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SIGNIFICANT IMPROVEMENTS OF LUTS (LOWER URINARY TRACT SYMPTOMS) AFTER THE TREATMENT OF BPH (BENIGN PROSTATIC HYPERPLASIA) USING THE LFD (LEVELED FIELD DENSITY) THERAPY

Hypothesis / aims of study

Lower Urinary Tract Symptoms (LUTS) remain a common problem among more than 30% of men above 50 years old. Despite advances in the treatment of BPH (Benign Prostatic Hyperplasia), a frequent issue for the surgeon to be considered remains the share of risk or high-risk patients. The likelihood of bleeding and other complications intra- and post-operatively is not only an issue for patients taking blood-thinning drugs. The aim of our clinical study was to show the significant improvements in the treatment of LUTS and its causes with the LFD Therapy.

Study design, materials and methods

During 12 months time, we included in our comparative study a total of 98 patients (n=51 with DIOLAS LFD 3000; n=47 with an 80W green laser) suffering from BPH. 38 patients took blood thinning drugs among the first group, the second group included another 35 patients. The selection of patients was oriented towards the attempt to achieve a similar sample composition to obtain comparable results and analyse the impact of each treatment on risk and high-risk patients. Various pre-, intra- and postoperative settings were evaluated during and after treatment, in particular IPSS, QoL, PSA, maximal flow rate (Qmax) and post-voiding residual volume (Vres).

Results

	LFD 3000 n = 51	Green laser n = 47
Permanent catheter	1,8 days	2,6 days
PSA	2,4 +1,2 -2,3	2,9 +0,8 -1,6
Anti-inflammatory	2 days	5 days
Flow	changed from 4,1 to 20,9	changed from 4,2 to 19,7
IPSS	changed from 14 +3 -5 to 2 +2 -1	changed from 14 +5 -6 to 3 +2 -3
Vol	41,3 +21,6 -23,9	45,0 +11,3 -29,7
Treatment time	51 min +38 -29	58 min +36 -22
Re-TURP	0	4
Post-operative bleeding	0	3
IPSS improvement	9%	7%

Interpretation of results

To understand the importance of our clinical findings, one has to consider the main factors that are important with respect to the treatment of risk and high-risk patients. Among these, on the one hand we have the immediate intra- and post-operative conditions such as the likeliness of (strong) bleeding, treatment time needed and the requirement to cancel the intake of blood-thinning drugs in especially risky cases. On the other hand, we need to take into consideration factors such as the required stay in the hospital for controlling post-operative complications such as swelling and inflammation, and the mid to long-term patient outcome. Of course, lasting results that cure LUTS are preferable over the need to conduct a Re-TURP or further treatment due to a lack of improvement in the IPSS score.

Our clinical data has shown that the LFD Therapy brings important advantages that helped to treat our patients more efficiently with lasting results. Of particular visibility was the fact that the need to exclude patients from curing the lower urinary tract symptoms because of a negative pre-operative risk-assessment was virtually ignorable for the LFD group, as the complication rate went down towards 0%.

Concluding message

One of the main messages we can take from this clinical trial is that there are significant improvements possible in the treatment of BPH by the latest advancements in laser technology. In contrast to known green lasers, the LFD Therapy seems to enable a much more careful and less risky treatment than formerly available. It has been proven effective also for high-risk patients and allows the cure of LUTS among a much larger group of patients. The study has been extended to a multicenter trial for generating further data that is expected to support our preliminary findings.

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Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**cathalic church thuine - germany - 67/2009**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**