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<tr>
<td>Citation</td>
<td>泌尿器科紀要 (1996), 42(9): 655-661</td>
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<tr>
<td>Issue Date</td>
<td>1996-09</td>
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<tr>
<td>URL</td>
<td><a href="http://hdl.handle.net/2433/115807">http://hdl.handle.net/2433/115807</a></td>
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<td>Departmental Bulletin Paper</td>
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Kyoto University
SERIAL CHANGES IN PROXIMAL URETHRAL FUNCTION AFTER TRANSURETHRAL BALLOON LASER HYPERTERMIA OF THE PROSTATE (TUBAL-H) IN A CANINE MODEL

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We performed transurethral balloon laser hypertermia of the prostate (TUBAL-H) in 6 mongrel dogs. To evaluate the changes in proximal urethral function after TUBAL-H, the urethral cross sectional area (CSA, cm²) and urethral pressure (Pu, cmH₂O) were measured using a balloon probe that allows their simultaneous measurement, and the urethral compliance (Comp, cm³/cmH₂O) was calculated from these parameters and serially evaluated. In addition, the changes in Pu, CSA and Comp after administration of an α-adrenoceptor antagonist were evaluated before and 16 weeks after TUBAL-H.

Before TUBAL-H, the mean Comp was 0.013, and the mean maximum CSA (MCSA) was 0.66. Eight weeks after TUBAL-H, the mean Comp was 0.038, and the mean MCSA was 1.39, showing a significant increase (p<0.01). Sixteen weeks, after TUBAL-H, the mean Comp was 0.026, and the mean MCSA was 1.21, being lower than those at 8 weeks after TUBAL-H, but significantly higher than those before TUBAL-H (p<0.05).

After administration of the α-adrenoceptor antagonist, phentolamine (1 mg/kg), before TUBAL-H, the mean Comp significantly increased to 0.046 (p<0.05), and the mean MCSA to 1.40 (p<0.01). The mean Comp was significantly increased to 0.033 (p<0.05), by phentolamine administration 16 weeks after TUBAL-H, but no other changes were observed.

After TUBAL-H, urethral elasticity increased, and this increase persisted for 4 months. The responses of Comp and MCSA to α-adrenoceptor antagonist administration before and 16 weeks after TUBAL-H suggested that part of the effects of TUBAL-H is due to damage to α-adrenoceptors.

INTRODUCTION

Recently, medication1), laser ablation (VLAP)2), hyperthermia3), and thermotherapy4) have attracted attention as less invasive treatment methods for benign prostatic hypertrophy (BPH). Hyperthermia has been reported to be effective5), and its action mechanism has been suggested to be damage to α-adrenoceptors6).

We have been studying the effects of transurethral balloon laser therapy (TUBAL)7-10). In this study, we evaluated the serial changes in proximal urethral function after transurethral balloon laser hyperthermia of the prostate (TUBAL-H) to clarify the action mechanism of the treatment.

MATERIALS AND METHODS

Animal model
Six male mongrel dogs each weighing 9-15 kg (median, 11.5 kg) were used. The median prostate volume was 8.0 cc (3.3-12.4 cc). Perineal urethrostomy was performed before treatment in all dogs. All dogs were handled according to the Institute's Guide lines for the Care and Use of Laboratory Animals.

Anesthesia
All procedure were performed under the following anesthesia. Anesthesia was induced with sodium pentobarbital (25 mg/kg) and atropine sulfate (0.05 mg/kg). Mask anesthesia was performed under spontaneous respiration. The nitrogen monoxide: oxygen ratio was 1:1 (1.5-2.0 l/min each). The halothane (Zeneca Co. Ltd., England) concentration was 2.0% during induction of anesthesia and 1.5% during maintenance.

TUBAL-H
The PROSTALASE™ system used for this experiment consisted of CL5OFS, which generates Nd: YAG laser, and CATM, which is a computer-assisted temperature monitor system. This system was described in our previous study7). The balloon was perfused and cooled with water at 10°C. After the tissue temperature 5 mm deep from the mid-prostatic urethral mucosa (TS) reached 45°C at an output of 30 W, TUBAL-H was performed for 30 minutes. The urethral surface temperature (Ts) was maintained at 40°C or less during treatment.

Measurement of proximal urethral function
Fig. 1 shows the probe that measured proximal urethral function. This probe was equipped with a 2
Fig. 1. Balloon probe for measuring urethral function.

cm balloon near its tip that contained two pairs of generating and detecting electrodes connected to an impedance plethysmograph amplifier (Nihon Koden Co., Ltd., Tokyo, Japan) that measures CSA using the field gradient principle\textsuperscript{11,12} \( \text{CSA} = \text{CSAp} + \sigma \text{L}/Z_0 \) (CSAp: cross sectional area of the probe=0.032 cm\(^2\), \( \sigma \): resistant ratio=651\( \text{cm} \), L: distance of detecting electrodes = 0.5 cm, Z\(0 \): impedance, \( \Omega \)). There was a good correlation between CSA' (caliper measured) and CSA: CSA' = 0.78 \( \times \) CSA + 0.0458, \( r=0.996 \) (Fig. 2). All values given below were obtained by the calculation (CSA'). It was also equipped with a pressure transducer connected to an amplifier (Nihon Koden Co., Ltd., Tokyo, Japan) that measured urethral pressure simultaneously. The balloon was made of latex condom (Yamanouchi Pharmaceutical Co., Ltd., Tokyo, Japan) and its intrinsic pressure (Pbi) was lower than that of the original Harada's balloon\textsuperscript{12} so that changes in the pressure could be measured more exactly. The actual urethral pressure (Pu) is the difference between the measured balloon pressure (Pbm) in the prostatic urethra and Pbi (Fig. 3).

Then, CSA' and Pu were plotted (Fig. 4). The main slope of the graph was constructed into a straight line determined by the regression equation of \( Y = B + AX \). Assuming that the urethral length is a unit length, i.e., \( dV = 1 \text{ cm} \times d\text{CSA} \) (\( dv=\text{volume change}, d\text{CSA}=\text{change in the CSA} \)), then Comp was represented as \( \text{Comp} = dV/dP = 1 \times d\text{CSA}/dP \) (cm\(^3\)/cmH\(2\)O, \( dP = \text{pressure change} \)), and by the constant value "A" in the regression equation. The maximum CSA (MCSA) was determined by the point where CSA' reached a plateau.

Actual measurements were performed as follows (Fig. 5). When the depth of anesthesia reached a...
constant level about 20 minutes after induction of anesthesia, the dogs were placed in the supine position. After stools in the rectum were completely removed, the balloon probe introducer (14 Fr, 15 cm long) was inserted into the bladder, and urine was adequately withdrawn. Under transrectal ultrasound (TURS) guidance, the balloon probe was inserted through this introducer to the prostatic urethra, and the introducer was removed. Air in the probe was adequately removed by physiological saline, and the probe was connected to an infusion pump for physiological saline and a pressure transducer. Physiological saline was infused at a rate of $0.39 \text{ ml/min}$ using the infusion pump, and $Z_0$ and $P_{bm}$ were measured at 30-second intervals. This plot is shown in Fig. 3. The measurement was terminated about 5–6 minutes after the initiation of measurement when $Z_0$ became constant, i.e., MCSA was observed. The reproducibility of this measurement under the same conditions was within 15% for $Z_0$ and MCSA.

Changes in these parameters after drug administration were evaluated by the following procedure. Phentola-mine (1 mg/kg) was infused as a bolus intravenously. The femoral arterial pressure began to decrease immediately after the infusion and reached a constant level after about 4 minutes, when measurement was performed\textsuperscript{13} (Fig. 6).

Measurement was performed before as well as 4, 8, 12, and 16 weeks after TUBAL-H in all dogs, and at 1-week intervals from immediately after TUBAL-H until after 11 weeks in dogs in which this was possible. In addition, changes after drug administration were evaluated before and 16 weeks after TUBAL-H.

Values were statistically analyzed using paired t-test, and p values less than 0.05 were considered to indicate significant differences.

**RESULTS**

**Changes in the prostate volume**

The median prostate volume was 8.0 cc (3.3–12.4 cc) before TUBAL-H, increased to 10.8 cc (6.8–16.3) immediately after TUBAL-H, but decreased to 7.0 cc (2.9–14.8) 16 weeks after TUBAL-H.

**Serial changes in Comp**

The changes in Comp ($\text{cm}^3/\text{cmH}_2\text{O}$) in all dogs are shown in Fig. 7. Comp was $0.013 \pm 0.015$ before TUBAL-H, slightly decreased immediately after TUBAL-H, but began to increase 1 week after TUBAL-H, reaching the maximum of $0.043 \pm 0.020$ 4 weeks after TUBAL-H ($P<0.05$). Comp slightly decreased thereafter, being $0.038 \pm 0.013$ 8 weeks after TUBAL-H ($p<0.01$), and continuously decreased, reaching $0.029 \pm 0.014$ 12 weeks after TUBAL-H ($p<0.05$). Comp 16 weeks after TUBAL-H was $0.026 \pm 0.0085$, showing a further decrease, but was still significantly higher than that before TUBAL-H ($p<0.05$).

**Serial changes in MCSA**

The changes in MCSA ($\text{cm}^2$) in all dogs are shown in Fig. 8. MCSA was $0.66 \pm 0.27$ before TUBAL-H,
Fig. 7. Serial change of compliance after TUBAL-H. baseline: 0.013±0.015 cm³/cmH₂O, 8 weeks: 0.038±0.013 (p<0.01), 12 weeks: 0.029±0.014 (p<0.05), 16 weeks: 0.028±0.0085 (p<0.05).

Fig. 8. Serial change of maximum cross sectional area (MCSA) after TUBAL-H. baseline: 0.66±0.27 cm², 8 weeks: 1.18±0.31 (p<0.01), 12 weeks: 1.39±0.29 (p<0.01), 16 weeks: 1.21±0.32 (p<0.01).

Table 1. Change of urethral functional parameters after administration of α-adrenoceptor antagonist at before treatment

<table>
<thead>
<tr>
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<th>Closure pressure (cmH₂ O)</th>
<th>Compliance (cm³/cmH₂ O)</th>
<th>Cross sectional area (cm²)</th>
</tr>
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<td>Baseline</td>
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<td>0.66</td>
</tr>
<tr>
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<td>14.3</td>
<td>0.015</td>
<td>0.27</td>
</tr>
<tr>
<td>Phenolamine</td>
<td>11.0</td>
<td>0.046*</td>
<td>1.40**</td>
</tr>
<tr>
<td></td>
<td>6.3</td>
<td>0.029</td>
<td>0.25</td>
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upper: Mean lower: SD ** p<0.05 * *: p<0.01

Table 2. Change of urethral functional parameters after administration of α-adrenoceptor antagonist at 16 wks post treatment

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<tr>
<th></th>
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<th>Compliance (cm³/cmH₂ O)</th>
<th>Cross sectional area (cm²)</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>17.5</td>
<td>0.0260</td>
<td>1.21</td>
</tr>
<tr>
<td></td>
<td>2.8</td>
<td>0.0085</td>
<td>0.32</td>
</tr>
<tr>
<td>Phenolamine</td>
<td>13.0</td>
<td>0.0330*</td>
<td>1.30</td>
</tr>
<tr>
<td></td>
<td>6.2</td>
<td>0.0100</td>
<td>0.26</td>
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upper: Mean lower: SD*: p<0.05

slightly decreased immediately after TUBAL-H, but began to increase 1 week after TUBAL-H and was 0.93±0.22 4 weeks after TUBAL-H (p<0.05). MCSA further increased thereafter to 1.18±0.31 8 weeks after TUBAL-H and to the maximum of 1.39±0.29 12 weeks after TUBAL-H. MCSA 16 weeks after TUBAL-H was 1.21±0.32, showing a slight decrease, but was still significantly higher than that
before TUBAL-H (p<0.01).

**Changes in Comp after administration of an α-adrenoceptor antagonist**

Table 1 shows the changes in Comp and MCSA caused by phentolamine administration before TUBAL-H. Comp and MCSA significantly increased after drug administration (p<0.05, p<0.01 respectively).

Sixteen weeks after TUBAL-H, Comp significantly increased after phentolamine administration (p<0.05). MCSA also increased after drug administration, but not significantly (Table 2).

**DISCUSSION**

Several studies have shown that hyperthermia improves symptoms of BPH. The action mechanism has been suggested to be damage to α-adrenoceptors. However, in these studies, hyperthermia was performed using a radiofrequency waves (RF). There are no studies on the effects of hyperthermia using a laser. We previously evaluated the temperature distribution in the prostatic tissue during TUBAL in dogs and examined the interstitial temperature appropriate for hyperthermia (42-45°C) under the conditions used in the present study. This temperature distribution showed a convex pattern with a peak (45°C) at a depth of 6 mm from the urethral mucosa. A similar study on interstitial temperature after hyperthermia using RF showed a gentle temperature distribution (4°C per 1 cm) with a peak (45°C) in the urethral mucosa. Since the effects of these differences in heat distribution and the heat source, remain unknown, we examined the effects and action mechanism of TUBAL-H.

To clarify the action mechanism of TUBAL-H, we noted the changes in proximal urethral function and evaluated this with the following devices. In dogs, Pu decreases to an extremely low value with deep anesthesia, resulting in a decrease in reproducibility. Therefore, to maintain a slightly shallow constant depth of anesthesia, we used mask anesthesia. In addition, a balloon was used to measure Pu since Breslin et al. reported the histological changes after TUBAL-H, and examined the interstitial heat source, remain unknown, we examined the effects and action mechanism of TUBAL-H.

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(Received on March 7, 1996)
和文抄録

犬モデルにおけるバルーンレーザーハイパーサーミア（TUBAL-H）後の近位尿道機能の経時的変化

群馬大学医学部泌尿器科学教室（主任：山中英雄教授）
黒川 公平、鈴木 孝憲、鈴木 和浩
深堀 能立、今井 強一、山中 英雄

雑種犬6頭を用いてバルーンレーザーハイパーサーミア（TUBAL-H）を行った。TUBAL-H後の近位尿道機能の変化を評価するために、尿道内圧と尿道断面積（CSA, cm²）を同時測定し、これらからコンプライアンス（Comp, cm³/cmH₂O）を算出し経時的に検討した。さらに、これらの値のαブロッカー投与による変化を、治療前、治療16週後に検討した。

TUBAL-H前にはComp、最大尿道断面積（MCSA）の平均は、それぞれ0.013、0.66であった。8週後には、それぞれ0.038、1.39に有意に増加した（p<0.05）。16週後には、それぞれ0.026、1.21とやや減少したが、TUBAL-H前に比して有意で高値であった（p<0.05）。

αブロッカーに対する反応性では、TUBAL-H前ではフェントラミン投与で、Comp、MCSAの平均はそれぞれ0.46（p<0.05）、1.40（p<0.01）と増加した。16週後には、フェントラミン投与でCompのみが0.033と有意に増加した（p<0.05）。

TUBAL-Hにより近位尿道の弾性は増大し、4カ月間持続することが確認された。αブロッカーに対する反応性の検討から、これらの効果の一部はα受容体の障害に起因すると考えられた。

（泌尿紀要 42: 655-661, 1996）