Dr Salvador Allende University Hospital

Geriatrics and Gerontology Service

CLINICAL TRIAL: TREATMENT OF RENAL LITHIASIS WITH FOOD SUPPLEMENT RENALOF

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ABSTRACT

An experimental research study (Clinical Trial Stage III) was conducted to assess the effectiveness, safety and toxicity of the product RENALOF, manufactured by Spanish Laboratorios Catalisis for the treatment of Renal Lithiasis —one of the most common conditions affecting the Genitourinary system. The study focuses on the introduction of a brand new natural health product—a new alternative created for the purpose of increasing the current therapeutic arsenal. The research involved 68 patients from the specialized Urology and Geronto-Geriatrics departments of the Dr Salvador Allende University Hospital. A total of 20.59% of patients were aged 60 to 69 and Ultrasonography was the most widely used method of diagnosis. AHT is the most frequent chronic condition affecting patients of our group (39.7%). Side effects are not significant, as only four patients developed diarrhoea (5.12%) and one, gastritis (1.28%). The largest reduction of kidney stones occurred during the first month of the treatment, and 42 patients had kidney stones completely removed during the first three months of treatment (61.66%) —which provides evidence of the effectiveness of a therapeutic treatment with the product RENALOF.

INTRODUCTION

The gradual increase of the prevalence of genitourinary conditions, and specifically Urinary Lithiasis, is directly related to the increase of the population aged over 15 and the elderly in our country. Their impact on the functional capacity and quality of life of the elderly has continuously encouraged researchers to focus on increasing the therapeutic arsenal, improving other specializations (Invasive and Non-invasive Surgery, etc.) and fostering the use of natural / traditional health products.

Historically, science has always attempted to provide solutions to this disease — acknowledged by many to be one of the most painful symptoms that can be endured and suffered by human beings— with the use of healing plants, painkillers, parenteral hydration or diuretics for the purpose of easing the movement of kidney stones. As a last resort, surgical procedures are used for those cases in which kidney stones cannot be removed by any other means, which are today highly developed techniques thanks to the advent of endoscopic surgery and extracorporeal lithotripsy. However, they do present contraindications, risks and limitations, even more frequently in elderly patients, as they are often associated with age and comorbidity. Therefore, the current tendency to use alternative forms of non-invasive treatment is gradually growing, as there is common consensus on the advantages it offers.

By and large, health professionals are capable of providing accurate and specific diagnosis of renal lithiasis, and there is also growing interest in the application of natural health products that help alleviate the pain and improve overall health —products based on the experience gathered over the years in the use of non-pharmacological therapy procedures for the treatment of other conditions, which are yielding promising results.

The ethipatogenic factors leading to urinary lithiasis are multiple and varied. Specially relevant in elderly patients is the occurrence of hydronephrosis, cyst pathology and, above all, the frequency of urinary infection, all of which can lead to complications in the long term, such as repeated infection, interference with daily life activities and, the most feared, long-term immobility and disability. Multiple epidemiological research studies have led to the conclusion that, in many cases, urinary lithiasis is connected with metabolic alterations that can cause an over saturation of lithogenic silica and facilitate precipitation. Said metabolic alterations include hypercalciurias, hyperuricosuria, hyperoxaluria, acidification defects, cystinuria, poor diuresis and urinary infection.

In short, Renal Lithiasis occurs more frequently in men than women, it is rare in children and black individuals, and can run in the family. It is a frequent condition that affects 10% of the population, and is suffered more frequently by middle age individuals and males. It occurs more often in sedentary people and people exposed to high temperatures.

Some of the diseases of the genitourinary system suffered more frequently by the elderly population include urinary infections, benign prostatic hyperplasia (BPH) and urinary lithiasis —the latter considered as a chronic condition associated with a high level of relapse and hospital admissions. Regarding occurrence, an overall increase of 60%-75% in recent years is generally accepted. An in-depth analysis of said data reveals that said increase largely corresponds to the group of elderly patients.

Over 5% of the elderly populations suffer the lithiasis disease, which represents one of the major indicators upon analysis of the amount of nephrology diagnosis of these patients, 32% of the total and ranked third in terms of frequency after cardiorespiratory and vascular processes.

Rates of clinical occurrence in the Western world range between 6% - 15% for males and 3% - 5% for females. Said increase of urinary lithiasis, which also includes the elderly population, is connected with the level of industrialization of the Western world and, specifically, with the introduction of specific changes in the diet, with extensively proven repercussion of calcium, purines and oxalic acid on the metabolism.

The clinical aspects of urinary lithiasis worsen with old age and complications increase, if we take into account, on the one hand, immunosenescence and, on the other, increased likelihood of infection in the event of occurrence of urinary obstruction due to kidney stones, which fosters ecstasy and thus reduces local bacterial resistance to hematogenous infection.

Approximately half of elderly patients suffer relapses of lithiasis, even after receiving the right treatments. The clinical course of the condition is associated with a high frequency of urinary infections that are hard to treat therapeutically and which eventually lead to the destruction of the renal parenchyma.

The presence of obstructions, or lack thereof, in urinary tracts (for example: ureteropelvic junction obstruction) can cause severe symptoms and renal damage, as the recurrence of kidney stones is likely. Also, a patient with non-obstructive kidney stones at any given time may have obstructive kidney stones developed at a later stage. This means that the analysis of the first kidney stone is crucial, as infection is the most common complication that arises from an obstructed kidney stone.

It is widely accepted that Urinary Lithiasis has a negative influence on the morbidity of said patients, which is reflected in: gradually poorer health; the need for extra treatments (analgesics, antibiotics); the risk of neoplastic transformation in the urothelium; contribution to the development and / or worsening of Renal Insufficiency; occurrence of urinary infection

(featuring specific symptoms) and development of obstructive uropathy. All this on the basis of the fact that pain as a clinical symptom represents one of the major problems affecting the quality of life of the population, including specifically the elderly. Furthermore, a second group of discomforts affecting this age group often occurs, leading in many cases to decreased self-esteem, loss of interest or motivation and ultimately depression.

There is no doubt that the treatment of Urinary Lithiasis remains to date a challenge for conventional therapeutics due to the variable degree of invasiveness and prediction of complications —all of which is lessened in the case of senior patients, whose problems are sometimes either difficult or impossible to resolve.

Generally, medical science and specifically pharmacology science continuously endeavour to look for more affordable and less invasive therapies that offer more advantages than current therapies.

The product **RENALOF** can increase expectations to said purposes: it is designed with specific antioxidant compounds triggered by means of a bio-catalyst process that enables improved control of the production mechanism of said anti-stress molecules.

This process features a formula with natural ingredients that increase their biological activity without modifying their chemical structure. Its new formula contains activated couch grass extract (Agropyron Repens) and its natural diuretic effect makes couch grass the ideal substance for the treatment of any type of infection of the urinary tracts. In addition, it can stimulate urine flow and help to remove renal calculi (kidney stones). Its soothing properties relieve irritation and inflammation. It also has an anti-microbial effect, as it either destroys germs or prevents their growth.

RENALOF: the best solution for solubility of renal stones and calcium oxalate crystal formation in urinary tracts.

Product Composition:

RENALOF: (90-capsule container)

ENERGY VALUE	(per 100g)
Energy value	318 kcal (1,330kjul)
Proteins	0,6g
Carbohydrates	78.0g
Fats	0.3g

AVERAGE VALUES PER CAPSULE

Composition	mg/capsule
Agropyron Repens (Couch Grass) extract …..…….12	mg
Mannitol……88	mg
Corn starch ……..200	mg
Magnesium Silicate ……..25	mg

GOALS

GENERAL:

- To demonstrate the effectiveness, safety and benefits of the product RENALOF in the treatment of renal lithiasis and the advantages it offers for joining the armamentarium.

SPECIFIC:

- Identify and classify clinically and ultrasonographically patients under assessment.
- Provide evidence of any side effects caused by the product RENALOF.
- Demonstrate the effectiveness and efficiency of RENALOF in the treatment of urolithiasis.

METHOD AND MATERIAL

This is a Clinical Trial Stage III conducted to demonstrate the therapeutic effectiveness of the natural product RENALOF in the treatment of renal lithiasis. An initial random sample was taken, involving 78 individuals diagnosed with probable urinary lithiasis by the specialized Comprehensive Geriatric Assessment practices and the Urology Service of the Hospital Clinico Quirurgico Docente Dr Salvador Allende, setting a final number of 68 individuals who passed all the required stages.

Inclusion criteria:

- Verification of the probable renal lithiasis disease via clinical and ultrasonographic assessment.

- Informed consent provided by patients stating approval of their participation in the research.(See annexes)
- Patients aged 15 and over, both sexes.

Exclusion criteria:

- Having previously undergone any surgical treatment for the condition.

- Having discontinued the treatment for any reason whatsoever.
(Side effects, acute condition, lack of willingness to continue, death, etc.).

System of Assessment

The initial interview was conducted for the purpose of clinically and ultrasonographically confirming the diagnosis.

Once the diagnosis was confirmed, patients started the treatment involving a 325mg tablet of **RENALOF** three times a day for a period of six months.

All patients were required to fill out a questionnaire for the purpose of gathering general and specific data including the following:

Personal data: age, sex, city/country of origin, clinical file number, health history and toxic habits.
Risk factors
History of nephritic colic, genitourinary symptoms
Further findings via physical check-up and radiology analysis

Follow-up:
Follow-up was conducted once a month during all six months of treatment by the same team of researchers and using identical assessment criteria.

ANALYSIS AND DISCUSSION OF RESULTS

Initially, 78 patients were selected for this Clinical Trial stage III, ten of whom did not continue for several reasons. As a result, the final number of patients was 68.

When assessing the characteristics of cases, we learnt from available bibliography that this is the most common disease of all urological disorders affecting adults, and the corresponding epidemiologic classification shows that it is highly predominant in middle-aged white males, can run in the family and be influenced by lifestyle and ecosystems.

TABLE 1: PATIENTS WITH RENAL LITHIASIS WHO STARTED TREATMENT WITH RENALOF (BY AGE AND GENDER)

AGE	GENDER		TOTAL PATIENTS	%
	MALE	FEMALE		
Under 20	2	0	2	2.56
20-29	3	4	7	8.97
30-39	5	5	10	12.82
40-49	13	3	16	20.51
50-59	7	5	12	15.38
60-69	7	9	16	20.51
70-79	5	6	11	14.10
80 and over	1	3	4	5.13
TOTAL	43	35	78	100

Source: Renalof Survey

This TABLE provides evidence of the clear predominance of this condition in males (55.13%) and same age groups (40-49 and 60-69). For females, the condition occurs more often in the 60-69 age group. This coincides with the reviewed data from the Cerro municipality, an area with a high level of elderly population.

CHART I: PATIENTS WITH RENAL LITHIASIS WHO STARTED TREATMENT WITH RENALOF (BY AGE AND GENDER)

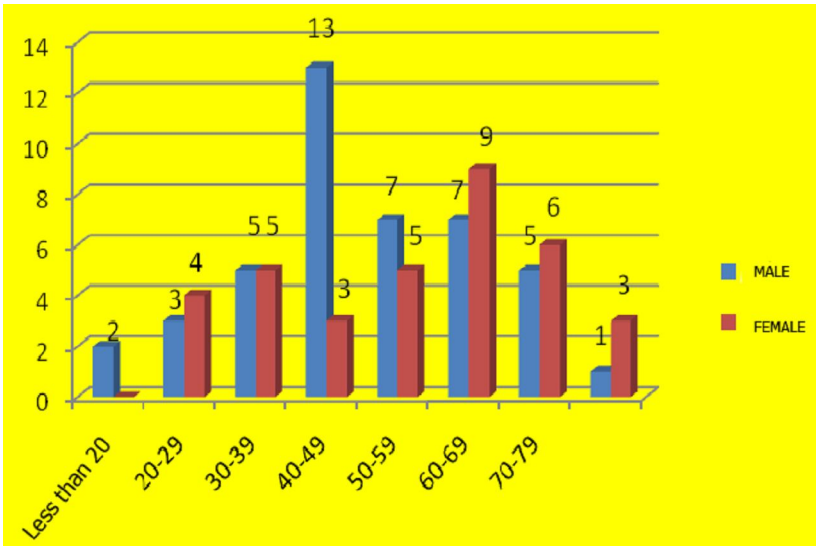
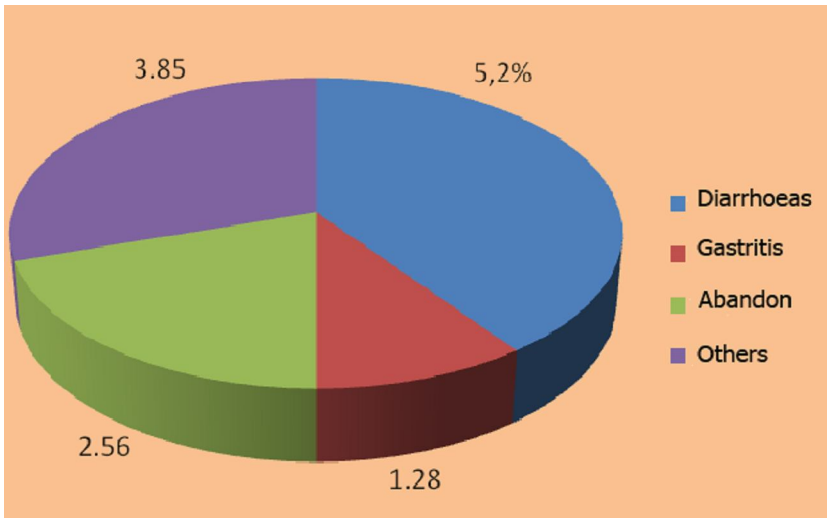


TABLE 2: PATIENTS WHO DISCONTINUED THE TREATMENT AND THEIR REASONS

REASONS	TOTAL	%
Diarrhoea	4	5.12
Gastritis	1	1.28
Discontinuance of T.	2	2.56
Other	3	3.85
Total	10	12.82

Source: Renalof Survey

Chart II



The effectiveness of a drug can also be measured by its therapeutic action, by its majority rate in relation to the side effects and / or collateral effects it may cause, which can affect the quality of the therapy. With the use of RENALOF, we have noticed to date that only five patients who discontinued the treatment (12.8% of the total) suffered unwelcome effects (6.41%), four suffered diarrhoeas (5.12%) and one reported possible gastritis (1.28%). All of them recovered rapidly once they discontinued the treatment.

We believe that diarrhoeas have a direct connection with the ingredient mannitol contained in the product. Indeed, one of mannitol's known side effects is diarrhoea.

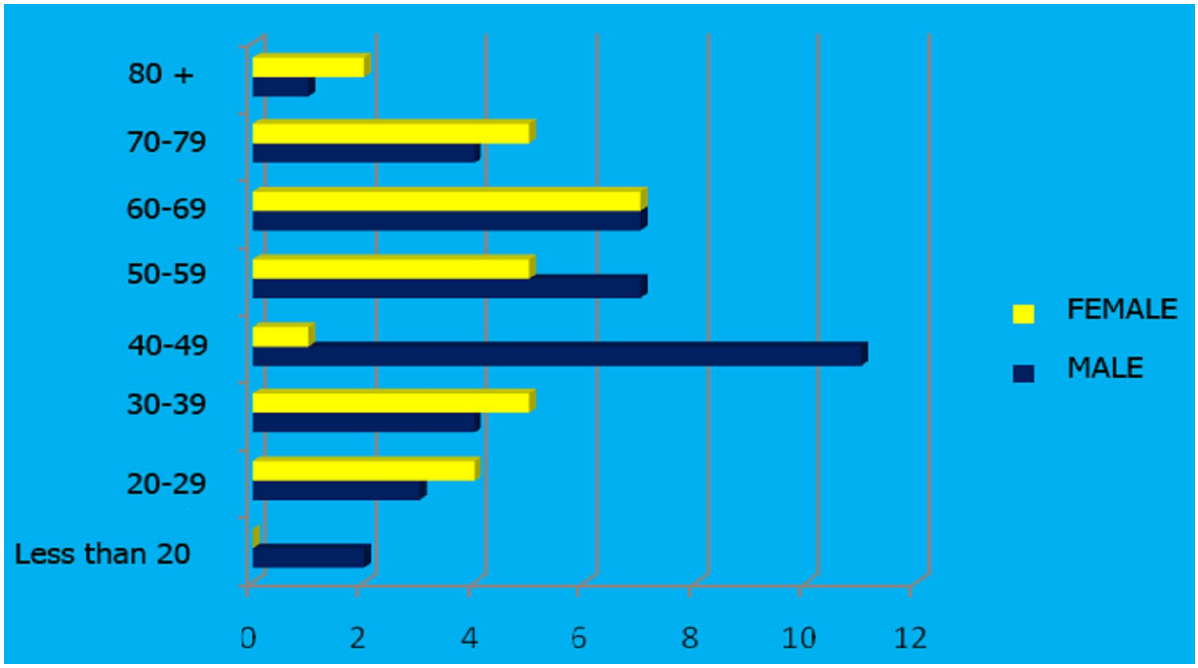
TABLE 3: PATIENTS WITH RENAL LITHIASIS WHO CONTINUED TREATMENT WITH RENALOF (BY AGE AND GENDER)

AGE	GENDER		TOTAL PATIENTS	%
	MALE	FEMALE		
Under 20	2	0	2	2.94
20-29	3	4	7	10.29
30-39	4	5	9	13.24
40-49	11	1	12	17.65
50-59	7	5	12	17.65
60-69	7	7	14	20.59
70-79	4	5	9	13.24
80 and over	1	2	3	4.40
TOTAL	39	29	68	100

Source: Renalof Survey

On this table we can observe the final group of patients included in the Clinical trial who were administered the pharmaceutical product RENALOF for their treatment, broken down into age and gender sub-groups. We can also observe that there is a predominance of individuals (7 males and 7 females) aged 60-69 (20.59%). The second largest group includes two age groups (40-49 and 50-59) with equal percentage, both featuring a predominance of males —all but one in the 40-49 age group. This data coincides with the data reviewed in the available literature, specifically in relation to males, as this pathology is more frequent in them. Likewise, we believe that the group age increase is directly connected to the sample selection; they are the majority because they were drawn from the Geriatrics comprehensive assessment service. Nevertheless, a number of research projects do suggest that this pathology increases by 5% in elderly populations.

CHART III: PATIENTS WITH RENAL LITHIASIS WHO CONTINUED TREATMENT WITH RENALOF (BY AGE AND GENDER)



Human technological and scientific development has led to a great improvement in the quality of life of the population, to a point in which social and health conditions enable greater control of infectious contagious diseases. However, this is not the case with chronic non-communicable diseases, as their sharp increase over the last decades has attracted the attention of health science professionals worldwide due to its psychosocial and functional impact on human beings. TABLE 4 AND CHART IV clearly show this behaviour, with a predominance of AHT patients (39.70%) in relation to all other conditions they suffered. This prevalence of hypertension is specially relevant because these patients currently suffer Renal Lithiasis, which obviously leads to additional risk factors in the short, mid or long term, including endothelial dysfunction, renal damage and chronic renal insufficiency. These diseases, if not treated with the right therapies, such as permanent control of AHT and the prevention and / or specific treatment for removal of Lithiasis from the urinary tract, can worsen said complications. Therefore, we believe that the product RENALOF is an excellent therapeutic option to help prevent obstructive uropathy.

TABLE 4: PREVALENCE OF CHRONIC NON-COMMUNICABLE DISEASES

DISEASE	GENDER		TOTAL	%
	Male	Female		
AHT	16	11	27	39.70
Ischemic Cardiopathy	4	2	6	8.82
Bronchial Asthma	3	2	5	7.35
Diabetes Mellitus	3	2	5	7.35
Gastritis	2	2	4	5.88
None	12	6	18	26.47

Source: Renalof Survey

CHART IV: PREVALENCE OF CHRONIC NON-COMMUNICABLE DISEASES

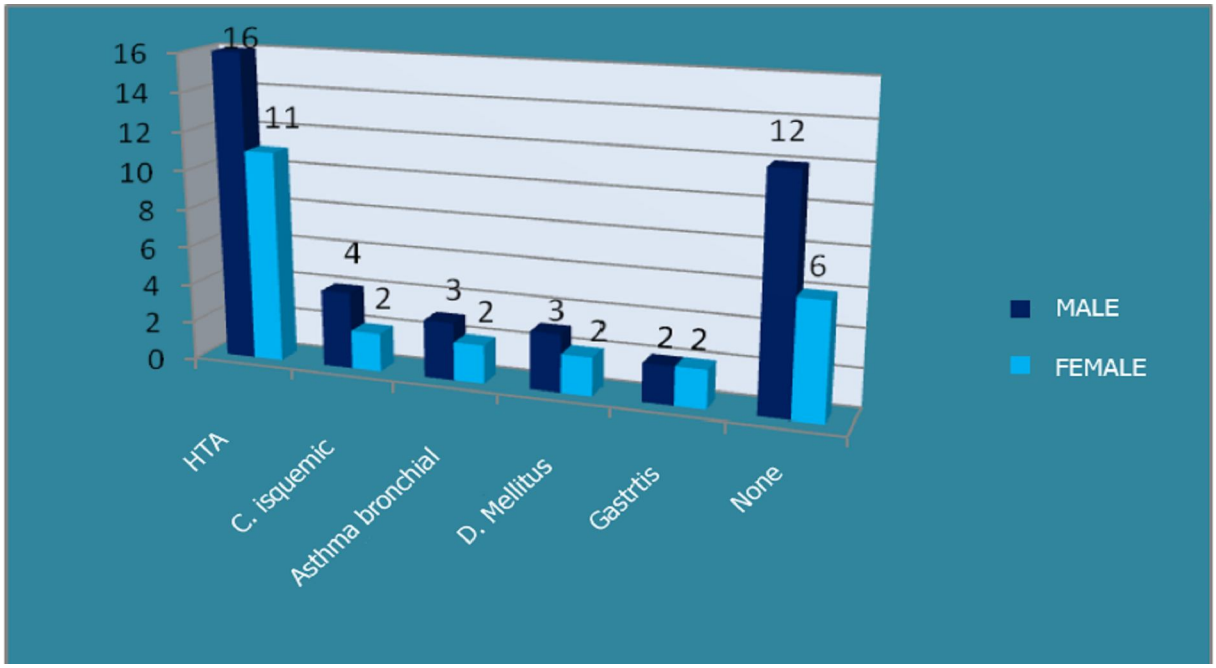


TABLE V: DIAGNOSTIC RESOURCES USED

DIAGNOSTIC RESOURCES	TOTAL	%
ULTRASOUNDS	61	89.70
CT scan	4	5.88
BOTH	13	19.12
X RAYS	0	0

Source: Renalof Survey

CHART V: DIAGNOSTIC RESOURCES USED

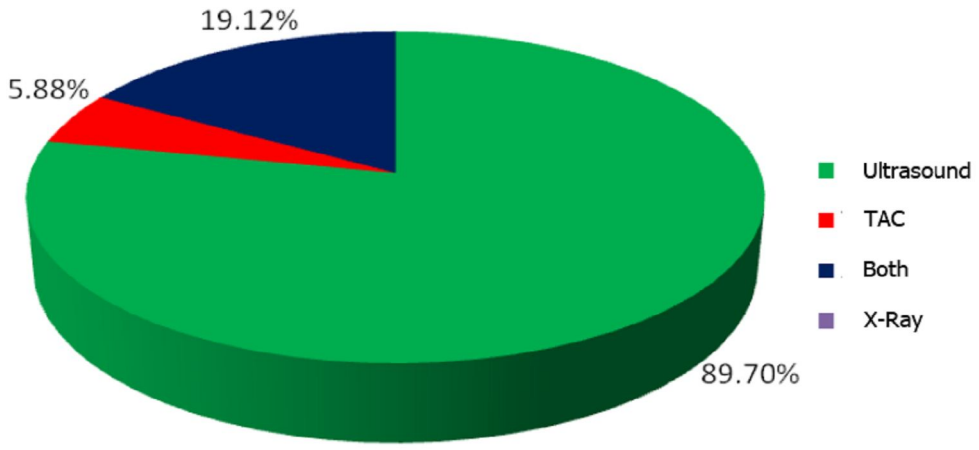


Table 5 and Chart V show the resources used for the diagnosis and monitoring of cases treated with RENALOF. All patients underwent a first evaluation to confirm their diagnosis plus monthly checks of the drug's effectiveness, in order to quantify how many patients had their renal calculi either unchanged, reduced or fully removed in relation to the initial diagnosis, which guarantees the objectiveness of the method used in the Clinical Trial. The Ultrasonography was the main diagnostic resource used in our research (89.70%) on account of being the most efficient and least invasive tool as well as widely accepted by patients. However, Computed Tomography (CT) was also required in a small number of cases, in order to obtain accurate measurement of renal calculi in the event of incongruence.

TABLE VI: ANATOMICAL LOCALIZATION AND NUMBER OF CALCULI

LOCALIZATION	NUMBER OF CALCULI					
	1	2	3	Microlithiasis	Total	%
RIGHT KIDNEY	26	5	2	1	34	50
LEFT KIDNEY	33	8	0	2	43	63.24
BLADDER	1	0	0	0	1	1.47
Meatus	1	0	0	0	1	1.47

Source: Renalof Survey

This table shows that 63.24 % of all calculi were found in the Left Kidney. Thirty-three patients had one calculus in said kidney, eight patients had two and two patients had microlithiasis at this level. A second group (50%) had calculi in their right kidney: 26 patients had one calculus, five had two calculi and two had three.

Only two patients had one calculus each in their bladder and meatus. Yet, this is a different variable with which we seek to highlight the effectiveness of this therapy.

TABLE VII: EFFECTIVENESS OF THE RENALOF TREATMENT ACCORDING TO THE MEASUREMENT OF THE CALCULUS' SIZE, AS PER MONTH OF EVOLUTION AND LOCALIZATION IN RIGHT KIDNEY (RD) OR LEFT KIDNEY (LK)

MONTH OF EVOLUTION	SAME SIZE		DECREASED < 5mm		DECREASED > 5-10mm		DECREASED >10mm	
	RK	LK	RK	LK	RK	LK	RK	LK
MONTH 1	6	8	21	25	3	3	2	5
MONTH 2	2	3	17	11	1	2	2	3
MONTH 3	1	2	5	2	0	1	1	0
MONTH 4	0	0	1	1	0	0	0	0
MONTH 5	0	0	1	1	0	0	0	0
MONTH 6	0	0	1	0	0	0	0	0

Source: Renalof Survey

On this Table we can view a comprehensive analysis of the evolution of the calculus treated with RENALOF, which leads to the following conclusion: all major changes take place between the first and third months of treatment, as by the end of the third month, no patients had the size of their calculi reduced in either kidney.

TABLE VIII: EVOLUTION OF PATIENTS WITH SINGLE LITHIASIS AS PER THE SIZE OF THE CALCULUS AT THE END OF THE RENALOF TREATMENT

Kidney	< 5 mm		5 to 10 mm		> 10 mm		Same size		Fully removed		Total cases	
	M	F	M	F	M	F	M	F	M	F	M	F
Right	3	6	0	0	0	0	4	2	2	3	9	11
Left	5	5	0	0	1	0	5	6	2	1	13	12
Total	8	11	0	0	1	0	9	8	4	4	22	23

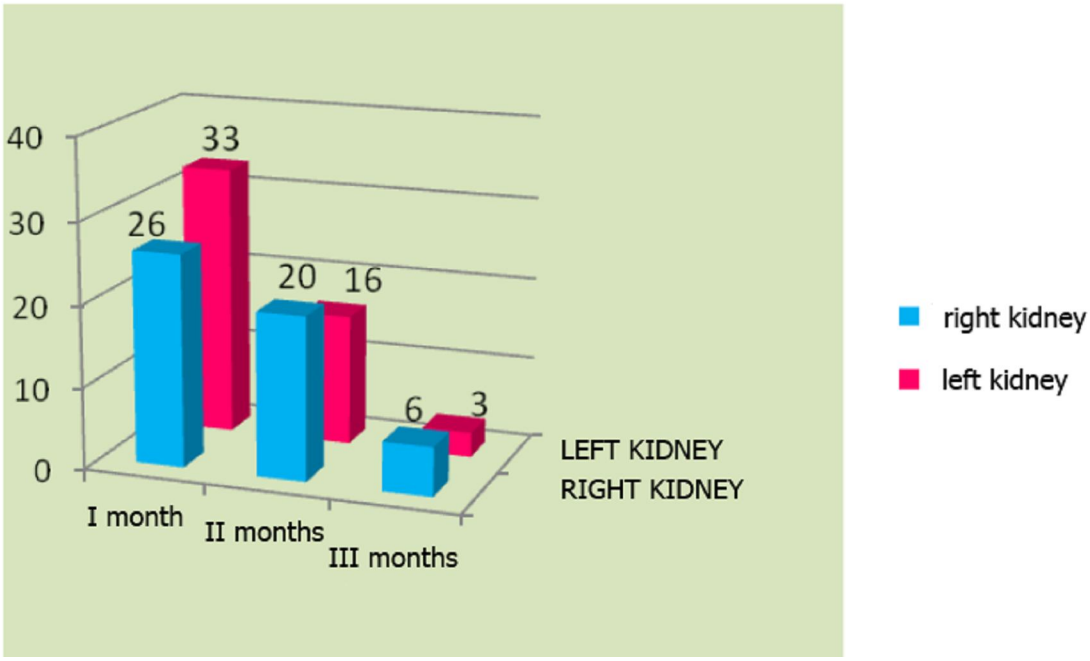
Upon analysis of the behaviour of patients with a single calculus, in either the right or left kidney, at the end of the first month of treatment, we can note a considerable decrease of the calculus' size, above all those that reduced their size by 5mm —more females than males.

TABLE IX: EFFECTIVENESS OF THE RENALOF TREATMENT ACCORDING TO REDUCTION OF CALCULUS' SIZE

KIDNEY	TOTAL	REDUCTION OF CALCULUS' SIZE IN RELATION TO MONTH OF EVOLUTION					
		Month 1	%	Month 2	%	Month 3	%
RIGHT KIDNEY	44	26	59.09	20	45.45	6	13.63
LEFT KIDNEY	55	33	60	16	29.09	3	5.45

Source: Renalof Survey

CHART VI: EFFECTIVENESS OF THE RENALOF TREATMENT ACCORDING TO REDUCTION OF CALCULUS' SIZE



On this table we can see how the size of calculi in both kidneys decreased during the first month of treatment.

TABLE X: EFFECTIVENESS OF THE RENALOF THERAPY ACCORDING TO REMOVAL OF CALCULUS AND LOCALIZATION IN ORGANS OTHER THAN KIDNEYS

LOCALIZATION	NUMBER	Time of Removal		
		Month 1	Month 2	Month 3
BLADDER	1	0	0	1
MEATUS	1	1	0	0
TOTAL	2	1	0	1

Source: Renalof Survey

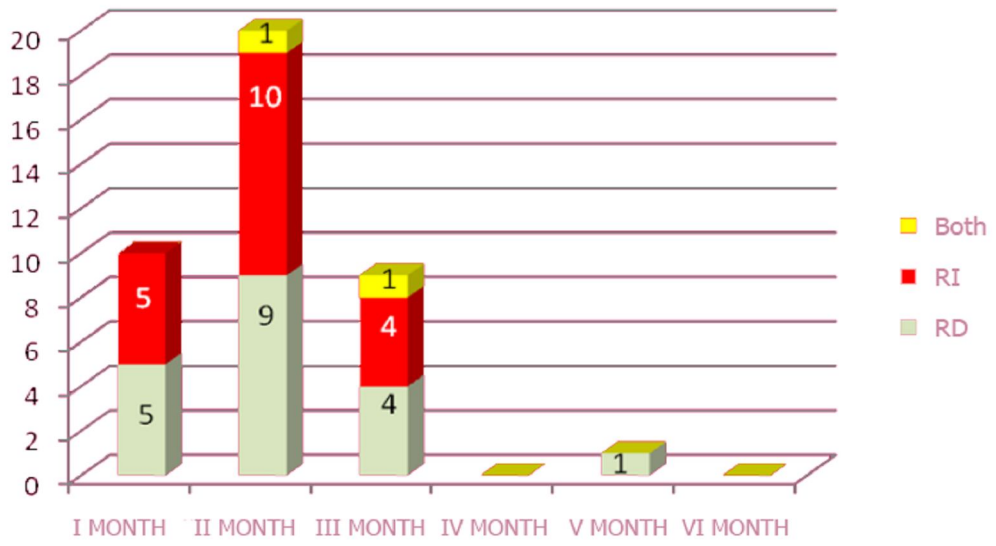
It can also be noted that the removal of calculi in organs other than kidneys (Bladder and Meatus) took place within the first three months of treatment. The calculus in the meatus was removed during the first month of treatment, while the calculus in the bladder was removed in the third month of treatment.

TABLE XI: EFFECTIVENESS OF THE RENALOF TREATMENT ON KIDNEY LITHIASIS

Month of treatment evolution	Number of removed calculi		CALCULUS-FREE PATIENTS	%
	RK	LK		
MONTH 1	11	9	11	16.17
MONTH 2	10	13	20	29.41
MONTH 3	7	5	10	14.70
MONTH 4	0	0	0	0
MONTH 5	1	0	1	1.47
MONTH 6	0	0	0	0

Source: Renalof Survey

CHART VII: EFFECTIVENESS OF THE RENALOF TREATMENT ON KIDNEY LITHIASIS



The effectiveness of a pharmacological product is measured by its capacity to remove or control a specific pathology, and also by whether its therapeutic effectiveness is largely unhindered by any adverse reactions or side effects. This table shows the effectiveness of the product RENALOF, which, on completion of the **first month of treatment**, 11 patients had had their calculi completely removed (16.17%). If the calculation takes into account the number of calculi removed, the number rises to 20, as 11 patients (16.18%) had the calculi removed from their right kidney and 9 (13.23%) from the left kidney. These figures increased during the second month of treatment, when 10 patients (14.70%) had calculus removed from the right Kidney and 13 (19.12%) from the left Kidney —while 29.41% of patients had all calculi removed, dropping to 14.70% **in the third month**. This represents 61.76% of cured cases within the first three months of treatment, including the patients with bladder and meatus calculus.

TABLE XII: EFFECTIVENESS OF THE RENALOF TREATMENT IN THE REMOVAL OF KIDNEY CALCULI

MONTH OF TREATMENT EVOLUTION	COMPLETELY REMOVED			TOTAL	%
	RK	LK	BOTH		
MONTH 1	5	5	1	11	16.17
MONTH 2	9	10	1	20	29.42
MONTH 3	4	4	1	9	13.24
MONTH 4	0	0	0	0	0
MONTH 5	1	0	0	1	1.47
MONTH 6	0	0	0	0	0
Total	19	19	2	40	58.83

Source: Renalof Survey

In relation to therapeutic effectiveness, the table provides a breakdown of fully removed calculi according to whether they were located in either or both kidneys. Forty patients had kidney stones completely removed on completion of the six-month treatment (58.83%), almost a third of which (29.42%) were removed during the second month of treatment.

Table XIII: CLINICAL EVOLUTION ACCORDING TO TIME OF TREATED WITH RENALOF

MONTH OF EVOLUTION	PAIN	HEMATURIA	CYSTITIS	INFECTION	ASYMPTOMATIC
MONTH 1	2	1	2	1	62
MONTH 2	1	0	2	0	65
MONTH 3	1	0	0	0	67
MONTH 4	0	0	1	0	67
MONTH 5	0	1	0	0	67
MONTH 6	0	0	0	0	68

Source: Renalof Survey

Pain is the clinical discomfort that demands more attention from patients, attention that increases as pain intensifies. Nephritic colic is widely hailed as one of the worst sources of pain that can be borne by humans. Along with hematuria, it is one of the symptoms than can extremely alarm patients and their families. On this table we can note how the symptoms related to lithiasis decreased gradually over the treatment period, which provides evidence of the product's antiseptic and analgesic properties, perhaps in combination with the decreasing size of calculi along the way, without compromising neighbouring structures or, all going well, disintegration and removal of calculi in the form of sediment.

Conclusions following the Clinical Trial with food supplement RENALOF

- Predominance of patients aged 60 – 69. Ultrasonography was the most often used diagnostic resource.
- AHT is the most frequent chronic disease affecting trial group patients.
- Side effects were not significant: only 4 cases of diarrhoea and 1 of gastritis.
- The greatest reduction of calculus size took place within the first month of treatment. The drug proved to be highly effective, as 42 patients had their calculi removed within the first three months of treatment.

RECOMMENDATIONS

- Conducting multicentric research would lead to increasing the number of cases treated with the product.
- Producing capsules with increased pharmacological concentration for single and mini dose forms, particularly for elderly patients.

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- La litiasis urinaria representa uno de los problemas urológicos más comunes….la edad de mayor incidencia de la litiasis urinaria oscila entre la 5ta y la 6ta década de ……

  Encombia.com/medicina/urología/urología11102-litiasisurinaria.htm35k-En caché –páginas similares.
- Desde ese momento , el tratamiento de la litiasis urinaria correspondió a los….Posteriormente y hasta nuestros días, la litiasis urinaria ha sufrido una…

  www.abcmedicus.com/articulo/paciente/1/id/12/página/1/litiasis_

  urinaria_calculos.html-33k

- Organización para la docencia, investigación y tratamiento de la nefrolitiasis, adscrita a la Universidad de la islas baleares, Mallorca,España…litiasisrenal.uib.es/-9k

- Litiasis Urinaria(Cristalografía). Manual de Urología esencial.Pontificia Universidad Católica de Chile.Litiasis vesical

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- Otras formas clínicas complejas:Malabsorción intestinal.Acidosis tubular.Infección urinaria(por gérmenes Urolíticos). Simples: Litiasis renal Úrica…

www.aeped.es/protocolos/nefro/16-litiasis-renal.pdf-páginas similares

ANNEXE I

Informed consent

I, the undersigned, Mr / Mrs _____ hereby state my agreement to participate in the clinical trial for the **RENALOF** therapy.

I hereby declare that I have been informed that I will be administered per one capsule of the product RENALOF (325mg) three times daily without interruption. I also understand that said product can improve my genitourinary disorder as well as my functional capacity to deal with daily life activities, and that a research specialist will conduct my clinical and radiological assessments on a monthly basis.

I participate in this trial of my own free will and I understand that all related information is confidential. However, I can discontinue the treatment any time if I so wish. I also understand that it is crucial to report the occurrence of any side effects.

And for the record, I sign this Informed Consent document of my own free will, along with the physician who provided me with said information, on the _____ of _____ 200__.

Signature of the Patient: _____

ANNEXE II

INSTITUTO SUPERIOR DE CIENCIAS MÉDICAS DE LA HABANA

FACULTAD ¨Dr. SALVADOR ALLENDE¨

CLINICAL TRIAL STAGE III OF THE NATURAL PRODUCT **RENALOF**

NAME _____ AGE_____

ADDRESS _____

TELEPHONE _____

DISEASE EVOLUTION TIME _____

PREDOMINANT CLINICAL SYMPTOMS: PAIN___ HEMATURIA____ DYSURIA_____

OTHER SYMPTOMS:

CYTURIA: Leucocituria___ Hematuria___ Albuminuria____ Cilindruria____

Ultrasound: Confirmation of Calculus, Localization ____ Size ____

Radiology: Confirmation of Calculus, Localization ____ Size ____

Renal CT: Confirmation of Calculus, Localization ____ Size ____

Associated diseases:

AHT__ IC__ DM__ COPD __ Bronchial Asthma___ Epilepsy___ Chemotherapy Syndrome___ Gastritis___ Other:_____

Other treatments for Urinary Lithiasis: Yes___ No___ Please specify

_____