

# ***MANAGEMENT OF HIP OSTEOARTHRITIS***

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# INTRODUCTION

- ❑ **Osteoarthritis (OA)** is the most common joint disorder in the elderly, **causing significant pain which negatively** affects mobility and quality of life.
- ❑ The knee is the most common joint affected in osteoarthritis, with up to 41% of limb arthritis being located in the knee, compared to 30% in hands and 19% in hips.
- ❑ **Relief pain with preservation or restoration of joint motion is the main objective of therapy.**
- ❑ Management of hip OA includes **nonpharmacological modalities** (patient education, balneal and physical therapy, assistive devices, and weight management) and **pharmacological treatments** ranging from oral to intra-articular (IA) therapy.

# OBJECTIVES

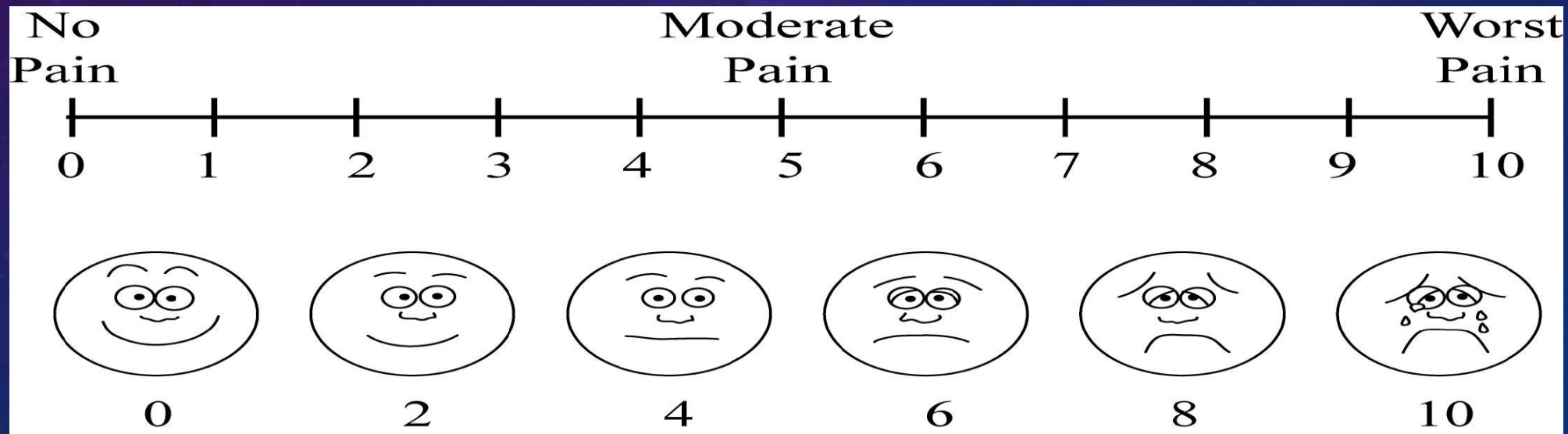
The aim of the study was to assess the effectiveness of **intra-articular injection** of Antalvisc<sup>®</sup> combined with **complex balneal and physical kinetic therapy** in the treatment of hip osteoarthritis.

# MATERIALS

1. sapropelic mud, mineral water from Techirghiol Lake, all facilities for treatment of our sanatorium;
2. visual analog scale for pain, Harris hip score;

# VISUAL ANALOGUE SCALE(VAS)

- Pain was investigated by the **Visual Analogue Scale (VAS)** consisting in a line ranging from 0, indicating the absence of pain, to 10 indicating unbearable pain.
- At each evaluation the patients were asked to respond in terms of their pain “at the present time” by indicating on the VAS their perceived pain.



# HARRIS HIP SCORE(HHS)

- Hip disability was investigated in terms of **Harris score**. The HHS was developed for the assessment of the results of hip surgery, and is intended to evaluate various hip disabilities and methods of treatment in an adult population. The original version was published 1969. The domains covered **are pain, function, absence of deformity, and range of motion**. The pain domain measures pain severity and its effect on activities and need for pain medication.
- The function domain **consists of daily activities** (stair use, using public transportation, sitting, and managing shoes and socks) and **gait** (limp, support needed, and walking distance).
- Deformity takes into account hip flexion, adduction, internal rotation, and extremity length discrepancy.
- Range of motion measures hip flexion, abduction, external and internal rotation, and adduction. The score has a maximum of 100 points (best possible outcome) covering pain (1 item, 0–44 points), function (7 items, 0–47 points), absence of deformity (1 item, 4 points), and range of motion (2 items, 5 points).

# STUDY DESIGN

- This was a prospective, open-label, investigator-initiated study. Sixty patients were enrolled and received complex balneal and physical kinetic treatment during 12 days, combined with one injection of Antalvisc<sup>®</sup>, at the end of treatment.
- The study was conducted between June 2016 and December 2017, in Balneal and Rehabilitation Sanatorium Techirghiol and a total of 60 patients were enrolled. The study is not completed, these are preliminary data.
- Clinical evaluations were performed **at baseline, after one month and 6 months patients were called and asked about the symptoms. One year after the injection, the patients returned to the clinic to perform a follow-up and final visit.**

# STUDY DESIGN

- ***Inclusion criteria*** were: subjects between 20 and 85 years of age suffering from primary or secondary hip osteoarthritis with a Kellgren-Lawrence grade II, III, IV and providing signed informed consent.
- ***Exclusion criteria:***
  - patients suffering from secondary hip osteoarthritis after rheumatoid arthritis and ankylosing spondylitis;
  - the presence of disorders that contraindicate the application of mud and the facilities from our center (neoplasia, cognitive impairment, pace-maker implant);
  - joint arthroplasty.



# KELLGREN AND LAWRENCE II, III, IV RADIOGRAPHY IN HIP OA



# TREATMENT APPLIED

## 1. Balneal treatment (usual applied in BRST):

- hydro-(kineto)-thermo-therapy: once a day; in the swimming pool with salt water from the lake ( $35^{\circ} - 36^{\circ} \text{ C}$ ), applied individual or to a group of patients with similar deficiency ;
- mud onction, mud bath ( $38^{\circ} - 38.5^{\circ} \text{ C}$ ) or mud wrapping ( $42^{\circ}-45^{\circ}\text{C}$ );
- individual kinetotherapy at gym room;

## 2. Adjuvant treatment (physiotherapy):

- 2 – 4 adjuvant electrotherapy procedures;

## 3. Kinetotherapy in the gym room 1-2 time a day and one session (daily) of massage.

# ANTALVISC CHARACTERISTICS

<b>COMPOSITION</b>	<b>HYALURONIC ACID CROSS-LINKED=MANNITOL</b> Mannitol, a natural sugar alcohol, is a strong antioxidant and free radical scavenger that protects HA from chemical degradation and rapid depolymerization.
<b>ORIGINE</b>	<b>NON-ANIMAL(Biofermentation)</b>
<b>CONCENTRATION HA</b>	<b>20 mg/ml</b>
<b>MOLECULAR WEIGHT HA</b>	<b>&gt;4 million DALTONS IN STERILIZED PRODUCT</b>
<b>INDICATIONS</b>	<b>OA KELLGREN 1 TO 4</b>
<b>EFFECTS</b>	<b>PAIN RELIEF, IMPROVE RANGE OF MOTION, PROTECTION OF CARTILAGE</b>
<b>LASTING EFFECT</b>	<b>TILL 15 MONTHS</b>
<b>ADMINISTRATION</b>	<b>ONE INTRAARTICULAR INJECTION</b>
<b>NEEDLE SIZE</b>	<b>18-22 G</b>
<b>PRIMARY PACKAGING</b>	<b>PREFILLED BD SYRINGE OF 3 ML WITH THIMBLE</b>
<b>SECONDARY PACKAGING</b>	<b>MEDICAL STERILIZED BLISTER IN CARDBOARD BOX</b>

# STATISTICAL ANALYSIS

➤ The statistical processing of the data from the present study used SPSS 17. The tests were performed one sample Kolmogorov Smirnov test, Chi-Square tests, linear Pearson correlation.

## ULTRASOUND GUIDED INJECTION TECHNIQUE

- Each subject underwent one ultrasound guided injection of Antalvisc<sup>®</sup>, using an anterior approach with a 20-gauge spinal needle after betadine preparation.
- Injections were performed **at the end of 12 days of balneal treatment** and were administered by the same physician on patients in a supine position.
- Excessive weight bearing and strenuous activity were discouraged for 48 hours after each injection.
- In the event of **bilateral hip osteoarthritis**, the both hip were treated in the same session.

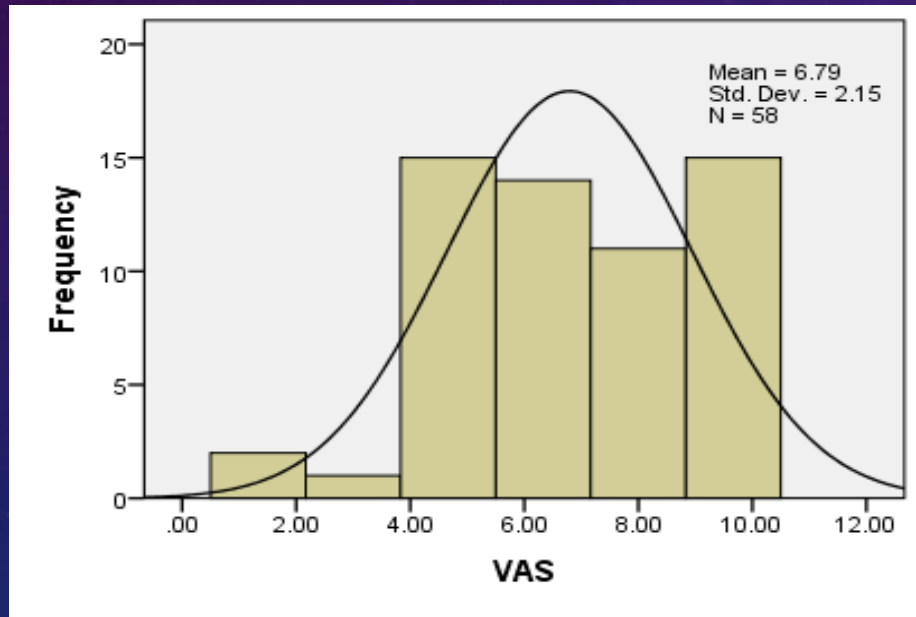


# RESULTS

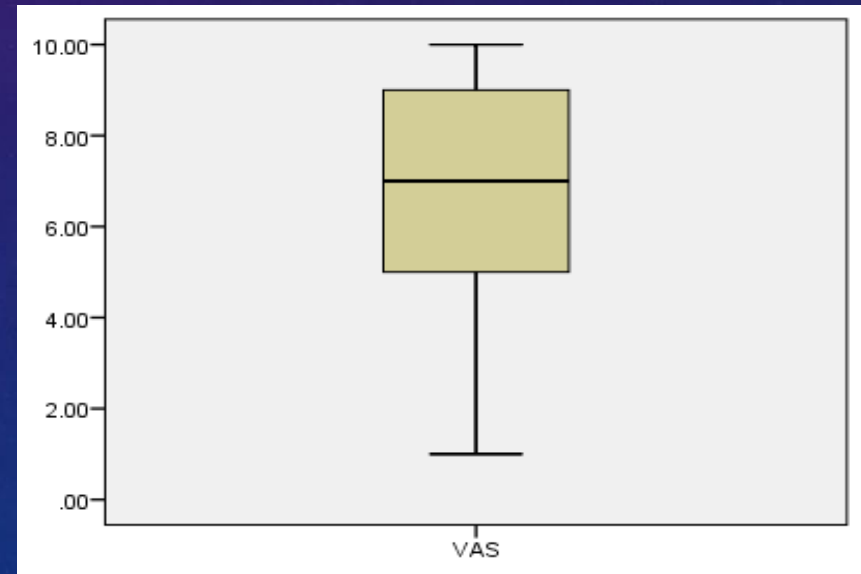
<b>Patients</b>	<b>58</b>
<b>Male</b>	<b>29(50%)</b>
<b>Female</b>	<b>29(50%)</b>
<b>Age</b>	<b>61.78,(+/- 11 s.d.)</b>
<b>Rural</b>	<b>20</b>
<b>Urban</b>	<b>38</b>
<b>Retired</b>	<b>32</b>
<b>Smoking and alchool habit</b>	<b>17</b>
<b>BMI(mean Kg / m<sup>2</sup>)</b>	<b>27.82,(+/- 14.86 s.d.)</b>
<b>Weight(kg, Mean)</b>	<b>79.74 Kg( 14.86 s.d.)</b>
<b>Height(cm, Mean)</b>	<b>168.53 cm (9.84 s.d.)</b>
<b>Right hip</b>	<b>30</b>
<b>Left hip</b>	<b>19</b>
<b>NSAIDS Intake(Days/Months)</b>	<b>22</b>

# RESULTS

The representation of VAS for the group of patients at **baseline**.

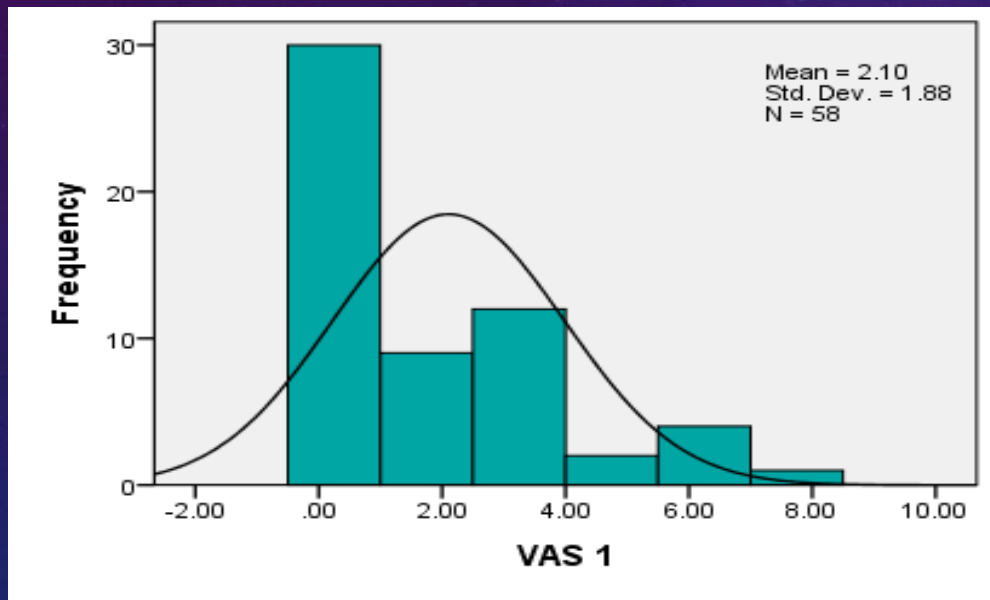


The mean values of VAS recorded at baseline was **6.79, (2.15 std.dev.)**

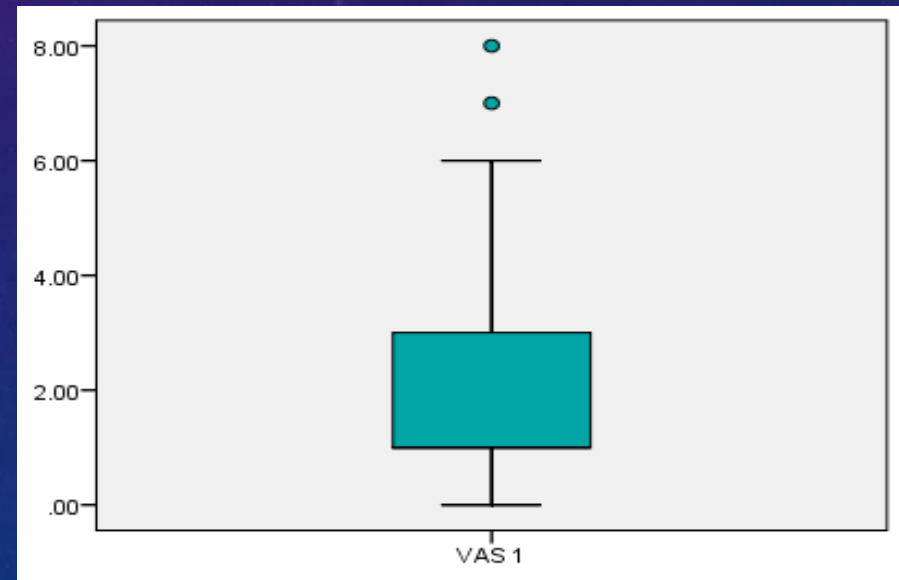


# RESULTS

The representation of VAS for the group of patients **one month after treatment**.



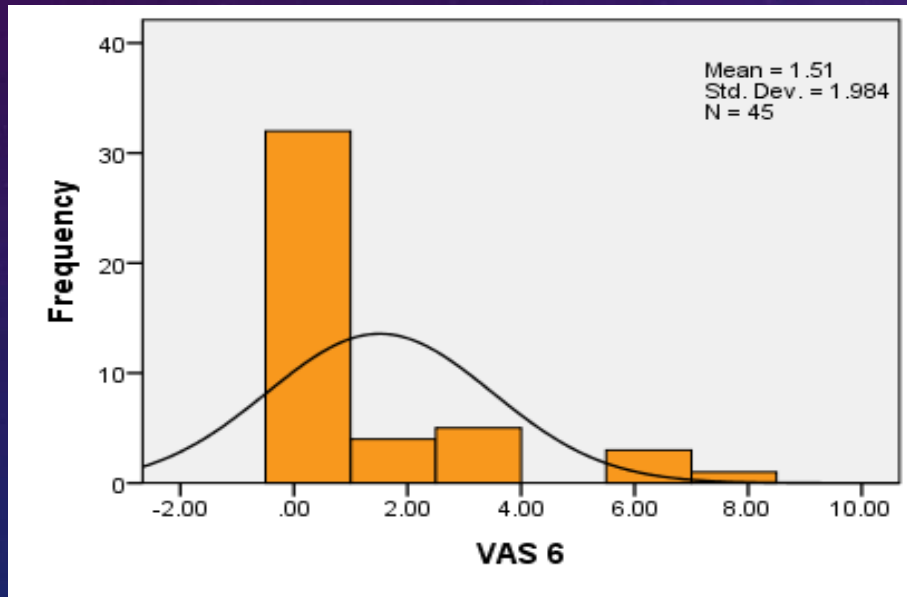
The mean values of VAS recorded one month after treatment was **2.10**, (**1.88 std.dev.**)



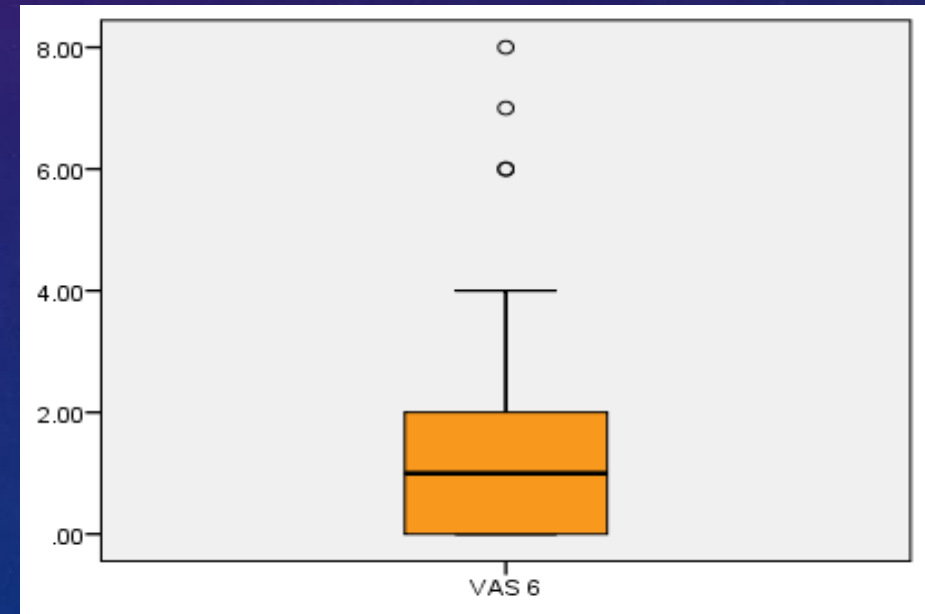


# RESULTS

The representation of VAS for the group of patients **six month after treatment.**

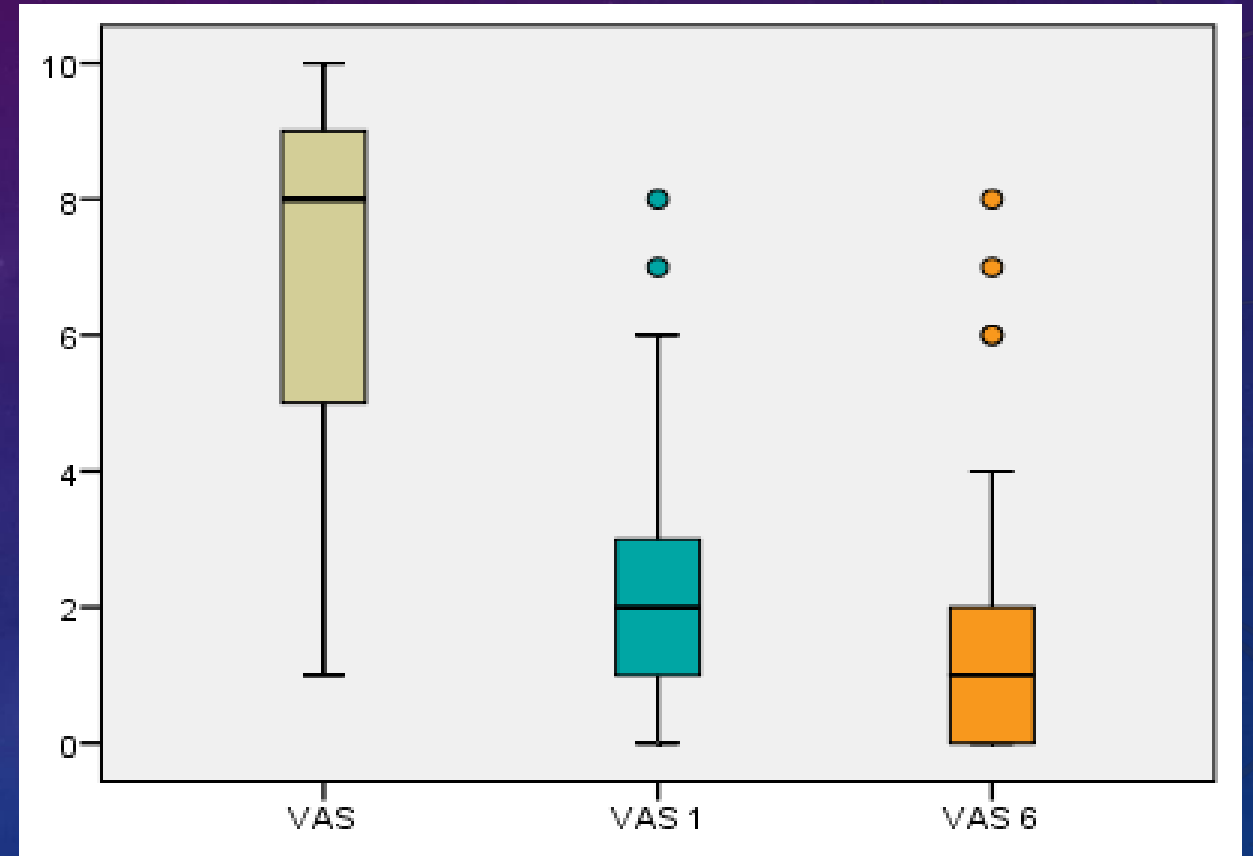


The mean values of VAS recorded six month after treatment was **1.51, (1.98 std.dev.)**



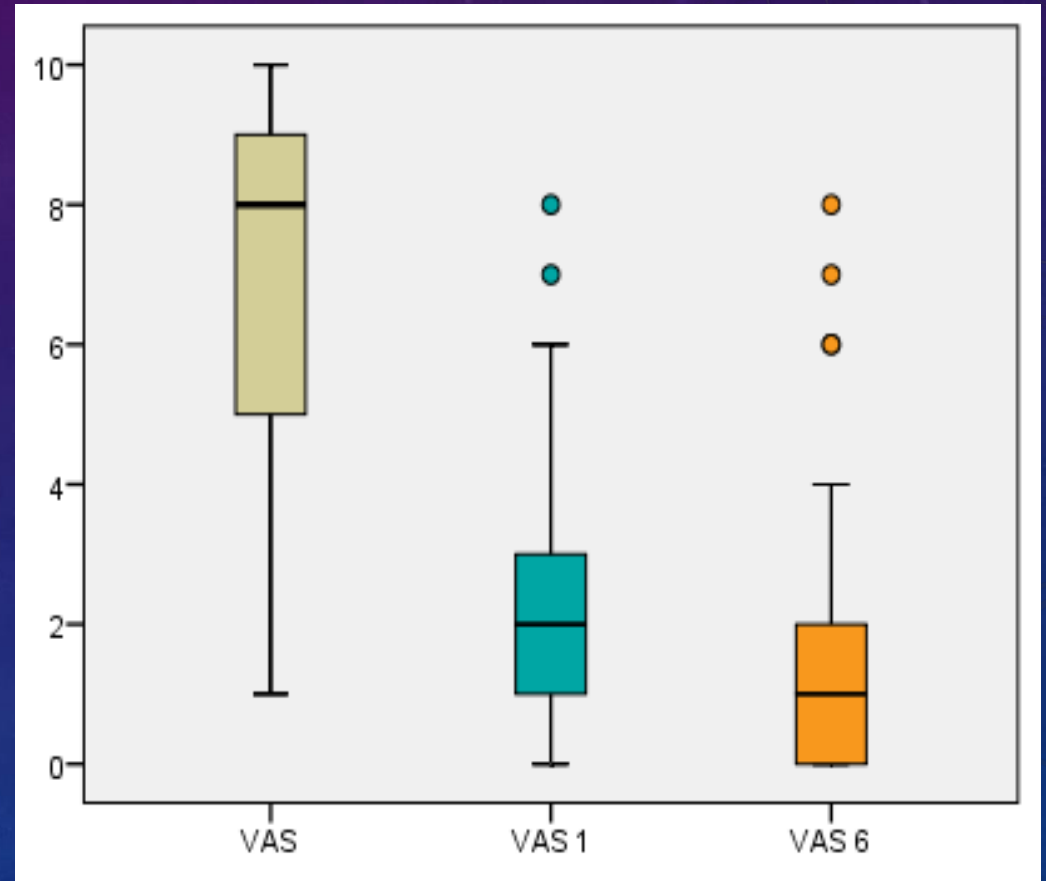
# RESULTS

- The results of Wilcoxon test confirms that there **are statistically significant differences between mean values of VAS at baseline and the mean values of VAS one month after treatment (Sig. Or  $p < 0.001$ )**; as seen from the associated Box-Plot representation, mean values of VAS recorded one month after treatment are significantly lower than the mean values of VAS recorded at baseline..



# RESULTS

- The results of Wilcoxon test confirms that there are statistically significant differences between mean values of VAS 1 (one month after treatment) and the mean values of VAS 6 (six month after treatment (Sig. Or  $p < 0.001$ ); as seen from the associated Box-Plot representation, mean values of VAS recorded six month after treatment are significantly lower than the mean values of VAS recorded one month after treatment.



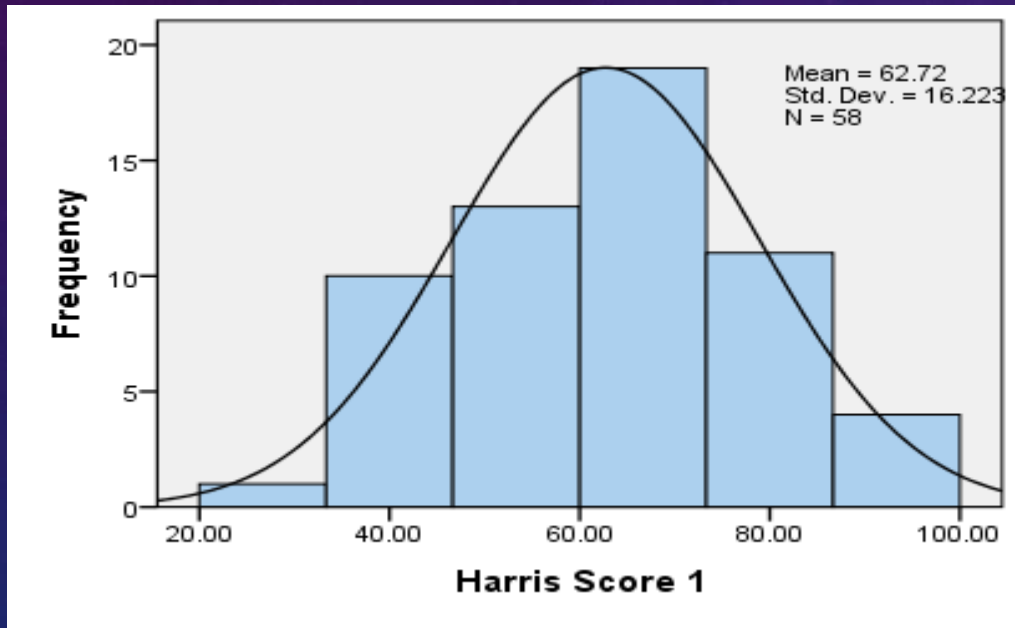
- In the present study, we noted that after one month of treatment, the mean values of **VAS decreased statistically significant** ( $p < 0.001 < \alpha = 0.05$ ) than the corresponding mean values of VAS at baseline. The mean values of VAS six month after treatment continue to decrease **statistically significant**. These results are in accordance with studies from international databases which showing the decrease of pain statistically significant, assessed by visual analogue scale for pain (VAS), under the effect of of intraarticular viscosupplementation.

Statistics											
	N		Mean	Media n	Mode	Std. Deviation	Minimu m	Maxim um	Percentiles		
	Valid	Missin g							25	50	75
VAS	58	0	6.79	7.00	8.00	2.15	1.00	10.00	5.00	7.00	9.00
VAS 1	58	0	2.10	1.00	1.00	1.88	.00	8.00	1.00	1.00	3.00
VAS 6	<b>45</b>	<b>13</b>	1.51	1.00	.00	1.98	.00	8.00	.00	1.00	2.00
VAS 12	<b>16</b>	<b>42</b>	1.56	1.00	.00	2.37	.00	8.00	.00	1.00	2.50

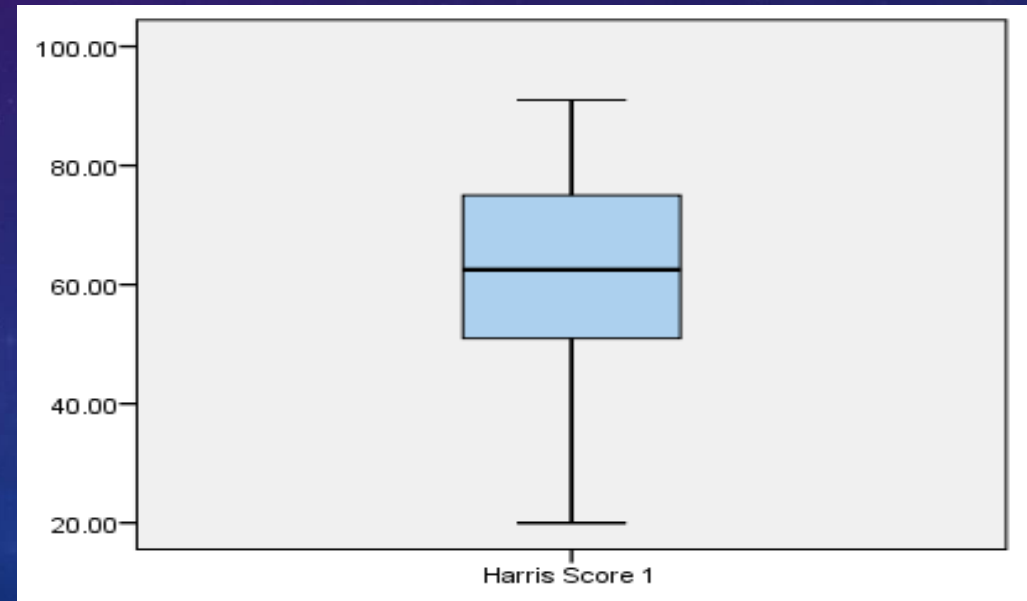
a. Multiple modes exist. The smallest value is shown

# RESULTS - HARRIS SCORE 1

Graphic representation for Harris score at baseline



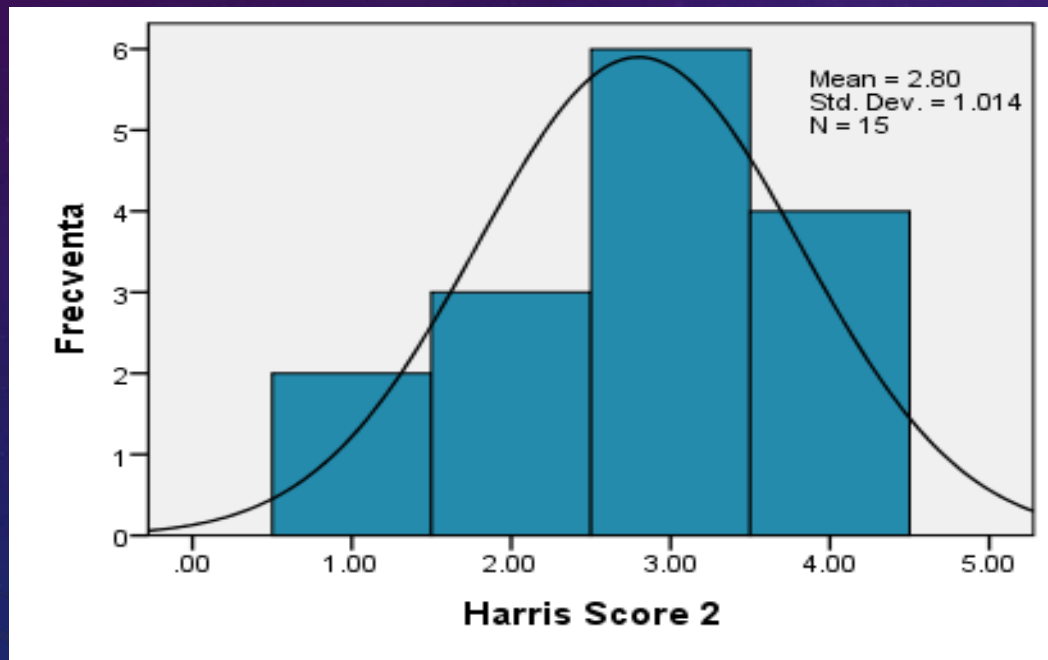
Box-Plot representation of Harris score. The values of Harris Score 1 were between 20 și 91, with mean values 62.72 and standard deviation 16.22.



# RESULTS - HARRIS SCORE 1

Harris Score 1		
	Frequency	Percent
Valid		
<70 (deficitary)(1)	36	62.1
70-79 (acceptable)(2)	11	19.0
80-89 (good)(3)	9	15.5
90-100 (excellent)(4)	2	3.4
Total	58	100.0

# RESULTS - HARRIS SCORE 2



Harris Score 2				
		Frequency	Percent	Valid Percent
Valid	1.00	2	3.4	13.3
	2.00	3	5.2	20.0
	3.00	6	10.3	40.0
	4.00	4	6.9	26.7
	<b>Total</b>	<b>15</b>	<b>25.9</b>	<b>100.0</b>
Missing	System	43	74.1	
Total		58	100.0	

# DISCUSSION

- Published data on viscosupplementation in the hip OA is limited. Only a small number of scientific papers containing statistically significant results about hip IA injection of HA are available in the literature despite the hip being the second most common site of osteoarthritis. One of the reason is because the intra articular injection of the hip is not as easy as for the knee.
- The intra articular injection of Hialuronic Acid(HA), called vascosupplementation, was first investigated in 1970s and now is commonly used in clinical practice for the management of OA.
- Recent studies has shown that intra-articular injection with HA may be a safe and effective treatment in hip OA.



# CONCLUSION

- ❑ The primary endpoint consisted in the evaluation of the Harris Hip Score over one-year follow-up, even if only 15 patients finished the study follow up, we observed a significant improvement when compared to baseline.
- ❑ The second endpoint was pain using VAS, who presented a statistically significant improvement in all follow up visit(VAS 1, VAS6, VAS 12)( $p < 0,0001$ ).
- ❑ Also we can note the reduction of NSAIDS intake by patients to modulate theirs symptoms. **It is an indirect demonstration of pain control exercised by intra-articular administration of HA.** NSAID intake is very common among patients affected by hip OA to reduce symptoms; it may cause gastrointestinal and cardiovascular side effects.
- ❑ No adverse events were recorded at each control visit, only an exacerbation of pain in the same day with injection.

# CONCLUSION

- ❑ The association of HA in hip OA with sapropelic mud from Techirghiol has been shown to have favorable effects (increase ROM, decrease pain).
- ❑ Sapropelic mud from Techirghiol lake has proven benefits in patients affected by OA, by its antiinflammatory and chondroprotective effects. These benefits were shown during last years in many studies developed in Balneal and Rehabilitation Sanatorium Techirghiol.
- ❑ In advanced cases of OA ( Kellgren Lawrence IV), HA supplementation has been improving pain for short term, but in the long-term, treatment remains surgical.

Thank you!

