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THE AT-HOME DELIVERY OF TREATMENT FOR BENIGN PROSTATE ENLARGEMENT AND CHRONIC PROSTATITIS ENABLED BY DR ALLEN'S DEVICE IS A VALUABLE HEALTHCARE INNOVATION DURING A PANDEMIC

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ABSTRACT

Introduction: The Coronavirus (COVID-19) outbreak has demonstrated the need for a novel delivery of treatment for benign prostate enlargement (BPE) and chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS). Their standard treatments with medications and surgeries require extensive contact between patients and healthcare professionals that worsens a pandemic. This study aims to determine whether therapeutic Dr Allen's Device (DATD) and Thermobalancing therapy (TT) can be used as an effective self-management tool and at-home treatment for chronic prostate diseases.
Methods: This is a retrospective cohort study of 45 men with CP/CPPS and 124 men with BPE who were observed before and after applying TT with DATD at home for 6 months in 2 clinical controlled trials. The dynamics of clinical characteristics and parameters, such as pain, urinary symptoms, quality of life (QoL), and prostate volume (PV) were compared to the control groups without DATD.
Results: DATD reduced pain scores from 10.3 to 3.5 (P<0.001) in men with CP/CPPS. In men with BPE, DATD reduced PV from 45mL to 31mL (P<0.001) and urinary symptoms from 14.3 to 4.9 (P<0.001). DADT significantly improved QoL in both treatment groups. In the control groups, no positive changes were observed.
Conclusions: The use of DATD with TT relieves chronic pelvic pain and reduces an abnormal prostate size in patients with CP/CPPS and BPE, improving their QoL and wellbeing. Thus, DATD is an effective at-home self-management tool and provides a novel delivery of treatment for non-cancerous prostatic diseases, especially important during a pandemic.

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INTRODUCTION

On March 11, 2020, the World Health Organization identified an outbreak of coronavirus as a public health emergency of international concern and declared it a pandemic [1]. Since evidence suggests that human-to-human transmission of the virus is a result of close contact, the prevention of transmission of infectious diseases to patients and the protection of health workers should be a top priority during viral epidemics [2].

Due to the pandemic, the outpatient face-to-face clinics are canceled or changed to telephone or video consultations. The urological surgical care has undergone significant changes, offering surgical intervention only in emergency cases [3], while routine treatments for benign prostatic hyperplasia (BPH) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) should mainly be carried out remotely [4].

At the same time, the prevalence of chronic non-malignant prostatic diseases is high. A large study involving 8,627 men aged 48–79 years showed that 75.3% of men reported mild form, 22.0% reported moderate, and 2.7% reported severe form of lower urinary tract symptoms (LUTS) due to benign prostate enlargement (BPE). The prevalence of symptoms increased with age [5]. According to this study, more than 97% of men with LUTS can handle the symptoms themselves without taking risky medications and undergoing surgeries. As for CP/CPPS, its prevalence is estimated to affect 8.2% of men [6].

Currently, the standard BPE management is only pharmacological and surgical [7]. As there is no appropriate therapy for LUTS caused by BPE, urologists prescribe various combinations of pharmacological treatments [8]. Self-control strategies can be implemented initially, but the debate continues that they can delay drug or surgical therapy, which can lead to negative consequences, especially for men with worsening symptoms [9]. At the same time, drugs and surgeries can lead to serious side effects, as a study by Giatti points to the development of severe sexual dysfunction and depression after taking BPE drugs [10].

The treatment guidelines for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) recommend using the “Five A’s” of CP/CPPS therapy: avoid dietary or physical activities (e.g., bike riding) that exacerbate symptoms, and use antibiotic therapy, alpha-blockers, anti-inflammatories, and 5-alpha reductase inhibitors in men >50 years old [11]. However, it is important to remember that all these drugs are responsible for severe adverse events. Discussing post-finasteride syndrome, for example, Dr. Traish says: “The medical community must not turn a blind eye to this rare but debilitating condition, especially when it concerns young men” [12].

Innovative utilization of body heat in the management of chronic diseases, including BPH and CP/CPPS, by Dr Allen’s Therapeutic Device (DATD) and Thermobalancing therapy (TT) has been assessed in International Journal of Quality Innovation [13]. DATD and TT are patented as the "Therapeutic device and method" [14]. For over 10 years, TT and DATD have been used successfully for the treatment of prostate enlargement and chronic pelvic pain [15, 16]. The purpose of this study is to assess the delivery of treatment with TT and DATD for BPE and CP/CPPS, and the use of this novel treatment as a self-management tool for BPE and CP/CPPS, especially during a pandemic.

MATERIALS

Study Protocol

Two clinical trials were conducted at the Department of Urology at the Yerevan State Medical University. The Ethics Committee approved the clinical studies with TT and DATD (approval No 1 - 18.09.2014). These studies were registered at the World Health Organization via the German Clinical

Trials Register. Dr Allen's Device has been registered with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom since 2010 as a class 1 medical device. Class 1 medical device without a measuring function and supplied in non-sterile condition does not require the involvement of a notified body.

Study design

The first clinical trial assessed 124 men with BPH who used DATD for 6 months, and their symptoms and parameters before and after the therapy were examined. This information was compared with the control group, i.e. data received from 124 men with BPH who were in watchful waiting. The second clinical trial involved 45 men with CP/CPPS who used DATD for 6 months and their parameters before and after the therapy were examined. This information was compared with the control group, i.e. data received from 45 men with CP/CPPS who did not receive TT. Patients with BPH were measured using the International Prostate Symptom Score & Quality of Life. In men with CP/CPPS, the National Institute of Health Chronic Prostatitis Symptom Index score was utilised. In both clinical studies, prostate volume (PV) in mL was investigated. The parameters were compared between groups accordingly.

Participants

45 males (age <55 years) with CP/CPPS (NIH category III) and 124 men with LUTS due to BPH with PV <60 mL were receiving the treatment with Dr Allen's Device at home, while being supervised by urologists.

Evaluation

Baseline evaluations were a full physical examination, medical history, digital rectal examination, serum biochemistry, measurement of prostate-specific antigen and electrolytes, urinalysis, and renal function tests. Written informed consent was obtained from all patients before the study. Evaluations were made at baseline and 6 months after treatment. The dynamics of the symptoms and indicators in each group were assessed at the beginning and at the end of treatment using the score systems.

1. The International Prostate Symptom Scale (I-PSS) is a validated and widely accepted tool that is used to assess the dynamics of urinary symptoms and quality of life (QoL) in BPH patients. The I-PSS consists of an 8-item questionnaire that measures urinary symptoms (seven questions evaluating incomplete bladder emptying, frequency, intermittency, urgency, weak stream, straining, and nocturia) on a scale of 0–35 with a higher score indicating higher severity of the urinary symptoms. The I-PSS consists of another component (1 question) that measures QoL on a scale of 0–6 with a lower score indicating a better quality of life.
2. The National Institute of Health chronic prostatitis symptom index (NIH-CPSI) is a validated and widely accepted tool that is used to assess the dynamics of pain and QoL in CP/CPPS patients. The NIH-CPSI assesses pain using 4 questions (evaluating pain location, frequency, and severity) on a scale of 0–21 with a higher score indicating more severe pain. The NIH-CPSI consists of another component that helps in assessing the QoL using 3 questions on a scale of 0–12 with a lower score indicating a better quality of life.

Ultrasound was used to determine the volume of the prostate gland. The standard ellipsoid formula length×width×height×0.52 was used to determine the prostate volume. Evaluation at baseline shows that characteristics of the men were identical between treatment and control groups in the CP/CPPS and BPH studies.

Statistical analyses

The independent-samples t-test and paired-samples t-test are suitable only for

interval and ratio data, so the Wilcoxon signed-rank test was employed. P<0.05 was considered significant. Statistical analyses were carried out using SPSS v22 (IBM, Armonk, NY, USA).

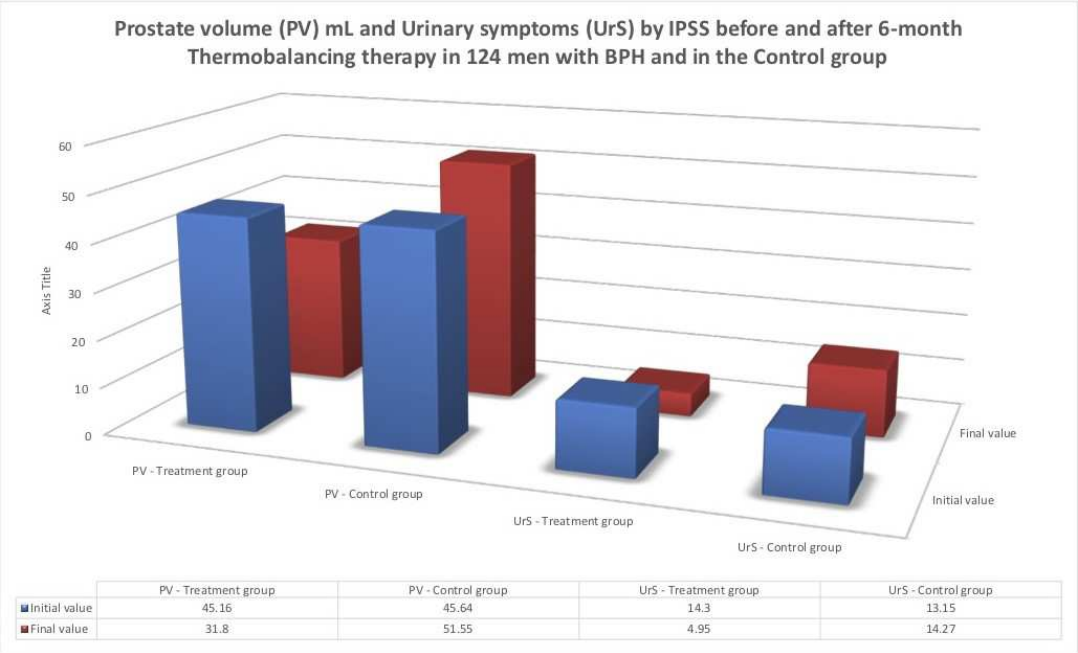
Therapeutic Dr. Allen's Device (DATD)

DATD applies a special thermoelement (comprising a mixture of waxes) topically in projection to the affected organ. The thermoelement accumulates the constantly emitted body heat and turns into a source of energy itself. DATD applies the thermoelement to the skin tightly, thereby overcoming the skin barrier and spreading the energy towards the prostate gland. It is comfortable to wear. In men with prostate diseases, the thermoelement is applied to the coccyx area and is supported by a specially designed belt (Figure 1).

Figure 1. The application of Dr Allen's Device to the coccyx area for the treatment of BPE and CP/CPPS

RESULTS

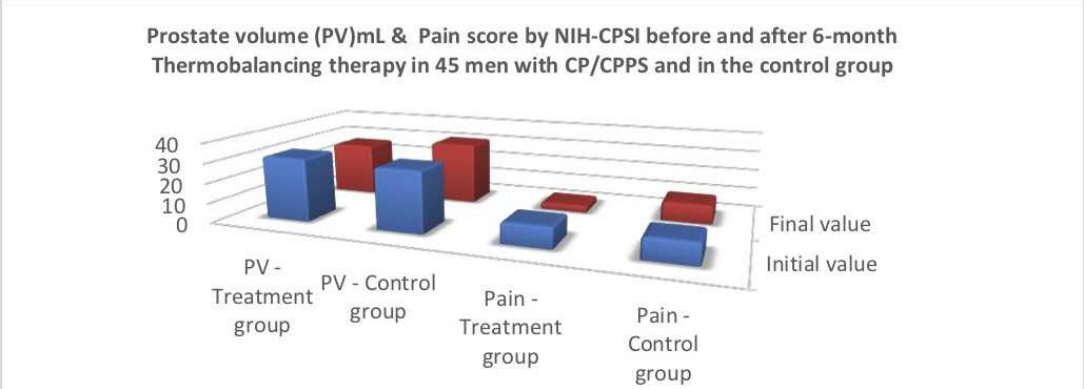
The clinical trial involving BPE patients reveals that, in the treatment group, PV decreased from 45.1 mL to 31.8 mL (*P*<0.001) and UrS score decreased from 14.3 to 4.9 (*P*<0.001). In the control group, changes were insignificant or even worse. These results suggest that DATD reduces PV and UrS significantly.



	PV - Treatment group	PV - Control group	UrS - Treatment group	UrS - Control group
Initial value	45.16	45.64	14.3	13.15
Final value	31.8	51.55	4.95	14.27

Figure 2. Dynamics of PV mL measured by ultrasound and urinary symptoms (UrS) measured by the International Prostate Symptom Score (IPSS) before and after a 6-month use of Thermobalancing therapy and DATD in 124 men with BPH and compared to 124 men in the control group.

The clinical trial involving CP/CPPS patients reveals that, in the treatment group, there was a significant decrease of PV mL from 31.7 to 27.07 (P<0.001) and the use of DATD reduced pain score from 10.3 to 3.5 (P<0.001). In the control group, changes were insignificant. This proved that TT with DATD decreases PV and pain in men with CP/CPPS.



	PV - Treatment group	PV - Control group	Pain - Treatment group	Pain - Control group
Initial value	31.75	30.77	10.38	10.49
Final value	27.07	31.58	3.58	9.71

Figure 3. Dynamics of PV mL measured by ultrasound and Pain Score measured by the National Institute of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) in 45 men with CP/CPPS before and after a 6-month use of DATD and compared to 45 men in the control group.

Side effects of TT with DATD were not observed in both clinical trials.

DISCUSSION

TT with DATD helped patients with BPH and CP/CPPS to reduce the size of the enlarged or inflamed prostate and, consequently, to achieve LUTS and chronic pelvic pain relief. The success of this treatment confirms the validity of DATD as an effective self-management tool for patients with BPH and CP/CPPS. It should be noted that all men used Dr. Allen's Device at home during a 6-month period. It confirms that DATD enables a novel at-home delivery of treatment for BPE and CP/CPPS.

The rapid spread of coronavirus (COVID-19) led to a pandemic, which affected people globally. A social lockdown has become the only preventative measure that can be taken to combat this pandemic [17]. The infection of 2019-nCoV is more likely to infect older men with comorbidities [18]. Patients over 60 years showed heavier clinical manifestations, greater severity, and longer disease courses compared with those under 60 years of age [19].

During a pandemic, patients are advised to reduce visits to doctors and hospitals; the abolition of planned operations is required, so urological surgeries have to be prioritised according to their urgency and adapt to local resources [20]. Many different surgical interventions remove a part of the prostate gland; and after all of them, men may experience the loss of antegrade ejaculation, orgasmic dysfunction, or even erectile dysfunction with possible thermal effects on the neurovascular bundles [21], and this should not be simplified as it is a serious adverse effect [22].

Men troubled by BPE and CP/CPPS can benefit from the effective prostate treatment with DATD in the safety of their home [23], avoiding unnecessary visits to clinics and hospitals and so minimising the risks of contracting coronavirus COVID-19 and passing it on to others. Therefore, TT with DATD should be used by healthcare providers for the management of BPE and CP/CPPS, particularly in older men [24]. The use of DATD can also reduce the burden of treating these prostate diseases on healthcare systems.

As medications can cause serious side effects, clinical consideration for BPH and CP/CPPS drugs is difficult [25]. The use of medication for BPH and CP/CPPS can aggravate these health conditions by adding side effects. Although there are many medical options for treating BPH, their safety and efficacy relating to older adults are still under assessment [26]. Alpha-blockers can cause adverse events, including ejaculatory dysfunction, hypotension, and depression [27, 28], and finasteride and dutasteride induce a constellation of persistent sexual, neurological and physical adverse side effects [29].

The COVID-19 pandemic is a serious challenge for global and national healthcare providers. Thus, during the pandemic, unselective or inappropriate administration of antibiotics should be avoided [30]. The use of non-steroidal anti-inflammatory drugs (NSAIDs) should not be recommended as they can cause both respiratory and cardiovascular adverse effects [31]. Patients who take angiotensin-converting enzyme inhibitors and angiotensin receptor blockers may be at increased risk of severe disease outcomes due to SARS-CoV-2 infections [32]. 5-alpha-reductase inhibitors, which are commonly used for BPE treatment, maybe one of the factors contributing to poorer prognosis in males [33].

Dr Allen's Device uses a patented mechanism of action redirecting the body's heat to the affected prostate to treat chronic prostatic diseases. It is, therefore, safe and can be used by various healthcare professionals for the management of BPH and CP/CPPS [34, 35]. By utilising the emitted body heat and not requiring other energy sources, the innovative

design of DATD advances sustainability in healthcare. DATD should be tried by men with BPH before any long-term pharmacotherapy is initiated [36]. Personalized care by using DATD allows to effectively treat CP/CPPS at home in 93.4% of men, including full recovery in 42% of cases [37].

Limitation

This is a retrospective analysis of 2 non-randomized clinical trials. The presence of a "placebo" or "sham" group as control could have provided more statistical rigor concerning results. However, a high level of mental incidence in patients with LUTS is important when choosing a treatment [38]; and collectively, depression and catastrophizing are critically important variables in understanding the experience of pain in patients with CP/CPPS [39]. Thus, most men with CP/CPPS and BPE have depression and anxiety, and this is important for medical professionals in the development and implementation of effective interventions to improve the quality of life and psychological well-being of patients with BPE. [40, 41]. 6 months may be considered an appropriate time for taking tablets/placebo, but not for using something tied to the body. Therefore, suggesting that patients should wear a "placebo-belt" for 6 months, which does not alleviate the symptoms, would be very difficult and impractical. Typically, patients included in the study experienced symptomatic relief within several weeks after starting to wear DATD and used the device as instructed.

Pandemic considerations

The need to prioritise an at-home BPE treatment is evident during a pandemic. In March-April 2020, out of 18 BPE patients who were admitted and treated at a hospital, 10 men (55.5%) became infected with the COVID-19 virus, 2 of them were transferred to the intensive care unit and one man died [42]. Thus, it is imperative to take preventive measures for elderly men with BPE that would decrease the patient hospitalisation rate. The use of Thermobalancing treatment with DATD as a monotherapy improves men's QoL and decreases their visits to hospitals, diminishing the risks of contracting a viral infection and transmitting it to others during a coronavirus outbreak or another pandemic [43].

During a pandemic, authorities in many countries recommend avoiding routine hospital visits as much as possible, but under certain conditions (especially in emergencies and cancer cases), care must be continued. Patients with benign prostate enlargement should not undergo surgery during a pandemic unless they develop a complication that will require hospitalization and possible surgery [44]. Most elderly people turn to urologists. Special strategies should be used to treat urological conditions during the COVID-19 pandemic, keeping in mind the golden rule for any infectious disease at any time: "prevention is better than cure." [45].

Thus, during the coronavirus outbreak, staying at home saves lives, and therapeutic Dr. Allen's Device allows men to treat BPE effectively in the safety of their homes [46]. It is essential to emphasize the importance of staying at home and not going to work in case of flu symptoms to prevent exposure to other workers [47]. Based on information from different countries, the following guidelines for older people have been proposed: stay home as much as possible; avoid all non-essential travel and non-essential in-person visits to your health provider (e.g., family physician check-ups), etc. [48]. Furthermore, the treatment of BPH with DATD increases men's healthspan [49].

CONCLUSIONS

This study has revealed several innovative aspects of treatment with Dr Allen's Device and Thermobalancing therapy for BPE and CP/CPPS that generate additional value during a pandemic. DATD enables a novel at-home delivery of treatment for BPH and CP/CPPS. It enables effective self-management of chronic pelvic pain and

urinary symptoms associated with BPE and CP/CPPS. The use of TT and DATD minimizes face-to-face contact between patients and healthcare professionals at clinics and hospitals, helping to protect them in times of coronavirus or another pandemic while reducing virus transmission and health risks to people. The efficient delivery of treatment with DATD and its innovative design advance sustainability in healthcare. Moreover, the use of DATD as a stand-alone self-management tool for BPE and CP/CPPS can significantly reduce the need for other interventions. Thus, it reduces the burden of treatment for these prostate diseases on healthcare systems. DATD is also particularly important during a pandemic. Dr Allen's Device supports wellbeing and should be recommended by healthcare providers to patients with CP/CPPS and BPE.

COMPETING INTERESTS

The authors declare that there are no competing interests.

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The studies do not have financial interests.

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REFERENCES:

1. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Published March 11, 2020 (accessed March 20, 2020).
2. Li Q, Guan X, Wu P, Wang X et al. Early transmission dynamics in Wuhan, China, of novel coronavirus infected pneumonia. N Engl J Med 2020; 382:1199-1207. https://doi.org/10.1056/NEJMoa2001316.
3. Ho HC, Hughes T, Bozlu M et al. What do urologists need to know: Diagnosis, treatment, and follow-up during COVID-19 pandemic. Turk J Urol. 2020 Apr 14. doi: 10.5152/tud.2020.20119.
4. Witherspoon L, Fitzpatrick R, Patel P, Flannigan R et al. Clinical pearls to managing men's health conditions during the COVID-19 pandemic. Can Urol Assoc. 2020; 14(5): E161-6. doi: 10.5489/cuaj.6631.
5. Rohrmann S, Katzke V, Kaaks R. Prevalence and Progression of Lower Urinary Tract Symptoms in an Aging Population. Urology. 2016; 95:158-63. doi: 10.1016/j.urology.2016.06.021.
6. Magistro G, Wagenlehner FM, Grabe M, et al. Contemporary Management of Chronic Prostatitis/Chronic Pelvic Pain Syndrome, Eur Urol. 2016 Feb;69(2):286-97. doi: 10.1016/j.eururo.2015.08.061.
7. Woodard TJ, Manigault KR, McBurrows NN et al. Management of Benign Prostatic Hyperplasia in Older Adults. Consult Pharm. 2016;31(8):412-24. doi: 10.4140/TCP.n.2016.412.
8. Dimitropoulos K, Gravas S. New therapeutic strategies for the treatment of male lower urinary tract symptoms. Res Rep Urol. 2016; 8:51-9. Published 2016 Apr 26. doi:10.2147/RRU.S63446
9. Norton JM, Bavendam TG, Elwood WN et al. Research needs to understand self-management in Men with LUTS: A review and summary of a NIDDK workshop. J Uro 2017; doi: 10.1016/j.juro.2017.11.079.
10. Giatti S, Diviccaro S, Panzica G, Melcangi RC. Post-finasteride syndrome and post-SSRI sexual dysfunction: two sides of the same coin? Endocrine. 2018 Aug;61(2):180-193. doi: 10.1007/s12020-018-1593-5.

11. Doiron RC, Nickel JC. Management of chronic prostatitis/chronic pelvic pain. syndrome. Can Urol Assoc J. 2018;12(6 Suppl 3): S161-S163.
12. Traish AM. The Post-Finasteride Syndrome: Clinical Manifestation of Drug-Induced Epigenetics Due to Endocrine Disruption, Curr Sex Health Rep (2018) 10: 88. https://doi.org/10.1007/s11930-018-0161-6
13. Allen S. Innovative Thermobalancing therapy using Dr. Allen's device for the first time employs the body energy to treat the chronic prostatic disease effectively, Int J Qual Innov, 2020, 6, 2. doi: 10.1186/s40887-020-00035-0.
14. Allen S, Adjani, A. Therapeutic Device and Method, United States Patent and Trademark Office. U.S. Patent 9,408,744 B2, 9 August 2016. Available online: https://www.google.com/patents/US9408744 (accessed June 11, 2021).
15. Allen S, Aghajanyan IG. Benign Prostatic Hyperplasia Treatment with New Physiotherapeutic Device, Urol J. 2015, 14;12(5):2371-2376.
16. Allen S, Aghajanyan IG. Effect of thermobalancing therapy on chronic prostatitis and chronic pelvic pain syndrome, Journal of Clinical Urology, 2016, Sept 20, 1-8. doi: 10.1177/2051415816671036.
17. Paital B, Das K, Parida SK. Inter nation social lockdown versus medical care against COVID-19, a mild environmental insight with special reference to India [published online ahead of print, 2020 Apr 23]. *Sci Total Environ*. 2020; 728:138914. doi: 10.1016/j.scitotenv.2020.138914.
18. Chen N, Zhou M, Dong X, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet*. 2020;395(10223):507-513. doi:10.1016/S0140-6736(20)30211-7.
19. Liu Y, Mao B, Liang S, et al. Association between ages and clinical characteristics and outcomes of coronavirus disease 2019 [published online ahead of print, 2020 Apr 27]. Eur Respir J. 2020;2001112. doi:10.1183/13993003.01112-2020.
20. Stensland KD, Morgan TM, Moinzadeh A, et al. Considerations in the Triage of Urologic Surgeries During the COVID-19 Pandemic. Eur Urol. 2020; S0302-2838(20)30202-5. doi: 10.1016/j.eururo.2020.03.027.
21. Descazeaud A, Robert G, de La Taille A. [Sexual consequences of BPH treatments]. Progres en Urologie: Journal de L'association Francaise D'urologie et de la Societe Francaise D'urologie. 2018 Nov;28(15):839-847. doi: 10.1016/j.purol.2018.07.278.
22. Koren G. Retrograde Ejaculation — a Commonly unspoken aspect of prostatectomy for benign prostatic hypertrophy. American Journal of Men's Health, 2020, Volume: 14 issue: 2. doi.org/10.1177/1557988320910870.
23. Aghajanyan IG, Allen S. Positive Response to Thermobalancing Therapy Enabled by Therapeutic Device in Men with Non-Malignant Prostate Diseases: BPH and Chronic Prostatitis, Diseases 2016, *4*, 18. doi:10.3390/diseases4020018.
24. Allen S. Dr. Allen's Therapeutic Devices Should be Implemented in the Healthcare System for the Treatment of Chronic Noncancerous Prostate and Kidney Diseases Saving People's Well-Being and Money, Ann Mil Health Sci Res. 2018; 16(2): e81033. doi: 10.5812/amh.81033.
25. Gandhi J, Weissbart SJ, Smith NL, et al. The impact and management of sexual dysfunction secondary to

pharmacological therapy of benign prostatic hyperplasia. Translational Andrology and Urology. 2017;6(2):295-304. doi:10.21037/tau.2017.03.57.

26. Bortnick, E., Simma-Chiang, V., Omidele, O, et al. Medical Therapies for Treatment of BPH: Special Considerations in Elderly Men, Curr Geri Rep. 2019, Nov. pp 1-5. https://doi.org/10.1007/s13670-019-00299-1
27. Kim JH, Shim SR, Khandwala Y et al. Risk of Depression after 5 Alpha Reductase Inhibitor Medication: Meta-Analysis. World J Men's Health. 2019 Jan;37: e27, https://doi.org/10.5534/wjmh.190046.
28. Baron M, Cornu JN. Medical Aspects of the Treatment of LUTS/BPH: Alpha-Blockers. Lower Urinary Tract Symptoms and Benign Prostatic Hyperplasia, 2018, Chapter 8, Pages 177-188, https://doi.org/10.1016/B978-0-12-811397-4.00008-1.
29. Traish AM. Post-finasteride syndrome: a surmountable challenge for clinicians. Fertil Steril. 2020 Jan;113(1):21-50. doi: 10.1016/j.fertnstert.2019.11.030.
30. Cascella M, Rajnik M, Cuomo A, et al. Features, Evaluation and Treatment Coronavirus (COVID-19) [Updated 2020 Apr 6]. In: StatPearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK554776/.
31. Paul L. Non-steroidal anti-inflammatory drugs and covid-19 BMJ 2020; 368:m1185. doi: https://doi.org/10.1136/bmj.m1185.
32. Diaz JH. Hypothesis: angiotensin-converting enzyme inhibitors and angiotensin receptor blockers may increase the risk of severe COVID-19, *Journal of Travel Medicine*, taaa041, https://doi.org/10.1093/jtm/taaa041
33. Adamowicz J, Juszczak K, Drewa T. May patients receiving 5-alpha-reductase inhibitors be at a higher risk of COVID-19 complications? [published online ahead of print, 2020 Apr 22]. *Med Hypotheses*. 2020; 140:109751. doi: 10.1016/j.mehy.2020.109751.
34. Allen S, Aghajanyan IG. Use of thermobalancing therapy in aging males with benign prostatic hyperplasia with a focus on etiology and pathophysiology, Aging Male, 2016,1-5, http://dx.doi.org/10.1080/13685538.2016.1247151.
35. Allen S. The Vascular Factor Plays the Main Role in the Cause of Pain in Men with Chronic Prostatitis and Chronic Pelvic Pain Syndrome: The Results of Clinical Trial on Thermobalancing Therapy. Diseases, 2017, 5(4), 25; doi:10.3390/diseases5040025.
36. Allen S, Aghajanyan IG. Thermobalancing conservative treatment for moderate – to - low - degree lower urinary tract symptoms (LUTS) secondary to prostate enlargement, Cogent Medicine, 2016, 3(1), 1195067. https://doi.org/10.1080/2331205X.2016.1195067.
37. Allen S. Personalized care using thermobalancing therapy can help men with chronic prostatitis / chronic pelvic pain syndrome to recover, Personalized Medicine Universe. 2019, 8, 48-52. doi: https://doi.org/10.1016/j.pmu.2019.04.002.
38. Coyne KS, Wein AJ, Tubaro A, et al. The burden of lower urinary tract symptoms: evaluating the effect of LUTS on health-related quality of life, anxiety, and depression: EpiLUTS. *BJU Int*. 2009;103 Suppl 3:4-11. doi:10.1111/j.1464-410X.2009.08371.x.

39. Kwon JK, Chang IH. Pain, catastrophizing, and depression in chronic prostatitis/chronic pelvic pain syndrome. *Int Neurourol J.* 2013;17(2):48-58. doi:10.5213/inj.2013.17.2.48.
40. Zhang GX, Bai WJ, Xu T, Wang XF. A preliminary evaluation of the psychometric profiles in Chinese men with chronic prostatitis/chronic pelvic pain syndrome. *Chin Med J (Engl).* 2011;124(4):514-518.
41. Pinto JD, He HG, Chan SW, Wang W. Health-related quality of life and psychological well-being in men with benign prostatic hyperplasia: An integrative review. *Jpn J Nurs Sci.* 2016;13(3):309-323. doi:10.1111/jjns.12115.
42. Topaktaş R, Tokuç E, Ali Kutluhan M, et al. Clinical features and outcomes of COVID-19 patients with benign prostatic hyperplasia in aging males: A retrospective study of 18 cases. International Journal of Clinical Practice. 2020 June13574. DOI: 10.1111/ijcp.13574.
43. Allen S, Adjani A. Benign Prostatic Hyperplasia and Chronic Prostatitis Thermobalancing Therapy Can Prevent Sexual Dysfunction and Depression Linked to Medications: Importance During a Pandemic. Andrology. 2020; 9:207. doi: 10.35248/2167-0250.2020.9.207.
44. A. Carneiro, M.L. Wroclawski, B. Nahar, et al. Impact of the COVID-19 pandemic on the urologist's clinical practice in Brazil: a management guideline proposal for low- and middle-income countries during the crisis period. Int Braz J Urol, 2020, 46, 4, 501-510. doi: 10.1590/S1677-5538.IBJU.2020.04.03.
45. Chen W, Wang XM, Fu GQ, et al. Special strategies and management of urological diseases during the COVID-19 pandemic: initial experiences from a Medical Center of China. Int Braz J Urol. 2020, 17;46(Suppl. 1): 19-25
46. Allen S. Thermobalancing therapy as a Self-management tool. World News of Natural Sciences, WNOFNS. 2019. Vol. 23. 84-93.
47. Belingheri M, Paladino ME, Riva MA. COVID-19: Health prevention and control in non-healthcare settings, *Occupational Medicine,* Volume 70, Issue 2, March 2020, Pages 82–83, https://doi.org/10.1093/occmed/kqaa048.
48. Montero-Odasso M, Goens SD, Kamkar N, et al. Canadian Geriatrics Society COVID-19 Recommendations for Older Adults. What Do Older Adults Need To Know? Can Geriatr J 2020, 23(1):149–151.
49. Allen S, Adjani A. Benign Prostatic Hyperplasia and Kidney Stone Disease Thermobalancing Therapy with Dr. Allen's Device: Key to Successful Ageing Without Medications, Surgery, and Risky Exposure to Coronavirus Infection, Nephro-Urol Mon. 2021 13(2): e110771. doi: 10.5812/numonthly.110771.