A novel compression technique on urethra by Turkish continence device for male urinary incontinence

Abstract

**Background/aim:** Although many techniques have been described until today, male sling operation and artificial urinary sphincter implantation are common methods for treating urinary incontinence. But there are some handicaps with these methods such as infection, urethral erosion, pain, inefficiency and technical difficulties of operations. We described a new device named Turkish Continence Device (TCD) which had some advantage over the other methods.

The aim of this study to experiment the prototype of TCD in vivo and ex vivo in terms of its efficiency, convenience of implantation and negative effects.

**Materials and Methods:** We implanted prototype device in male goats and sheep for compressing posterior urethra and fixed it by sutures on lateral sides of cavernosal bodies bilaterally. Than we obtain some urodynamic findings and urinary imaging. Additionally we measured urethral closure pressure ex vivo.

**Results:** New device's balloon volume for efficient urethral closure pressure was under 1 ml. It compresses urethra towards corpus cavernosum perfectly because the prototype device's wings fixed so near place, tunica of cavernosal bodies on each side.

**Conclusion:** Therefore a smaller device with small arms/wings would be efficient for obtaining enough pressure on urethra. Additionally the technique for implanting the device is very easy and learning curve of the operation would be very short probably.

**Keywords:** male urinary incontinence; treatment; novel compression technique; experimental study; Turkish Continence Device
1. Introduction

With the increasing number of radical prostatectomy, male urinary incontinence has become common. Multicentre studies and prostate cancer databases shows that after radical prostatectomy 1% to 40% of patients complain of persistent urinary incontinence [1-3]. This large variation may be based on the influence of the interviewing physician and lack of standardized description of post prostatectomy incontinence. Iatrogenic-induced sphincter incompetence is the reason of postoperative stress incontinence in 95% of cases [4]. There have been defined many equipments and techniques for treatment of urinary incontinence. But none of them is completely efficient since there are some handicaps with each of them such as infection, urethral erosion, serious pain, inefficiency and technical difficulties of operations. The aim of this experimental study is to develop a novel prototype device (TCD) for achieving urinary continence by compressing the male urethra towards corpus cavernosum.

2. Materials and Methods

We used 3 male goats and 3 male sheep for the study which each of them is approximately 12 months old. Before the study for elaborating anatomy of the animals, we made cadaveric dissection on penis and urethra of these species. After that we excised the urethra and penis as a block. Proximal urethra has been chosen for modelling and measuring the urethral pressure produced by TCD. We studied urethral closure pressures on the apparatus which consist of excised penis-urethra specimen and prototype device implanted on it. We created the apparatus by placing prototype device on the proximal urethra by suturing to lateral surfaces of tunica albuginea of cavernosal bodies bilaterally with two sutures on each side (Figure 1). Prototype of novel devices includes a Foley catheter (6F or 8F) covered all around with prolene mesh. Not to displace the Foley balloon on urethra, the mesh leaves were braided by prolene stitches around the Foley balloon. Two prolene wings were left bilaterally to fix the device by suturing on cavernosal body's tunica (Figure 1). After that we inflated the
Foley balloon with saline (0.3-1.5 ml) until making it stretched. We inserted a nelaton catheter from distal transection of urethra and this catheter was connected to saline bag via a serum set to measure the urethral pressure produced by external compression of TCD (Figure 2). When maximal stretch of the balloon inflated, flowing of fluid from saline bag is stopped. Then we shrank the balloon gradually and measured urethral closure pressure (UCP).

After post-mortem examination of animals, we made implantation of the novel prototype devices in live animal model. We operated three male sheep and three male goats for implanting TCD model. Before the operation we gave xylazine hydrochlorur (0.2 mg/kg) by intravenously for premedication after that ketamine (17.5 mg/kg) by intravenously for general anesthesia.

Under general anesthesia, perineal area was shaved and cleaned at decubitus position. After painting perineal region with batticon, we made a vertical incision on posterior part of penile structures. Than we find and isolated cavernosal and spongiosal bodies. We made an incision on corpus spongiosum which is thin and very adherent to urethra in ram and goat. After incising of posterior urethra, we indwelled a 6F or 8F nelaton catheter for filling cystometry. It was very difficult to put on catheter by transurethrally in ram and goat without giving muscle relaxant.

We implanted TCD prototypes on posterior urethra by fixing it tunica albuginea of cavernosal bodies on each lateral side at all the animals. Foley catheter's opposite side has two tips which one is for balloon inflation/deflation and the other is for urine drainage. We cut the tab of urine drainage channel to facilitate the catheter passing inner scrotal wall and getting out of an incision on lateral scrotal wall. We purposed to inflate/deflate the balloon from this tip to arrange urethral pressure after operation. Implantation of device and getting Foley catheter's inflating/deflating channel tip out of the body we finished operation closing urethrostomy and skin incision.
We inflated the Foley balloon with 0.3-1.5 ml saline according to stretching it very tightly. After closing the incision all animals were clothed to check wetting with urine. We wondered if the animals would urinate or not. We injected diuretic (frosemid 2 mg/kg) to observe the results quickly.

On the 7th day, a ram and a goat were underwent imaging study to evaluate the degree and effect of urethral obstruction. We made intravenous nephro-pyelography and retrograde urethrography.

We fed all the animals for 1 month and then sacrificed them. We excised posterior urethra including implanted TCD prototype for pathologic investigation.

3. Results

After insertion of nelaton catheter to urethra in prototype device complex (apparatus 1), we measured UCP. We saw that a little balloon volume was enough to obtain efficient urethral closure pressure. The necessary balloon volume for efficient UCP is under 1 ml which shows that continence would be achieved in incontinent men by using very small devices. We repeated this measurement procedure on apparatus 2 and gave all UCP values at different volumes of Foley balloon at Table 1.

We could do urodynamic study intra operatively on two rams and one goat. The findings of these studies are at Table 2.

We decided that TCD prototype didn't cause complete obstruction because the clothes on all animals got wet.

We couldn't establish any pathology at renal and vesicourethral images. Then we controlled Foley balloon and we saw that it was shrunk. At least the half of saline which injected to balloon at operation was emptied. We reinjected saline mixed radiopaque substance then performed urethrography and saw balloon impression on urethra and effects of partial urethral
obstruction (Figure 3). We reinjected to previous amount of saline in to Foley balloon on all
animals.

When we sacrificed the animals and checked balloons of the Foley catheters we saw that they
were shrunk again. Macroscopically, prolene mesh was embedded in surrounding tissues of
urethra. It was dissected and urethral wall was isolated. There were not any findings of
urethral erosion or damage because of prolene mesh (Figure 4). Microscopic examination
confirmed these findings which there were not any microscopic pathologic changes in urethra
and corpus spongiosum (Figure 5).

4. Discussion

The first artificial urinary sphincter was introduced in 1973 to treat urinary incontinence [5].
The AUS 800 which is the fifth generation model created in 1983 [6]. Recently, new devices
have been developed to eliminate some disadvantages of AUS 800.

In an effort to improve efficacy of AUS and continence, some have used tandem cuffs with
though that increasing resistance over a greater area may improve continence. Brito et al was
first described successful tandem cuff placement with 95% success [7]. The using two cuffs
would lead to increase resistance to leakage without increasing pressure on a single segment
of the urethra. But subsequent longer follow up demonstrated a higher risk of complications
when using tandem cuffs [8].

In patients with recurrent incontinence secondary to erosion, sub cuff urethral atrophy,
inadequate urethral coaptation or for patients undergoing revisions where more proximal
placement couldn't be achieved, trans corporal cuff placement may improve continence [9]. In
a prospective series of trans corporal AUS placement, dry or socially continent rates were
reported to be 76% at median follow up of 20 months [10].

There is a concern that trans corporal cuff placement affects erectile dysfunction. However
most patients already have some degree of erectile dysfunction at baseline because of prostate
cancer treatment [10-12]. A small series reported that the majority of patients maintain their erectile function even after trans corporal cuff placement (5/6, 83%) [10]. Tran corporal cuff placement is the only described method that corpus cavernosum serve for purpose of incontinence treatment. In our study, we also used corpus cavernosum's tunica albuginea for fixing TCD, but our method didn't include dissecting cavernosal body like trans corporal cuff placement. Because of that, it is less invasive than that procedure and we expect that it wouldn't have any effect on erectile function.

The flow secure sphincter was manufactured with a supplemental reservoir to relieve stress pressure during intra abdominal pressure increase. During bladder filling phase, at low pressure the pressure regulating reservoir maintains the bulbous urethra closed. When intra abdominal pressure rises stress relief balloon ensures additional pressure to the cuff to secure continence [13-15]. ZSI 375 (Zephyr Surgical Implants Geneva, Switzerland) has been developed recently to facilitate AUS implantation [16]. The ZSI 375 is one -piece and made up of 2 parts connected by tubing. One of these parts is an adjustable cuff formed to fit around the urethra . The other part is a pressure regulating tank and pump that is placed in the scrotum [17,18]. Another improvement in artificial urinary sphincter area is a novel remotely-controlled sphincter [19]. It was developed using an AMS 800 to replace the pump. The new electronic pump has been designed as small as possible to facilitate its implantation and to be compatible with the existing AMS 800 tubing, cuff and balloon. The device is totally wireless. It has been tested on a fresh pig’s bladder and continence is achieved. A novel artificial urinary sphincter which tested in the canine model is the tape mechanical occlusive device (TMOD) [20]. TMOD is a one- piece device for urinary incontinence that utilizes a spring loaded mechanism to apply constructive circumferential pressure on the
urethra. Malaeb et al executed the functionality and biocompatibility of the device in canines and examining the sizing and occlusive efficiency in human cadavers.

An animal model was also used to improve a new electromechanical artificial urinary sphincter (emAUS) [21]. The emAUS consist of two parts; a contractile unit, including two or more urethral cuffs that apply synchronized sequential compression to the urethra, which is implanted intra-corporeally and an electronic board which controls it extra corporeally. The fibers of each contractile unite are composed of nitinol, a metal alloy of nickel and titanium. When the artificial muscles forming each contractile unite are relaxed, urethra opens. The animal study which performed on male sheep shows that the emAUS can provide continence. This new electronic controlled sequential alternating compression mechanism can avoid damage to urethral vascularity, at least up to 3 months after implantation.

Fabio Vilar improved periurethral constrictor (PUC) device in 1996 [22]. The PUC is a one-piece, two part device. It is comprised of a constrictor cuff linked by a 20 cm silicone tube to a valve, which is elliptical in shape. The valve is placed in a space accessible by percutaneous puncture and the system works hydraulically by the injection of sterile saline solution. A limited number of studies with controversial results have been published about using PUC in post prostatectomic urinary incontinence (PPUI). In a study 30 patients with PPUI were treated with PUC implantation. In 22 patients (73.3%), a good continence was achieved [23]. In another study performed by Introini et al, 66 patients with urinary incontinence following radical prostatectomy were treated by PUC implantation. Continence was recovered totally in 49 cases (79%), partially in 9 (15%) cases, and remained unchanged in 4 (6%). In 4 cases (6%), the device was removed because of infection/periurethral erosion [24]).

Lima et al reported a study with a very high device removal rate 41.7% [25]. The most frequent complication was urethral erosion in 15 patients (26.78%). Other complications were
mechanical malfunctions in 5, urethral stenosis in 3, urinary fistula in 2, infection in 2 and persistent urinary tract infection in 1 case. Overall success rate was 30.35%.

Male sling procedures are the common used methods for the treatment of urinary incontinence. Some kinds of tapes are available and the mechanism of sling is based on the concept of passive external urethral compression. The various sling systems have been described. The Argus system is adjustable sling including silicone cushion, two silicone columns and silicone rings / washers. It allows implant adjustment and regulation of the desired tension. There are two techniques for implantation; retro pubic approach and trans obturator approach (Argus T).

Hübner reported a series of 101 male patients treated with Argus sling for SUI [26]. Of these 22 (21.8%) were treated with RT for local recurrence of prostate cancer. After Argus implantation, adjustment was necessary in 39 cases (38.6%). The second adjustment to the sling tension was made in 7 patients. The third and the forth adjustment were made 3 and 1 patients respectively. The median follow up was 2.2 years and 80/101 (79.2%) patients were considered dry, with a pad test of 0-1 g. Sixteen patients (15.8%) had complications requiring device removal due to urethral erosion or infection after a mean of 371 (range: 20-1260) days.

The other male sling type is four arm I-STOP trans obturator male sling (TOMS) (CL Medical) is a monofilament polypropylene device. The dimensions are 45x1.4 cm with a 2.8 cm central part placed over the urethra. Grise and colleagues reported a multicentric prospective study including 122 patients with PPUI (94.9% is radical prostatectomy) [27]. At 12 months only 69 patients were available and 60 (87%) of them had improvement in the number of pads used daily; 41, 14, and 5 patients reported 0, 1 and >1 per pad daily (PPD), respectively. Only complication described was wounding of the corpus cavernosum (4 % of the patients).
AdVance trans obturator male sling (AMS, Minnetonka) is also polypropylene monofilament mesh placed retro urethrally passing tapes bilaterally through the obturator fossa. AdVance male sling essentially realigns the anatomy of the urethral sphincter complex towards the normal configuration. Rehder et al reported a multi-institutional study with 156 patients treated with AdVance male sling for SUI [28]. Patient were approved as cured based on no pad or 1 dry pad for security were used and if there was a reduction in daily pad usage of 50%. All other situation was approved as failure. After implantation of AdVance sling, pad usage was significantly decreased compared with baseline (p<0.0001) at 1 and 3 years. At the 1st year, 76.9% of patients were classified as cured or improved and this improvement is 75.7% at the 3rd year. In total 109 complications were registered which mostly Dindo grade 1 (90 patients). The most common complication was mild perineal pain. One sling device was explanted because of symphysitis. Transient urinary retention rate was 9%. The adjustable trans obturator hydraulic male system (ATOMS, AMI, Vienna, Austria) that has some similarity of our device (TCD). The ATOMS has two components; The adjustable cushion with mesh tapes suspending it by trans obturator approach and the implantable titanium port for adjusting the tension of the cushion and pressure on the urethra [29]. Honda et al reported the first results of ATOMS implantation [30]. The most common indications for placement of this device were SUI after RP (92/99 patients) and failure of previous continence devices implantation surgeries (34/99). The mean pad use decreased from 7.1 to 1.3 pads daily (p<0.001). 63% patients were classified dry (0 pad, <10 ml at 24.hour pad test) and 29% were improved (1-2 pads, 10-40 ml daily). Overall success rate was 92%. The most frequent (68.7%) reported complication were transient pain or numbness referred to the perineum, scrotum or thighs which required using non-opioid analgesics for three to four weeks. The wound infection at the site of titanium port (which leading to complete explantation of the device) occurred in 4/99 patients.
TCD isn't a real artificial urinary sphincter and it is different from sling materials and methods also. In mail sling methods, posterior bulbous urethra is hanged by passing the arms of sling material through obturator foramen or retro pubic space bilaterally. But TCD doesn't need long arms/tapes for fixation. Short wings is enough to fix it cavernosal tunica in both side. Furthermore it will be adjustable in human which the inflation-deflation port would be placed under scrotal skin. The pressure on urethra would be adjusted changing balloon volume by an injector needle inserting to inflation-deflation port from punctured scrotal skin.

In conclusion, our device (TCD) is much smaller than the others because it doesn't need long arms/tapes unlike them. It provides sufficient pressure for continence because of sitting exactly on the urethra. We use cavernosal fascia for holding and fixing TCD instead of passing the tapes retro pubic or trans obturator routes. Because of the reasons of small devices and the least invasive implantation technique, we estimate complications like as pain, infection or urethral erosion minimally. Additionally the surgical procedure is simpler, its learning curve might be shorter and peroperative complications (organ, vessel or nerve injury) might be much less than all other continence devices operations.

References


Figure 1

Figure 2
Figure 3

Figure 4
Figure 5

Legends for Figures
Figure 1: Prototype of novel devices includes for a Foley catheter (6F or 8F) which its balloon covered with prolene mesh. Two prolene wings fixed by suturing on cavernosal body's tunica bilaterally.

Figure 2: Measuring urethral closure pressure at different volumes of TCD's balloon.

Figure 3: Urethrography that shows balloon impression on urethra and effect of partial urethral obstruction (B: Bladder, BN: Bladder Neck, U: Urethra, B-TCD: Balloon of TCD).

Figure 4: Dissecting and separating of prolene mesh from urethral wall shows that there were not any findings of urethral erosion or damage.

Figure 5c (x1) and 5d (x4): Microscopic examination confirmed that there were not any pathologic changes in urethra and corpus spongiosum (Ü: Urethra, CS: Corpus Spongiosum, CC: Corpus Cavernosum) are normal on section at TCD implanted level. There aren't any pathologic changes due to TCD.

Table 1: Urethral Closure Pressures at different volumes in the balloon on apparatus 1 and 2

<table>
<thead>
<tr>
<th>Saline volume in the balloon (ml)</th>
<th>Apparatus 1 Urethral closure pressure (cmH2O)</th>
<th>Apparatus 2 Urethral closure pressure (cmH2O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 ml</td>
<td>160</td>
<td>145</td>
</tr>
<tr>
<td>1.2 ml</td>
<td>115</td>
<td>95</td>
</tr>
<tr>
<td>0.9 ml</td>
<td>88</td>
<td>65</td>
</tr>
<tr>
<td>0.6 ml</td>
<td>56</td>
<td>34</td>
</tr>
<tr>
<td>0.3 ml</td>
<td>28</td>
<td>16</td>
</tr>
<tr>
<td>0 ml</td>
<td>12</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 2: Bladder pressures at different bladder volumes in 4 subjects.
<table>
<thead>
<tr>
<th></th>
<th>Goat 1</th>
<th>Goat 2</th>
<th>Ram 1</th>
<th>Ram 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detrusor pressure of full bladder (cm H2O)</td>
<td>40</td>
<td>30</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>Bladder Capacity (ml)</td>
<td>480</td>
<td>420</td>
<td>250</td>
<td>400</td>
</tr>
</tbody>
</table>