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SAFETY OF REGIONAL ANESTHESIA: PARESTHESIA TECHNIQUE VERSUS ULTRASOUND-GUIDED ANESTHESIA IN PATIENTS WITH LIMB TRAUMA. A PILOT STUDY

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БЕЗПЕКА В РЕГІОНАРНІЙ АНЕСТЕЗІЇ: ПОРІВНЯННЯ ТЕХНІКИ ВИКЛИКАННЯ ПАРЕСТЕЗІЇ З УЛЬТРАЗВУКОВОЮ НАВІГАЦІЄЮ ДЛЯ АНЕСТЕЗІЇ У ПАЦІЄНТІВ З ТРАВМАМИ КІНЦІВОК. ПІЛОТНИЙ ПРОЕКТ **Р. Балтага, О. Арнаут, С. Шандру, С. Кобалетчі, Е. Гросу, Г. Рожновеану**

Дана стаття знайомить читача з результатами пілотного проекту в респ. Молдова щодо порівняння техніки викликання парестезії та ультразвукової навігації при виконанні регіонарних блокад у пацієнтів з травмами кінцівок. Стаття буде цікава до прочитання практикуючим анестезіологам, травматологам, хірургам, а також інтернам.

Ключові слова: ультразвукова навігація при регіонарній анестезії, парестезія, безпека пацієнта.

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This article introduces the reader to the results of a pilot project in rep. Moldova regarding the comparison of techniques for inducing paresthesia and ultrasound

navigation when performing regional blockades in patients with limb injuries. The article will be interesting to read for practicing anesthetists, traumatologists, surgeons, as well as interns.

Keywords: ultrasound navigation during regional anesthesia, paresthesia, patient safety.

1. Introduction

From the first official data, published in 1994 until now, according to worldwide statistics, the last decade has been characterized by an important increase in the popularity of regional anesthesia. This fact is determined, in particular, by the implementation of innovative technologies for localization of the anatomical structures and the real-time visual control of the procedure; success achieved mainly, due to availability of use of ultrasound in different fields of the Anesthesia and Intensive Care. [1; 2]

The application of ultrasound in performing regional anesthesia has rediscovered this anesthetic technique by developing new types of nerve blocks, implementing new approaches that have redefined existing blocks; having also a significant impact on patient safety, by increasing the success rate of the procedure, by decreasing the rate of complications and improving the clinical outcome of the patient. [3; 4]

A strong argument for the widespread use of ultrasound guidance in performing regional anesthesia is determined by the disadvantages and possible complications to which the patient is predisposed, when practicing the method of transcutaneous localization of the nerves through paresthesia technique: by reaching / involvement of other anatomical structures than the targeted nerve plexus, with their injury, the possible development of bleeding or accidental intravascular injection of local anesthetic. An aspect of no lesser importance is the actual injury of the sought nerve, due to the impossibility of real-time visual control of the needle. Limitations in the use of regional anesthesia performed by paresthesia technique are also imposed by the difficulties in cooperation with children, the elderly, patients with disabilities (deafness, aphasia, etc.). [5; 6] In addition to the fact that use of ultrasound avoids those disadvantages and complications mentioned above, one of the multiple benefits of ultrasound-guided regional anesthesia over the paresthesia technique is the recognition of anatomical variations of the structures of the anesthetized area, which could restrict or influence to some extent, injection and spread of local anesthetic. Ultrasound guidance detects these anatomical particularities in patients, and allows the controlled needle redirection to the target structure and its hydro-localization. [7; 8]

In Institute of Emergency Medicine, Chisinau, Republic of Moldova, the introduction of the ultrasound guidance in the Anesthesia and Intensive Care Department represented a very important step, because in this institution, are concentrated the majority number of regional anesthesia performed throughout the country; this phenomenon is due to the specificity of this clinic, in which, in particular, patients with trauma / injuries of the extremities and not only, are directed to the Institute of Emergency Medicine's Microsurgery service.

Since 2006, with the purchase of the ultrasound device in the Department of Anesthesia and Intensive Care of the Institute of Emergency Medicine, the first medical procedures under ultrasound guidance were performed: the first ultrasound-guided catheterizations of the central veins, and the first ultrasound-guided regional anesthesia cases. Following the trends and recommendations of the international reference

societies (The European Society of Anaesthesiology, The European Society of Regional Anaesthesia & Pain Therapy, The American Society of Regional Anesthesia and Pain Medicine), the implementation of the ultrasound-guided method of regional anesthesia represents an important aspect for patient safety, and nowadays, worldwide, the use of ultrasound for this type of anesthesia represents the gold standard. [2; 9; 10]

Those already 12 years of experience, accumulated from the first regional anesthesia performed under ultrasound guidance and up to now, have formed the prerogative of starting a retrospective analysis on this subject, highlighting not only the successes, but also analyzing the deficiencies in the technique used, in training of the practitioners, evaluating the effectiveness and possible long-term complications; aspects intended to be subject, if necessary, to changes, in order to increase the patient's safety vis-à-vis the discussed anesthetic technique.

2. Materials and methods

The study is a retrospective one and was performed on a total number of 200 patients, divided into 2 groups of 100 patients, which underwent regional anesthesia performed: by traditional paresthesia technique (group P) and by ultrasound-guided method (group E).

The **aim** of this study was to analyze the two methods of performing regional anesthesia, in order to highlight the optimal method.

The failure rate of each anesthesia technique was analyzed, the patient's safety was investigated regarding the doses and combinations of local anesthetics used, as well as the use of other type of medication (opioids / sedatives) during the surgery. The inclusion criteria were: patients with trauma / limb injury, admitted to the Microsurgery department of the Institute of Emergency Medicine, Chisinau, Republic of Moldova, who underwent regional anesthesia performed by paresthetic technique (inclusion in group P) or regional anesthesia carried out with ultrasound-guided method (including group E). The statistical analysis was performed based on the χ^2 test with the correction for continuity to the nominal / dichotomous variables, the risk calculation and the bootstrapping being used to detail the obtained results. For continuous variables, the Mann-Whitney test was applied. Multivariate logistic and linear regression was used to analyze the interrelationships between variables with coefficient adjustment.

3. Results

The comparative evaluation of the examined groups revealed significant differences according to the following criteria: the anesthetized limb, lignocaine dose, midazolam dose and diazepam dose (Table 1).

The rate of anesthesia on the upper limb in group P compared to group E was higher (91% and 79%, $p = .029$, effect size, 0.24). Considering the magnitude of the low effect, we assume that the type I error was omitted and the constant significance had no practical value. The dose of lignocaine was higher in group P, having the median and moda 600 mg compared to the median and moda 400 mg in group E, $p = .001$, the mean effect size = .242. Frequency analysis revealed that in 166 cases out of 200, the dose of 400 mg or 600 mg of lignocaine was found, respectively, not being associated with the anesthetized area (Spearman $\rho = -.129$, $p = .068$). It was found that, probably, when calculating the initial dose of lignocaine, a standard is applied regardless of the technique of anesthesia used with the idea of reducing the dose of lignocaine when using the ultrasound-guided method. In group P, 38 patients received the 400 mg dose and 44 patients

Table 1. Comparative evaluation of the 2 groups of patients

	Group P=100 patients				Group E=100 patients				p	The size of the effect
	Mediane or %	Percentiles 25	Percentiles 75	Moda	Mediane or %	Percentiles 25	Percentiles 75	Moda		
Female Gender	25%				19%				,393	,004
Male Gender	75%				81%					
Age	43	32	62		42	31	57		,259	,079
Lenght of surg., min	60	60	120		60	55	103		,154	,100
Upper limb	91%				79%				,029	,024
Lower limb	9%				21%					
Lignocaine	6	4	6	6	4	4	6	4	,001	,242
Bupivacaine	50	50	50	50	50	50	50	50	,483	,049
Fentanyl	1	1	2	1	1	1	2	1	,227	,085
Ketamine	0	0	0	0	0	0	0	0	,072	,127
Midazolam	0	0	3	0	3	0	4	0	<,001	,366
Tiopenthal	0	0	0	0	0	0	0	0	,778	,019
Diazepam	0	0	10	0	0	0	5	0	<,001	,251
Adequate block	87%				80%				,253	,007
Insufficient block	13%				20%					

the 600 mg dose; in group E were 52 and 32 patients, respectively. Thus we find the moderate decrease of the dose of lignocaine when using the ultrasound-guided method (quantitative evaluation of this aspect will be addressed by multivariate analysis). The anesthetist uses from the beginning a lower dose of lignocaine, being aware that the ultrasound-guided method allows direct visualization of the anatomical structures. The dose, most likely, is not calculated according to body mass of the patient.

The dose of midazolam was higher in group E (median 3 compared to median 0, $p < ,001$, mean effect size = ,336), meaning that, in most patients from group P, midazolam was not used at all. At the same time, patients who underwent regional anesthesia performed by ultrasound-guided method, received midazolam from the beginning of the surgery and in a higher dose, or it has been given during the course of the surgical procedure. Perhaps the anesthetist was not sure of the effectiveness of the block or was the pre-selection of patients for this group. Of course, there are not extremely high doses, but doses around 3-4 mg per intervention were used.

The use of diazepam predominated in group P (75th percentile equal to 10 mg versus 5 mg in group E, $p = ,001$, mean effect size = ,251). Diazepam, most likely, was not used from the beginning in both groups (the median is 0), but was probably applied under the conditions of unsuccessful anesthesia at higher doses in group P, because group E has already been under midazolam protection. Again, we are not talking about high doses, because 75% of the respondents from both groups were given 10 and 5 mg diazepam respectively.

Age ($p = ,259$), gender ($p = ,393$), duration of intervention ($p = ,154$), doses of bupivacaine ($p = ,483$), fentanyl ($p = ,227$), and thiopental ($p = ,772$), given the small effect size, did not present statistical significance. In contrast, ketamine ($p = ,072$), with a medium effect $= ,127$ is of interest because it was used in higher doses in group E, probably in case of insufficient block installation, or it was used from the beginning in the patients undergoing ultrasound-guided regional anesthesia. In contrast, in group P, to provide anesthesia, the use of only benzodiazepines or thiopental was sufficient. Another argument regarding the standardization of regional anesthesia was the use of bupivacaine at a dose of 50 mg in both groups, its value rarely being changed (median, moda, percentiles in both groups being 0). The characteristics obtained from the analysis of the use of the thiopental indicate that it was administered as an adjuvant, if necessary.

The rate of failed anesthesia cases, representing a strong argument for the use of a certain technique: paresthesia or the ultrasound-guided method, was obtained by two means: bivariate analysis and multivariate analysis.

The bivariate analysis showed that, out of 100 anesthetics in group P, a number of 13 were reported as unsuccessful, compared with a number of 20 in group E. The χ^2 test with corrections for continuity did not determine significance (test value 1.306, $df = 1$, $p = ,253$, effect size $= ,007$), RR (relative risk) being 1.67 (95% CI 0.78-3.58), the result being stable (RR through bootstrap 1.67; CI 95% 0.71-4.1). Notwithstanding the fact that we did not find any significance, we speculate that the rate of failed anesthetics in both groups cannot be higher than that reported.

At the preventive analysis of the examined groups, the feeling about standardization of the process is created, the decrease of the dose of lignocaine being “compensated” by the increased use of ketamine and midazolam. It is important to mention that, the regional anesthesia performed by the ultrasound-guided method does not decrease, but on the opposite, it has the tendency to increase the rate of failed cases.

The multivariate analysis, which involves the introduction of several variables (factors) in the equation, did not reveal any significance regarding the technique of anesthesia and the rate of failed anesthesia cases, even if the results were adjusted for gender, age, anesthetized limb, doses of lignocaine, bupivacaine, fentanyl, ketamine, midazolam, thiopental, diazepam used; the coefficient of determination for different models being maximum 20%, which reflects the lack of the “efficient” variables introduced in the equation. At the same time, the data from table 2 shows that the dose of midazolam in group E increases by 44% compared to group P, OR (odds ratio) being 1.44 (95% CI 1.22-1.70), and the lignocaine dose reduction by 28% (95% CI 9-43%). As a result, the dose of lignocaine decreases, most probably, due to the increase in the dose of midazolam.

Table 2. Equation variables

	B	S.E.	Wald	df	Sig.	Exp (B)	95% CI for Exp (B)	
							Lower	Upper
Lignocaine	-,327	,120	7,408	1	,006	,72	,57	,91
Midazolam	,365	,085	18,303	1	,000	1,44	1,22	1,70
The Constant	,982	,634	2,400	1	,121	2,67		

Table 3. Equation variables

	Non-standardized coefficients		Standardized coefficients	t	Sig.	CI 95% for B	
	B	Std. Error	Beta			Lower	Upper
The Constant	4,558	,223		20,401	,000	4,117	4,999
Paresthesia/Ultrasound-guided group	-,565	,189	-,205	-2,989	,003	-,938	-,192
Male Gender	,526	,222	,159	2,372	,019	,089	,964
Thiopental, mg	,002	,001	,149	2,220	,028	,000	,004
Diazepam, mg	,041	,014	,201	2,900	,004	,013	,068

Linear regression for lignocaine dose modeling (Table 3), in patients included in the research, showed a decrease of the dose by 57 mg in group E, the confidence interval being quite wide (95% CI, 938, -, 192). That is, the actual decrease is within the limits of 19 and 94 mg of lignocaine. For men, the dose is higher by 53 mg (95% CI, 09; 96). The combination of the dose of lignocaine administered with that of sedatives is also expected. It is important to mention that the coefficient of determination for this equation is 13.6%, of which the regional anesthesia performed by the ultrasound-guided method represents only 5.1%. This coefficient of determinations, together with a 95% wide CI indicates the lack of effective variables included in the study. The application of the efficient variables can radically alter the relationships and at the moment, based on the data obtained, we cannot state any benefits to using the ultrasound-guided method for performing the regional anesthesia.

The statistical analysis of the 2 groups of patients determined that:

1. The study did not show the decrease, but, on the opposite, a tendency towards increasing the rate of failed anesthesia cases when applying the ultrasound-guided method.
2. The decrease in lignocaine dose is practically insignificant in the group of patients who have benefited from ultrasound-guided regional anesthesia; doses of sedatives are increased.
3. The ultrasound-guided regional anesthesia, performed by the medical staff in the absence of special training, as well as the lack of clear contact criteria with the anesthetized plexus, does not bring expected benefits and does not guarantee the safety in anesthesia.
4. In the field of regional anesthesia, many questions and aspects remain unresolved, which could not be reached in this study exposed, due to the retrospective type of the study and due to lack in sufficient and qualitative documentation of important aspects of regional anesthesia regarding evaluation of success and safety of the procedure (BMI, length of block installation, immediate/late neurological complications, etc.). A prospective study in this area is needed, with the inclusion of the "effective" variables and the monitoring of the late complications after regional anesthesia.

4. Discussions

The apparently "surprising" results of the study were somehow expected and welcome, these results reveal some problems related to a technique of regional anesthesia

considered to be superior, from all points of view, compared to the classical paresthesia technique. We take the responsibility to affirm that, the situation created, is based on the desire of medical staff from our country to implement a new, worldwide recognized and used method in modern medicine, but which, when brought into local medical system, it collides with some rooted skills, passed down from generation to generation, which are hardly subject to change, correlated with a closed mindset and concepts constrained by prejudices and fear of failure.

The problems revealed as a result of this study, as well as the possible ways of solving them, according to the data obtained from the international practice published in reference journals, will be reported below:

1) *The use, according to the results of this study, in both regional anesthesia techniques (ultrasound-guided and paresthesia), of local anesthetics in high doses and in combinations that, according to the research, do not have clinical benefit for patients.*

Standardization of local anesthetic doses administered, depending on the anesthetic area (plexus) or the method used: ultrasound-guided / paresthesia, as well as the absence of correlation of their dose with the body weight, exposes the patient to very high doses of local anesthetic, which is in contradiction with the worldwide recommendations regarding the use of minimum effective dose of local anesthetic when real-time visual control of the procedure is available. [11; 12; 13]

Also, the combination of long-acting local anesthetics with lignocaine decreases the total length of the block. [14; 15; 16] Thus, the combination of local anesthetics, widely used in the Institute of Emergency Medicine: lignocaine + bupivacaine, does not, according to international publications, present any clinical benefit. On the opposite, the combination of these local anesthetics prolongs the beginning of the block, as well as shortening of its total length. [14; 16; 17]

Although ultrasound guidance is a compound part of the strategy for prevention of Systemic Toxicity of Local Anesthetics (LAST), [11; 18; 19; 20], the lack in practical dexterities in the use of the equipment are one of the problems that would favor the direct intravascular injection of the local anesthetics. By applying an excessive pressure of the probe, the tissues are constraint and an iatrogenic collapse of the veins occurs. This phenomenon, when trying to assess by aspiration the intravascular localization of the needle, gives a false negative result, with the risk of injecting the local anesthetic intravenously. [4; 7]

2) *The use, according to the results of the study, of higher doses of sedatives in patients undergoing ultrasound-guided regional anesthesia versus the paresthesia technique.*

At moment, it is complicated to state whether the use of sedatives during surgical procedures performed under regional anesthesia aimed "covering" an ineffective block, or if it was part of the measures taken to ensure intraoperative comfort of the patient. Patient satisfaction with a specific procedure, including anesthesia, has become an important component of the quality of the medical act performed. [21] The patient's comfort during regional anesthesia means his comfort during the puncture and the introduction of the local anesthetic, during the entire surgical intervention, as well as during the postoperative period. Worldwide trends and recommendations include 1) use of premedication, 2) intraoperative sedation of the patient, 3) use of ultrasound guidance, and 4) professionalism of the physician as compulsory compo-

nents in optimizing patient's comfort during regional anesthesia, along with 5) psychological communication and preparation, and 6) a pleasant environment of the operating room. [22; 2. 3; 24]

3) *The impossibility of determining, according to the results of the study, of the degree of practical training of the anesthetists in performing the ultrasound-guided regional anesthesia, and the possible correlation of this aspect with the higher failure rate compared with regional anesthesia performed by paresthesia technique.*

The ultrasound machine, used in Anesthesiology and Intensive Care practice as a "borrowed" tool from another medical specialty, was a real challenge for the Anesthesiology and Intensive Care department of the Institute of Emergency Medicine, in 2006, when this device was assigned to the technical endowment of this department. The first ultrasound-guided procedures, including regional anesthesia cases, were performed by anesthetists who were familiar with this technique after viewing on-line video courses, following the application of theoretical and practical knowledge learned at international congresses, workshops and other educational events regarding the field of regional anesthesia, followed by the subsequent interpersonal training of all the members of the team. However, in the Republic of Moldova, an official training course for specialists in Anesthesia and Intensive Care on ultrasound-guided regional anesthesia, from 2006 to 2018, did not exist.

According with recommendations of the international reference institutions, as well as following the results obtained in this retrospective evaluation of those 12 years of experience gained since the first ultrasound-guided regional anesthesia was performed, the decision was made to organize, legislate and include in the Department of Continuing Medical Education's option of an Ultrasound-guided Regional Anesthesia course, implemented by the Society of Anesthesiology and Reanimatology from Republic of Moldova in collaboration with the Department of Anesthesia and Reanimatology no.1 "V. Ghereg "of the State University of Medicine and Pharmacy" Nicolae Testemitanu ". [2; 9] The rate of success in introducing a new method depends on the availability of the required equipment and the level of training of physicians. The learning process of a new procedure / technique is a complex one and depends on a variety of factors, such as: the technical endowment of the institution, the existence of a training strategy with the necessary number of procedures to obtain the learning curve, as well as the on-going performance of the procedure in order to maintain the acquired dexterities and maintaining their continuous improvement. [1; 7] Procedures related to regional anesthesia are significantly more difficult to learn than the practical tasks related to general anesthesia. [7]

In April 2010, the Joint Committee of the American Society for Regional Anesthesia (ASRA) and the European Society for Regional Anesthesia (ESRA) published the recommendations required for education and training in ultrasound-guided regional anesthesia. [7; 10] Ultrasound guidance is currently the gold standard for regional anesthesia, [2; 3; 9] but this is only valid if the anesthetist has good technical dexterities and is familiar and feels comfortable using the equipment. [5; 7]

It is obvious that the theoretical and practical training represents an important prerogative in achievement of practical skills regarding ultrasound-guided regional anesthesia. [1; 5] Therefore, one of the biggest challenges in this field is the implementation of the practical training guidelines for the Anesthesia and Intensive Care practitioners, as well as the elaboration of the efficient tools for the assessment of the practical compe-

tences gained in performing ultrasound guided regional anesthesia. [1; 3; 5] According to the published data, nowadays, next to the classic checklists, the MCQ questions, the Global Rating Scales, for the appreciation of the practical dexterities, learned from the training courses and the workshops regarding regional anesthesia, high-performance radio frequency recording systems are used, with manual dexterity monitoring through a sensor attached to the practitioner/trainee's gloves. The computerized analysis of the time required to perform the procedure, the number of movements required, as well as the amplitude of the movements as a surrogate value of the efficiency of the movements sum these variables into an index of performance and assimilation of the manual skills regarding the learned procedure. [21; 25; 26; 27; 28] Evaluation of psychological / cognitive aspects, such as the analysis of the visual-analogue ability, with the assessment of the cognitive ability to generate, retain, use, manipulate and process visual information; as well as the analysis of psychomotor ability, which reflects the ability to bimanual control of the objects as a result of the efficiency of eye-to-hand coordination and reaction speed, are particularly important for success in obtaining practical skills. [25; 28; 29; 30]

4) According to the results of the study, lack of some statistically significant variables.

It is well-known that any retrospective study has its limitations. The correctness of the results obtained is influenced, first of all, by the responsibility with which the medical documentation was fulfilled at that time. Another very important aspect is that, in order to obtain statistically significant variables, it is necessary to register some clinical parameters for which the documentation in the medical file is not mandatory, but which would have a major impact in the research (the length from the performance of anesthesia to the beginning of the block, total length of the block, monitoring of neurological immediate and late complications, etc.). Thus, in order to extend this study, as well as to cover the issues that remain unclear at the moment regarding the ultrasound-guided regional anesthesia performed within the Institute of Emergency Medicine, it is necessary to start a prospective study.

5. Conclusions

The purpose of this study, to analyze the two methods of performing regional anesthesia: ultrasound-guided and paresthesia technique and to highlight the optimal method, was not fully accomplished, due to the limitation of the retrospective study to fully investigate all aspects regarding a technique or other of regional anesthesia set out above. However, some "skills" widely applied in clinical practice, such as the use of standardized doses of local anesthetics, which are not related to the patient's body weight, and the use of combinations of local anesthetics that have no clinical benefit for the patient were highlighted in this study, being very important factors, which influence the safety of the patient and the medical act itself.

The higher failure rate in successfully performing an ultrasound-guided regional anesthesia, being in contradiction with the international statistical data, revealed deficiencies in the training of the practitioners of the medical system in our country, and respectively, deficiencies in the assessment of their achieved skills, with the probability that the real cause of the failure in an adequate performance of a regional anesthesia is placement of the practitioner between the limits of the learning curve. An important step in solving this problem was the implementation in 2018 of the ultrasound-guided

Regional Anesthesia course, developed by the Society of Anesthesiology and Reanimatology from Republic of Moldova in collaboration with the Department of Anesthesia and Reanimatology no.1 "V. Ghereg "of the State University of Medicine and Pharmacy" Nicolae Testemitanu "; this being the first educational event, legislated and approved by the Ministry of Health, included in the Continuing Medical Education Course, organized for the correct training and re-education, according to the international standards of anesthetists in the Republic of Moldova.

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