CONTASURE NEEDLELESS: A SINGLE INCISION TOT FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE

Rafael Navazo, Jesus Moreno, Cristina Hidalgo, Miguel Angel Herraiz, Jose Antonio Vidart, Jesus Salinas and Angel Silmi.

Pelvic Floor Unit. Universidad Complutense. San Carlos Clinic Hospital of Madrid, Madrid. Spain.

Summary.- OBJECTIVES: The aim of this study is to describe the surgical technique, and assess the complications and middle-term results of the Contasure Needleless (Neomedic International), a single incision TOT sling for the surgical treatment of stress urinary incontinence.

The main concept of this device is that it is not a mini-sling, it has 138% more surface area. We are analyzing the results of a minimally invasive solution that is a TOT like sling with the same known benefits of a TOT and the advantages of a single incision technique. The surface area to support the urethra of the Needleless is very similar to the surface area of the TOT. (16% less surface area of tissue ingrowths) It is 100% macroporous polypropylene without any additional material.

METHODS: 120 patients were evaluated retrospectively. They were all treated of SUI with the Contasure Needleless. Female patients were evaluated under clinical study protocol consisting in cough test, urodynamic and Quality Of Life questionnaire, before and after the procedure. Inclusion criteria: patients with genuine SUI and patients with SUI plus concomitant procedures as prolapse. Exclusion criteria: patients with ISD and or neurogenic incontinence. Anesthesia used: general (30%) or epidural (70%), patients with associated pathology.

PROCEDURE: The 114 mm long and tension-free mesh was placed beneath the midurethra. The central part is 12mm wide. The sling can be repositioned during surgery due to the 22mm wide TPocket Positioning System located at the 2 edges. These pockets fixed the sling to the surrounding tissue in order to have the proper tissue in growth and anchoring. A 20mm sub urethral incision was made to dissect the paraurethral spaces only up to the ischiopubic ramus. A surgical forceps with the Tpocket folded was inserted into the dissected spaces and penetrates at the contra lateral side, like the standard transobturator technique. The forceps was introduced until the fascia of the Internal Obturator muscle was perforated. Then the forceps is opened to extend the pocket inside the muscle fibers for fixation.

RESULTS: 120 patients with a mean age of 55 years (from 36 to 79) and a mean number of deliveries of 3 (0-7). Follow-up period: 24 months. Success rate: 100 patients (84%) Improved rate: 10 patients (8%) Failure rate: 10 (8%) Mean operating time of sling procedure alone: 9 minutes (4-12). Complications: 3 patients had mesh extrusion solved with estrogens and 2 patients required short term catheterization due to voiding difficulties and no patients had inguinal pain.

CONCLUSIONS: The results of the study suggest that the Contasure Needleless can be considered a minimally invasive TOT with no-needles and maintaining the same cure rate than our TOT cases at 2 years follow up.

CORRESPONDENCE

Jesus Moreno
Urology Department
Hospital Universitario San Carlos
Avda. Martín Lagos s/n
28040 Madrid (Spain).

jmoreno-sierra@orange.es

Accepted for publication: April 23th, 2009.
Resumen.– OBJETIVO: El objetivo de este estudio es describir la técnica quirúrgica, medir la seguridad, resultados y posibles complicaciones a medio plazo de una técnica sin agujas Contasure Needleless (Neomedic International) un TOT de una sola incisión para el tratamiento quirúrgico de la incontinencia urinaria de esfuerzo.

Un Concepto básico de esta malla es que no es un Minislings, el Contasure Needleless es un TOT de una sola incisión posee una superficie de fibrosis 138% mayor que los minisling. Analizaremos el resultado de este procedimiento mínimamente invasivo. El área de soporte uretral del Contasure Needleless es muy similar al TOT (un 16% menor). El material es 100% polipropileno macro poroso.

MÉTODO: 120 pacientes fueron evaluadas retrospectivamente. Todas las pacientes fueron operadas por incontinencia urinaria de esfuerzo con Contasure Needleless. El protocolo clínico que se siguió en todas estas pacientes fue test de esfuerzo, estudio urodinámico y cuestionario de calidad de vida antes y después del procedimiento. El criterio de inclusión fueron pacientes con incontinencia urinaria de esfuerzo en muchos casos con cirugía asociada. Pacientes con déficit intrínseco del esfínter o incontinencia neurógena fueron excluidas del estudio. La anestesia fue general en un 30% de las pacientes y epidural en un 70%.

Se coloca una malla de polipropileno libre de tensión en la uretra media de 114 mm de largo (Contasure Needleless). La parte central la malla tiene 12mm ancho. La Malla puede ser ajustada durante la cirugía, posee dos bolsillos a cada lado. Estos bolsillos ayudan en un primer momento a mantener la malla y mas adelante proporcionaran un soporte a la malla debido a la fibrosis. Se hace una incisión suburetral de 20mm y se disecan los espacios pararetrales hasta la rama isquio-pubica. Una Bengolea se introduce en los bolsillos y se cierra, después se inserta en los espacios disecados hasta penetrar el músculo obturador interno abriendo el bolsillo una vez penetrado el músculo, los mismos pasos se realizan en el lado contrario.

RESULTADOS: 120 pacientes con una edad media de 55 años (36 a 79) y una media de 3 partos (0-7). Seguimiento medio: 24 meses. De los 120 pacientes 100 de ellos (84%) están totalmente curados, Mejorados 10 pacientes (8%) y fracasos un 10 (8%). El tiempo medio de operación de colocación de la malla fue de 9 minutos (4-12). Complicaciones: 3 pacientes tuvieron una extrusión vaginal de la malla resuelta con estrógenos y 2 pacientes tuvieron dificultades temporales de vaciado, ningún paciente sufrió de dolor inguinal.

CONCLUSIONES: Los resultados del estudio sugieren que el Contasure Needleless puede ser considerado un tratamiento de elección para tratamiento quirúrgico de la incontinencia urinaria de esfuerzo. Es un tratamiento mínimamente invasivo, sin el uso de agujas y mantiene resultados similares de curación a dos años de seguimiento que el TOT convencional.

PALABRAS CLAVE: Incontinencia Urinaria de Esfuerzo. TOT con una sola incisión.

INTRODUCTION

Stress urinary incontinence (SUI) is defined by the International Continence Society (ICS) as the involuntary loss of urine that create an hygienic and social problem and affect in the quality of life of the patient (1). It’s a pathology that affects an important number of females, with an important social and economic consequences with a prevalence approx. 2.5 (2). SUI is more frequent after several deliveries, after menopause as a result of changes in the urethral support or the sphincter mechanism (3). Several surgical procedures have been developed to treat this anatomical defect. Retropubic colposuspension described by Burch in 19612, is the procedure that have demonstrated higher success rate at short and long term, with success of 85-90% at five years and 70% of continence during the following five years3. In spite of these good results, the Burch technique is not free from secondary effects as the voiding dysfunctions, “de novo” urgency or anterior prolapse in aproximity 20% of the cases (4).

Following the principles of the integral theory of the SUI developed by Petros and Ulmsten, the incontinence mechanism is based on a combination of anatomical structures (pubourethral ligaments, vaginal hammock and pubococcigeus muscle) integrated in a complex coordination to open and close the bladder neck and the urethra (5). The laxity of the vaginal hammock drives to the bladder neck descending when abdominal pressure increases; based in this model, in 1995, Ulmsten developed a new technique based on a polypropylene sling to support the urethra tension free (TVT®) (6).

When the sling is inserted we pretend:

- Reestablish the pubourethral ligaments
- Support the suburethral vaginal wall (hammock)
- Connect the urogenital structures (Integral Theory)

The vaginal tension free techniques have done similar results to the Burch Colposuspension
with the advantage of a minimal invasive procedure with less morbidity. Based on the published data, we can consider the tension free technique a procedure with the same short (7) and long term (8,9,10). The most frequent complications of this technique are a consequence of the pass of the needles to place the sling. Bladder perforation (0-23%) or Retzius hematoma (0.8-3.3%). Also described cases of bowel perforation, vascular and nerve lesions (11). Based on the original technique, Delorme develops a new technique passing the sling through the obturator foramen, avoiding the pass of the needless through the retropubic space (12) to minimize the risk of bladder perforation and Retzius space hematoma, reducing surgical time avoiding cystoscopy (13). Jean de Leval modifies this technique inserting the sling from the vagina to the obturator foramen (14), to avoid even more the potential complications (vascular and neurologic) related to the pass of the needle through this territory. Initial results show a cure rate similar to the retropubic technique but with a lower intra and postoperative complications (15). All of that have driven to an improvement of the complication rate from a revolutionary SUI treatment maintaining the good initial results in a very short period of time.

Jean Leval modified the technique following the route from the vagina towards the obturator muscle (16) to avoid vascular and neurological problems related to the pass of the needless through this route. The initial results were similar to the retropubic technique but with less risk of during surgery and in the postoperative period (17). All of these points allowed to had an important descend of complications in this technique.

**OBJECTIVE**

With objective to simplify the previous techniques and minimize the complication rates related to the pass of the needless, a new technique has been developed maintaining the principle of a tension free sling, and introducing the concept of Needleless. The sling is positioned without needless, maintaining the sling under the midurethra as a hammock (Needleless Technique®).

**MATERIAL Y METHODS**

The first 120 patients have been analyzed prospectively using the Needleless technique in the Pelvic Floor department of the Hospital Clinico San Carlos de Madrid. All the patients had a clinical anamnesis with Quality of life questionnaire and a urodynamic study.

All the patients presented SUI for urethral hypermobility from a moderate to a severe grade. The Needleless sling is manufactured in Polypropylene monofilament of 0.4mm diameter, macroporous (Amid I), and a porosity of 55%, with a dimension of 114 x 12 mm. The extremes of the sling are wider 22 mm with a pocket conformation to help in the sling positioning and better support the stress (Figure 1). This Pockets are the major feature of this sling. We analyze age, parity, associated surgery, incontinence degree, surgical time, intra and postoperative complications, and the continence short term results.

**TECHNIQUE**

The technique can be performed under whatever anesthesia, preferably local or regional. With the patient in lithotomic position and the legs flexed, the bladder is emptied by a Foley catheter. A longitudinal incision (1 – 2 cm.) is made at the vaginal mucosa under (0.5 cm.) the urethral meatus. A submucosal blunt dissection of the paraurethral spaces to this incision are performed at both sides (at 10 and 2 o’clock) until the descending ramus of the isquiopubic ramus is reached. A surgical forceps (Kocher or Ben...
R. Navazo, J. Moreno, C. Hidalgo et al.

golea) is placed inside the pocket positioning system of the Needleless mesh and by opening and closing the forceps the mesh is folded into the forceps (Figure 2).

The forceps with the folded mesh is introduced into the paraurethral space and the internal obturator muscle is penetrated by controlled pushing force (Figure 3).

The forceps is then open to extend the “T” pocket positioning tip of the Needleless sling (Figure 4), and then closed and pulled off the vagina, leaving the Needleless fixed.

To control the penetration of the forceps tip and the sling into the internal obturator muscle, the surgeon may hold the central part of the sling by the two traction threads connected to the sling. The same maneuver is done at the contralateral side to complete the sling insertion. Once the sling is introduced, it can be repositioned up to give more support to the urethra, by introducing again the tip of the forceps into the pocket positioning system and pushing the sling further up. To decrease the sling urethral support, the surgeon can pull the traction suture placed at the center of the sling. When the sling is fully positioned, in full contact with the submucosa, the traction thread will be cut in one of its sides and by pulling the other side the thread will be completely withdrawn from the sling. The vaginal incision will be closed by an absorbable suture of 2/0. A urethral catheter is maintained until the anesthesia effect disappears and the patient will be discharged after checking that the post voiding residual is less than 100 cc.

RESULTS

The following parameters from the first 120 patients operated with the Needleless system are analyzed: Mean age, vaginal deliveries, years of evolution of the SUI, associated surgery, urodynamic, Sandvik severity test, mean surgical time, post surgical urethral catheterization, immediate postoperative complications, and Sandvik severity test after 1 month. The mean age of the patients was 50 years (40-70), mean vaginal deliveries was 3 (1-4). Time with incontinence before the intervention: 10 years (1-30).

All the patients present clinical symptoms of urinary incontinence that were confirmed by the urodynamic study. The mean Sandvik severity test rate was 8 (3-11). There was an associated anterior vaginal repair in 70 patients, 30 patients had a hysterectomy at the same intervention and the rest had no associated prolapse.

The mean intraoperative time was 10 minutes (5-15) and the mean urethral catheterization was 1.5 days (1-2) taking in consideration that the patients with 2 days catheterizations were the ones with associated repairs due to cystocele III or IV.

During immediate postoperative there was one acute urine retention that was solved by catheterization. In this patient an anterior vaginal repair was performed. There are no cases of inguinal pain, hemorrhage, hematoma, urinary infection or vascular or visceral damage.

After a mean follow up period of 5.3 months (range 3-12), 100 patients (84%) are objectively cured of incontinence (Sandvik and stress test negative). 10 of them improved their incontinence (8%) and 10 (8%) patients are considered failures.
Later complications include one case of partial sling extrusion (0.5 cm) that actually is in faze of resolution by estrogens medication.

CONCLUSIONS

The Needleless technique provides a new concept to treat SUI with a tension free sling, and due to its easy of use and low complication rate it accomplishes the criteria of minimal invasive treatment.

REFERENCES AND RECOMMENDED READINGS
(*of special interest, **of outstanding interest)