

Thermobalancing therapy with Dr Allen's Device improves health-related quality of life in patients with kidney stone disease – A randomised clinical trial

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Research Article

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Abstract

Objective: To investigate the efficacy of Dr Allen's Therapeutic Device in improving quality of life in patients with nephrolithiasis.

Materials and Methods: A randomized, interventional, parallel group study was conducted investigating 54 patients aged 18-60 years with nephrolithiasis. 29 of the 54 patients were randomised (1:1) into a treatment group of 15 patients (Group 1) and a control group of 14 patients. The remaining 25 (Group 2) were treated but not randomised as they had stones larger than 10 mm. Both treatment groups used Dr Allen's Device for 6 months. Their quality of life was measured using the Wisconsin Stone Quality of Life Questionnaire (WISQoL) at regular intervals and compared between the groups. The change in size of the kidney stones was also measured and compared. The trial was registered at the World Health Organisation via the German Clinical Trials Registry (DRKS00009367).

Results: Thermobalancing therapy with Dr Allen's Device for Kidney Treatment showed a significant improvement in HRQoL across all domains of the WISQoL and a significant reduction in size of kidney stones in both treatment groups ($p < 0.001$). There was no significant change in stone size in the control group.

Conclusions: The use of Thermobalancing therapy with Dr Allen's Device for Kidney Treatment is effective in both dissolving kidney stones as well as improving quality of life.

Introduction

Health-related quality of life (HRQoL) is reduced in patients with urolithiasis, especially during acute urolithiasis [1]. The Wisconsin Stone Quality of Life Questionnaire (WISQoL) is the validated HRQoL instrument specific for nephrolithiasis and can be used to evaluate the quality of life in patients treated with different treatment modalities [2, 3].

Despite the high prevalence of urolithiasis, only recently has the WISQOL questionnaire appeared to assess the quality of life in these patients [4]. The suitability of this questionnaire in patients with urolithiasis was demonstrated in 2017 during a multi-centric study performed in 8 geographically diverse centers in the United States and Canada [5].

According to clinical guidelines, in symptomatic urolithiasis with a total non-lower pole renal stone burden < 20 mm, Extracorporeal Shock Wave Lithotripsy (ESWL) or Ureteroscopy (URS) is the suggested treatment and in symptomatic urolithiasis with a total renal stone burden > 20 mm, Percutaneous Nephrolithotomy (PCNL) is offered as first-line therapy [6].

The effectiveness of various surgical techniques used for nephrolithiasis treatment is indicated by the so called "stone-free rate" that depends on several factors and seems to vary over a wide range (63–87%) [7]. In a study, it was found that only 42.5% patients achieved stone-free status after PCNL [8].

Furthermore, rates of complications in ESWL, PCNL, and Retrograde Intrarenal Surgery (RIRS) were 12.5%, 20.2%, and 15.0%, respectively. The percentage of major complications out of all reported complications was 15.4%, 13.8% and 18.3% respectively [9].

Almost 40% of first-time stone formers will have recurrence within 3 years of the first episode if no prophylactic measures are instituted to prevent it, since removal or disintegration of the stone as treatment for the first occurrence does not treat the underlying cause of stone formation in the majority of patients [10]. A study showed that 42.7% of a total of 38,274 stones from different patients were recurrent, which were also more frequent in men (44.4%) than in women (38.9%, $p < 0.001$) [11].

The Innovative technique of utilisation body heat in the management of chronic diseases, including urolithiasis, by Dr Allen's Therapeutic Device and Thermobalancing therapy has been assessed in the International Journal of Quality Innovation [12]. Thermobalancing therapy and Dr Allen's Device received was patented in the USA as a "Therapeutic device and method" [13]. For over 12 years, Thermobalancing therapy and Dr Allen's Device have been used successfully in the treatment of prostate enlargement and chronic pelvic pain. Two clinical studies were conducted on Thermobalancing therapy in men with benign prostate enlargement (BPE) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) [14, 15].

The present study was aimed to determine the possibility of using the WISQOL questionnaire to assess the efficacy of treatment with Dr Allen's Device on the HRQoL in patients with nephrolithiasis.

The objectives of this clinical trial are:

1. Studying the efficacy of Thermobalancing therapy in patients with kidney stones < 10 mm by measuring the improvement in their HRQoL
2. Studying the efficacy of Thermobalancing therapy in people with kidney stones > 10 mm by measuring the improvement in their HRQoL

Materials And Methods

Study design and participants:

Our study was a prospective, randomized, interventional, parallel group study conducted to demonstrate the superiority of Dr Allen's Device for Kidney Treatment. It was conducted between 2021–2022 at the Government College University, Faisalabad-Pakistan. The study was approved by the ethics committee of the Yerevan State Medical University and was registered at the World Health Organisation via the German Clinical Trials Registry (DRKS00009367).

Patients aged 18–60 years having a kidney stone measuring at least 3 mm in size confirmed by ultrasonography were recruited for the trial. They were excluded if they had severe co-morbidities like cancer, heart failure or infection. A total of 54 patients with urolithiasis met the eligibility criteria and were recruited for the study. After recruitment, a decision to randomise only those patients with kidney stones

smaller than 10 mm was taken to avoid any serious consequences of leaving large kidney stones untreated for the period of the trial. Patients with kidney stones less than 10 mm (n = 29) were randomised into two groups (1:1). 14 patients were randomly assigned to the control group and 15 were assigned to the treatment group (Group 1) using simple randomisation procedures and computer-generated random numbers. The remaining 25 patients with kidney stones greater than 10 mm in size were assigned to a separate group (Group 2). No blinding was done due to the nature of the intervention. Written consent was obtained from all the study participants.

Intervention:

The intervention was Thermobalancing therapy using Dr Allen's Device for Kidney Treatment for a 6-month period.

Dr Allen's Device for Kidney Treatment

Dr Allen's Device was registered with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom in 2010 as a Class I medical device. A Class I medical device, which is a device without a measuring function supplied in non-sterile condition does not require the involvement of a notified body. Thus, it is permitted to use Thermobalancing therapy with Dr Allen's Device by anyone at home.

This device applies a thermoelement, made from a special mixture of waxes, topically to the skin over the affected organs. In people with KSD, 2 thermoelements are applied to the back over the kidneys (Fig. 1). The thermoelements accumulate the emitted body heat and turn themselves into a source of energy, directing this energy towards the kidneys. Wearing and using Dr Allen's Device for Kidney Treatment is comfortable.

In order to understand the effectiveness of this device on urolithiasis and particularly, on the HRQoL of the patients, the WISQoL was presented to the participants of the treatment groups as physical copies at the beginning of the study, at 2 weeks and then once each month for the duration of the trial and at the end, therefore they were assessed a total of 8 times. The participants of the control group were assessed 3 times, that is at the beginning of the trial, at 2 weeks and at the end of 6 months. These were evaluated in the Urology department, Madinah Teaching Hospital. Also measured by ultrasonography was the size of the stones at the beginning of the trial in the Radiology Department, Madinah Teaching Hospital and repeated again at the end of 6 months to calculate the change in size of the kidney stones.

Outcomes:

The primary outcome of this trial was the change in the HRQoL of the participants measured using the WISQoL to demonstrate the effectiveness of Dr Allen's Device for Kidney treatment in urolithiasis. An improvement in the HRQoL indicated by the increase in scores in all the domains of WISQoL during the course of the treatment was considered to be an indicator of the efficacy of the device in improving the HRQoL of participants by effectively treating their kidney stones. A change in the size of the kidney stones after using Dr Allen's Device for Kidney Treatment was considered the secondary outcome. Any decrease in the size of the stone was considered to be an indicator of the efficacy of the device. The

change in size was measured by comparing the sizes of the stones measured by ultrasonography before and after the trial.

Sample size estimation:

Sample size was calculated using G Power software. With a power of 80% and a type I error of 5%, it was found that a total of 54 patients were required to conduct the study.

Statistical analysis:

The data collected was organised in Microsoft Excel and statistical analysis of the results was performed using the PAST software and the Data Analysis module of Microsoft Excel 2010. Paired sample t-tests were used for the comparison of continuous data. A p-value < 0.05 was considered statistically significant.

Results

After screening 57 patients at the Madinah Teaching Hospital, 3 patients were excluded as they did not meet eligibility criteria. Out of the remaining 54 patients, 25 were excluded from randomisation as they had kidney stones that were greater than 10 mm in size and therefore, could not be allocated to the control group in view of the risks associated with untreated large kidney stones. 29 patients were randomised, resulting in two groups. The treatment group consisted of 15 patients (group 1) and the control group consisted of 14 patients. The 25 patients with stones larger than 10 mm in size were grouped together and assessed separately (group 2).

The clinical characteristics in the two treatment groups and the control group were similar and presented in Table 1.

Table 1
Clinical characteristics of the 54 participants with KSD

	Group 1	Group 2	Control Group
Number of patients (n)	15	25	14
Mean age in years	38.6	38.5	39.8
Gender (Male/Female)	4/11	12/13	13/1
Location of stone (n):			
Left kidney	9	14	10
Right kidney	12	19	11
Bilateral kidneys	6	8	7
Composition of stone (n):			
Calcium oxalate	11	12	11
Uric acid stones	1	8	2
Triple Phosphate stone	3	5	1

Symptom progression and health-related quality of life were measured using the domains of the WISQoL. The two treatment groups were investigated separately. The average scores of the 4 domains of the WISQoL in the treatment groups are presented in Figs. 2 and 3.

In group 1, the WISQoL scores increased in all domains. The mean Social Influence (SI) score increased slightly in 2 weeks from 9.47 ± 4.79 to 10.27 ± 4.03 and significantly to 16.67 ± 1.45 in next 5–6 months ($p < 0.001$). The Emotional Influence (EI) score increased slightly in 2 weeks from 8.6 ± 4.88 to 12.67 ± 4.81 and significantly to 21.3 ± 2.35 in the next 5–6 months ($p < 0.001$). The Health Effect (HE) score increased slightly in 2 weeks from 12.13 ± 3.14 to 16 ± 5.74 and significantly to 26.4 ± 2.13 in the next 5–6 months ($p < 0.001$). The Influence on Vital Activity (IVA) score increased slightly in 2 weeks from 3.8 ± 1.57 to 7.47 ± 2.90 and significantly to 12.67 ± 1.54 in the next 5–6 months ($p < 0.001$). Total score increased slightly in 2 weeks from 34.0 ± 9.15 to 46.4 ± 16.49 and significantly to 77.07 ± 7 in the next 5–6 months ($P < 0.001$).

The control group showed improved scores across all domains but the increase was only significant in SI and HE. The mean SI score increased from 9.43 ± 4.88 to 12.43 ± 3.27 in 6 months ($p = 0.03$) and the mean HE score increased from 14.00 ± 5.43 to 17.29 ± 3.67 in 6 months ($p = 0.03$). The p-values for mean EI and IVA were 0.22 and 0.1 respectively.

In the 25 patients in Group 2, the WISQoL scores also increased in all domains. The mean SI score decreased slightly in 2 weeks from 11.24 ± 5.45 to 10.6 ± 3.33 and increased significantly to 16.32 ± 1.75 by the end of 6 months ($p = 0.020$). The mean EI score increased slightly in 2 weeks from 9.0 ± 5.68 to 14.08 ± 4.71 and significantly to 20.88 ± 1.81 by the next 6 months ($p < 0.001$). The mean HE score

increased slightly in 2 weeks from 15.48 ± 4.54 to 17.08 ± 6.26 and significantly to 26.40 ± 1.81 by the next 6 months ($p < 0.001$). The mean IVA score increased slightly in 2 weeks from 4.88 ± 3.05 to 8.12 ± 2.12 and significantly to 12.60 ± 1.22 in next 6 months ($p < 0.001$). Total score increased slightly in 2 weeks from 40.60 ± 14.22 to 49.88 ± 16.67 and significantly to 76.20 ± 5.56 in next 6 months ($p < 0.001$).

A comparison of the improvement in the domains of the WISQoL are demonstrated in Table 2.

Table 3: Comparison of the scores of different domains of WISQoL between the control group and treatment groups

		Initial evaluation (mean \pm SD in mm)	Final evaluation (mean \pm SD in mm)	p-value
Control Group	SI	9.43 ± 4.88	12.43 ± 3.27	0.03
	EI	12.79 ± 5.44	14.43 ± 2.98	0.22
	HE	14.00 ± 5.43	17.29 ± 3.67	0.03
	IVA	7.36 ± 3.56	9.00 ± 2.04	0.1
	Total Score	43.13 ± 17.33	53.14 ± 9.46	0.04
Group 1	SI	9.47 ± 4.79	16.67 ± 1.45	< 0.001
	EI	8.6 ± 4.88	21.33 ± 2.35	< 0.001
	HE	12.13 ± 3.14	26.4 ± 2.13	< 0.001
	IVA	3.8 ± 1.57	12.67 ± 1.54	< 0.001
	Total Score	34 ± 9.15	77.07 ± 7	< 0.001
Group 2	SI	11.24 ± 5.45	16.32 ± 1.75	< 0.001
	EI	9.00 ± 5.68	20.88 ± 1.81	< 0.001
	HE	15.48 ± 4.54	26.40 ± 1.96	< 0.001
	IVA	4.88 ± 3.05	12.60 ± 1.22	< 0.001
	Total Score	40.60 ± 14.22	76.20 ± 5.56	< 0.001

Note. WISQoL domains: SI – social influence, EI – emotional influence, HE – health effect, IVA – influence on vital activity.

The presented results of the dynamics of WISQOL indicators demonstrate that Dr Allen's Device for Kidney Treatment significantly improves the quality of life of patients with urolithiasis starting from 2 weeks of wearing the device and in the following 6 months.

Also measured were the sizes of the kidney stones in all the participants at the beginning and the end of the trial. Figures 4 and 5 summarise the change in the sizes of the kidney stones in group 1 and group 2 respectively.

Out of 15 patients with stones size less than 10mm, 9 patients had stones in the right kidney and 12 patients had stones in the left kidney.

After use of Dr Allen's Device for Kidney Treatment, the kidney stones were dissolved completely in most patients or were reduced to 3 mm, ($p < 0.001$).

Out of 25 patients with stones size larger than 10mm, 19 patients had stones in the right kidney and 14 patients in the left kidney. After the use of Dr Allen's Device for Kidney Treatment, the size of the stones reduced in 22 patients, ($p < 0.005$).

In the control group, there was either no change in the size of kidney stones in either kidney or an increase in size.

These results suggest that Dr Allen's Device for Kidney Treatment is effective in treating kidney stones.

Discussion

For many years, it has been difficult to evaluate the effectiveness of kidney stone treatment, especially assessing long-term HRQoL of patients. Some researchers evaluated the impact of urolithiasis on quality of life using the NIH-sponsored PROMIS-43 questionnaire [16]. Others used The Medical Outcome Study Short-Form 36-item survey (SF-36) [17]. However, neither instrument is specific for urolithiasis. On the other hand, WISQOL scores were found to significantly correlate with, and had good predictive validity for HRQoL [18].

In our study the changes in the QoL of patients with urolithiasis in the control and treatment group was measured throughout the duration of the study while the participants underwent Thermobalancing therapy and it was measured using the WISQoL. All four domains of the WISQoL, social influence, emotional influence, health effect and influence on vital activity, were reviewed 3 times in the control group and 8 times in the treatment groups.

The results differed in patients with stones up to 10 mm in size (group 1) and in patients with stones larger than 10 mm (group 2). It was recorded that in patients with stones less than 10 mm, a significant increase in all domains of WISQOL was detected in the 2nd month of using Dr Allen Device. In group 2, the rise in all domains developed gradually, with a significant increase in all domains of WISQoL after 3 months. The numbers in all domains increased to their maximum possible score at the end of treatment,

i.e., in Group 1, SI was 16.6 (max = 20), EI was 21.3 (max = 25), HE was 26.4 (max = 30) and IVA was 12.6 (max = 15). In Group 2 after treatment, SI was 16.3, EI was 20.8, HE was 26.4 and IVA was 12.8.

The use of the WISQoL questionnaire in different countries has proven that it is a consistent, reliable, and valid instrument to assess HRQoL. Its efficacy was demonstrated in Spanish-speaking patients with kidney stones in a study [19]. The validation of the Turkish version of the WISQoL questionnaire showed the effectiveness of this questionnaire only in patients with symptomatic urolithiasis [20].

In our study, the improvement in HRQoL correlated with a reduction in kidney stone size. Thus, Dr Allen's Device reduced the size of kidney stones in the treatment group and thereby improved their HRQoL. Our study also highlights the efficacy of the body's energy with Dr Allen's device in the treatment of urolithiasis by showing a reduction in the size of stones and by improving HRQoL. In the past, two clinical studies demonstrated a decrease in prostate volume and a reduction in urinary symptoms in men with enlarged prostate and chronic prostatitis by improving the blood circulation in the prostate gland [21]. This type of therapy allows treatment without the risk of adverse effects and complications commonly associated with the use of surgical modalities of treatment.

After ESWL was introduced into practice, it was supposed that 85% of all patients with kidney stones could be cured by this surgical procedure [22]. The initial promising results of ESWL were challenged by adverse effects such as bleeding, pain, and urinary tract infections [23], rare complications, such as spleen rupture or intrarenal hematoma [24, 25], and long-term consequences such as hypertension and diabetes mellitus [26, 27].

PCNL, which was established in the 1970s to replace open surgery [28] is usually used for removing kidney stones over 2 cm in size, and may produce various complications, such as bleeding, extravasation or urine, pleural drain, renal embolization etc. [29] RIRS, considering the severe complications after PCNL, can be an effective treatment alternative to PCNL, particularly in lower pole stones larger than 2 cm [30]. As RIRS affords a comparable success rate to PNL and is associated with fewer complications, it should be used as the primary treatment for renal stones [31].

However, the prevalence of infectious complications among patients undergoing RIRS for kidney stones is 7.7%, and it is impossible to predict which patients will develop these complications [32]. Whereas, Dr Allen's Device has shown to be completely safe in all patients with kidney stones, small or large. Improvement in QoL during Thermobalancing therapy was recorded in all patients, even in the absence of significant changes in the size of kidney stones. This demonstrates that Dr Allen's Device improves kidney health.

We recognise that the presence of a "placebo" group as control could have provided more statistical rigor concerning results. 6 months may be considered an appropriate time for oral medication as placebo, but not for using a belt required to be worn for most of the day for 6 months. Therefore, this trial was conducted without the use of a placebo and we consider this a limitation of our study.

Conclusion

The results of the study is evidence that in patients with kidneys stones less than 10 mm, a significant increase in all domains of WISQoL can be expected in a span of two months. In those with larger stones, the improvement develops gradually, but significantly by the end of 6 months. Dr Allen's Device reduced the size of kidney stones in patients with nephrolithiasis significantly while no significant decrease was noted in the control group. The changes in WISQoL are also insignificant in the control group. All participants of the treatment groups used Thermobalancing therapy at home during a 6-month period without side effects and complications. Thus, we can conclude that the study is evidence of the efficacy of Dr Allen's Device for Kidney Treatment as a novel and safe at-home treatment for urolithiasis.

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Figures



Figure 1

Dr Allen's Device for Kidney Treatment tightly attaches thermoelements to the back for projection to the kidneys to dissolve kidney stones

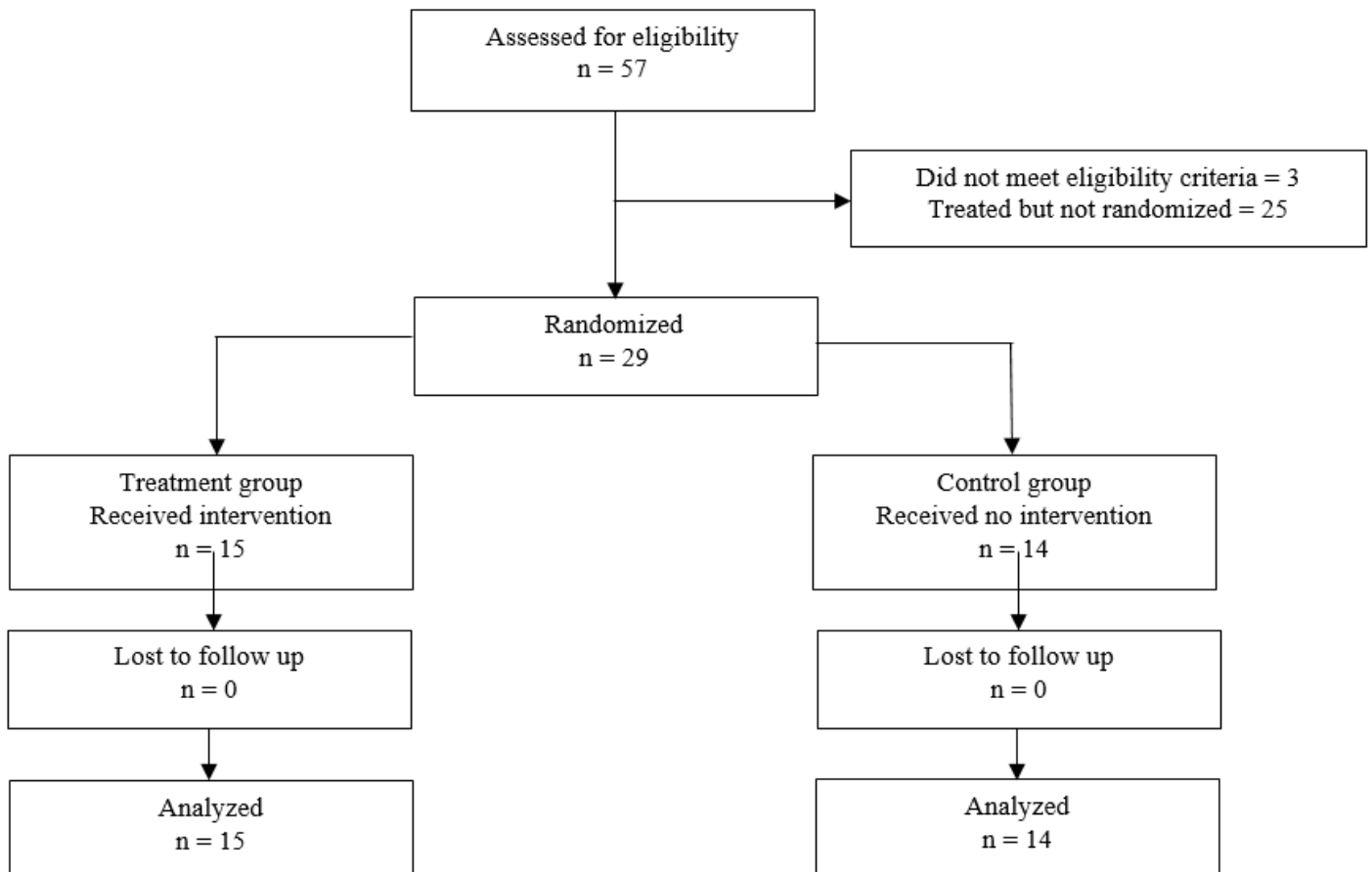


Figure 2

Patient allocation flow diagram

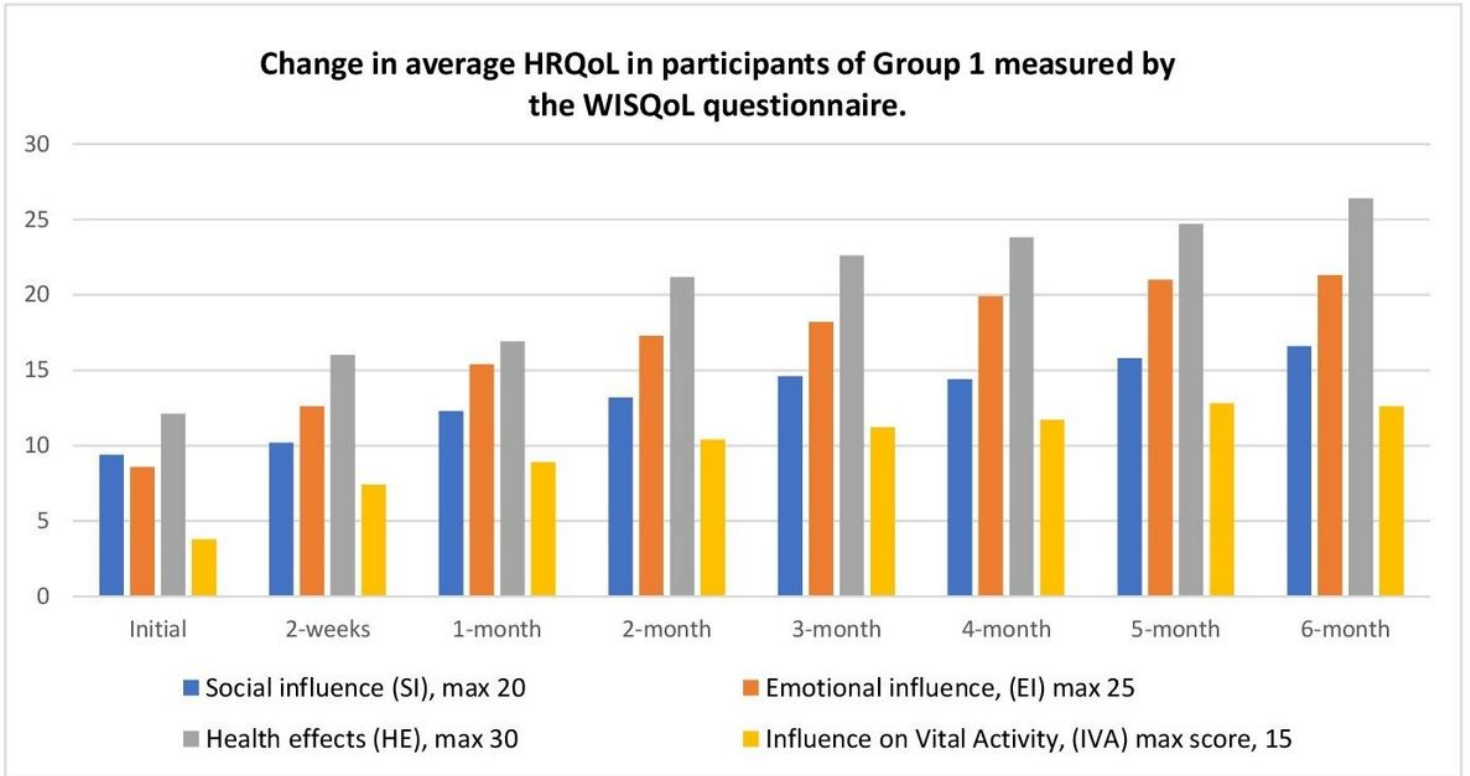


Figure 3

The change in the HRQoL measured by the WISQOL questionnaire in Group 1 during the 6 months of thermobalancing therapy

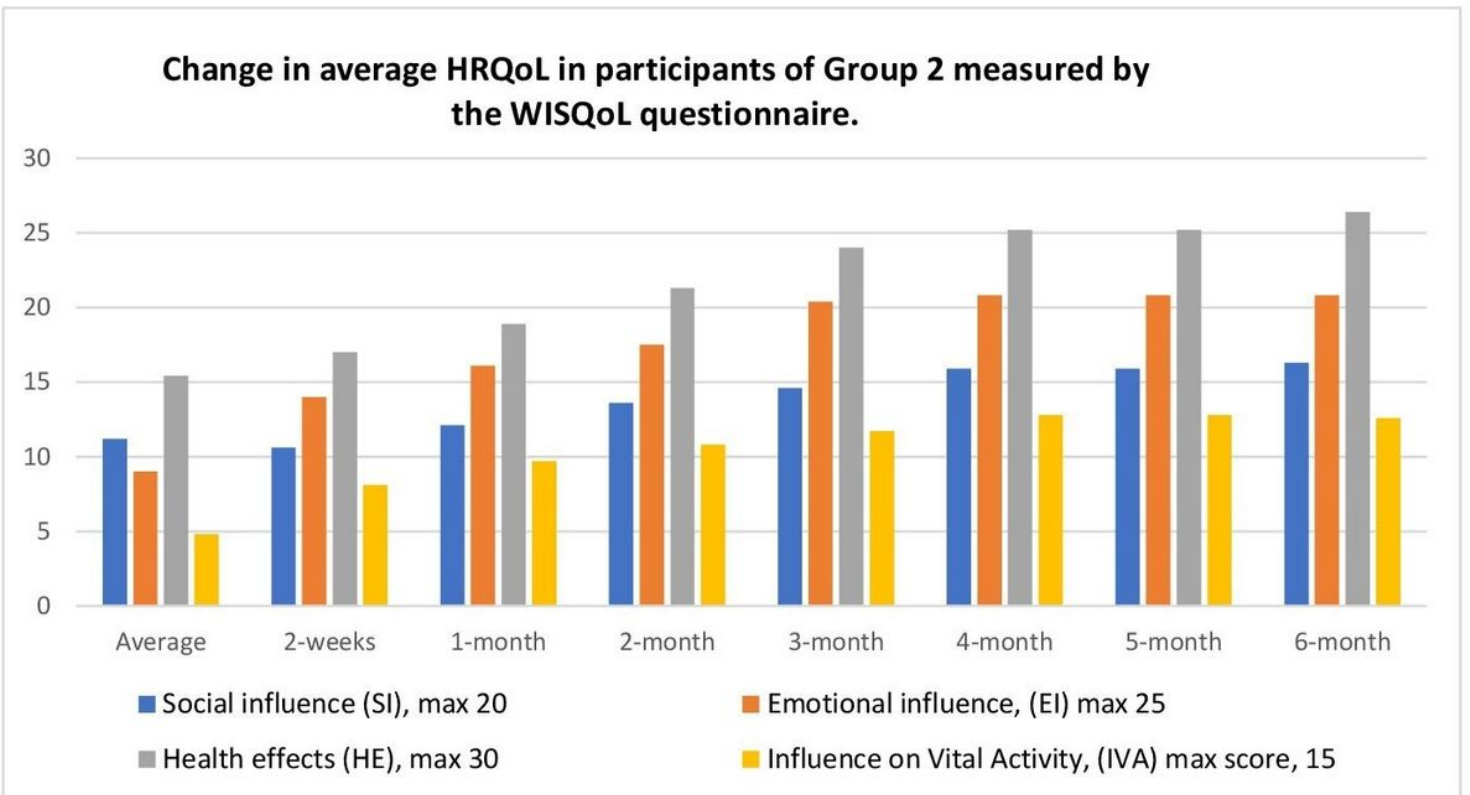


Figure 4

The change in HRQoL of 1 patient in average measured by the WISQoL questionnaire in Group 2 during the 6 months of thermobalancing therapy

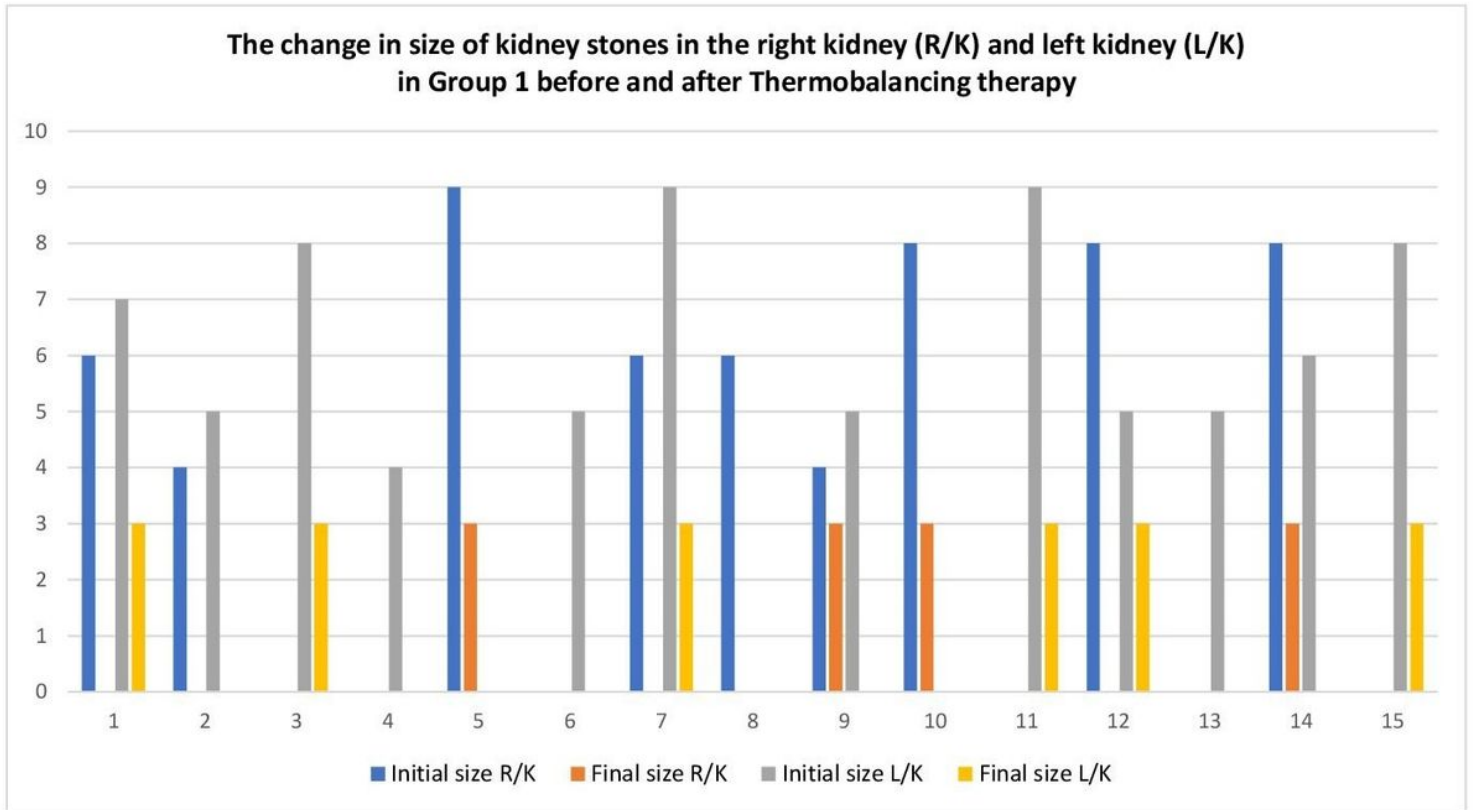


Figure 5

The change in size of kidney stones in Group 1 measured by ultrasound before and after 6-month Thermobalancing therapy.

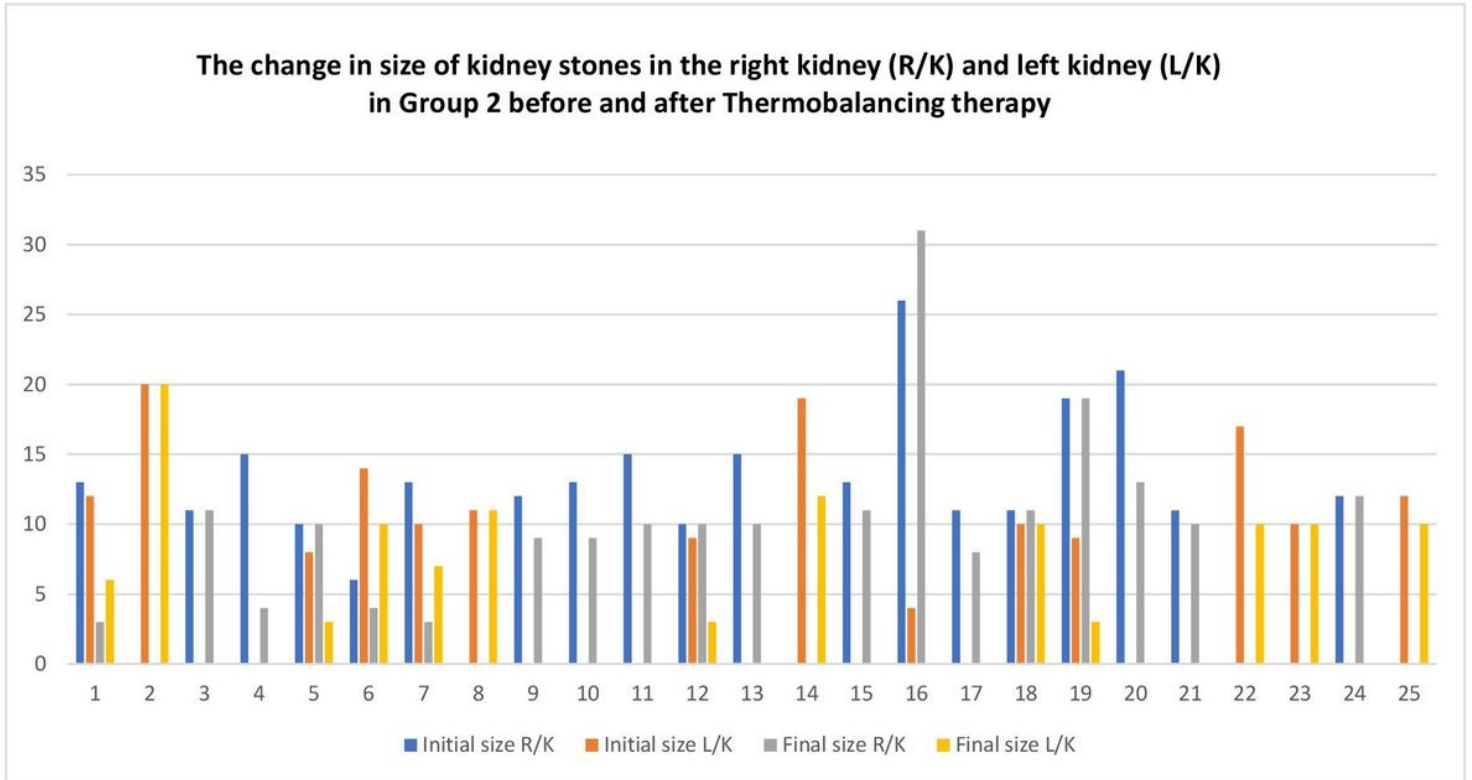


Figure 6

The size of kidney stones in Group 2 measured by ultrasound before and after 6-month Thermobalancing therapy.