Dr. R. Moulton-Barrett
01-2015

STANDARDIZED PROCEDURE FOR REGISTERED NURSES(RN) AND MEDICAL ASSISTANTS(MA) /PHYSICIANS (PA) TO PERFORM THERMIva (TIva)

I. POLICY

A. Circumstances under which the RN may perform ThermiVA(Tiva)

1. Setting:
   Aesthetic Medicine Program, in designated Treatment Room
2. Applicable Device:

a. Once clinically trained and certified upon completion and by Thermi, Inc , the RN can treat patients **TiS** Devise.

b. **Tiva**is a class II devise and therefore the placement and removal of devise on/from the skin may only be performed by an Registered Nurse(RN), Physician's Assistant (PA), Nurse Practioner (NP) or Medical Doctor (MD). Patient scheduling, education and comfort management during the procedure may be performed by a medical assistant/front office staff.

c. **Tiva** is used for the reduction of (including but not limited to) unwanted labial skin or stress incontience, irritable bladder, vaginal laxity, vulovovaginal decreased sensitivity and atrophic vaginitis.

3. Supervision:

a. Physician, PA or NP will assess patient and/or review chart prior to treatment should there be any question regarding the patients suitability for **Tiva**. This will involve a comprehensive initial health risk assessment followed by a care plan that addresses goals and objectives, services and benefits provided, and measurable outcomes.

b. No direct MD or RN supervision required during treatment.

c. MD will be available for questions or concerns in person or by phone.

d. All charts will be reviewed and signed by the MD within 10 working days of **Tiva** treatment

e. All consent forms must be signed by the RN prior to the onset of treatment and then counter signed by the MD according to 'd.'

4. Patient Conditions:

a. Consultation regarding patient's chief complaint completed. Specifically location of unwanted vulovvaginal laxity and the above described conditions listed 'A.2.b'.

i. Ensure patient is a candidate for **Tiva** by discussing precautions below.

ii. shave one day before procedure

c. Relative contraindications include:

- Pregnancy

- Recent or ongoing bladder infection, vaginitis or urethritis, Bartholin's Cyst, STD's, perineal infection
- < 18 yrs of age
- pacemaker unless magnet and cardiology clearance note
- if has sling needs Ob/Gyn cleanace note

d. Patient is aware of the potential risks, such as mild pain or tenderness which may last several days

e. Patient understands that results are not immediate and may take several months

f. Patient may understands that multiple treatments may be required to obtain desired result for a given area, the number of which and the frequency of which as well as the cost including a package price is to be determined and documented in the chart prior to the onset of the first treatment

g. Informed consent given and consent form completed.

II. PROTOCOL

A. Definition:

1. **Tiva** is the reduction of skin laxity and underlying structures such as the urethra as well as stimultio of nerve fibers and gland secretion by transcutaneous radiofrequency collagen heating immediate remodelling and secondary subepidermal contracture through post imflammatory collagen deposition as well as by creating an immediate inflammatory reaction to the sub surface structures.

B. Assessment:

1. <u>Subjective:</u>
   from whom a relevant medical history was obtained including but not limited to contraindications for the procedure
2. <u>Objective:</u>
   Patient presents with unwanted labial skin or stress incontience, irritable bladder, vaginal laxity, vulovovaginal decreased sensitivity and atrophic vaginitis. and has had a good faith relevant history and physical from which there are no contraindications ot the procedure.

C. Plan:

1. <u>Preparation for treatment:</u>
   a. Patient to remove any lotions, creams and deodorant from area to be treated.
2. <u>Treatment:</u>
   a. Hand piece to be cleaned with isopropyl alcohol or Sniwipes and dried off with towel prior to each treatment.
   b. Input patient data into computer re Tiva
      - Pre treatment photos are obtained
      - Witnessed consents obtained
   c. Start treatment at the given parameters unless reasons are noted to start at higher settings. Parameters vary according to

location of the skin and body type. Parameter sheet is discussed and provided at training/educational class.

Treatment Check List:

1. History, Physical, Consent
2. Void before procedure
3. Place ultrasonic gel in bottle warmer
4. Cover the face of the ThermI generator with Press and Seal
5. Plug in ThermiUnit to mains
6. Turn on black console switch at back of unit
7. Start right bottom white button, has been turned on
8. set time :0, RF again right bottom button
9. set temp to 38 for start outside then increase to 40, then 42 and as much as 45 if tolerated over time
10. place ground pad under left buttock and connect to the ThermI machine blue end to blue female receiver on unit
11. connect reusable AC-RFDE-VA adaptor cable to generator grey short cable, black arrow to black arrow line up
12. connect disposable RFDE-VA electrode to end of reusable cable
13. apply rapid-roll sheath
14. place patient in lithotomy position
15. take before photos from bas eof buttock inferiorly to top of Mons superiorly
16. apply warmed ultrasound gel to electrode and labia majora
17. press white bottom right button to start, wait for solid blue light top left corner, then choose ThermiVA or Smooth
18. zero timer
19. default temp is 35C press arrow at upper right until set at 38C:start at 38 for majora majora and minora, then move to 40 for 3-5 minutes each side if tolerated my go as hig as 45C for 3-5 minutes.
20. then move to the inside start with warm up to 45C and increase as tolerated to a maximum of 47C for 3-5 minutes ,working: in circular and in and out motion right lateral wall and finally anterior wall with posterior to urethral area to finish,
21. with head of non reusable electrode in contact with skin press foot pedal to start RF energy, solid blue light will folllow and beep every 10 seconds during therapy.
22. should be total of 6 x 3-5 minutes treatments which is preceeded by a 1-3 minute heat up: total treatment time 30 minutes
23. Wipe excesss ultrasonic gel off
24. Take post photso same position and sup/inferior borders as befores
25. Post care instructions given to the patient
26. Schedule next treatment

27. Sanitize equipment: remove rapid roll sheath, remove Press and seal from generator and wipe including down handle using Protex wipes or Saniwipes

d. Monitor for response of patient's skin and increase parameters only if indicated.
e. Expected responses:
   - erythema
   - hardending

   Note: These expected skin responses should resolve within several hours

3. Patient Education:
   a. Any prolonged pain, redness and swelling should be reported to RN, PA, NP or MD.
   b. Any severe pain reaction which continues more than a few days should be reported immedicately to ThermI
   c. patient given post procedure instruction sheet
4. Follow up:
   a. Subsequent treatments to the same area 4-6 weeks later for 3 treatments and then 9-12 month treatments thereafter. There is no maximum of treatments can be peformed to the same area over time.
   b. Other areas can be treated simultaneously or at convenient timing thereafter without restriction.
5. Documentation: The following information must be recorded in patient's chart with each treatment.
   a. Patient's verbal response to last treatment (if any).
   b. Area treated.
   c. Photos taken using standardized positioning 1-4 and entered into the computer not greater than the end of the 4 week period
   c. Parameters used.
   d. Patient's response to treatment.
   e. Any conditions or problems that may have arisen prior or during treatment, such as: tanned skin and sensitivity. Note: If infection is present, no treatment should take place.
   f. Procure physician's review and sign-off on patient charts within 10 days post treatment.

III. REQUIREMENTS FOR RN and For Front Office / Medical Assistant

Education: 1. Graduate of RN program with current California RN license.
2. Certified Medical Assistant or Certfied with letter of verification from MD regarding proficiency and in office training as medical assistant
3. Completion ThermIRF In service course and passing training examination: for RN & medical assistant /front office staff

Training:
1. Formal radiofrequency (RF) trasncutaneous collagen remodelling and contraction education and training covering the biophysics and

the safe use of TiS training of choice. Successful completion of basic training program devoted to the principles of RF, instrumentation and physiological effects and safety requirements. The initial program should include clinical applications of the TiVa hand piece in the particular locations, how to place successfullly and use the ultrasonic jel, positioning the patient, turning off the devise and hands-on practical sessions with Tiva with the appropriate therapeutic delivery

2. Experience: No previous experience necessary prior to the above training. See Initial Evaluation below.

3. Initial Evaluation: Successful completion of appropriate Tiva training.

4. Ongoing evaluation:

5. Random MD visits during treatment sessions. MD will observe 1 treatment quarterly, specifcally:

a. Safety and efficacy issues
b. Contraindications and Precautions
c. Complications and side effect
d. Managing complications and adverse events (side effects)
e. Consultation, Assessment, and Patient education
f. Safe application of Tiva
g. Formal completion on on ine inservice and vendor presentation followed by observed CS by qualified MD,PA or NP

6. Formal re-education Tiva by product representatives to increase knowledge, experience and proficiency in the proper administration of the product.

IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of CS as a comprehensive working model.

This model will be reviewed annually and documented in the minutes of the meeting and will be kept in the Administrative office of Rex Moulton-Barrett,MD

This Standardized Procedure and Protocol (standing orders) have been approved by:

Rex Moulton-Barrett,MD
Medical Director Date: 01-18-2015

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Administrative Signature Date: