



CLINICAL STUDY REGARDING OUTCOMES OF HYDRO-/ THERMO-/ PHYSIO-KINESIS THERAPY COMPARED TO THOSE OF PHYSICAL-/ KINESIS THERAPEUTIC PROCEDURES IN SPASTIC PATIENTS. PRELIMINARY RESULTS

Irina ALBADI^{1,2,*}, E.V. IONESCU^{1,3}, M.G. ILIESCU^{1,3} and Gelu ONOSE^{4,5}

¹ University “Ovidius”, Faculty of Medicine, Constanta, Romania

² Teaching Emergency County Hospital “Sfantul Apostol Andrei” Constanta, Romania

³ Techirghiol Balneal and Rehabilitation Sanatorium, Constanta, Romania

⁴ University of Medicine and Pharmacy “Carol Davila”, Bucharest, Romania

⁵ Teaching Emergency Hospital “Bagdasar-Arseni”, Bucharest, Romania

* Corresponding author: Irina Albadi irina.albadi@yahoo.com

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Introduction. Background. Spasticity – a pathological condition that occurs as a result of lesions/ disorders of the central nervous system of various etiologies and is a major semiological component in the dys-morpho-functional and clinical ensemble represented by the upper motor neuron syndrome – is a factor that alters in many cases, to various degrees, the overall neuro-myo-arthro-kinesis functionality of the affected individuals and their quality of life; therefore, its medical management as efficiently as possible is essential, including for the results and prognosis of the rehabilitation process. This study aims to objectivize whether there are favorable changes in terms of influencing the degree of spasticity, possibly also pain – and thus improving the functionality and quality of life – in patients who have received hydro-/ thermo-/ kinesis-therapy versus patients who underwent only physical-/ kinesis-therapeutic procedures.

Methods. The study includes 2 groups of 30 patients each, aged over 18 (45 men, 15 women), hospitalized in: Techirghiol Balneal and Rehabilitation Sanatorium, respectively in the Outer Division of Rehabilitation, Physical Medicine and Balneology, Eforie Sud (Teaching Emergency County Hospital “Sf. Apostol Andrei” Constanta) as well as in the Division for Traumatic Spinal Cord Injury and Neuromotor Rehabilitation (Mangalia Municipal Hospital). The 1st group included patients who underwent hydro-/ thermo-/ kinesis-therapy in therapeutic pool with water from Techirghiol Lake and other physical-/ kinesis-therapeutic procedures, and the 2nd group (considered a control group) includes patients who underwent only physical-/ kinesis-therapeutic procedures, without hydro-/ thermo-/ kinesis-therapy. As a study method, we relied on clinical assessment and quantification of spasticity and its consequences according to the corresponding standardized scales (Modified Ashworth Scale – MAS; Penn Spasm Frequency Scale – PSFS; Visual Analog Scale – VAS; Activities of Daily Living – ADL; Functional Independence Measure – FIM; Quality of Life – QOL). The software required for statistical-mathematical processing and graphical expressions was mainly the Statistical Package for Social Sciences (SPSS) 16.0 and Microsoft Excel 2010. In addition to the elements of descriptive statistics, in the data processing there were 2 stages: the first established the concordance, respectively the correlation data at discharge with those at admission, and in the second stage the comparison of the evolutions of the groups between admission and discharge was performed. We also calculated, where possible, the “effect size” and the efficiency of the two types of rehabilitation treatment (related to the groups: study and control); comparative analyses on the post-therapeutic results between the two groups, by age groups, may be conclusive later, on an increased number of patients, with a higher statistical power. All differences found were considered statistically significant if $p \leq 0.05$, the confidence level being 95%, with confidence intervals related to the calculated averages.

Results and discussion. The favorable results of hydro-/ thermo-/ kinesis-therapy in therapeutic pool on the pathological condition approached in our clinical study were objectivized by the score obtained on at least 3 of the 6 clinical-functional measuring instruments used – two of them: MAS and Penn Scale, being dedicated to quantified assessments related to spasticity.

Conclusions. Considering the results, the use of this therapeutic procedures by such patients is justified, but at the same time it is necessary for us to continue our research on larger groups, with an increased statistical power.

Keywords: spasticity, hydro-/thermo-/physio-kinesis therapy, therapeutic pool.

INTRODUCTION

Spasticity is a complication due to neuro-pathological conditions of various causes; it represents a significant semiological manifestation of the upper motor neuron syndrome and adds to the basic motor deficit a potential pronounced disabling amount, often constituting a major disruptor of motor function and autonomy in affected patients as well as of the effectiveness and prospects of rehabilitation programs administered and not lastly, a morbidity that alters their quality of life. Among the formulations that characterize spasticity, the definition given by Lance (1980) is commonly found: "Spasticity is a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex as one component of the upper motor neuron syndrome."¹ It should be noted that details on the pathophysiology of spasticity and the clinical entities in which it occurs, as well as the main notions and current data on the physiological treatment of spasticity, have been published by the main authors – and collaborators – of this article, in the paper entitled: "News on spasticity and possibilities to control it through hydro-/ thermo-/ kinesis-therapeutic means – synthetic and systematic literature review"²

SYNOPSIS OF THE STUDY

Working hypothesis: This prospective study aims to verify whether there are favorable changes in terms of influencing the degree of spasticity, possibly pain and thus improving the functionality and quality of life in patients who have undergone hydro-/ thermo-/ physio-/ kinesis-therapy versus patients who have undergone only physical- / kinesis-therapeutic procedures, without hydro-/ thermo-/ kinesis-therapy.

Objectives: Analysis/ objectivation by statistical processing methods of the primary data obtained from quantified assessments of the results of spasticity treatment in patients with this medical condition, in order to support – if the data obtained confirms it – in a manner reasonably integrated into the concept of Evidence Based Medicine (EBM), of the physical hydro-/ thermo-/(kinesis-) therapeutic procedures in the spasticity rehabilitation approach.

- primary objectives: objectivation/ quantification, comparatively between the study group and the control group, of the dynamics/ evolution of spasticity and respectively, of the presence of spasms between admission/ discharge.
- secondary objectives: objectivation/ quantification, comparatively between the study group and the control group, of the dynamics/ evolution of the functionality and respectively, of the quality of life of the patients between admission/ discharge.

Study duration: March 2018 – December 2019.

METHODS

The study includes 2 groups of patients aged over 18 hospitalized in the Techirghiol Balneal and Rehabilitation Sanatorium, respectively in the Outer Division of Rehabilitation, Physical Medicine and Balneology, Eforie Sud (Teaching Emergency County Hospital "Sf. Apostol Andrei" Constanta), as well as in the Division for Traumatic Spinal Cord Injury and Neuromotor Rehabilitation (Mangalia Municipal Hospital) and who were asked for the informed consent in order to be included in the study. The **1st group** includes 30 patients with spasticity who underwent, in the Techirghiol Balneal and Rehabilitation Sanatorium, hydro-/ thermo-/ kinesis-therapy in therapeutic pool with water from Techirghiol Lake, as well as other physical-/ kinesis therapeutic procedures, according to a prescribing and administration algorithm (thermo-therapeutic procedures, electro-/ magneto-ultrasound and photo-therapy sequences, kinesis therapy on land). The **2nd group**, considered a control group, includes 30 patients with spasticity hospitalized in the Outer Division of Rehabilitation, Physical Medicine and Balneology, Eforie Sud (Teaching Emergency County Hospital "Sf. Apostol Andrei" Constanta) or in the The Division for Traumatic Spinal Cord Injury and Neuromotor Rehabilitation (Mangalia Municipal Hospital), patients who underwent only physical-/ kinesis therapy, according to a prescription and administration algorithm without hydro-/ thermo-/ kinesis-therapy. We mention that in setting up these patient groups we also took into account the technical equipment of the three treatment units. In this context, as the therapeutic pool exists only in the Techirghiol Balneal and Rehabilitation Sanatorium, all patients in the 1st group come from

the Techirghiol Balneal and Rehabilitation Sanatorium, while the patients included in the control group underwent treatment in the Outer Division of Rehabilitation, Physical Medicine and Balneology, Eforie Sud (Teaching Emergency County Hospital "Sf. Apostol Andrei" Constanta) or in the Division for Traumatic Spinal Cord Injury and Neuromotor Rehabilitation (Mangalia Municipal Hospital).

INCLUSION CRITERIA:

- Freely expressed consent based on the explanation and, respectively, on the understanding of all the related procedural steps;
- Aged over 18;
- Compensated cardiovascular status;
- Clinical spastic syndrome with known etiology;
- Score on the modified Ashworth Scale (mAS) of at least 1, maximum 3 for the spastic muscles tested.

EXCLUSION CRITERIA:

- Patient's refusal;
- Aged under 18;
- Pregnancy, breastfeeding;
- Neurogenic bladder;
- Trophic skin disorders, bedsores;
- Neurological diseases of infectious cause during the period of contagion;
- Epilepsy;
- Associated neoplastic diseases;
- Uncompensated organ/ apparatus disorders: cardiovascular, hepatic, renal, respiratory;
- Major psychiatric disorders.

As a study method, we relied on the clinical-functional assessment, with the performance/ completion (in a classical manner) of the following approaches: anamnesis, including personal pathological antecedents and medical history; clinical examination on apparatuses and systems; specialized clinical-functional neuro-myo-arthrokinetic examination, including quantification of spasticity and its consequences according to the related standardized scales. Patients were assessed at admission and at discharge after treatment – which lasted about 12 days.

"The assessment of muscle tone involves the rapid handling of the tested joint – as far as its level of mobility allows – and the quantification of the tonic response. The most commonly used clinical instruments for the quantified assessment of spasticity can be divided into two categories: specific/ dedicated (first two) and non-specific/ indirect (next five)."² (reproduced with permission!)

- modified Ashworth Scale (mAS);^{3,4}
- Penn Spasm Frequency Scale (PSFS);^{5,6}

- Pain assessment scale (Visual Analog Scale – VAS);⁷

- Katz Index of Independence in Activities of Daily Living (ADL);⁸

- Functional Independence Measurement Scale (FIM);^{9,10}

- Quality of Life scale (QOLS).¹¹

These scales/ grids for quantified spasticity assessment (specific and indirect/ collateral), developed over time by various authors, have the advantage that they can be available to any clinician, not being expensive or invasive. At the same time, there is the disadvantage that they are inherently burdened by a certain subjectivism and thus, in scientific studies the measurements should be performed by the same examining person/ team assessing the intensity of spasticity and its repercussions on the functional status and quality of life of the patient.^{12,13}

Given that spasticity is a consequence of an upper motor neuron injury, usually chronic, as well as the neuro-functional deficits caused by such lesions, the general principle that guided us in addressing/ selecting the cases included in the study was the comparative assessment: admission/ discharge, during a single admission (because conceptually: later, during the evolution, usually long, of the sufferings we deal with, the patients of this type – hyperchronic¹² – undergo various therapeutic approaches and thus the effects of a certain type of intervention or group of interventions somewhat standardized, cannot be monitored under conditions of reproducible assessment); however, we have derogatively decided, in order to ensure, numerically, some groups of patients with reasonable statistical power, to accept (being a limitation of the present study) to include in this research older cases, so which had previous admissions but are at the first admission under our supervision.

Inevitably, any clinical-functional classification/ quantification instrument/ scale is burdened on the one hand by the fact that the biological and situational reality is more complex than the possibilities of classifying the assessment instruments used, whatever they may be; thus, without claiming to be able to achieve a full folding of the clinical- (dis) functional reality on the score levels related to the scales we used, we established detailing, we believe, acceptable in terms of consistency and objectivity, while admitting objective limits related both to the bio-contextual diversity of each case analyzed and to

the inherent elements of subjectivism of the evaluator/ – (s).

Regarding the statistical-mathematical analysis, the software used for graphical processing and representations was mainly the Statistical Package for Social Sciences (SPSS) 16.0 and Microsoft Excel 2010.

In addition to the elements of descriptive statistics – preliminary, related – in the data processing there were 2 stages: the first established the level of concordance (correlation) of data provided by the various assessment scales (ADL, VAS, mAS, Penn Scale, FIM Scale and QOL Scale). In the second stage the comparison was performed – by differentiation tests – for the evolutions (of the component patients of) the groups, between admission and discharge – and later also for their evolution, comparatively, between the two groups – using the T (Student) test where possible, i.e. if the parameter values had an approximately normal distribution, namely for the QOL scale assessment, respectively the chi-square test and Fisher's exact test where the population distribution was not normal. The effect size and efficiency of the two types of

Rehabilitation treatment (related to the groups: study and control) were also calculated where possible. The differences found were considered statistically significant if $p < 0.05$, the confidence level being 95%, with confidence intervals related to the calculated averages.^{14, 15}

RESULTS AND DISCUSSION

The descriptive statistical analysis shows that out of a total of 60 patients, according to gender, there were: 15 women (25%) and 45 men (75%).

We divided the age of the patients in the two groups into two levels: 18–60 years and over 60 years (considered elderly people – whose bio/pathology, as it is known, differs to a certain extent from that of adults – because: “According to data from World Population Prospects: 2015 Revision (United Nations, 2015), the number of older persons – those aged 60 years or over – has increased substantially in recent years in most countries and regions ... ”¹⁶), distributed according to the table below (including by gender and percentage, respectively):

Table 1

Gender * Age group (2 categ.) Crosstabulation

		Age group (2 categ.)			
			18–60 yrs	61 yrs or older	Total
Gender	Male	Count	29	16	45
		% within Gender	64,4%	35,6%	100,0%
	Female	Count	7	8	15
		% within Gender	46,7%	53,3%	100,0%
	Total	Count	36	24	60
		% within Gender	60,0%	40,0%	100,0%

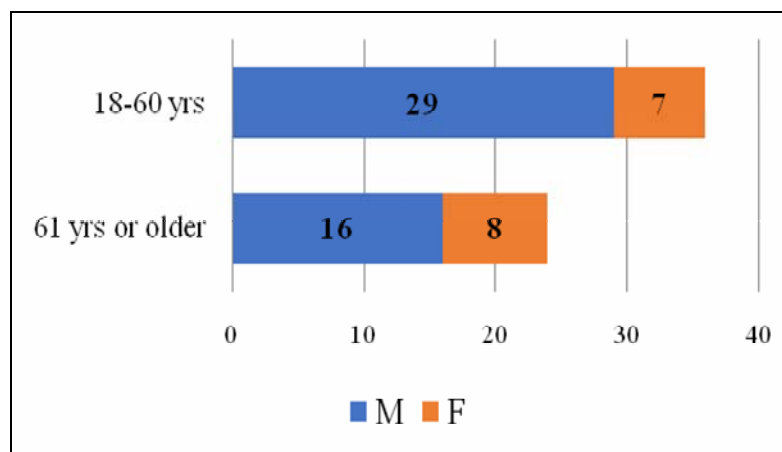


Figure 1. Patient's distribution by age group and gender.

Table 2

Treatment in therapeutic pool * Age group (2 categ.) Crosstabulation

			Age group (2 categ.)		
			18-60 years	61 years or older	Total
Treatment in therapeutic pool	No	Count	13	17	30
		% within Treatment in therapeutic pool	43,3%	56,7%	100,0%
	Yes	Count	23	7	30
		% within Treatment in therapeutic pool	76,7%	23,3%	100,0%
	Total	Count	36	24	60
		% within Treatment in therapeutic pool	60,0%	40,0%	100,0%

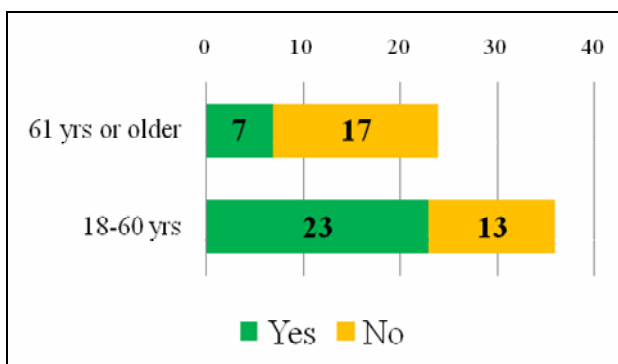


Figure 2. Patient’s distribution by age group and type of treatment administered.

In terms of the environment of origin, several patients are from urban areas (36 in number), while the remaining 24 patients are from rural areas.

Regarding the treatment performed, the two groups consisted, each, of 30 patients: those in group 1 underwent hydro-/ thermo-/ kinesis-therapy at the therapeutic pool and other physical-/ kinesis therapeutic procedures, while patients in group 2 (control group) underwent only physical-/

kinesis therapeutic procedures, without hydro-/ thermo-/ kinesis-therapy.

STAGE I

For the assessments on the mAS, the table of values obtained in the “admission-discharge” dynamics is the following:

Table 3

mAS assessment at admission * mAS assessment at discharge – Crosstabulation

Count		mAS assessment at discharge				
		1,0	1,5 (+)	2,0	3,0	Total
mAS assessment at admission	1,0	5	0	0	0	5
	1,5 (+)	6	3	0	0	9
	2,0	1	6	5	0	12
	3,0	0	0	12	22	34
	Total	12	9	17	22	60

It can be noted that there are no situations in which the results go from a lower value to a higher one (over the diagonal – marked in **green**). Instead, there are $6 + 1 + 6 + 12 = 25$ patients (*i.e.* 41.7%) whose condition improves (going from a higher value to a lower one). The Somers (delta) concordance coefficient is the third, as it is obvious that the discharge values depend on the admission

values. It has a value of 0.886, which indicates a fairly high concordance between the values obtained at the mAS assessment at admission and those obtained at discharge.

For the assessments on the **Penn scale**, the Table of values obtained in the “admission-discharge” dynamics is the following:

Table 4

Penn scale assessment at admission * Penn scale assessment at discharge – Crosstabulation

Count	Penn scale assessment at discharge					
	0	1	2	3	Total	
Penn scale assessment at admission	0	14	0	0	0	14
	1	5	7	0	0	12
	2	0	12	5	0	17
	3	0	0	5	1	6
	4	0	0	3	8	11
	Total	19	19	13	9	60

It can be noted that there are no situations in which the results go from a lower value to a higher one (over the diagonal – marked in **green**). There are instead $5 + 12 + 5 + 3 + 8 = 33$ patients (55%) whose condition improves (going from a higher value to a lower one). The Somers (delta) concordance coefficient has the value of 0.842, which indicates the

very strong concordance between the values obtained by the Penn scale assessment at admission and those obtained at discharge.

For the **VAS** assessments, the table of values obtained in the “admission-discharge” dynamics is the following:

Table 5

VAS assessment at admission * VAS assessment at discharge – Crosstabulation

Count	VAS assessment at discharge									
	0	1	2	3	4	5	6	7	Total	
VAS assessment at admission	0	16	0	0	0	0	0	0	0	16
	1	1	0	0	0	0	0	0	0	1
	2	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0
	4	0	0	0	1	0	0	0	0	1
	5	0	0	5	4	0	0	0	0	9
	6	0	1	2	2	3	0	1	0	9
	7	0	0	3	2	1	0	2	1	9
	8	0	0	0	1	3	2	1	0	7
	9	0	0	0	1	0	1	0	1	3
	10	0	0	1	1	1	0	1	1	5
	Total	17	1	11	12	8	3	5	3	60

It can be noted that there are no situations in which the results go from a lower value to a higher one (over the diagonal – marked in **green**). Only 18 patients (of which all 16 who had the 0 score at

the admission assessment) maintain their condition, the rest having an improved condition (going from a higher value to a lower one). The Somers (delta) concordance coefficient has the

value of 0.676, which indicates the strong concordance between the values obtained through the VAS assessment at admission and those obtained at discharge.

For the **ADL scale** assessments, the Table of values obtained in the “admission-discharge” dynamics is the following:

Table 6

ADL assessment at admission * ADL assessment at discharge – Crosstabulation

Count	ADL assessment at discharge								
	0	1	2	3	4	5	6	Total	
ADL assessment at admission	0	1	0	0	0	0	0	0	1
	1	0	8	0	0	0	0	0	8
	2	0	0	6	0	0	0	0	6
	3	0	0	0	8	0	0	0	8
	4	0	0	0	0	13	2	0	15
	5	0	0	0	0	0	21	0	21
	6	0	0	0	0	0	0	1	1
Total	1	8	6	8	13	23	1	60	

It is noted that almost all patients maintain their assessment. Only 2 of them (3.3%) improve their score values from admission, going from 4 to 5. The Somers (delta) concordance coefficient has a value of 0.97, which indicates the almost perfect concordance between the values obtained in the

ADL assessment at admission and those obtained at discharge.

For the **FIM scale** assessments, first we compare the distributions of values at admission and discharge (using descriptive statistical data – namely mean and median):

Table 7

FIM scale assesments

FIM scale assessment at:	N	Minimum	Mean	Median	Maximum	Std. Deviation
admission	60	35	82,35	88,50	115	20,663
discharge	60	36	83,97	89,50	119	20,872
Total	120	35	83,16	89,00	119	20,696

It is noted that the mean (but also the median) value is slightly increasing between admission and discharge (with only one unit, respectively the mean value with a little more than one unit). The correlation between discharge and admission values is assessed by the Pearson (correlation) coefficient which has the value 0.997, reflecting an

almost perfect correlation of the FIM scores from discharge to those from admission.

For the **QOL scale** assessments, first we compare the distributions of values at admission, respectively at discharge (using descriptive statistical data – namely mean and median):

Table 8

QOL scale assessments

QOL scale assessments at:	N	Minimum	Mean	Median	Maximum	Std. Deviation
admission	60	33	64,98	67,00	94	16,238
discharge	60	39	68,37	70,00	94	15,899
Total	120	33	66,68	69,00	94	16,092

It is noted that the mean of the QOL values (but also their median) is slightly increasing between admission and discharge, more precisely by (over) 3 units for the mean and by 3 units for the median value. We evaluate the correlation between the values from discharge and those from admission by the Pearson (correlation) coefficient which has a value of 0.991, reflecting an extremely strong correlation of QOL scores from discharge with those from admission.

STAGE II

At this stage we compared the progressive results obtained in patients in the study group to the control group, between admission and discharge, the difference of therapeutic-Rehabilitation approach between the two groups consisting in the fact that patients in the study group also underwent treatment in therapeutic pool.

The diagram below shows the distributions of the values obtained in the dynamics, from admission to discharge, of patients' scores in each of the two groups, assessed by the mAS.

It is noted that, out of the total of 30 "YES" patients, only 7 (representing 23.3%) did not have

modified scores, the remaining 23 having values lower by 0.5 or even by 1 point. By contrast, in the "NO" group, the vast majority (28 out of 30, representing 93.3%) did not have modified scores. Fisher's exact test, used to confirm the assertion that there is an association of decreased scores on the mAS (by at least 0.5) in the group of those "treated in therapeutic pool", produces a "P value" – 0.001, so the association is statistically confirmed.

The treatment efficiency is calculated based on the formula:

Efficiency (%) = (value at admission – value at discharge) / value at admission where possible, *i.e.* unless the patient has, at hospitalization, a score of 0 (a value that is minimal, *i.e.* without spasticity) on the mAS.

It is noted that in the "No" group for most patients the highlighted efficiencies were zero, only for two of them were higher (25% for one, 33% for the other). But there were also 5 patients for whom the efficiency could not be calculated. For the "Yes" group, only 7 patients showed zero efficiencies, for all the other 23 there were efficiencies of 25% (which we consider "low") – 50% (which we consider "high").

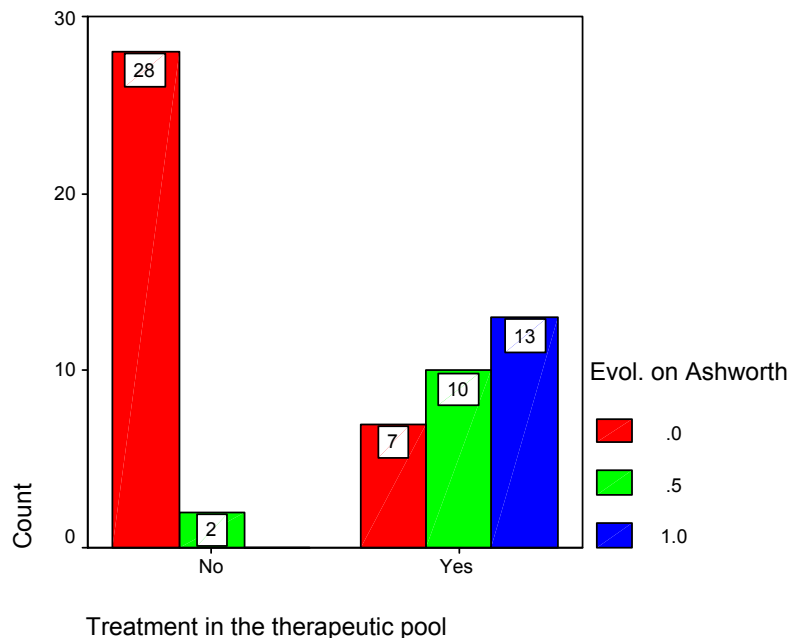


Figure 3. Distributions of patients' scores in each of the two groups, in dynamics, from admission to discharge, assessed through the mAS.

There is, therefore, a difference between groups in favor of the "Yes" group, a difference that can be considered **statistically "highly significant"**, as

Fisher's exact test produces a "unilateral P value" below 0.001. A graphical representation, in this sense, can be found in the following figure:

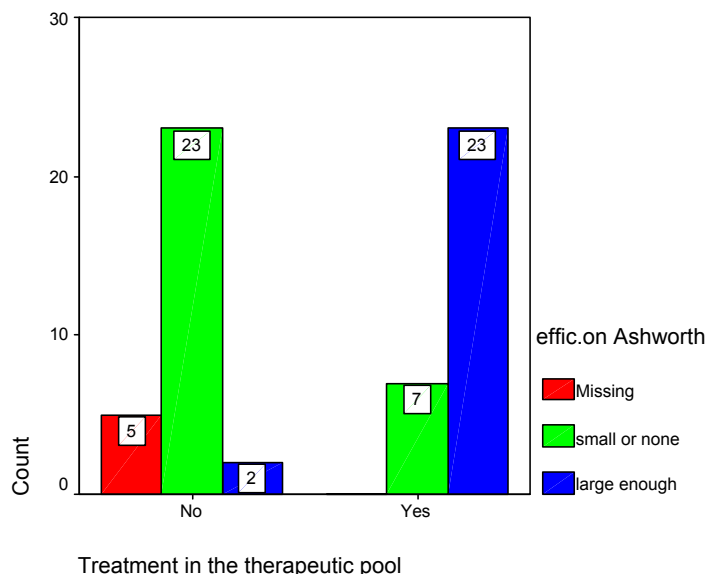


Figure 4. Graphical expression of the efficiency of the hydro-/ thermo-/ kinesis- therapy in therapeutic pool (“Yes” vs. “No”), on the mAS.

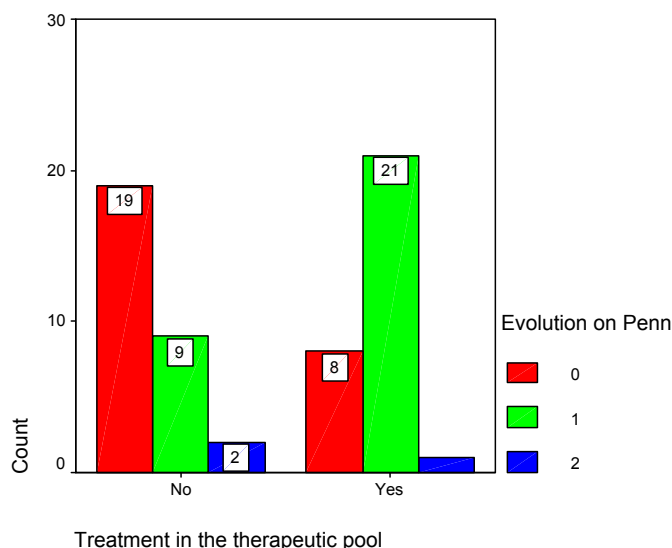


Figure 5. Distributions of patients’ scores in each of the two groups, in dynamics, from admission to discharge, assessed by the Penn scale.

It should be noted that due to the small number of items/ steps of the mAS, the calculation of the “effect size” is inadequate.

The diagram below shows the distributions of the values obtained in the dynamics, from admission to discharge, of the patients’ scores in each of the two groups, assessed by the **Penn scale**.

It is noted that, out of the total of 30 “YES” patients, only 8 (representing 26.7%) did not have modified scores, the remaining 22 having values lower by 1 or even by 2 points. By contrast, in the “NO” group, the majority (19 out of 30, representing

63.3%) did not have modified scores. Fisher’s exact test, used to confirm the assertion that there is an association of decreased scores on the Penn scale (by at least one step) in the group of those “treated in therapeutic pool”, produces a “P value” of 0.009, so the association is confirmed.

And based on Penn scale assessments the treatment efficiency is calculated using the formula:

Efficiency (%) = (value at admission – value at discharge)/ value at admission where possible, *i.e.*, if the patient does not have, at admission, the score

0 (value which is minimal *i.e.* without spasms) on the Penn scale.

It is noted that in the “No” group for 10 patients the highlighted efficiencies were zero and for other 4 they were 25%, which we will appreciate as “low”. Higher efficiencies were obtained for 7 patients (33% for 3 patients, 50% for other 3 and even 100% for one patient). But there were also 9 patients for whom the efficiency could not be calculated. For the “Yes” group, zero efficiencies were highlighted only for 3 patients and for

4 patients low efficiencies, of only 25%. For 18 patients, “high” efficiencies of 33–100% were highlighted. However, there were also 5 patients for whom the efficiency could not be calculated. There is therefore a difference between the groups in favor of the “Yes” group, a difference that can be considered as “**statistically significant**”, as Fisher’s exact test produces a “unilateral P value” of 0.017. A graphical representation, in this sense, can be found in the following figure.

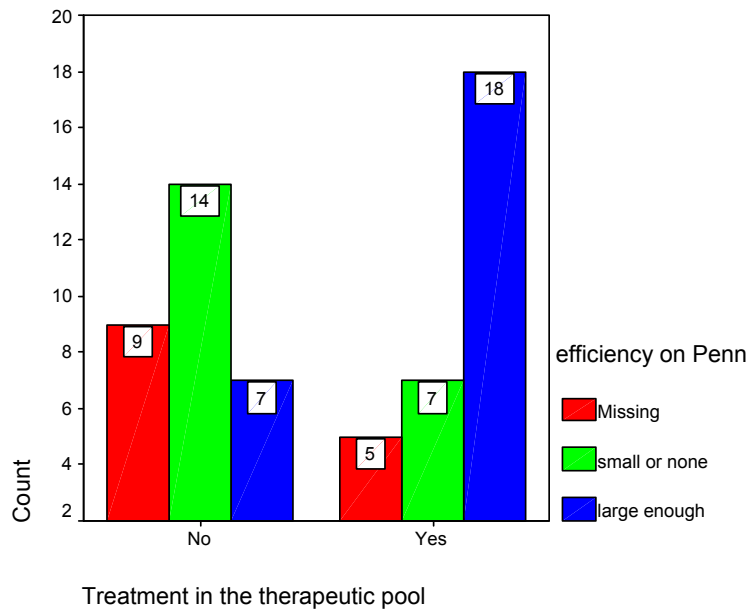


Figure 6. Graphical expression of the efficiency of the hydro-/ thermo-/ kinesis- therapy in therapeutic pool (“Yes” vs. “No”), on the Penn scale.

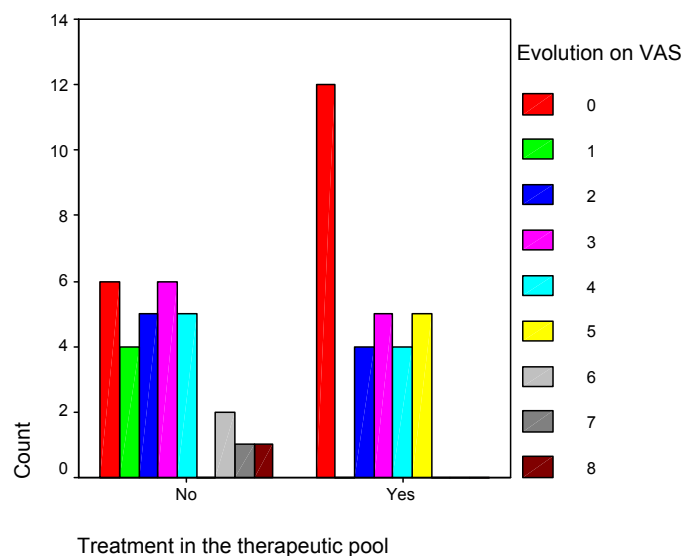


Figure 7. Distributions of patients’ scores in each of the two groups, in dynamics, from admission to discharge, assessed by the VAS.

It should be noted that due to the small number of items/ steps of the Penn scale, the calculation of the “effect size” is inadequate.

The diagram below shows the distributions of the values obtained in the dynamics, from admission to discharge, of patients’ scores in each of the two groups, assessed by theVAS.

It is noted that, in the “NO” group, three subgroups can be distinguished: a number of 6 patients (20%) who did not have modified scores; 20 patients had lower scores with 1–4 points at discharge and, respectively, a number of 4 patients with a significant decrease in their scores at discharge, namely with 6–8 points. Out of the total of the 30 “YES” patients, 12 (representing

40%) did not have modified scores, the remaining 18 having lower scores by 2–5 points at discharge, so apparently, poorer results. However, the data distributions make it inappropriate to use statistical tests to confirm/ refute any association.

And based on the assessments by the VAS, the treatment efficiency is calculated with the formula:

Efficiency (%) = (value at admission – value at discharge)/ value at admission where possible, *i.e.* unless the patient has, at admission, a score of 0 (a value which is minimal *i.e.* without pain) on the VAS.

Histograms of patients’ efficiencies, per groups, are as follows:

Treatment in the therapeutic pool

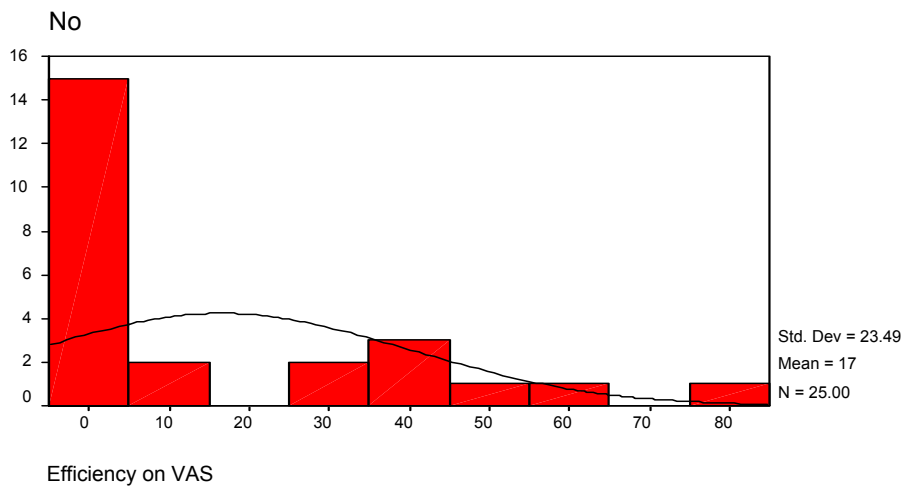


Figure 8. Histogram of the efficiency of the "No" hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

Treatment in the therapeutic pool

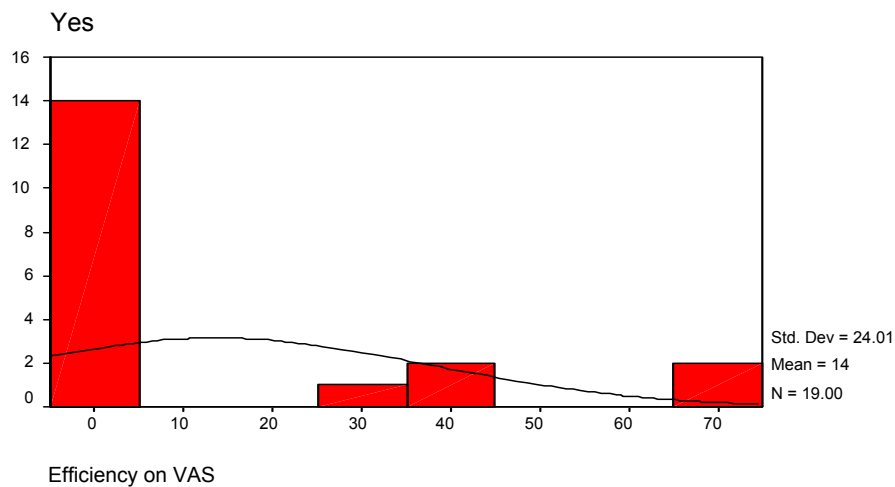


Figure 9. Histogram of the efficiency of the "Yes" hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

It is noted that in both groups there are relatively many patients for whom the highlighted efficiency was “low” (less than 25% or even 0%). In the “No” group, “high” efficiencies are obtained only in proportion of 32% (8 out of 25 patients). In the “Yes” group, the proportion of those for whom “high” efficiencies are obtained is 35.7% (5 out of 14). Therefore, as an effect of the treatment in therapeutic pool, an increase of “high” efficiencies of only 3.7% (35.7%–32%) – NNT = 26.9 is obtained. There is no clear difference between the groups in favor of any of them; Fisher’s exact test produces a “bilateral P value” of 0.749, which does not allow us to draw any conclusions.

The diagram below shows the distributions of the values obtained in the dynamics, from admission to discharge, of patients’ scores in each of the two groups, assessed by the **ADL index**.

There is a complete similarity between the two groups: out of the total of 30 patients in each group, the vast majority (*i.e.* 29, representing 96.7%) did not have modified scores, with only one finding an increase of 1 level of the score. Given this situation, the calculation of the “effect size” and, respectively, of the efficiency – identical – cannot discriminate between the two groups.

The diagram below shows the distributions of the values obtained in the dynamics, from admission to discharge, of patients’ scores in each of the two groups, assessed by the **FIM** scale.

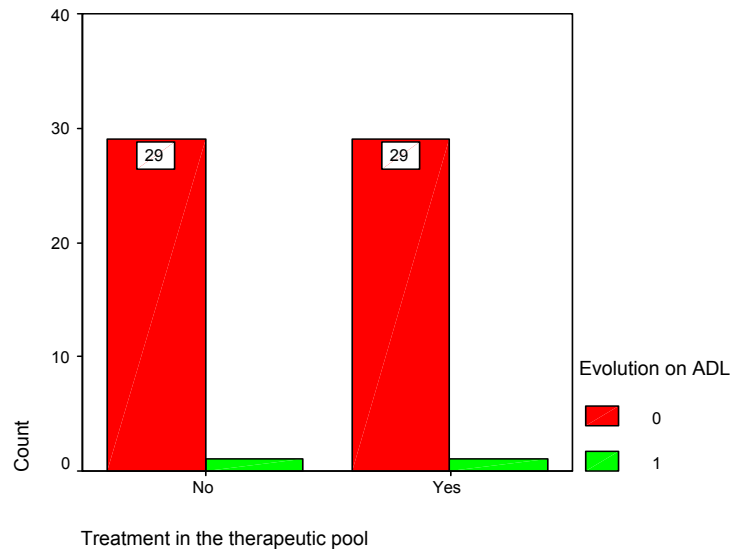


Figure 10. Distributions of patient scores in each of the two groups, in dynamics, from admission to discharge, assessed by the ADL index.

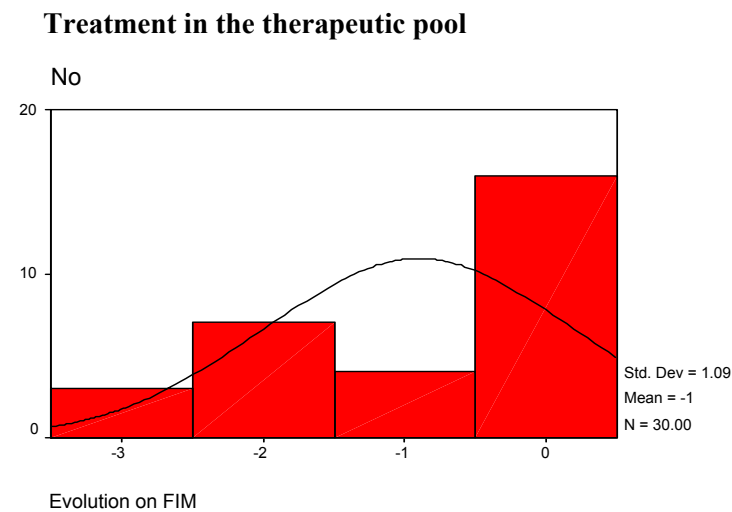


Figure 11. Diagram of the “No” hydro-/thermo-/kinesis- therapy in therapeutic pool.

Treatment in the therapeutic pool

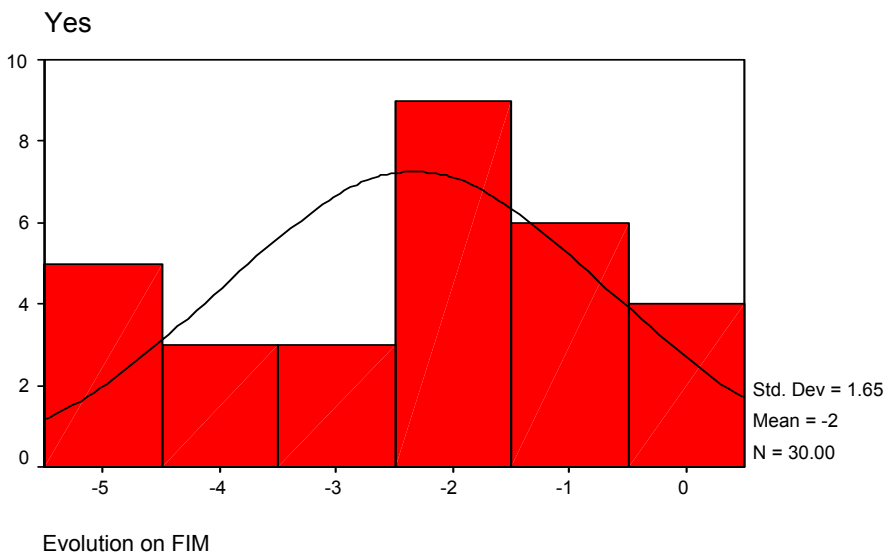


Figure 12. Diagram of the “Yes” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

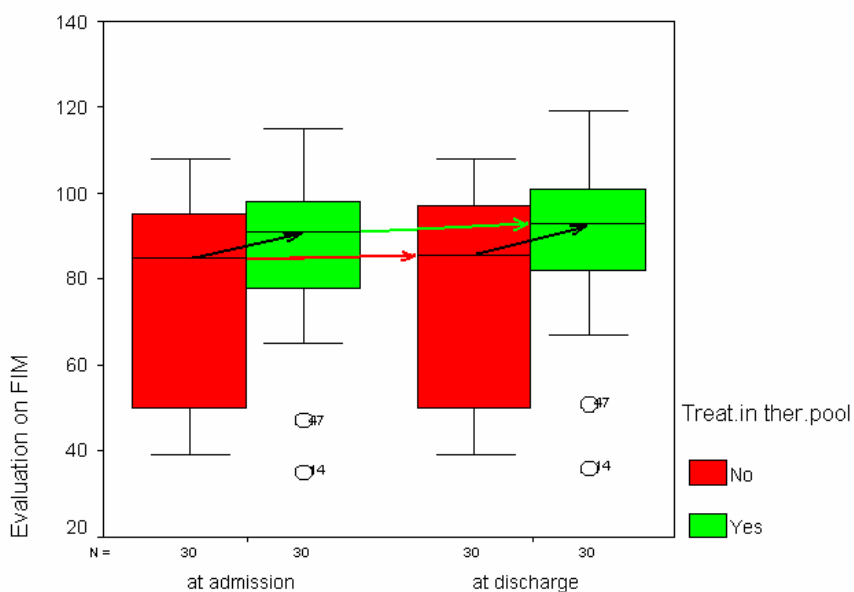


Figure 13. Box-plot emphasizing the effect size objectivized on the FIM scale.

It is found that in the “NO” group there is an average increase of 0.9 levels of the scores on the FIM scale, between admission and discharge (with a median of 0, the maximum increase being 3 levels). For the “YES” group, the average increase is 2.3 levels (with a median of 2 levels, the maximum increase being 5 levels). Apparently, for the “YES” group, the increase is more intense, and we will continue to statistically verify this finding. Thus, the Kolmogorov-Smirnov normality test produces an “asymptotic significance” of 0.003 for the data obtained from the “NO” group while for

the data obtained from the “YES” group the significance is 0.130. Both significances are therefore below the threshold of 0.2 of normality acceptance, which prevents us from using the t test. The Mann-Whitney test shows a significant discrepancy between the mean ranks and calculates a “bilateral significance” of 0.00. Consequently, the statement that the evolutions of the scores on the FIM scale differ between the two groups is **statistically “highly significant”**.

At admission, the FIM scores have an average of 77.7 (units) for the “No” group, respectively

87.0 (units) for the “Yes” group, so it has a better situation (explainable, at least in part, by the fact that the indication of hydro-/ thermo-/ kinesis-therapy in therapeutic pool depends on a relatively balanced/ stable general biological condition of the patient – many serious pathological conditions representing contraindications for this type of therapeutic-recovery procedure), on average with 9.7 (units). At discharge, the values of the FIM scores for the “No” group have an average of 78.6 (units), with only 0.9 levels of a larger scale. On the other hand, for the “Yes” group, the average FIM values at discharge are 89.3, 2.3 levels higher than at admission. We can appreciate that the

“effect size” of the treatment in therapeutic pool is very weak, of 1.4 (= 2.3–0.9) scale units. The box-plot below (although it is made up highlighting medians and not means) reflects this finding.

The treatment efficiency, based on assessments on the FIM scale, is calculated with the formula: Efficiency (%) = (discharge value – admission value)/ (126 – admission value), where possible, i.e. if the patient does not have the FIM score 126 at admission (value that is maximum, corresponding to functional normality).

Histograms of patient efficiencies, per groups, are as follows:

Treatment in the therapeutic pool

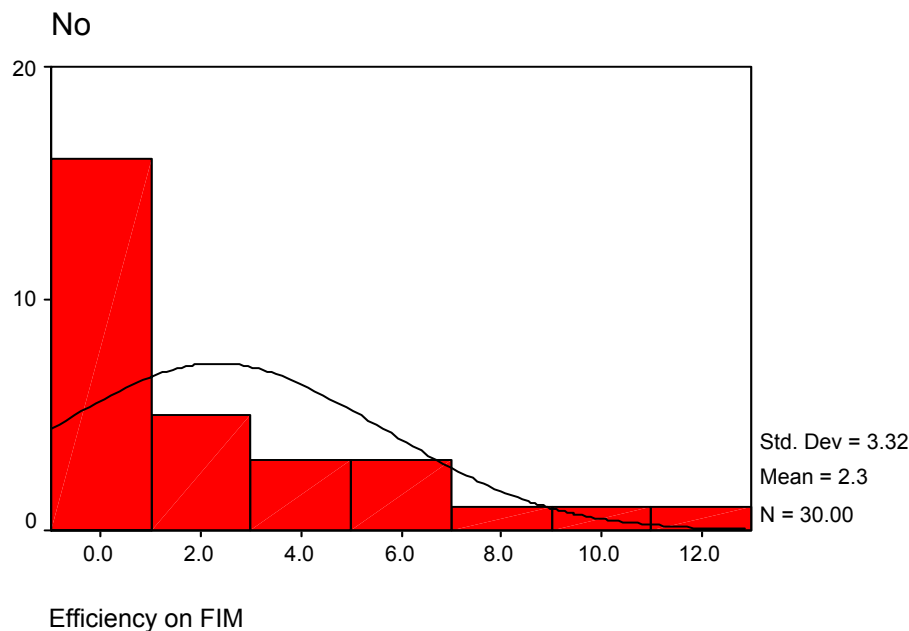


Figure 14. Histogram of the “No” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

It is noted that in both groups there are relatively many patients for whom the efficiency obtained was “low” ($\leq 5\%$). In the “No” group, “high” efficiencies are obtained only in proportion of 20% (6 out of 30 patients). In the “Yes” group, the proportion of those for whom “high” efficiencies are obtained is 50% (15 out of 30). Therefore, as an effect of the treatment in the therapeutic pool, an increase of “high” efficiencies of 30% (50% – 20%) – NNT = 3.33 is obtained. There is a clear difference between the groups, in favor of the “Yes” group, for which several “high” efficiencies are obtained; Fisher’s exact test produces a “unilateral P value” of 0.015, which

allows us to conclude that this difference between efficiencies is **statistically significant**.

The diagram below shows the distributions of the values obtained in the dynamics, from admission to discharge, of patients’ scores from each of the two groups, assessed by the **QOL scale**.

It is found that in the “NO” group there is an average increase of 3.1 levels of QOL scores between admission and discharge (with a median of 3 and a maximum increase of 10 levels). For the “YES” group, the average increase is 3.67 levels (with a median of 3.5 levels and the same maximum increase of 10 levels). Apparently, for

the “YES” group, the increase in QOL values is slightly higher, and we will continue to statistically verify this finding. Thus, the Kolmogorov-Smirnov normality test produces an “asymptotic significance” of 0.265 for the data obtained from the “NO” group, while for the data obtained from the “YES” group, the significance is 0.727. Both significances are therefore above the threshold of 0.2 of normality acceptance, which allows us to

use the t test to compare groups and the t test produces a bilateral significance of 0.328, therefore a significance of 0.164 ($= 0.328/ 2$) attached to the statement that “the evolution on the QOL scale is better in the case of treatment in therapeutic pool”, as the comparison of the media would suggest. So, the statement is not statistically significant.

Treatment in the therapeutic pool

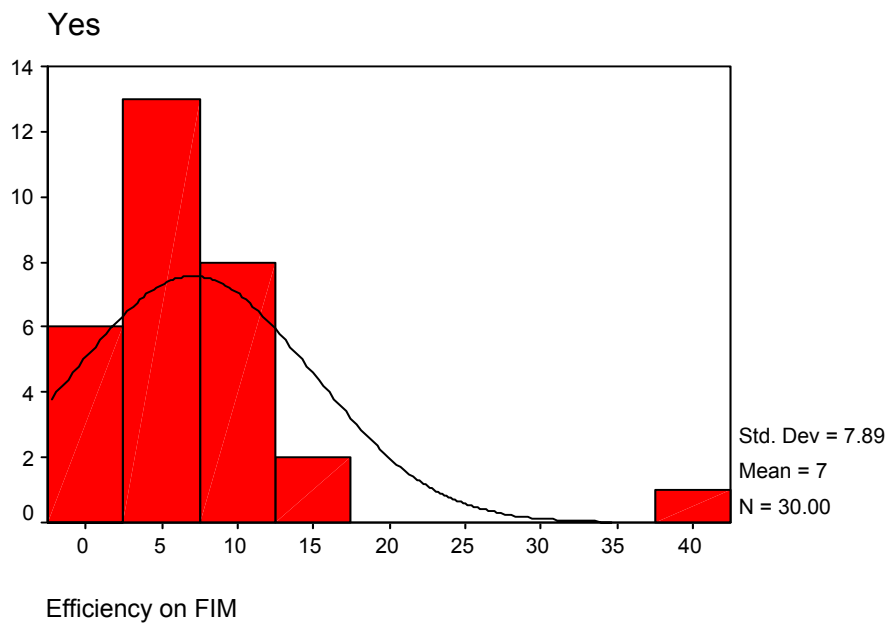


Figure 15. Histogram of the “Yes” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

Treatment in the therapeutic pool

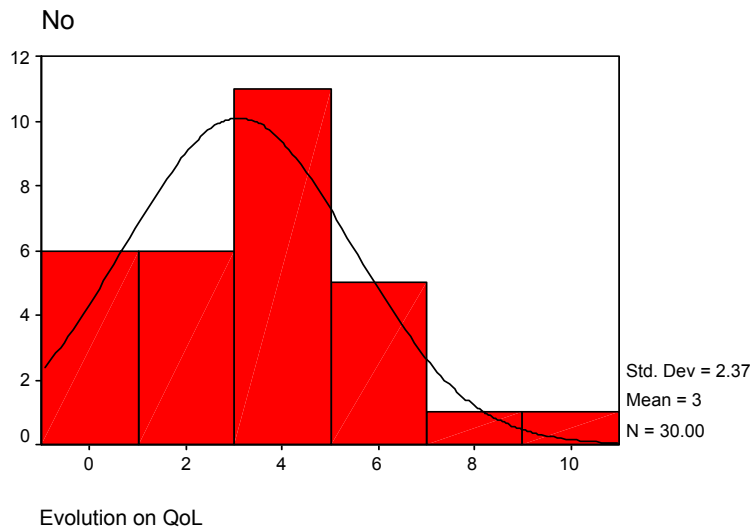


Figure 16. Diagram of the “No” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

Treatment in the therapeutic pool

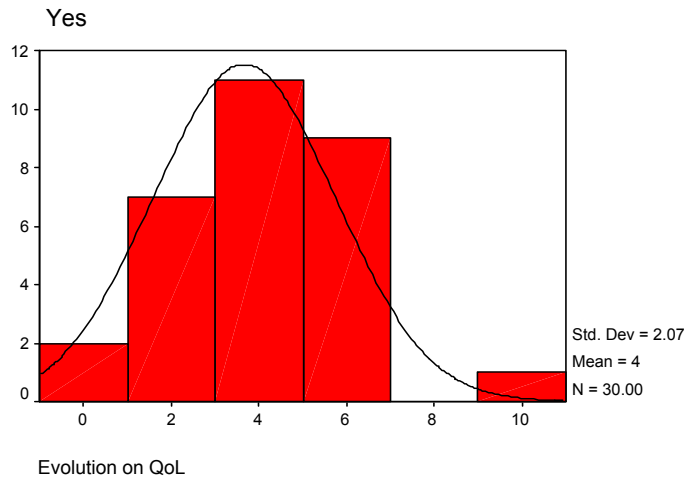


Figure 17. Diagram of the “Yes” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

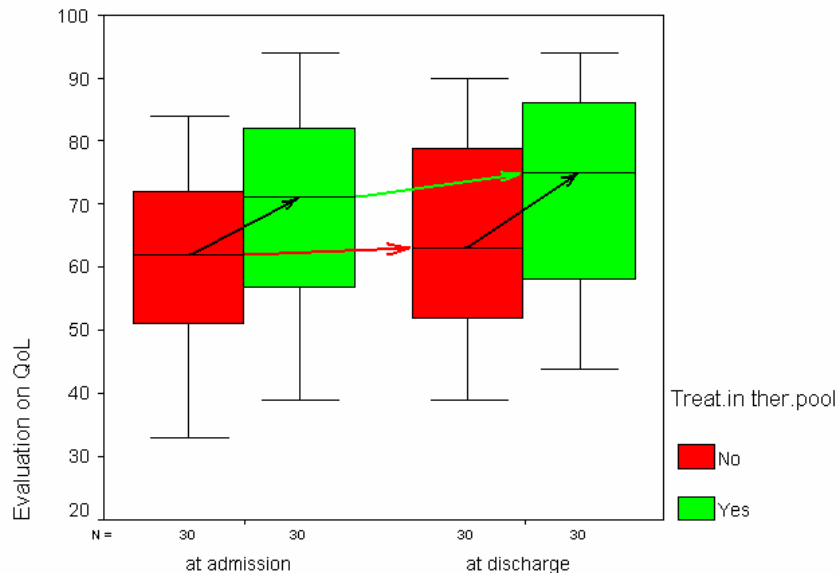


Figure 18. Box-plot emphasizing the effect size objectivized on the QOL scale.

In fact, at admission the QOL values have an average of 61.2 (units) for the “No” group, respectively 68.8 (units) for the “Yes” group, so the “Yes” group has a better situation, on average with 7,6 (units). At discharge, the values of the QOL scores for the “No” group have an average of 64.3 (units), only 3.1 levels higher and for the “Yes” group the mean of the QOL values at discharge is 72.5, therefore 3,7 levels higher than at admission. It can thus be appreciated that the effect size of the treatment in the therapeutic pool – expressed by the values of the QOL scores – is very low, of 0.6 (= 3.7–3.1) scale units (the

explanation is similar to the one mentioned in the effect size objectivized on the FIM scale). The box plot below (although it is made up of medians and not means) reflects this finding.

The treatment efficiency, based on the scores obtained on the QOL scale, is calculated with the formula: Efficiency (%) = (discharge value – admission value)/ (112 – admission value), where possible, *i.e.* in case the patient does not have the QOL 112 score at admission (a value which is the maximum).

Histograms of patient efficiencies, per groups, are as follows:

Treatment in the therapeutic pool

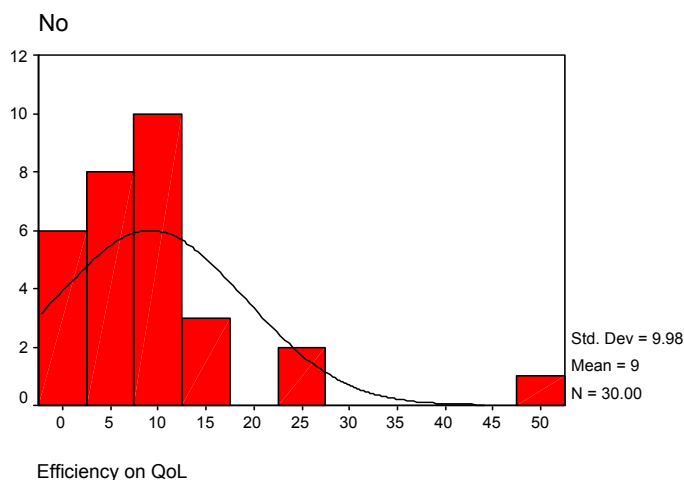


Figure 19. Histogram of the “No” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

Treatment in the therapeutic pool

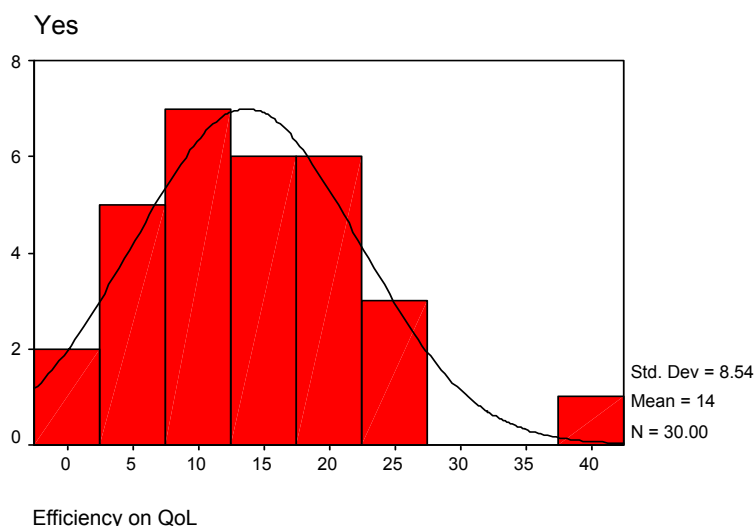


Figure 20. Histogram of the “Yes” hydro-/ thermo-/ kinesis- therapy in therapeutic pool.

It is noted that in both groups there are relatively many patients for whom the efficiency obtained was “low” (less than 10%). In the “No” group, “high” efficiencies are obtained in a proportion of 50% (15 out of 30 patients). In the “Yes” group, the proportion of those for whom “high” efficiencies are obtained is 76.7% (23 out of 30) Therefore, as an effect of the treatment in the therapeutic pool, an increase of “high” efficiencies of 26.7% $76.7\% - 50\%$ – $NNT = 3.75$ is obtained. The table shows a clear difference between the groups, in favor of the “Yes” group, for which several “high” efficiencies are obtained;

Fisher’s exact test produces a “unilateral P value” of 0.004, which allows us to find that this difference in efficiencies is **statistically significant**.

An interesting aspect to be discussed is the discrepancy between the results regarding the “effect size” and respectively, the efficiency of the hydro-/ thermo-/ kinesis-therapy in therapeutic pool calculated based on the QOL score; a possible explanation of it has already been given.

NB. Considering the editorial space – normally limited – the tables corresponding to our statistical

analysis has not been included in the article; they are available at the authors.

CONCLUSIONS

Although not spectacular, our results objectify the overall beneficial effects of hydro-/ thermo-/ kinesis-therapy in therapeutic pool.

Therefore, we consider necessary to extend our clinical study enrolling more patients for an enhanced related primary database – prone to more comprehensive conclusions.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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