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Efectividad de Renalof® en pacientes con nefrolitiasis cálcica

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RESUMEN

Es posible reducir la recurrencia de la litiasis mediante la realización de un tratamiento médico que implique el uso de un producto como Renalof®, ya que este producto destruye y elimina los cálculos renales del sistema genitourinario. Para el propósito de evaluar la eficacia de la terapia con Renalof® en el tratamiento de la urolitiasis cálcica, un Se realizó un estudio observacional, prospectivo y longitudinal en 100 pacientes adultos del Centro Julio Trigo López. Consulta hospitalaria de nefrolitiasis renal (2008), a quienes se les diagnosticó urolitiasis cálcica idiopática, con cálculos de menos de 2,5 cm a lo largo de todo el trayecto renoureterovesical por Ecografía, Tractus Urinario Simple y TAC renal. Se administró una dosis de 975 mg de Renalof® al día durante tres meses, se evaluó la presencia de cálculos en cualquier localización del tractus urinario por Ecografía, TUS y / o TAC abdominal una vez al mes durante tres meses. Se creó una base de datos y se realizó un análisis descriptivo para determinar la frecuencia. La afección fue más frecuente en hombres (86%), caucásicos (80%) y de 30 a 59 años (68%). Los principales factores metabólicos y físico-químicos detectados fueron los siguientes: Índice de Riesgo de Cristalización y Volumen urinario bajo (100% de los pacientes), el 98% con hipercalcemia; Dependiendo de la ubicación del los cálculos antes del tratamiento, cálculos caliceales y ureterales (54% y 43% respectivamente) presentaron disminución en el tiempo. La actividad de la litiasis también disminuyó con el tiempo, con un 100% de los pacientes que se encontraban activos al inicio y el 92% se inactivó. En conclusión, este estudio ha demostrado que Renalof® puede trabajar eficazmente en pacientes con urolitiasis cálcica idiopática.

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498. EFFECTIVENESS OF **RENALOF** ON PATIENT CARRIERS OF CALCIUM NEPHROLITHIASIS

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It is possible to reduce the recurrence of lithiasis by conducting a medical treatment that involves the use of a natural product such as Renalof, as this product destroys and removes renal calculi from the genitourinary system. For the purpose of assessing the effectiveness of the therapy with Renalof in the treatment of Calcium Urolithiasis, an observational, prospective and longitudinal study was conducted on 100 adult patients from the Julio Trigo Lopez Hospital's Renal Nephrolythiasis consultation (2008), who were diagnosed to have Idiopathic Calcium Urolithiasis, with calculi under 2.5 cm in size along the entire length of the renal - ureterovesical junction via Simple Urinary Tract, Renal CT and Ultrasound scans. A dose of 975 mg of Renalof was administered daily for three months, while the occurrence of calculus was evaluated on any point of the urinary tract via Ultrasound, UUS and/or abdominal CT scans once a month for three months.

A database was set up, and a descriptive analysis conducted to determine frequency. The condition was more frequent in males (86%), Caucasians (80%) and 30-59-year olds (68%). The main metabolic and physical-chemical factors detected were the following: low Urinary Volume and Crystallization Risk Index (100% of patients), Hypercalciuria (98%); depending on the location of the calculus prior to the treatment, calyceal and ureteral calculi (54% and 43% respectively) which decreased over time. Lithiasis activity also decreased over time, as lithiasis was deactivated in 92% of all patients (100%) who had it at the start of the study. In conclusion, this study has demonstrated that Renalof can work effectively on patients with Idiopathic Calcium Urolithiasis.

EFFECTIVENESS OF RENALOF ON PATIENT CARRIERS OF CALCIUM NEPHROLITHIASIS

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INTRODUCTION

Calcium Urolithiasis is a highly recurring condition that affects 0.1%-0.3% of the population. It is characterized by a morbidity and recurrence that vary depending on the region under assessment. Between 60% and 70% of calculi are made up of calcium oxalate. Evidence shows that it is possible to reduce the recurrence of lithiasis with a medical treatment applied selectively to patient carriers of Calcium Nephrolithiasis, and supported by this therapy, not only dealing with any physical / chemical, metabolic or physiological abnormalities involved in the formation of the calculus, but also with the use of drugs such as Renalof, which destroys and removes calculi from the genitourinary system to stop the metabolic activity.

RENALOF or COUCH GRASS (*agropyrum repens*) is a very common native species in Europe. Its rhizome has numerous roots and shoots that can spread shallowly over long distances. It is widely regarded as an invading species, merely a weed. Its active ingredients are the following: Rhizome, Triacitine (3%-8%), polysaccharide with inulin-like structure; mucilage (10%); Mannitol, Inositol; Saponosides; traces of essential oil (0.01% - 0.05%); agropyron, vanilloside; phenol carboxylic acids.

The task of determining the feasibility of a Renalof-based therapy for Calcium Urolithiasis involved the description of the main metabolic and physical-chemical risk factors, observation of patient behaviour in terms of pre- / post-treatment lithiasis activity, and identification of the main side effects of the treatment.

METHODS

The study was conducted on 100 adult patients from the Hospital's Kidney Nephrolythiasis consultation.

Diagnostic criteria: occurrence of small calculi (2 cm) along the entire length of the renal - ureterovesical junction as confirmed by Renal Ultrasounds, Excretory Urography, Simple Urinary Tract and / or Abdominal CT scans.

Inclusion criteria: male and female patients diagnosed with Recurrent Calcium Urolithiasis and over 2 years of evolution of the condition, all of whom agreed to participate in this study.

Exclusion criteria: patients with calculi over 2 cm in size, and patients with lithiasis triggered by other causes.

Practical organisation of the study: accepted patients underwent an initial assessment involving metabolic study, renal ultrasound, UUS, Excretory Urography and abdominal CT scan. Upon the results of these tests, patients were classified according to location of calculus, quantity of calculi, lithiasis activity prior to treatment, and current metabolic alteration. All patients underwent a treatment with Renalof (325 mg capsules) to be taken 30 minutes before breakfast, lunch and dinner for a maximum period of 3 months. The treatment evaluation was conducted once a month, and involved Renal Ultrasound Scan, Urography and / or UUS. The treatment was suspended as soon as the calculus of a patient was no longer there. In the third month, a post-treatment renal CT scan was conducted, and an assessment of the occurrence of calculi anywhere along the renal - ureterovesical junction assessed. Even though we are aware of the fact that lithiasis activity must be determined during a whole follow-up year, in the light of the specific characteristics of our study it was decided to determine said activity only during the period of use of the product.

The metabolic study protocol designed by the Cuba Institute of Nephrology was applied to the study, including determination of metabolites and ions (calcium, phosphorus, uric acid, creatinine, cystine) in blood and urine, and processed by an automated system that allows calculation of all substance clearances, urinary flow and excretion of said metabolites. Urinary Saturation is calculated according to Tiselius' ion-activity product index and the Calcium Oxalate Crystallization Index.

The study was conducted on patients following habitual hygiene and dietetic regimes.

Statistical Analysis: the SPSS v. 16.0 software application was used. The descriptive analysis of data was conducted with absolute and relative frequencies. The McNemar test (5% significance level) was carried out for the purpose of detecting any significant differences between metabolic, physical and chemical alterations and lithiasis activity prior and following the treatment with Renalof

RESULTS

1. Population Demographic Characteristics

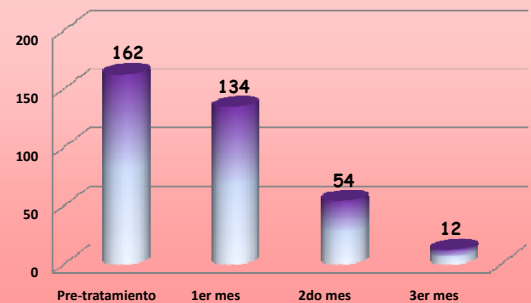
Variables	n	
Age	<30	7
	30-59	68
	≥60	25
Gender	Female	14
	Male	86
Skin Colour	White	80
	Black	12
	Mixed Race	8

3. Physical / Chemical alterations before and after the treatment

Physical / Chemical alteration	Pre treatment	Post treatment	P Value
Crystallization Risk Index	100	8	0,00
Low Urinary Volume	100	12	0,00
Triggered by Calcium Oxalate activity	89	15	0,00
Triggered by Calcium Phosphate activity	70	8	0,00

McNemar test conducted ($\alpha = 0.05$); NS: non-significant N=100

4. Amount of calculi as per duration of study



2. Metabolic alterations before and after the treatment

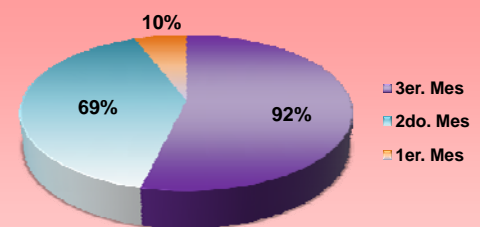
Metabolic alteration	Pre-treatment		Post treatment		P Value
	n	%	n	%	
Hiper calciuria	98	98	8	8	0
Hiper oxaluria	52	52	15	15	0
Hipocitraturia	61	61	2	2	0
Hiperuricosuria	4	4	1	1	N/S

McNemar test conducted ($\alpha = 0.05$); NS: non-significant N=100

5. Global lithiasis activity as per duration of treatment

Time	Lithiasis activity		
	Active	Inactive	Unspecified
Start	100	0	0
1st month	90	9	1
2nd month	31	69	0
3rd month	8	92	0

6. Percentage of patients free of calculi



CONCLUSIONS

- The use of Renalof was successful in reducing lithiasis activity in patients with Recurrent Calcium Urolithiasis
- Renalof was well tolerated by patients.
- Hiper calciuria, Crystallization Risk Index and low Urinary Volume were the most common metabolic and physical / chemical factors.

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