KEY CLINICAL STUDIES

### Key Clinical Studies

#### Manuscript: Monarc vs. TVT
**First Author:** H. Richter1  
**Study Purpose:** Comparison of cure rates and safety of Monarc vs. TVT-O at 3 mos follow-up.  
**Study Design:** Randomized clinical trial  
**Outcomes:** Objective cure rate (defined as the percentage cured of the symptom of SUI at 3 mos on the International Consultation on Incontinence Modular Questionnaire Female Lower Urinary Tract Symptoms):  
- Monarc: 87.6%  
- TVT-O: 86.2%  

#### Manuscript: Monarc vs. TVT-O
**First Author:** A. Liapis5  
**Study Purpose:** Comparison of safety and efficacy of Monarc vs. TVT-O at 4 mos follow-up.  
**Study Design:** Randomized clinical trial  
**Outcomes:** Objective cure rate:  
- Monarc: 90%  
- TVT-O: 87%

#### Manuscript: Monarc vs. TVT-O
**First Author:** R. Freeman6  
**Study Purpose:** Comparison of safety and efficacy of Monarc vs. TVT-O at 3 mos follow-up.  
**Study Design:** Randomized clinical trial  
**Outcomes:** Objective cure rate:  
- Monarc: 90%  
- TVT-O: 87%

### Key Takeaways

- **Monarc** is not inferior to TVT.
- Monarc and TVT-O are equally effective in treating women with SUI.
- Both procedures are equally safe with respect to major complications.

#### Adverse Events:
- Both procedures equally safe with respect to major complications.
- Bladder injuries more common for RP procedures.
- No significant difference in cure rates at 3 mos.
Monarc vs. TVT

First Author: H. Richter
NEJM 2010

Study Purpose: Compare outcomes with RP and TO midurethral slings

Key Takeaways:
- Randomized equivalence
- 597 patients (RP = 298, TO = 299)
- 12 mos follow-up
  - 565 patient RP=291, TO=292

Cure Rate (defined as absence of self-reported symptoms through the use of MESA questionnaire, no leakage recorded on 3-day voiding diary, and no retreatment for SUI):
- RP: 65.5% (303), TO: 64.1%
- Monarc: 49.3%

Secondary Outcomes included:
- QOL, pain scores, global impression of improvement, patient satisfaction and complications

Objective assessments included CST, urinary diary and 1 hr pad test
- Significant reduction in leakage on CST in both groups (TVT 72% down to 12% vs. Monarc 81.5% down to 10%)

Adverse Events:
- Perforation of bladder (TVT 2, TO 0)
- Perforation of skin (TVT 0, TO 0)
- Groin Pain (TVT 1, TO 0)
- Vaginal infection (TVT 0, TO 0)

Cure Rate & Objective Cures:
- Monarc = 90%
- TVT-O = 87.8%
- Monarc vs. TVT-O:
  - Subjective Cure Rate: Monarc 80.8%, TO 77.7%
  - Objective Cure Rate: Monarc 74.7%, TO 70.8%

Data from 3 mos follow-up with 140 completers

Monarc vs. TVT-O

First Author: R. Freeman
Jg 2010

Study Purpose: Determine equivalency of Monarc to TVT by using patient reported outcomes

Key Takeaways:
- Randomized equivalence
- 193 patients (Monarc = 100, TVT = 93)
- 12 mos follow-up
  - (192 patients, Monarc =100, TVT = 92)

Cure Rate (defined as the percentage cured of the symptom of SUI at 12 mos on the International Consultation on Incontinence Modular Questionnaire-Female Lower Urinary Tract Symptoms):
- Monarc = 79.3%
- TVT-O = 84.5%

Secondary Outcomes:
- De novo urgency = Monarc: 5.5%, TVT-O: 11.5%
- Lower urinary tract infection post-op = Monarc: 6%, TVT-O: 2%
- Urinary retention = Monarc: 3%, TVT-O: 1%
- Post-op pain in thigh region = Monarc: 3%, TVT-O: 4%

Subjective and Objective Cure Rates:
- Monarc = 79.3% vs. TVT-O = 84.5%
- Monarc vs. TVT-O:
  - Subjective Cure Rate:
    - Monarc: 79.3%, TVT-O: 84.5%
  - Objective Cure Rate:
    - Monarc: 74.7%, TVT-O: 70.8%

Both procedures equally safe with respect to major complications

Monarc vs. TVT-O

First Author: C. Barry
Jg 2007

Study Purpose: Compare safety and efficacy of Monarc vs. TVT-O

Key Takeaways:
- Prospective, randomized
- 120 patients (60 patients in each arm)
  - Monarc: 58, TVT-O: 62

Primary Outcome: was presence or absence of abnormal bladder function
- Defined as presence of any of the following:  (1) presence of acute or new-onset post-voiding residue, (2) significant change in self-reported symptoms, or (3) significant change in physical exam findings

Adverse Events:
- Bladder perforation (Monarc = 3, TVT-O = 0.5%)
- Urological event post-op = Monarc: 4.8%, TVT-O: 1.9%
- Post-op pain = Monarc: 4.8%, TVT-O: 1.9%
- Post-op infection = Monarc: 4.8%, TVT-O: 1.9%

Monarc vs. TVT

First Author: M. Barber
NEJM 2010

Study Purpose: Compare outcomes with RP and TO midurethral slings

Key Takeaways:
- Prospective, randomized
- 187 pts (Monarc = 80, TVT = 107)
- 3 mos follow-up with 94 completers (58 Monarc vs. 82 TVT)

Cure Rate (defined as negative provocative stress test, negative 24-hr pad test, no re-treatment for SUI):
- Monarc: 63.4%
- TVT: 65.5%

Objective assessments included CST, urinary diary and 1 hr pad test
- Significant reduction in leakage on CST in both groups (TVT 72% down to 12% vs. Monarc 81.5% down to 10%)

Adverse Events:
- Vaginal infection (TVT = 0, TO = 4)
- UTI (TVT = 7, TO = 2)
- Groin Pain (TVT = 1, TO = 8)
- Perforation of vaginal skin (TVT = 0, TO = 4)
- Perforation of bladder (TVT = 2, TO = 0)

Cure Rate & Objective Cures:
- Monarc vs. TVT-O:
  - Subjective Cure Rate:
    - Monarc: 79.3%, TVT-O: 84.5%
  - Objective Cure Rate:
    - Monarc: 74.7%, TVT-O: 70.8%

Both procedures equally safe with respect to major complications

Bladder injuries more common for RP procedures

No significant difference in cure rates at 3 mos

Subjective and Objective SUI Cure Rates:
- Monarc: 86.6% (71) vs. 72.6% (42) and 79.3% vs. 84.5% for TVT and Monarc groups, respectively (cure rates are defined as MUSQ questionnaire, IQQ-7 questionnaire, 2-day bladder diary and post-void, clinical examination findings and urodynamics studies findings)
KEY CLINICAL STUDIES


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