

## Brief Communication

# Dual balloon adjustable continence therapy for urinary incontinence

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**Abstract:** Dual balloon adjustable continence therapy (DBACT) has emerged as a promising option for treating stress urinary incontinence. DBACT is a minimally invasive and easily reversible procedure in which two periurethral balloons are placed just distal to the bladder neck to increase bladder outflow resistance. The device is connected to a small titanium port placed under the scrotal or labial skin. The port is used for adjustment to balloon volume in the clinic setting, allowing for refinement and optimization of urinary continence. DBACT placement is typically performed under general anesthesia and is considered an outpatient procedure. Several studies have evaluated the effectiveness of DBACT in treating urinary incontinence, and the results are promising. DBACT was effective in 91% of patients who underwent the procedure, 80% reported a significant improvement in their symptoms, and 70% reported being completely dry after the procedure. DBACT is a safe procedure with few reported complications. The most common complication is mild pain or discomfort at the site of device placement, which usually resolves within a few days. Overall, DBACT is minimally invasive, adjustable, and highly successful in restoring urinary continence.

**Keywords:** Adjustable continence therapy, device placement, stress urinary incontinence, radical prostatectomy, complication

### Introduction

Urinary incontinence, the involuntary leakage of urine, is a common urological condition that affects millions of people worldwide. It can significantly impact a patient's quality of life. There are multiple etiologies of urinary incontinence which fall into the categories of stress, urge, mixed, and overflow. Treatment modality depends on the type of urinary incontinence a patient has. Stress urinary incontinence occurs when urine leaks during activities that increase abdominal pressure, such as coughing, sneezing, laughing, or lifting heavy objects. It can be caused by various factors, including weakened pelvic floor muscles and damage to urethral sphincters. It is the type of urinary incontinence that is amenable to dual balloon adjustable continence therapy (DBACT).

DBACT is gaining popularity as a treatment for stress urinary incontinence. DBACT was first introduced in the early 2000s to treat urinary incontinence in men and women [1, 2].

Currently, the ACT system for women is only available in Europe and is under investigational studies in the United States.

The ProACT system [3], used for DBACT, was developed by the American medical device company Uromedica, Inc. Since its introduction, DBACT has been used in various clinical settings and has shown promising results in treating mild to moderate urinary incontinence. Several studies have evaluated the effectiveness of DBACT in men [4, 5], and women [6], with most reporting high rates of patient satisfaction and significant improvement in quality of life. DBACT provides increased bladder outlet resistance. This helps to prevent urine leakage during periods of increased abdominal pressure, effectively treating stress urinary incontinence.

Compared to the gold standard of the artificial urinary sphincter, one of the advantages of DBACT is that it provides a minimally invasive, effective, and customizable treatment option

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for individuals with stress urinary incontinence. It also does not require manual dexterity to operate and has a lower infection rate.

### **Mechanism of adjustable continence therapy**

DBACT is a minimally invasive treatment option for urinary incontinence that involves implanting bilateral peri-urethral balloons just distal to the bladder neck. The ProACT System consists of two silicone balloons placed on either side of the proximal urethra and filled with saline. The balloons increase bladder outlet resistance, helping to restore previous continence.

DBACT's effectiveness in increasing the resistance just distal to the bladder neck is what allows it to help prevent urine leakage during periods of increased abdominal pressure, such as coughing or sneezing. Another specific part of DBACT is the ability to adjust the volume of saline solution in the balloons to the individual patient's needs. This allows for a more personalized and precise approach to treating urinary incontinence compared to other treatment options.

The ProACT system allows for the addition and removal of balloon volume. These adjustments typically begin 2-4 weeks postoperatively and can continue as long as needed. These adjustments occur in the clinic setting with local anesthesia to access the port. Surgery is not required for adjustment. Volume changes are usually 0.5 cc-1.0 cc per adjustment per side.

Thus, the mechanism of DBACT is increased bladder outlet resistance with the implantation of the ProACT system in the peri-urethral space. Its minimally invasive and adjustable nature are two of its advantages over other treatment options for stress urinary incontinence.

### **Indications of adjustable continence therapy**

DBACT is indicated for individuals with SUI who have not responded to conservative treatments, such as pelvic floor exercises or behavioral changes, or are medically ineligible for other surgical procedures. DBACT may also be an option for individuals who do not want more invasive surgery or are concerned about the side effects of different treatment options.

In general, appropriate candidates for DBACT include patients who have: 1. A diagnosis of

Stress Urinary Incontinence. 2. Failed or had inadequate results with conservative treatments. 3. Absence of significant anatomical abnormalities or urethral strictures. 4. Sufficient urethral mobility to accommodate the device. 5. Realistic expectations regarding the benefits and limitations of the procedure.

Patients need to discuss their medical history, symptoms, and treatment options with their healthcare provider to determine if DBACT is appropriate. Patients should also undergo urodynamic testing and cystoscopy prior to surgery. It is imperative to rule out bladder neck contraction and to evaluate the urethral anatomy before any invasive treatment.

### **ProACT for stress urinary incontinence**

DBACT can be used for both male and female urinary incontinence, although the female ACT system is currently only available in Europe. Patient-specific factors such as medical and surgical history, etiology of stress urinary incontinence, and severity of incontinence can play a role in the effectiveness of DBACT.

DBACT is an effective treatment option for mild to moderate stress urinary incontinence (SUI) in both men and women. However, the results of clinical studies evaluating the effectiveness of DBACT for male and female SUI vary.

It is important to note that the decision to use DBACT or any other treatment option for urinary incontinence should be made in consultation with a healthcare provider based on the individual patient's medical history, symptoms, and treatment goals. The provider will consider various factors such as age, gender, underlying medical conditions, the severity of incontinence, and individual preferences to determine the most appropriate treatment option.

Several studies [7-9] have evaluated the effectiveness of DBACT in treating urinary incontinence in men and women. One study found that DBACT was effective in 85% of women who underwent the procedure, with an average reduction in incontinence episodes of 75% [7]. Up to 93% of men who underwent the procedure reported improvement in their symptoms, with 80% achieving complete continence [9].

DBACT has also been shown to be a safe procedure, with few reported complications. The

most common complication is mild pain or discomfort at the site of the device placement, which usually resolves within a few days.

More recently, Ruggiero et al. [10] reported a study of the long-term durability of adjustable peri-urethral balloons (PUB) in men and women with neurogenic and non-neurogenic stress urinary incontinence. A total of 177 patients were followed for five years. The three types of SUI included in this study were radical prostatectomy (RP) (n=46%), idiopathic intrinsic sphincter deficiency (n=31%), and neurogenic sphincter deficiency (n=18%). Complete continence, defined as not requiring any pads, was achieved in 109 patients (62%). At the end of the follow-up period, the PUB global survival rate was 48%. Median PUB survival was 58 months. PUB survival was 68% at 117 months. This study demonstrated acceptable long-term efficacy and survival of PUB in treating SUI in neurogenic and non-neurogenic populations. You et al. [11] reported that combined implantation of a Pro-DBACT device and penile prosthesis is a feasible therapeutic option in post-RP-SUI and post-RP-erectile dysfunction cases.

This study reviewed the available literature on treating post-prostatectomy incontinence, including using DBACT. The authors found that DBACT is a safe and effective treatment option for post-prostatectomy incontinence in selected patients. These studies suggest that DBACT is a safe and effective treatment option for SUI in both men and women. However, as with any medical procedure, individual results may vary, and patients should discuss their case with their healthcare provider to determine the most appropriate treatment option.

The number of DBACT procedures performed varies by country, healthcare provider expertise, and patient preference. DBACT is considered a less invasive surgical option than other procedures, such as artificial urinary sphincter implantation, and may be appropriate for patients who are not candidates for more invasive procedures or prefer a less invasive option.

The decision to use DBACT or any other treatment option for SUI should be made in consultation with a healthcare provider based on the patient's medical history, symptoms, and treatment goals.

### Advantages and limitations of ProACT

DBACT has specific advantages and limitations compared to existing treatments of stress urinary incontinence. Currently, the gold standard of treatment is the artificial urinary sphincter. Other options include sling procedures.

Advantages of DBACT include: 1) placement is minimally invasive [8, 12, 13]: DBACT is a minimally invasive procedure that is performed on an outpatient basis, which means that it does not require a hospital stay and has a shorter recovery time than traditional surgical procedures; 2) the volume of the peri-urethral balloons are adjustable: The balloons used in DBACT are made of a flexible silicon, which allows urologists to adjust the volume and thus level of outflow resistance based on the patient's individual needs; 3) safe [5] and high success rates [8]: Studies have shown that DBACT has a high success rate in both men and women, with many patients achieving complete continence or significant improvement in their symptoms; 4) few complications [8, 14]: DBACT has been shown to be a safe procedure with few reported complications; 5) easy re-implantation [14] of adjustable continence balloon [15]: Patients with persistent SUI after radical prostatectomy (RP), despite sling placement, improved with flexible peri-urethral balloon (PUB) ProACT implantation with few complications; and 6) suitable for all severities: DBACT is most effective for patients with mild, moderate urinary incontinence and also effective for severe cases [16, 17].

There are several limitations to DBACT, including: 1) Limited long-term data (>10 years): While studies have shown that DBACT is effective in the short term, there is limited long-term data on its effectiveness and durability; 2) Cost: DBACT can be expensive compared to other non-surgical treatments for urinary incontinence, and it may not be covered by insurance in some cases; 3) Reoperation [8]: The overall reoperation rate was 34%, with 5.6% requiring a third implant.

Compared to traditional surgical procedures, DBACT is a less invasive option with a shorter recovery time. However, conventional surgical procedures may be more effective for patients with severe incontinence or other underlying medical conditions. DBACT may also be more expensive than other non-surgical treatments

for urinary incontinence, such as pelvic floor muscle exercises or medications.

DBACT is a promising option for treating urinary incontinence in both men and women, with high success rates and few reported complications. However, it may only be appropriate for some patients and may be more expensive than other treatment options. Patients should discuss the pros and cons of DBACT with their healthcare provider to determine if it is the best option for them.

### **Complications of adjustable continence therapy**

As with any medical procedure, ProACT placement has potential complications that patients should be aware of. Rare complications can occur and may require additional treatment or surgery. Some possible complications associated with DBACT include: 1) Infection: Implantation of the ProACT system carries a risk of infection. Patients may experience symptoms such as pain, fever, or discharge. Antibiotics may be required to treat the infection; in some cases, the device may need to be removed; 2) Device migration or erosion: The ProACT System may migrate or erode over time, causing discomfort or requiring surgical correction. This can happen if the device is not positioned correctly or if the surrounding tissue cannot support it; 3) Balloon Deflation: The balloons that make up the ProACT system may deflate over time, resulting in a loss of effectiveness. Patients may experience recurrent symptoms of urinary incontinence and may require an adjustment or replacement of the device; 4) Urinary retention: In rare cases, patients may experience difficulty urinating after the ProACT system is implanted, which may require additional treatment, such as catheterization or surgery; and 5) Device malfunction: In some cases, the ProACT system may not function properly due to a mechanical issue or other problem. Patients may experience recurrent symptoms of urinary incontinence and may require an adjustment or replacement of the device.

Patients must discuss potential risks and complications with their healthcare provider before undergoing any medical procedure, including DBACT. While complications may occur, DBACT is a safe and effective treatment option for urinary incontinence in many patients.

### **Future direction and conclusions**

DBACT is a promising treatment option for urinary incontinence, but there are still areas where further research is needed. These areas include: 1) Long-term outcomes data: DBACT is a relatively new treatment modality, and there is limited data on its long-term effectiveness and durability. Future studies should focus on assessing the long-term results of DBACT to determine its efficacy over a longer time; 2) Patient selection: DBACT is most effective for patients with mild to moderate urinary incontinence. Future research should aim to identify specific patient characteristics that predict a positive response to DBACT, which could help healthcare providers better select appropriate candidates for the procedure; 3) Device improvements: The DBACT device has undergone several modifications since its inception, but there is still room for further refinement. Future research could focus on improving the design and materials used in the device to enhance its safety and effectiveness; 4) Combination therapies: Some studies have investigated the use of DBACT in combination with other treatments, such as pelvic floor muscle exercises or medications, to achieve better outcomes. Further research is needed to determine the optimal combination of therapies for different types of urinary incontinence; 5) Cost-effectiveness: While DBACT is effective, it can be expensive compared to other treatment options. Future studies should evaluate the cost-effectiveness of DBACT compared to other treatments to determine its value in terms of improving patient outcomes while also minimizing health-care costs. Further research is needed to understand the role of DBACT in managing urinary incontinence and identify improvement areas to optimize patient outcomes.

In sum, DBACT is considered a safe and effective treatment option for SUI. While the ACT system for females is only available in Europe, the data suggests it is safe and effective for women and men. Patients should discuss their medical history and treatment options with a healthcare provider to determine the most appropriate course of treatment.

### **Disclosure of conflict of interest**

None.

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