



December 30, 2019

Centers for Medicare and Medicaid Services
Mail Stop: C4-01-26
7500 Security Boulevard
Baltimore, MD 21244

RE: POTENTIALLY MISVALUED CODES

Dear Sir/Madam:

Please consider this letter my official petition of the misvalued **CPT code 53850 Transurethral destruction of prostate tissue; by microwave thermotherapy.**

Background:

As per , 42 CFR Parts 405, 410,411, 4141, 415, 425 and 495 (CMS-1693-F, CMS-1693-IFC, CMS-5522-F3, and CMS-1701-F, please find our comments to the final rule which addresses changes to the Medicare Physician Fee Schedule (PFS) reflecting updates in medical practices and relative value of services. This specifically relates to (24) Transurethral Destruction of Prostate Tissue (CPT Codes 53850, 53852, and 53854) as reviewed as a family of codes related to the CPT Editorial Panel to create a new code (CPT Code 52854).

Comment:

For CPT code 53850, which we currently fall under due to the lack of a proper code for our specific Prolieve BPH treatment device, is strictly only microwave single modality. The Prolieve BPH is the only Transurethral Thermodilatation (TUTD) approved by the FDA which is a combinational thermotherapy with Microwave, plus a “Prostatic Urethral Dilation Balloon.” As a result of this, the reviewers and commenters of the AMA /Specialty Society RVS Update Committee (RUC) were not able to address many of the procedural, time, cost, etc. factors when they recommended and proposed to CMS. CMS accepted a major reduction of the RVU to 5.42 for the CPT code 53850, which represents almost a 24% reduction of the fees collected. Although this may be reasonable for the 1st and 2nd generation TUMT treatment devices, this does not capture the resources and cost involved to provide the benefits of our Prolieve TUTD device and is considered as the 3rd generation TUMT (*Aleksic I, Mouraviev V, Albala DM: Transurethral Microwave Therapy. In: Chughtai B, Te AE, Kaplan SA, editors. Treatment of Benign Prostatic Hyperplasia: Modern Alternative to Transurethral Resection of the Prostate, New York: Springer; 2015, p. 121-129. ISBN: 978-1-4939-1586-6*).



As per the minutes of the January 10-13, 2018 meeting, the Facilitation Committee #1 did have the latest FDA approved information on our 5 year follow up post approval study (PAS) for our TUTD Prolieve device dated March 8, 2018 (Attachment A) and the final FDA approved labeling on November 21, 2018 (Attachment B).

In addition, which is very important to the justification of our request and comments, in November 2018, which was after the review by the AMA RUC meeting and the final acceptance by CMS in Sept. 2018, the FDA approved our PMA Supplement for new labeling based on a recently FDA approved 5 year follow-up Post Approval Study (PAS). This demonstrated not only Prolieve was effective for immediate improvement to their LUTS caused by BPH, but now Prolieve has demonstrated durable and long-term benefits for up to 5 years of follow-up for the responder group. The durability of response of up to 5 years can have a major savings impact to the overall healthcare costs for the treatment and management of the many men with LUTS caused by BPH. The Prolieve treatment is truly an office-based treatment. It does need to be performed in a surgical center and/or hospital, which can involve major added expenses, such as: sterile treatment room, high cost facility fees, addition support staff, general anesthesia, etc. as required for some of the other minimal or invasive treatments or surgery for the treatment and relief of LUTS.

We believe our immediate and long-term benefits of our office-based treatment, as approved by the FDA, is attributed to the combinational thermotherapy, plus the Prostatic Urethral Dilation Balloon. As a result of the requirement of the dilation balloon modality, it adds significant cost to the treatment console. In addition, the incorporation of the dilation balloon to the disposable treatment kit increases the cost of the equipment and supplies by 50%. The complexity of the dilation balloon to optimize the pressure and placement requires increased pre and post service time of an additional 15 minutes from that of the 1st and 2nd generation TUMT. For the unique Prolieve treatment to enable immediate relief and formulate a biological stent, an additional 5-minute cool down period is also required. Unlike the 1st and 2nd generation TUMT, which in order to be effective, these modalities have over time shortened the procedural time to 28.5 minutes and increased higher powers which causes increased pain and potentially increased adverse events, and the majority require post treatment catheters. The Procedural Protocol of the Prolieve which enables effective prostatic tissue ablation at lower powers, resulting in a more patient friendly treatment, does not require pain blockers or general anesthesia and, the majority of the patients will not require a post treatment catheter. This treatment requires a total procedural time of 45 minutes, plus 5 minutes cool down, increasing the treatment time by 50%.

The FDA approved Indication for use of Prolieve is below:



Indications for Use

The Prolieve® Transurethral ThermoDilatation™ (TUTD) System:

Prolieve® is a transurethral thermodilatation microwave therapy device that provides a non-surgical, minimally invasive procedure for the treatment of symptomatic BPH in men with a prostate size of 20 to 80 grams, a prostatic urethra length of 1.2 to 5.5 cm and in whom drug therapy (e.g. Proscar®) is typically indicated.

Note: In addition to the fact we are the only TUTD device, we are the only category CPT 53850 with an indication for use of “and in whom drug Therapy (e.g. Proscar®) is typically indicated” as well as the only thermodilatation device.

This means, this could be an additional health care costs savings for the men who are on drug therapy and may eliminate the need and cost for drug therapy for up to 5 years.

The Prolieve FDA PAS study is the very latest 5 year follow up of minimally invasive BPH treatments in this class of treatment options and has fully demonstrated the safety and effectiveness of both immediate and long-term benefits. The following are additional and unique comments for the Prolieve Device, which is why we believe our CPT code 53850 Prolieve is potentially misvalued.

1. The cost of the treatment console is higher to be able to control and inflate the transurethral prostatic dilation balloon used in the treatment.
2. The cost of incorporating the transurethral prostatic dilation Balloon which expands to 44 French adds to the manufacturing and material cost for the single use treatment kit.
3. There is extra time and steps required to inflate/deflate and pretest the dilation balloon prior to inserting it into the patient.
4. There is extra time requirement to insert, position and expand the dilation balloon readying for treatment.
5. An additional 5-minute cool down period is required with the dilation balloon fully inflated after the microwave session is completed.
6. After the cool down period, an additional step would be the dilation balloon must be fully deflated to remove.



7. The Prolieve TUTD 3rd generation TUMT requires an increase of 50% treatment procedural time over the 1st and 2nd Generation TUMT to provide the proven safe and effective treatment of the recent FDA approved treatment protocol to deliver the added clinical and safety benefits of our TUTD treatment modality.

Since this is a multi modality treatment, we believe the additional CPT code 74485 with an RVU of .083 could be added. Although, it still may not cover the full impact of RVS and cost associated for the Prolieve treatment. We recognize CPT 74485 is diagnostic and is for another indication however, it is similar in scope. 74485 is the Dilation of urether(s) or urethral, radiological supervision and interpretation which was also just reviewed by RUC and CMS recommended. This will revalue our Prolieve treatment to incorporate and justify the revaluation of the Prolieve treatment.

Thus, in summary, we hope that for the upcoming CY 2020 CMS, PFS can be revised to incorporate the unique cost and time required to perform the Prolieve treatment. We understand the CY2019 is already fixed. However, for CY2019, would it be acceptable for the Prolieve users to bill with the extra CPT code 74485, even though it may not cover the entire cost.

Approximately 200 Urologists over the past 3 years have provided the Prolieve treatment in the USA as a truly office based BPH treatment option. With the significant, reduction in the CPT (2019) reimbursement by CMS/RUC, economically, the clinicians cannot cover the costs of providing the Prolieve treatment in their office to the benefit of their BPH patients. We cannot cover the costs of manufacturing to provide the Prolieve disposable kits without going out of business.

I have attached the original letter to CMS and AMA dated Dec. 13, 2018 (Attachment C). In addition, urologic colleagues in Asia have similar findings to the benefits of Prolieve treatment for BPH (see Attachment D).

Finally, we are the only FDA approved dual modality treatment and as mentioned prior it requires more time and expertise due to the added steps of the urethral dilation balloon, higher material and manufacturing cost for both the disposable treatment kit and treatment console in order to deliver the treatment which we believe is safer, less adverse events, less painful, yielding immediate relief, as well as durable long term efficacy as demonstrated by the most recent FDA approve 5 year follow-up post approval study . The recent deductions may be justified for the other single modality treatment using this CPT, which is without the dilation balloon and their treatment was shortened to 28.5 minutes. Our treatment requires 45 minutes



plus a 5-minute cool down period, for a total of 50 minutes treatment time, plus addition pre-treatment time for the urethral dilation balloon. As mentioned, we believe our treatment is misvalued and should be increased and/or allow us to bundle and add a urethral dilation CPT when using our treatment modality.

Without the revaluation, it is not economically feasible for the physicians to provide the Prolieve treatment and it is not economically feasible for Medifocus to stay in business. Plus, this will reduce the few truly safe and effective office based BPH treatment options, which not only benefits patients and improves their quality of life but significantly reduces the overall healthcare cost of the management of symptoms caused by BPH.

We hope that you can provide us with a revaluation for our Prolieve treatment modality.

Sincerely,

A handwritten signature in blue ink, appearing to read "John Mon".

John Mon, General Manager Medifocus, Inc.

March 8, 2018

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medifocus, Inc.
Mr. Jon Mon
Chief Operating Officer
8320 Guildford Road, Suite A
Columbia, MD 21046

COPY

Re: P030006/R027
Prolieve Thermodilatation System
Study Name: OSB Lead-Prolieve PAS
Received: June 15, 2017
Amended: November 6, 2017

Dear Mr. Mon:

The Center for Devices and Radiological Health of the Food and Drug Administration (FDA) has completed the review of your final post-approval study report for the Prolieve Thermodilatation System. This post-approval study requirement was described in the approval order dated February 19, 2004 for premarket approval application (PMA) P030006. FDA is pleased to inform you that you have fulfilled your post-approval study requirement for the study name referenced above.

Please submit a PMA supplement, within 30 days from the date of our letter, which modifies the labeling to reflect the findings of the study. This supplement should include a new section of the label that reflects long-term data from the Post-Approval Study. The labeling supplement should include a summary of the post-approval study design, results, and study strengths and limitations.

The format below is recommended. There are no fees associated with labeling change supplements based on post-approval study results; thus, please clearly indicate that this is a "Post-Approval Study Labeling Update."

Post-Approval Study

Summary of the Post-Approval Study Methods

Study Objective

Study Design

Study Population

Data Source

Key Study Endpoints

Total number of Enrolled Study Sites and Subjects, Follow-up Rate

Study visits and length of follow-up

Summary of the Post-Approval Study Results

Final safety findings (key endpoints)

Final effectiveness findings (key endpoints)

Study Strength and Weaknesses

Please be advised that once you have submitted this supplement, you should also submit an amendment to this post-approval study final report that notifies us of the date you submitted the labeling supplement and what number the supplement was assigned by FDA. **Your post-approval study report will remain open until we receive this amendment.**

Please be advised that your study status will be marked as “Progress Adequate” on the Post-Approval Studies webpage **until we receive your amended report** (www.fda.gov/devicepostapproval).

The required 3 copies of your PMA supplement should include the FDA reference number to facilitate processing, be identified as a “PMA Post-Approval Study Labeling Update” and should be submitted to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this letter, please contact Allison O'Neill, PhD, MA at (301) 796-4141 or Allison.oneill@fda.hhs.gov.

Sincerely yours,

Benjamin C. Eloff -S

on behalf of

Danica Marinac-Dabic, M.D., Ph.D.

Director, Division of Epidemiology

Office of Surveillance and Biometrics

Center for Devices and Radiological Health

ATTACHMENT B



November 21, 2018

John Mon
General Manager
Medifocus, Inc.
10240 Old Columbia Road, Suite G
Columbia, MD 21046

COPY

Re: P030006/S028
Trade/Device Name: Prolieve Thermodilation System
Product Code: MEQ
Filed: March 30, 2018

Dear John Mon:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 180-day supplement, which requested approval for a labeling update with the results of the Post-Approval Study (PAS). Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number

of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, <http://www.fda.gov/udi>.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm>.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> and on combination product postmarketing safety reporting is available at (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a

risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at

<http://www.fda.gov/Safety/Recalls/IndustryGuidance.default.htm>.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Jim Seiler at (301) 796-6558 or James.Seiler@fda.hhs.gov.

Sincerely,

Joyce M. Whang -S

for

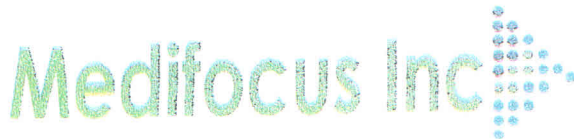
Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health



December 13, 2018

Centers For Medicare and Medicaid Services
 Department of Health and Human Services
 Attention CMS-1693-IFC,
 Marge Watchorn, Deputy Director, Practitioner Services
 P.O. Box 8010
 Baltimore, MD 21244-8016

RE: Comments to 59452 Federal Register/Vol. 83, No. 226

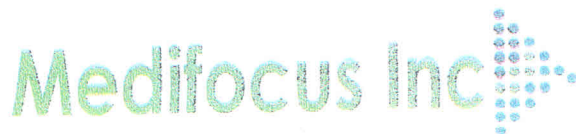
To Whom It May Concern:

Background:

As per, 42 CFR Parts 405, 410, 411, 4141, 415, 425 and 495 (CMS-1693-F, CMS-1693-IFC, CMS-5522-F3, and CMS-1701-F please find our comments to the final rule which addresses changes to the Medicare Physician Fee Schedule (PFS) reflecting updates in medical practices and relative value of services. This specifically relates to (24) Transurethral Destruction of Prostate Tissue (CPT Codes 53850, 53852, and 53854) as reviewed as a family of codes related to the CPT Editorial Panel to create a new code (CPT Code 52854).

Comments:

For CPT code 53850, which we currently fall under due to the lack of a proper code for our specific Prolieve® BPH treatment device, CPT code 53850 as described above is strictly reimbursed for microwave only single modality. Unlike the 1st and 2nd generation Non-Dilating Transurethral Microwave Therapies (TUMT), our Prolieve® BPH treatment is the only FDA approved Transurethral Thermolatilation™ (TUTD™) which is a unique combination thermotherapy with Microwave plus a "Prostatic Urethral Dilatation Balloon". As a result, we believe that the reviewers and commenters of the AMA/Specialty Society RVS Update Committee (RUC) had overlooked such important differences and did not address the many procedural, time, cost, etc. factors in their recommendations and proposals to CMS. CMS accepted a major reduction of the RVU to 5.42 for the CPT code 53850 which represents an approximately 24% reduction of the fee schedule for CPT code 53850. Although such fee reduction may be reasonable for the 1st and 2nd generation TUMT treatment devices, this does not capture the resources and costs involved to produce and provide treatment using our Prolieve® TUTD™ device equipped with a highly pressurized and built-in safety feedback system.



In addition, as another important consideration to the justification of our request and comments, the FDA recently on November of 2018, which was after the review by the AMA RUC meeting and the final acceptance by CMS in Sept. 2018, approved the Prolieve® device an FDA PMA Supplement approval for new labeling based on a recently FDA approved 5-year follow-up Post Approval Study (PAS). This demonstrated not only Prolieve® was effective for immediate improvement of lower urinary tract symptoms (LUTS) caused by BPH, but also durable and long-term clinical benefits for up to 5 years of follow-up for the responder group. The durability of response of up to 5 years can have a major cost savings impact to the overall healthcare costs for the treatment and management of the many men with LUTS caused by BPH. The Prolieve® treatment is truly an office-based treatment performed under local anesthesia and does not require to be performed in a surgical center and/or Hospital, which can involve major added expenses such as sterile treatment room, high-cost facility fees, additional support staff, general anesthesia, etc. as needed for most other minimal invasive or invasive treatments or surgery for the treatment and relief of LUTS. It would also save the patients from unnecessary exposures to IV sedation or general anesthesia, and their associated risks.

The FDA approved Indication for use of Prolieve is as follows:

Indications for Use

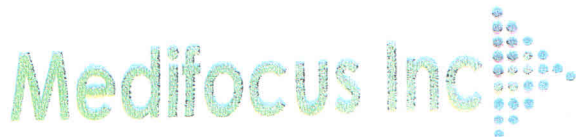
The Prolieve® Transurethral ThermoDilatation™ (TUTD™) System:

Prolieve® is a transurethral thermodilatation microwave therapy device that provides a non-surgical, minimally invasive procedure for the treatment of symptomatic BPH in men with a prostate size of 20 to 80 grams, a prostatic urethra length of 1.2 to 5.5 cm and in whom drug therapy (e.g. Proscar®) is typically indicated.

Note: In addition to the fact we are the only TUTD™ device, we are the only category CPT 53850 with an indication for use "in whom drug Therapy (e.g. Proscar®) is typically indicated", as well as being the only thermodilatation™ device.

This translates into additional Healthcare cost savings for those men who are on drug therapy and who may eliminate the need and cost of drug therapy for up to 5 years, and to avoid the potential long-term side effects of these BPH medications.

The following are additional and unique comments for the Prolieve® Device compared to other Non-Dilating 1st and 2nd generation Transurethral Microwave Therapies (TUMT):



1. The cost of the computerized treatment console is higher to be able to feedback control and inflate the high-pressure transurethral prostatic dilatation balloon used in the treatment.
2. The cost of incorporating the transurethral prostatic dilation balloon which expands to 46 French adds to the manufacturing and material costs for the single-use treatment kit.
3. There are extra time and steps required to inflate/deflate and pretest the dilation balloon prior to inserting it into the patient.
4. There is extra time requirement to insert, position and expand the dilation balloon readying for treatment.
5. There is an additional 5-minute cool down period with the dilation balloon fully inflated after the 45-minute microwave session is completed. The total treatment time is significantly longer than other TUMT and minimally invasive procedures.
6. After the cool down period, additional steps are needed before the dilatation balloon can be fully deflated and removed.

Since this is a multi-modality treatment, we believe the additional CPT code 74485 with an RVU of .083 could be added. Nevertheless, it still may not cover the full impact of RVS and cost associated with providing the Prolieve® treatment. We recognize CPT 74485 is diagnostic and is for another indication; however, it is similar in scope. CPT 74485 is the Dilation of Urethra(s) or urethral, radiological supervision and interpretation which was also just reviewed by RUC and CMS recommended.

In summary, we hope that for the upcoming CY 2020 CMS, PFS can be revised to incorporate the unique costs and time required to provide the Prolieve® treatment. We understand the CY2019 is already fixed. However, for CY2019, would it be acceptable for the Prolieve® users to bill with the extra CPT code 74485, even though it may not cover the entire cost?

Sincerely,

A handwritten signature in black ink, appearing to read "John Mon", written over a light blue horizontal line.

John Mon
General Manager, Medifocus Inc.

($n = 231$, our hospital; $n = 16$, outside hospitals), two patients died (malignant disease) with stents in-situ, three had long-standing stents plans in progress, and two were missing despite these reminders. Four patients were traced via postal letters. Mild stent-related symptoms were reported in 186 patients, with the most common being frequency with urgency; however, 12 patients had severe stent-related symptoms. In total, 87% of patients preferred voice reminder system to text-based reminders, and 91% preferred reminders in their regional language.

Conclusion The use of UroSTENTBOOK voice-based application resulted in increased on-time extraction of stents, which could greatly reduce the incidence of forgotten ureteric stent patients.

540

Microwave thermodilatation therapy for symptomatic benign prostatic hyperplasia: the first Asian experience

W. M. P. CHOW,^{1,*} W. JOW²

¹UMP Medical Services, Hong Kong, HongKong SAR,

²Department of Urology, Hckensack Meridian Health-Bayshore Medical Centre, Holmdel, U.S.A.

3-Minute Oral Presentation 20 | Technology, August 9, 2019, 4:30 PM - 5:30 PM

Background Transurethral ThermoDilatation (TUTD) offers a unique treatment for symptomatic benign prostatic hyperplasia (BPH) by simultaneously using focused microwave heating together with pressurized balloon dilation therapy. The treatment is a 45-minute, in-office, outpatient procedure which is performed and well tolerated under local anaesthesia. About 90% of patient do not require a post-treatment Foley catheter and the majority of patients experience significant and immediate relief of their lower urinary tract symptoms (LUTS). The 5-year follow-up USFDA Post Approval Study of TUTD confirms long-term safety, efficacy and durability with improved LUTS, urinary flow rate, quality of life, and no sexual side effects when compared to an untreated age-matched male population. We performed TUTD treatments on 15 Asian patients and presents our initial experience and clinical data pertaining to the clinical safety and efficacy of this minimally-invasive treatment for symptomatic BPH.

Methods From August-December 2018, 15 patients (Age 54–79, mean 62) were each treated once for their LUTS with the TUTD device, PROLIEVE by Medifocus inc Their IPSS (17–35, mean 24), QOL (4–6, mean 4.5), PSA (0.57–7.7, mean 3.5), prostatic volumes (35–84 cc, mean 54 cc), Qmax (1.7–10.5 mL/s, mean 7.5 mL/s) and PMRV (50–330 mL, mean 190 mL) were recorded pre-treatment. At 6 weeks and 3 months post-treatment, IPSS, QOL, Qmax, and PMRV were reassessed.

Results IPSS: 2–23 (mean 12) at 6 weeks; 2–22 (mean 10) at 3 months.

QOL: 1–3 (mean 2.5) at 6 weeks; 2–3 (mean 2.75) at 3 months.

Qmax: 3.6–14.9 mL/s (mean 10 mL/s) at 6 weeks; 6.8–17.5 mL/s (mean 13.2 mL/s) at 3 months.

PMRV: 0–33 mL (mean 8 mL) at 6 weeks, and 0–45 mL (mean 20 mL) at 3 months.

Urological complications such as clot retention and sepsis (as evidenced by symptoms and MSU culture) were not observed. One patient required temporary post-treatment Foley catheterization for 72 h. Treatment related incidence of retrograde ejaculation or erectile dysfunction has not been reported. The procedure was well tolerated under local anaesthesia. We also observed that both the voiding and storage IPSS improved in all patients treated.

Conclusion Our initial experience with TUTD in a cohort of 15 Asian patients compares favorably to the clinical outcomes and efficacy of the Caucasian population treated in the recently completed USFDA 5-year follow-up post approval study. We observe significant improvements in post-treatment IPSS, QOL, Qmax and PMRV with minimal side effects; therefore, we conclude that TUTD is clinically safe and efficacious in the Asian population. Long-term prospective data collection in a larger patient population is in progress.

576

PSMA Tc-99 m SPECT vs Ga-68 PET for the staging of prostate cancer: a pilot case series

H. J. SOH,^{1,*} J. KAM,^{1,2,3} A. AL-SAMERAAH,¹

H. F. CHAN,¹ D. GILBOURD,¹ K. HART,¹ M. KAHLOON,¹

S. MCCREDIE,¹ H. HAXHIMOLLA,^{1,4} I. DUNCAN⁵

¹Department of Urology, The Canberra Hospital, ACT,

Australia, ²University of Newcastle, Australia, ³University of

Sydney, Australia, ⁴Australian National University, Australia,

⁵Garran Medical Imaging, Garran, Australia

3-Minute Oral Presentation 20 | Technology, August 9, 2019, 4:30 PM - 5:30 PM

Introduction and objectives Prostate Specific Membrane Antigen (PSMA) scans are becoming increasing prevalent for primary staging of prostate cancer or following biochemical recurrence. The most commonly utilized modality remains Gallium-68 PET which requires a PET scanner which are less readily available. PSMA bound to Tc-99 m is a more recent development which requires a SPECT scanner which are more prevalent and cheaper. We aimed to compare the imaging findings in patients undergoing PSMA scans with both modalities

Methods Analysis of a prospective database of all patients undergoing a Tc-99 m PSMA scan was used to identify patients undergoing concurrent Ga-68 PSMA PET scans between June 2017 and August 2018. Patients were included if the 2 PSMA modalities were performed within 3 months of each other. Demographic data and imaging findings were collected for analysis. Data was analysed using SPSS 24.0

Results Six patients underwent both PSMA Tc-99 m and Ga-68 scans within 3 months of each other. Five were done for primary staging while one was performed for biochemical recurrence.

In the primary staging group, one case had localized disease on Ga-68 PSMA while Tc-99 m PSMA showed a single external iliac lymph node metastasis. Histopathology showed the Tc-99 m scan to be correct with positive lymph node metastasis found at radical prostatectomy and lymph node dissection. Two cases showed localized disease only on both Ga-68 and Tc-99 m PSMA. One case showed widespread bony and lymph node metastasis, though the volume of disease was slightly higher on Ga-68 compared to Tc99 m PSMA. One further case showed the presence of a sacral lymph node metastases on both Ga-68 and Tc-99 m PSMA.

For the patient with biochemical recurrence both the Tc99 m and Ga-68 scan showed no evidence of recurrent or metastatic disease.

Conclusions Our study is the first Australian study to directly compare Ga-68 to Tc-99 m PSMA imaging. It shows early evidence that Tc-99 m PSMA may be a suitable alternative to Ga-68 with the additional benefits of lower cost and more widespread availability of the required SPECT scanners.

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Utility of MRI fusion-targeted transrectal prostate biopsy and prostate health index in detection of clinically significant prostate cancer

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Background MRI Fusion-Targeted Transrectal Prostate Biopsy is commonly offered to patients with clinical suspicion of prostate cancer with a targetable lesion seen on MRI. In an update to our early experience (J Endourology 2017; 31(11):1111–6), we aimed to test the hypothesis that targeted biopsy has a higher detection rate for clinically significant prostate cancer (csPCa) than systematic biopsy.