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INITIAL HUMAN STUDIES WITH A NEW DEVICE FOR THE MANAGEMENT OF URINE INCONTINENCE

Aims of Study

Urinary incontinence (UI) is one of the major social and medical problems affecting about 40 million adults of both sexes in the Western world. From diapers to vaginal pessaries, from surgery to bulking injectables, to intraurethral plug-like devices are currently being used for the management of (UI). Although some of the surgical techniques are successful in the treatment of stress incontinence, about 50% of the patients need re-treatment after 5 to 7 years. Intraurethral plug-like devices which were introduced during the last years can mechanically block the involuntary leaking in female patients. However, these devices by being positioned in the urethra caused a communication between the bladder and the vulva, resulting in very high rates of ascending urinary infections.

Methods

In order to block the bladder outlet (BO) in both sexes and open it voluntarily for voiding a family of intra-vesical devices were designed. The in-vitro and animal study results were presented a year ago. From the 3 device designs presented a year ago 1 was found to be most comfortable to the patient and successful in preventing urine leakage. The device was inserted very easily and was retrieved as easily. It was activated voluntarily using a small magnet placed in the underwear.

Results

The device was left in the bladder up to 29 days in 20 patients. In 70% of the patients the device could occlude the BO completely (0 to 3 gr. in pad weight test). 10% reported significant improvement (1 pad per day instead of 4-7 a day). 20% of the patients could not tolerate the feeling of a foreign body in their bladder. The BO could be opened by removing the magnet situated in the underwear. Voiding measured by uroflow was unobstructed. Device related UTI developed in 15% of the patients.

Conclusions

The use of an entirely intravesical device for the management of incontinence is a novel approach. The initial clinical studies showed that this device is safe and effective in the management of UI. The device is in its final stages of development and large scale clinical studies will commence in the near future.