LONG-TERM EFFICACY AND SAFETY OF TRANSURETHRAL NEEDLE ABLATION (TUNA®) IN OVER 500 MEN WITH LUTS/BPH: THE EAU REAL-LIFE DATA REGISTRY

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OBJECTIVE

The electronic Real-Life Data Registry on Transurethral Needle Ablation (TUNA®) of the Prostate was designed to assess the long-term (≥ 5 years) clinical outcome and economics of TUNA® treatment with Precision™ Plus and Prostiva™ RF in ≥ 500 patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH) in real life clinical practice. The registry was set up by the European Association of Urology (EAU) Clinical Research Office in collaboration with Medtronic International Trading Sàrl.

MATERIALS & METHODS

Patient data are uploaded by the investigators in a centrally-managed, internet-based data collection and analysis tool (enCapture™ Advanced Patient Management System) and stored on a desktop-based version of the software.

RESULTS

Between November 2003 and July 2007, the registry included 526 patients (mean age 66 years) undergoing TUNA® at 20 centres in 9 European countries. Before TUNA®, mean prostate size was 43 g, 13% of patients had a history of acute urinary retention (AUR), 64% had previously received pharmacological treatment for BPH (58% α-adrenoceptor antagonists) and 2.7% had undergone minimally invasive therapy. The mean procedure time was 31 minutes; 99% of patients were satisfied or very satisfied with the comfort during the procedure. By September 2010, the mean follow-up was 28.0 months. 47 patients completed the study. Therapy failure occurred in 132 patients (25%), amongst others 92 requiring pharmacological BPH therapy and 33 requiring TURP; 106 of these patients discontinued from the study. 1-, 2-, 3- and 4-year follow-up data were available for 313, 243, 182 and 107 patients, respectively. In the patients with ≥ 1 year follow-up, significant improvements from baseline were seen in the total I-PSS, IPSS-QoL, maximum flow rate (Qmax), and post void residual (PVR) for up to 4 years after TUNA®, whereas the International Index of Erectile Function (IIEF-5) remained stable (Table). 89 complications (mainly AUR (41), gross haematuria (10), voiding symptoms (5) and infection (4)) were reported for 71 patients (23%). 81% of complications were resolved at analysis; AUR was resolved in 34 (83%) patients and required hospitalisation in 4 patients.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median (Q25, Q75) Baseline</th>
<th>Median (Q25, Q75; % change) after TUNA® Endpoint analysis</th>
<th>Median (Q25, Q75; % change) Endpoint analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total I-PSS (n=301)</td>
<td>21.0 (17.0, 25.0)</td>
<td>10.0 (6.0, 15.0; 52%)</td>
<td></td>
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<tr>
<td>IPSS-QoL (n=310)</td>
<td>4.0 (3.0, 5.0)</td>
<td>2.0 (1.0, 3.0; 60%)</td>
<td></td>
</tr>
<tr>
<td>Qmax (mL/s) (n=295)</td>
<td>9.0 (6.4, 11.0)</td>
<td>12.0 (9.0, 16.0; 37%)</td>
<td></td>
</tr>
<tr>
<td>IIEF-5 (n=227)</td>
<td>18.0 (12.0, 23.0)</td>
<td>19.0 (14.0, 22.0; 9%)</td>
<td></td>
</tr>
</tbody>
</table>

Endpoint: after mean follow-up of 34.8 months; * P<0.0001

CONCLUSION

Current data from the Electronic Real Life Data Registry on TUNA® in over 500 patients show that the majority of patients have clinical benefit (improved I-PSS, IPSS-QoL, Qmax), which was maintained for almost 3 years. 25% of patients failed therapy.

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INTRODUCTION

Electronic Real-Life Data Registry on Transurethral Needle Ablation (TUNA®) Therapy with Precision® Pro Plus and Precision® RF in the treatment of lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH)

Collaboration between the EAU (European Association of Urology) and Medtronic International Trading Sàrl (enCapture™ Advanced Patient Management System)

Aims: to document information on the long-term (≥ 5 years) use of TUNA® Therapy in >500 patients with LUTS/BPH managed in real-life clinical practice

Primary objective: evaluate re-treatment rate

Secondary objectives:
- Analyse subjective and objective improvement
- Obtain health-economic data

RESULTS

Patient enrolment was completed in July 2007

Patient enrolment started in November 2003

- 4-year FU was available for 107 patients
- 3-year FU was available for 182 patients
- 2-year FU was available for 243 patients

- 52% improvement in symptom score
- 60% improvement in quality of life
- 37% improvement in urinary flow

Is a safe procedure with no negative effect on sexual function

Has a failure rate of 25%

Materials and Methods

- enCapture™ Advanced Patient Management System
- Data collection and analysis tool that enables the investigators to electronically maintain their patient records (Figure 1) and upload these in the centrally-managed, internet-based database

Patient enrolment was completed in July 2007

Outcomes are evaluated at 6 months, and will further be collected at 12 months and then yearly for up to 5 years

RESULTS

Patient population

- An interim analysis was performed in September 2010
- All enrolled patients (N=525; mean follow-up (FU) of 28.6 months) (Figure 2)
- 60 patients (11.5%) were lost to follow-up
- 25% of patients were lost to follow-up

- 4 of these patients (3%) were rescheduled for TUNA® therapy, 92 patients (17.5%) required antimuscarinics and 33 patients (25%) were scheduled for TURP

- 106 patients (20%) discontinued from the study

- 47 patients (9%) discontinued due to lack of efficacy

- 18 patients (3.5%) were rescheduled for TUNA® therapy

4. Clinical outcome variables

- In 12m FU (Figure 1) group at endpoint, i.e. after mean FU of 38.8 months

Satisfaction

- Compared to baseline, there was a median improvement of 52% (P < 0.0001) in total International Prostate Symptom Score (IPSS) at endpoint (Table 2)

- The improvement in total IPSS was maintained over time (Figure 4)

- The percentage of patients with mild symptoms (total IPSS ≤ 7) increased from 1% at baseline to 35% at endpoint

- The percentage of patients with severe symptoms (total IPSS ≥ 25) decreased from 60% at baseline to 11% at endpoint

Table 2: Clinical outcome variables at baseline and endpoint.

52% improvement in symptom score

60% improvement in quality of life

37% improvement in urinary flow

CONCLUSIONS

This interim analysis shows that TUNA® Therapy

- Provides clinical benefit in the majority of patients which is maintained for almost 3 years

- 52% improvement in symptom score

- 60% improvement in quality of life

- 37% improvement in urinary flow

- Is a safe procedure with no negative effect on sexual function

- Has a failure rate of 25%

Acknowledgments

The EAU and Medtronic International Trading Sàrl would like to thank all investigators for their continued participation in the EAU Real-Life Data Registry on TUNA® Therapy. We strongly believe that this collaboration will continue to be a success.

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Figure 1: The electronic Advanced Patient Management System (enCapture™) - screenshot

Figure 2: Indication for TUNA®

Figure 3: Baseline parameters

Figure 4: Median total IPSS over time, TUNA® group

Figure 5: Satisfaction with TUNA® therapy

Figure 6: Maximum flow rate (Qmax) versus time, TUNA® group

Table 1: Patient distribution per centre

Table 2: Clinical outcome variables at baseline and endpoint.

Table 3: Complications (Table 1)

Table 4: Complications reported in the study period.

Table 5: Total number of complications.

Table 6: Patient satisfaction with TUNA® therapy

Table 7: Patients considered a success.

Table 8: Clinical outcome variables at baseline and endpoint.

Table 9: Satisfaction with TUNA® therapy

Table 10: Maximum flow rate (Qmax) versus time, TUNA® group

Table 11: Complications reported in the study period.

Table 12: Total number of complications.

Table 13: Patient satisfaction with TUNA® therapy

Table 14: Patients considered a success.

Table 15: Clinical outcome variables at baseline and endpoint.

Table 16: Satisfaction with TUNA® therapy

Table 17: Maximum flow rate (Qmax) versus time, TUNA® group

Table 18: Complications reported in the study period.

Table 19: Total number of complications.

Table 20: Patient satisfaction with TUNA® therapy

Table 21: Patients considered a success.

Table 22: Clinical outcome variables at baseline and endpoint.

Table 23: Satisfaction with TUNA® therapy

Table 24: Maximum flow rate (Qmax) versus time, TUNA® group

Table 25: Complications reported in the study period.

Table 26: Total number of complications.

Table 27: Patient satisfaction with TUNA® therapy

Table 28: Patients considered a success.

Table 29: Clinical outcome variables at baseline and endpoint.

Table 30: Satisfaction with TUNA® therapy

Table 31: Maximum flow rate (Qmax) versus time, TUNA® group

Table 32: Complications reported in the study period.

Table 33: Total number of complications.

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Table 35: Patients considered a success.

Table 36: Clinical outcome variables at baseline and endpoint.

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Table 38: Maximum flow rate (Qmax) versus time, TUNA® group

Table 39: Complications reported in the study period.

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Table 72: Satisfaction with TUNA® therapy

Table 73: Maximum flow rate (Qmax) versus time, TUNA® group

Table 74: Complications reported in the study period.

Table 75: Total number of complications.

Table 76: Patient satisfaction with TUNA® therapy

Table 77: Patients considered a success.

Table 78: Clinical outcome variables at baseline and endpoint.

Table 79: Satisfaction with TUNA® therapy

Table 80: Maximum flow rate (Qmax) versus time, TUNA® group

Table 81: Complications reported in the study period.

Table 82: Total number of complications.

Table 83: Patient satisfaction with TUNA® therapy

Table 84: Patients considered a success.