonferon significance level correction is used.

SPSS versions - SPSS for Windows 13.0 and IBMSPSSStatisticsVersion 19 were used to process the data from the research related to the dissertation.

- In patients with clinical and radiographic evidence of severe deformity and low SRS22r score, more aggressive, albeit higher-risk, surgical interventions and actions should be considered in preoperative discussion. There are no alternative and less invasive techniques.

- In patients with clinical and radiographic evidence of severe deformity but with a high SRS22 score, discussion of operative action should be aimed at maintaining functionality without seeking maximum correction. Vertebrodesis alone (stopping the progression of the deformity) would be sufficient, even without significant correction - "in situ". There are no alternative and less invasive techniques here.

- In patients with clinical and X-ray data for mild deformity and high SRS22r score, in the preoperative discussion, less minimally invasive techniques can be considered: "Selective fusion" or alternative methods: VBT, Apifix, VEPTR.

- In patients with clinical and radiographic evidence of mild deformity and low SRS22r scores, it is appropriate to initiate surgical treatment at an earlier stage. This would ensure the achievement of excellent postoperative both objective and subjective results.

- In the postoperative follow-up of patients and evaluation of the long-term results of the surgical treatment of children with scoliosis using a combination of the two methods, diverse results can be obtained:

- In patients with significantly improved clinical and X-ray data and increased SRS22r data: the assessment is strongly positive. These children are clinically better looking and satisfied with the actions taken. The result of the operative treatment is excellent and the approach in the preoperative planning was correct.

- In patients with not so good improvement in clinical and radiographic data, but significantly increased SRS22r data: the assessment is strongly positive. Here one can look for an objective impossibility to make a better correction. These children are very happy with the operation, although only with a slight improvement in the clinical outcome. The result of the operative treatment is excellent and the approach in the preoperative planning was correct.

- In patients with significantly improved clinical and radiographic findings and a slight increase in SRS22r data: positive. These children are clinically better looking, but not entirely satisfied. The result of the operative treatment is good, but the approach in the preoperative planning should have been different: discussion of the possibilities for correction and the purpose of the operation.

- In patients with a slight improvement in clinical and X-ray data, and in SRS22r data there is only a slight increase or even decrease: the assessment is negative. In these children there is no improvement in their appearance and self-esteem. The result of surgical treatment is not optimal and expectations. The reasons for this can be different: poorly performed operation, objective impossibility for better correction, limitation of the correction possibilities predetermined by IONM.

- In patients with severe intraoperative or postoperative complications, the result is presumed to be poor.

In order to correctly interpret the results of the surgical treatment of patients with scoliosis, it is necessary to analyze the data for each specific case. The overall picture of the correctness of the decision taken, the approach taken and the specific actions and the result gives a comprehensive assessment of quantitative and qualitative indicators, as well as their comparison with preoperative data.

The author draws his conclusions and substantiates some recommendations for practice:

1. The SRS22r questionnaire is accessible, easy to use as a tool and a practical way to measure subjective self-assessment of health. It provides an excellent opportunity to study the achieved quality indicators on several different criteria: function, pain, self-assessment, mental health, overall satisfaction. The SRS22r rating is very reliable, easy to implement, cheap and does not require special equipment.

2. Each of the methods for evaluating the results of the surgical treatment of scoliosis gives a different view of the individual case. The combination of the specific data derived from each method provides complex, clear, accurate and reliable information. When used in combination, they complement each other and allow for a comprehensive analysis.

3. There is a lasting positive dependence when comparing the results of surgical treatment with both methods. However, the present study reveals some specific differences in the simultaneous assessment with the two methods. This requires special attention in the interpretation of the data and gives grounds to revise some aspects of current perceptions of the actual assessment.

4. Patients with AIS are most suitable for testing and evaluation with the SRS22r questionnaire. In children suffering from other forms of scoliosis, this assessment is not always adequate and informative and its use is more difficult to apply and not reliable enough.

5. When planning and conducting surgery in children with scoliosis, an individual approach to each individual patient is needed, based on both clinical and X-ray data and the assessment of the SRS22r questionnaire. This approach includes an in-depth discussion of the upcoming surgical intervention with children and parents regarding the objective and subjective possibilities, the expected results and possible complications for the specific case.

6. The provided data, conclusions, recommendations and protocols would provide useful information and greater accuracy in determining the time, type, extent and scope of operational intervention. This would improve the results of surgical treatment of children with scoliosis. The following can be mentioned as original contributions:

1. Data from a large-scale and long-term study of the health status of very diverse groups of children with scoliosis before and after their surgical treatment are presented, which allows to achieve a significant statistical result.

2. For the first time in our country a study of a qualitative indicator of the outcome of surgical treatment of scoliosis is being done. A tool developed by the Scoliosis Research Association (SRS) is used: the SRS22r questionnaire.

3. A comparative analysis of the introduced method for qualitative assessment of the achieved results with the generally accepted objective results from the quantitative examinations before and after the surgical treatment of scoliosis is made. Dependencies have been identified, conclusions have been drawn and recommended algorithms for preoperative preparation and planning of surgical treatment and postoperative follow-up have been presented.

The following are defined as mainly confirmatory contributions:

4. The need is substantiated and the importance of the quality methods used as reliable and sensitive for evaluation is strongly confirmed. The advantages of joint use with generally accepted methods for objective quantitative assessment of surgical treatment of scoliosis in children have emerged.

5. The need for an individualized approach to each patient and assessment of the patient's point of view in the process of treatment of this disease is confirmed.

Contributions of an attached nature:

6. The present study initiated and conducted testing of the SRS22r questionnaire in our conditions as a reliable and high-quality tool for assessing the quality of life in children with spinal deformities.

7. Based on this study, recommendations and practical clinical algorithms for effective diagnosis, clinical indications, preoperative planning, postoperative assessment of therapeutic outcome and follow-up of children to ensure adequate treatment of sick children. They are logical, aimed at individual approach, easy and convenient to use in practice.

In conclusion, I can say:

The topic is socially significant, the problem is relevant. The material is sufficient and allows quality static processing, which the dissertation has benefited from, presenting everything in graphs, tables, diagrams, histograms. Modern methods have been used to assess the patient's condition before and postoperatively, including objective examination, subjective complaints, imaging, functional assessment. Such a comprehensive assessment has been made for both different age groups and different forms of scoliosis. Significant contributions of an original, confirmatory and practical nature have been reported.

I also have some remarks that have been discussed with the dissertation: correction of the title, grouping of the material with correction of numbering, numbering of the illustrative material, minor stylistic and grammatical omissions.

In general, the work is dissertable, the material is sufficient for the conclusions made and has specific scientific and practical contributions.

The dissertation presented for defense has certain scientific and practical contributions, meets the scientometric criteria and has the qualities that give me the right and pleasure to propose to the scientific jury to award Dr. Evgeni Vlaev scientific degree "PhD".

May 9, 2022. Reviewer: Prof. Tsekov