A NOVEL COMPRESSION TECHNIQUE ON URETHRA BY TURKISH CONTINENCE DEVICE FOR MALE URINARY INCONTINENCE

Odabaş Ö[1] MD, Prof.Dr., Sancak İ G[2] Phd, Assoc.Prof.Dr., Morgülle F[2] Vet.Dr., Kasap Y[1] MD, Mahmut Z[2] Vet.Dr., Ölçücüoğlu E[1] MD, Taştemur S[1] MD, Zengin N[3] MD

[1]Urology Clinic of Türkiye Yüksek İhtisas T&R Hospital, Sağlık Bilimleri University, Ankara, Turkey
[2]Surgery Department of Veterinary Faculty of Ankara University, Ankara, Turkey
[3]Pathology laboratory of Türkiye Yüksek İhtisas T&R Hospital, Sağlık Bilimleri University, Ankara, Turkey

Introduction

Since radical prostatectomy has become more common, male urinary incontinence was seen more common too at recent years. There are different equipments and techniques for treatment of urinary incontinence. Bladder neck injection of bulking agents, balloon implantation to periurethral space, male sling operations and artificial urinary sphincter implantation are common methods for treating urinary incontinence. Although many methods have been described until today, there are some handicaps with each of them such as infection, urethral erosion, serious 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.

Methods

We used 3 male goats and 3 male sheep for the study. 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 sides (Fig 1). Prototype of novel devices includes a Foley catheter (6F or 8F) covered all around with prolen mesh. Not to displace the Foley balloon on urethra, the mesh leaves were braided by prolen stitches around the Foley balloon.Two prolen wings were left bilaterally to fix the device by suturing on cavernosal body's tunica (Fig 1). After that we inflated the Foley balloon with saline (0.3-1.5 ml) until making it stretched. We inserted a Nelaton sonde from distal transection of urethra and Nelaton catheter was connected to saline bag via a serum set to measure the urethral pressure produced by external compression of TCD model. 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) repeatedly for each volume.
After postmortem examination of animals, we made implantion of the novel prototyp devices in live animal model. We operated three male sheep and three male goats under general anesthesia. We implanted TCD prototypes on posterior urethra by fixing it tunica albugnea 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 drenage. We cut the tab of urine drainage channel to facilitate the catheter passing throughout 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 sond'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 streching 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 (frocemid 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 sacrified them. We excised postrior urethra including implanted TCD prototype for pathologic investigation.

Figure 1: The apparatus including prototype of novel devices that is a Foley catheter (6F) which its balloon covered with prolen mesh.Two prolen wings fixed by suturing on cavernosal body's tunica bilaterally

Results

After insertion of nelaton catheter to urethra with prototype device complex (apparatus 1), we measured UCP. We saw that a little 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 useing very small devices. We repeated this measurement procedure on apparatus 2 and gave all UCP values at different volumes of Foley balloon at the table 1 .
We decided that TCD prototype didn't cause complete obstruction because the clothes on all live animals got wet.
We couldn't estabilish any pathology at renal and vesicourethral images. When we sacrified the animals and checked balloons of the Foley catheters we saw that they were shrunk due to fluid leakage because of high pressure on it. Macroscopically prolene mesh was embeded 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. Microscopic examination confirmed these findings that there were not any pathologic changes in urethra and corpus spongiosum.

Table 1: UCPs at different volumes in the balloon on aparatus 1 and 2

Saline volume in the balloon (ml)	Apparatus1 UCP (Cm H2O)	Apparatus 2 UCP (Cm H2O)
1,5	160	145
1,2	115	95
0,9	88	65
0,6	56	34
0,3	28	16
0	12	10

Conclusions

There have been defined many equipments and techniques for treatment of urinary incontinence (1). But non of them is completely efficent since there are some handicaps with each of them such as infection, urethral erosion, serious pain, inefficiency and technical difficulties of operations.
Transcorporal cuff placement is the only described method that corpus cavernosum used for incontinence treatment (2). In our study, we also used corpus cavernosum's tunica albugnea for fixing TCD, but our method didn't include dissecting cavernosal body like transcorporal cuff placement. Because of that, it is less invasive than that procedure and we expect that it has no effect on erectile function.
Our device (TCD) is much smaller than the others because it doesn't need long mesh tapes or cuff-pump-reservoir unlike them. It provides sufficent pressure for continence because of sitting exactly on the urethra. We use cavernosal fascia for holding and fixing TCD instead of passsing the tapes retropubic or transobturator 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 operations for implanting other continence devices.

References

1.Caremel R, Corcos J. Incontinence after radical prostatectomy: Anything new in its management? *Can Urol Assoc J*. 2014; 8(5-6): 202–212.
2. Wiedemann L, Cornu JN, Haab E, Peyrat L, Beley S, Cathelineau X, Haab F.. Transcorporal artificial urinary sphincter implantation as a salvage surgical procedure for challenging cases of male stress urinary incontinence: surgical technique and functional outcomes in a contemporary series. *BJU. Int*. 2013; 112(8): 1163–1168.