SINUG CONSENSUS DOCUMENT ON THE USE OF MESHES IN THE TREATMENT OF URINARY INCONTINENCE.

C. Muller, A. Martín, B. Padilla, P. Blasco, M. Espuña, F. Cruz, C. Errando, R. Martínez, E. Vicente, D. Castro, L. López-Fando, B. Madurga, C. Ros, S. Arlandis.

1.- INTRODUCTION

a. **Definition.**
b. **Types of urinary incontinence**
c. **Prevalence of urinary incontinence**
d. **Impact of UI on quality of life**
e. **Surgical treatment of urinary incontinence**
f. **Meshes in the treatment of urinary incontinence**

Most scientific societies use the definition proposed by the International Continence Society (ICS) to define UI. According to the ICS, UI is defined as any involuntary loss of urine[1]. This definition covers various aspects of UI, including symptoms, physical signs and urodynamic parameters [2].

Urinary incontinence (UI) is an important medical and social problem that is becoming more and more common due, among other reasons, to the ageing of the population. Recent estimates put adults with UI at 200 million. UI is highly prevalent in the adult population and two to four times more common in women than in men. The incidence of UI increases almost linearly with age, to the extent that it is considered as one of the geriatric syndromes due to both its high prevalence in people over 65 years of age and its negative impact in the elderly with UI [3].

At the same time, the rate of consultations generated by this important health problem is surprisingly low [4] and most patients living in communities use absorbent products, influenced by individual, sociocultural and purely healthcare-related factors[5]. The prevalence figures reported in different studies vary enormously,

depending on a series of factors such as the concept of incontinence, study method, level of care studied and other sample characteristics[4]. In epidemiological studies in adult women of all ages, UI prevalence rates range between 20 and 50%. Institutionalised patients, particularly women, represent a specific group with a high UI prevalence in the 50-60% range[3,9].

UI is not a life-threatening disease, but it significantly deteriorates patient quality of life as it reduces their self-esteem and undermines their autonomy[6]. The impact of the health-related quality of life (HRQoL) due to UI may be even greater than that of certain chronic diseases such as diabetes or high blood pressure.

Types of urinary incontinence

It is considered that UI and voiding dysfunctions can be classified according to symptomatic and urodynamic criteria, in accordance with ICS guidelines published in a standard terminology document[1]. According to symptomatic criteria, stress urinary incontinence (SUI) is included as one of the main types of UI.

Stress urinary incontinence (SUI) is defined as the involuntary loss of urine during physical effort, such as coughing, laughing, running or walking, causing an increase in abdominal pressure. It occurs when intravesicle pressure exceeds urethral pressure as a consequence of a failure of the mechanisms responsible for urethral resistance, for two non-exclusive causes:

- Urethral hyper-mobility, with failure of the urethral closure mechanisms, causing the urethra to drop from its correct anatomical position.
- Intrinsic sphincter deficiency, in which there is insufficient coaptation of the urethral walls, resulting in diminished urethral resistance.

SUI is the most frequent form of UI in women under 75 years of age, affecting almost 50% of these women [5,10]. It is rare in elderly males and is usually associated with previous prostate surgery (both transurethral and suprapubic)[4].

Prevalence of urinary incontinence by subtypes

Some extensive epidemiological studies claim that SUI is the most frequently reported symptom of UI. Pure SUI affects 10-20% of incontinent women, while 30-40% present mixed urinary incontinence (MUI) symptoms[11,12]. Since MUI is a combination of SUI and UUI, most women, regardless of their age, complain of SUI with or without other symptoms in the lower urinary tract. The foregoing percentages are in line with those reported in the extensive EPINCONT study[7], in which 50% of incontinent women presented symptoms of SUI, 11% symptoms of UUI and 36% symptoms of MUI.

The percentage of incontinent women with SUI peaks in around the fifth decade of life (range: 28% to 65%)[5,10]and then declines after the sixth decade. In contrast, MUI is more frequent in older women, affecting between 40 and 48% in the range of 60 years and older[5].

Impact of UI on quality of life

Several studies have attempted to measure health-related quality of life (HRQOL) in incontinent women. These studies vary in their design, methodology, criteria for diagnosing UI and even definition of quality of life. However, they all affirm that UI has a significant negative impact on multiple aspects of daily life, in both the social context (less social interaction or greater isolation, abandonment of certain hobbies, etc.), and physical (performance limitations for sports), sexual (loss of sexual activity, avoidance of partner), psychological (loss of self-esteem, apathy, depression, feelings of guilt, etc.), work (absenteeism, fewer relationships) and domestic (special precautions with clothing, bed protection, etc.) contexts[13].

Women with UI develop behavioural habits as defense mechanisms against the problem, such as reduced fluid intake, isolation and social withdrawal, the use of absorbent pads and specific voiding frequency, as well as other voiding habits[14].
UI mainly affects the HRQOL of younger people and is related to the type of UI in each case[15]. The ICS recommends including quality of life parameters in the evaluation of UI treatments using mixed symptoms and quality of life questionnaires.

Surgical treatment of stress urinary incontinence

Treatment options for women diagnosed with SUI are: *conservative* (change of habits and re-education of pelvic floor muscles) or *surgical* to eliminate hyper-mobility or increase urethral resistance during exertion. Recommendations in clinical practice guidelines indicate that the surgical treatment of SUI is indicated when conservative treatment has failed[16]. Its purpose is to increase urethral resistance to prevent urine from escaping through the urethra during increases in intra-abdominal pressure, preserving full bladder voiding at low pressure. There are around 200 different surgical procedures for treating SUI, but according to some authors, these may be grouped into three basic types: colposuspensions, suburethral slings and urethral injectables[17].

Surgical treatment aims to improve urethral support and thus increase urethral resistance during stress. In cases of clear urethral hyper-mobility, and even in cases of intrinsic sphincter insufficiency that is not serious or associated with a fixed urethra, tension-free urethral suspension techniques (minimally invasive techniques such as TVT or TOT) have become reference techniques, displacing

colposuspension techniques such as Burch's technique, which was the most used and effective technique for many years. Tension-free urethral suspension techniques are based on the studies by Petros and Ulmsten, who proposed a new concept within the functional anatomy of the pelvic floor (the Integral Theory developed by Petros)[18], consisting of inserting a synthetic mesh (made of monofilament braided polypropylene) under the urethra, towards the posterior face of the pubis in the case of TVT or towards the obturator holes in the TOT technique (as with mini-slings), to reinforce the pubic-urethral ligament. The tape is placed without tension to support the urethra that is only activated when the patient makes efforts.

In cases of suspected predominant intrinsic sphincter deficiency, with fixed urethra, a more occlusive technique should be more used. For many years, sling-based techniques were used in which the urethra was suspended by means of a tape, normally with autologous aponeurosis, and located near the bladder neck. Today, minimally invasive and adjustable techniques are used and are mainly recommended for treating this type of incontinence. Other techniques have been used, such as the injection of different substances into the peri-urethral zone (*bulking* techniques), but so far their effectiveness has not been fully demonstrated. In selected female patients, artificial sphincter implants may be the solution, although this is a more complex solution from a technical standpoint than in men.

Tension-free mid-urethral slings (MUS) have become the most popular procedure for the treatment of SUI. This treatment is less aggressive than any of the other sling procedures, and can even be performed under local anaesthesia. Its purpose is to restore the adequate fixation of the mid urethra to the pubis, reinforcing the pubic-urethral ligaments. A tension-free polypropylene tape is inserted at the level of the mid urethra so that it exerts sufficient pressure on the urethra during increases in abdominal pressure to prevent the escape of urine. Cure rates stand at around 66-91%, with efficacy maintained beyond 5 years and a satisfaction rate of 85% in operated patients[17]. Available data also indicate that these cure rates are similar to those obtained with open colposuspension procedures, although it is important to clarify that published results may vary depending on the criteria used to define "cure" and the follow-up time, which may fall to 50%[19]. The most frequent intra-operative complication is bladder perforation (affecting around 9% of patients), although bladder voiding dysfunctions (3-5% of patients), urinary tract infections (6-22%) and "de novo" bladder over-activity (3-9%) have also been reported[20].

Meshes in the treatment of UI

Synthetic meshes are made from polymers designed to strengthen soft tissues in areas of tissue weakness. They were first used in the 1950s to treat abdominal

hernias. and were later employed to repair pelvic organ prolapse (POP). In the nineties, surgical meshes began to be used to treat SUI. The success of the transvaginal *tension-free* mechanism introduced by Ulmsten and Petros in 1995 fuelled the widespread development of transvaginal synthetic mesh systems. Consequently, in 1996 the *Food and Drug Administration* (FDA) approved the first surgical mesh manufactured specifically for use in SUI and in 2002 it approved the first mesh for use specifically in POP. Since then the use of transvaginal meshes to treat pelvic floor pathologies has increased exponentially, especially the different forms of female POP[21].

The FDA classifies prosthetic materials according to their risks and complications as follows:

- Class I Very low risk. Only general controls are required.
- Class II Low-moderate risk. Special controls are required.
- Class III High risk. Premarket approval is required, and efficacy and safety studies are necessary.

Data from synthetic mesh manufacturers indicate that in 2010, 300,000 women underwent surgical procedures to repair POP and approximately 260,000 were operated on for SUI. According to these estimates, approximately more than 80% of the surgical techniques for UI treatment were performed transvaginally with meshes[19,22].

MESH CHARACTERISTICS

Based on published experimental data, polypropylene seems to be the most suitable material for use in tension-free meshes used to correct SUI[23]. Descriptions have been provided of the required characteristics of meshes for use as slings in anti-incontinence surgery: Type I on the Amid classification[24] (macroporous, monofilament, 20-35% elasticity and low grammage).

The FDA includes meshes used in urogynaecology for POP repair in class III and those employed in colposacropexy by the abdominal route and meshes for anti-incontinence surgery in class I (Reclassification of Urogynecologic Surgical Mesh Instrumentation Food and Drug Administration Gastroenterology-Urology Medical Devices Advisory Committee Panel. February 26, 2016).

Meshes for SUI

Mid-urethral slings (MUS) have been widely used to treat SUI, with successes rate between 51% and 99%. The mesh must be made from Amid type-1 tape (as described previously). The MUS must be inserted tension free. However, no standard method has been established for achieving this, and difficulties exist in evaluating

tape tension tension intra-operatively. The placement of prosthetic meshes can have complications. These complications include vaginal extrusion with associated symptoms: bleeding, discharge, or pain during the sexual activity of the patient (dyspareunia) or her partner. Erosion of the urinary tract is the main complication and very frequently involves the bladder and/or the urethra, with an incidence rate of 0 to 30% [15] in different series. This wide variability can be explained in reports on series of cases, but in long-term studies with larger series the reported percentages are significantly lower (less than 10% in general and more specifically 2.5% in TOT and 2.1% in TVT)[19,22,25]; different symptoms may appear, such as urinary frequency, urgency, dysuria or urinary tract infections. Other studies have reported pelvic pain and dyspareunia, affecting between 0.6 to 24% of patients, with unclear aetiology. These results can be partially attributed to the fact they were reported in studies of personal series with short follow-up times; pain is more common in the first 2 weeks, affecting 30% of patients but diminishing significantly at 6 months, and more specifically 5.1% in TOT and 3.1% in TVT patients, and only requiring pharmacological analgesia in 1% of cases[26]. Erosion and contraction of the inserted material are thought to be the cause, affecting between 3% and 13% of patients[17,25]. Infection is rare, affecting less than 1.6% of all cases reported in literature[27].

In initial studies, similar efficacy was observed when comparing treatment involving the use of tension-free tapes with retro-pubic colposuspension. However, in long-term follow-up, better cure rates have been reported for MUS when compared to retro-pubic colposuspension[20, 27].

2.- CURRENT STATE OF THE TOPIC

Before the appearance of MUS in the 1990s, the surgical treatment of choice for UI was colposuspension. The appearance of meshes facilitated the simplification of the technique, with efficacy and safety rates comparable and even superior to those obtained with the open technique (Burch)[28], and presenting huge advantages for treated women and for surgeons tackling this pathology. However, the procedure was often undervalued, so it was sometimes performed by staff with insufficient training and/or knowledge to establish an adequate diagnosis and recommendations. Consequently, the efficacy and clinical safety of MUS, despite having been widely demonstrated in literature in studies with follow-up periods of more than ten years, has been marred by reports of complications, often attributable to incorrect indication or poor execution of the technique.

The foregoing must also be considered taking into account data regarding the safety of meshes in POP treatment. Despite being a completely different pathology to UI, these two conditions are often described as being associated, often resulting

in erroneous evaluations of their treatments and results when considered on a joint basis, which prompted the FDA to issue a Public Health notification in October 2008 in response to reported complications associated with the urogynecological use of surgical meshes[29].

For a clear understanding of the current situation, it is necessary to briefly summarise the historical evolution of the use of meshes in UI treatment. To this end, we will divide this process into three periods: before, at the time of and after the FDA notification.

Before the FDA notification: Synthetic meshes are polymers designed to strengthen areas of soft tissue weakness. They were first used in the 1950s to treat abdominal hernias. and were later employed to repair pelvic organ prolapse (POP). In the nineties, surgical meshes began to be used to treat SUI. The success of the transvaginal *tension-free* mechanism introduced by Ulmsten and Petros in 1995 prompted the widespread development of transvaginal synthetic mesh systems. Consequently, in 1996 the Food and Drug Administration (FDA) approved the first surgical mesh produced specifically for use in SUI and in 2002 it approved the first mesh specifically for use in POP. Since then there has been an exponential increase in the use of transvaginal meshes to treat pelvic floor pathologies, particularly the different types of female POP.

In 2004, the ICS issued clear recommendations on the use of meshes in surgery, which are the same as the ones that should be applied in any proposed surgical technique.

1. Validate the technique, based on clinical evidence.
2. Record the actions, establishing the indications, techniques and the type of material used.
3. Detailed information to the patient on the type of prosthesis used and the potential complications of this technique. Informed consent.
4. Objective evaluation and monitoring of the process for at least one year.

A detailed analysis of these recommendations reveals that they have not been fulfilled, since the large number of meshes released on the market made it impossible to perform a standardized follow-up. Similarly, precise indications have not been established and information to patients has not always been correct.

FDA notification: The FDA issued a Public Health Notification in October 2008 in response to complications associated with the urogynecological use of surgical

meshes. It conducted an investigation of reported adverse events registered in the MAUDE (Manufacturer and User Device Experience) database. This investigation identified 3,979 cases with adverse effects from January 2005 to December 2010, with reports of a five-fold increase in adverse events in repairs of POP from January 2008 to December 2010 (FDA. Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. July 2011).

The FDA issued two definitive orders for manufacturers and the general public to establish stringent requirements on the use of surgical meshes in transvaginal POP repair. Firstly, it reclassified the use meshes for POP correction from class II (generally moderate-risk devices) to class III (normally high-risk devices). Secondly, it required manufacturers to apply for premarket approval (*PMA*) to improve the safety and effectiveness of surgical meshes for transvaginal POP repair. Manufacturers were required to increase safety controls, including the control of severe pelvic pain and organ perforation, through a rigorous PMA process to demonstrate their safety and efficacy. The measures covered only mesh devices marketed for transvaginal POP repair; they did not include surgical meshes used with other indications, such as SUI or abdominal POP repair.

In September 2011, a panel of experts met in an open public hearing with presentations from both industry and the FDA, to address aspects relating to the safety of meshes in urogynecological applications to treat POP and UI. Regarding transvaginal mesh placement, the panel meeting reached a consensus on, among others, the following matters:

1. For the use of transvaginal meshes in the treatment of POP:
   a. The safety, effectiveness and benefits of transvaginal meshes have not yet been established.
   b. Premarket studies comparing the use of meshes versus the non-use of meshes should have at least one year of follow-up.
   c. Transvaginal meshes should be reclassified to Class III.
   d. Post-market studies need to be ongoing.
   e. Meshes for use in abdominal sacrocolpopexy do not require reclassification, continuing in group II.
2. For the use of meshes in UI treatment:
   a. The panel of experts concluded that retro-pubic and transobturator meshes inserted transvaginally were safe and effective, while mini single-incision slings require further investigation and should be used in studies with long-term follow-ups.

After the FDA notification: the notification caused social alarm that has transcended the scientific field. In the case of the meshes for use in UI, these have been "contaminated" by the adverse results associated with the use of meshes in POP.

Most scientific societies differentiate their recommendations on the use of meshes in SUI from those in POP treatment.

This public alarm has prompted many governments to address this issue, as explained below.

The FDA has recommended that surgeons and doctors report complications and adverse events deriving from the use of meshes through its Medical Surveillance Bulletin, through its Safety Information and Adverse Event Reporting Program or the respective national equivalent. However, given its voluntary nature and the time required to report such complications and adverse events, these are under-reported. Many authors acknowledge the need for a Detailed and Comprehensive National Registry of the use of meshes and their results [30,31].

A national registry of results on the use of meshes in UI and POP is being prepared in Australia and in the United Kingdom, at the initiative of their urogynecological societies *(Urogynaecological Society of Australia. UGSA Pelvic Floor Surgery Database. Melbourne, Australia [10/3/2012]; Available at:http://www.ugsa.org.au/UGSAdb.html.)*. The database of the Urogynecologic Society of Australia (UGSA) urges its members to report their results by offering them the database at a low annual price, granting them CME credits for participating and supporting the common good, since the availability of accurate surgical information will better support clinical and regulatory decisions. Mesh manufacturers should be urged to place codes on their products and use tracking systems to facilitate the identification of meshes and their follow-up.

Classification of mesh complications

The International Urogynecological Association (IUGA) and the ICS introduced a system for classifying complications directly related to the insertion of prostheses for female pelvic floor surgery[32]. This classification system was an effort to standardize terminology and obtain more accurate information on complications and adverse effects, with a view to establishing a reliable registration system. The coding of the classification system is based on the categorisation of complications, clinical diagnosis times and mesh placement locations. Pain is sub-classified into five grades ranging from "a" (asymptomatic/painless) to "e" (spontaneous pain). Although patients may suffer different complications at different times, each complication must be classified in a category within a range of minimum to maximum categories.

Patients with meshes inserted for SUI and POP are recommended to undergo long-term follow-up (more than 10 years) to register complications or symptoms[33,34,35].

In July 2018, the British government announced a pause in the use of meshes for both POP and UI treatment[36].

This political decision was taken in response to a recommendation form Baroness Cumberlege, who chairs an independent review committee of the procedures with surgical meshes and represents associations of women who have suffered mesh-related complications, without differentiating whether the meshes were used for treating UI or POP. The decision was taken to stop their use until the publication of the updated UI and POP guidelines of the British National Health Service (NHS), which is available from April 2019 (available at: Urinary incontinence in women: Management | Guidance and guidelines | NICE https://www.nice.org.uk/guidance/cg123).

The NHS has issued the following recommendations (NICE Guidelines) for surgeons on the use of meshes in UI:

1. Advise patients that the meshes are permanent implants and their complete removal might not be possible.
2. Use devices manufactured from type-1 macroporous polypropylene mesh.
3. Consider using slings coloured for high visibility, for ease of insertion and revision.
4. Procedures that involve a transobturator orifice should be avoided except in cases of previous surgical procedures.
5. A "top-down" retro-pubic approach or single-incision suburethral short mesh sling insertion should not be used, except as part of a clinical trial.
6. When a suburethral mesh is inserted, give patients written about the name of the implant, including its commercial name, manufacturer, date of insertion, and the implanting surgeon's contact details.

As regards meshes used for the treatment of POP, these guidelines establish the following recommendations: explain to patients the type of mesh to be inserted and the condition that it may not be completely removed in the future, and ensure that the results and complications are recorded in databases (national registry). When offering a MUS, written information must be given to the patient about the implant, including its name, manufacturer, date of insertion and the implanting surgeon's contact details (Available at: https://www.nice.org.uk/guidance/cg123).

Surgeons inserting meshes must be adequately trained and implant procedures must be performed in specialised centres.

A Scottish cohort study with a follow-up of almost 20 years has been widely referenced in scientific literature and led to Scottish parliament prohibiting meshes for POP treatment. The results of this study support the use of mesh procedures in UI patients, although they highlight the need for additional research on longer-term results. Mesh procedures for prolapse of the anterior and posterior compartment cannot be recommended for primary prolapse repair. Vaginal and abdominal mesh procedures for the repair of vaginal vault prolapse are associated with efficacy and complication rates similar to those in vaginal mesh-less repair. Therefore, these results do not clearly favour any specific vaginal vault repair procedure[37].

The British Society of Urogynecologists (BSUG) has expressed its discrepancy with the British government's decision to temporarily suspend the use of meshes (2018). In its statement, it claimed that this is a safe procedure, endorsed by more than twenty years of clinical efficacy and safety data, and that 95% of patients undergoing this type of treatment do not present any complications. It also highlighted that government requirements that must be fulfilled for their use (experience of surgeons and accreditation of centres) have already been made effective and it expects the suspension to be withdrawn promptly (available at: www.bsug.org/news-details/vaginal-mesh-high-vigilance-restriction-period/76/0/0).

3.- EFFICACY AND SAFETY OF TREATMENT OF UI WITH MESHES

Prosthetic meshes have been used to treat SUI with a wide variety of retro-pubic mid-urethral, transobturator and mini single-incision slings. The estimated success rate is between 51% and 99% in the case of retro-pubic and transobturator slings. So far, mini single-incision slings have proven to be less successful, with success rates ranging from 31% to 91.9%, although in older women these percentages may be lower. Very few studies were found in specialised literature on intestinal or vascular damage and death in patients with retro-pubic MUS. Some surgeons prefer to use transobturator MUS to avoid these serious complications and reduce the risk of bladder damage. Mini-slings were designed as a less invasive product that can be safely inserted during a consultation. Despite these technological advances, the placement of prosthetic meshes for the treatment of SUI can also have mild and severe complications. Lower urinary tract symptoms may worsen or appear as de novo urgency and as UUI in 11% to 28% of cases. The MUS must be placed so that the sling is tension free, but no standard insertion method has been defined and intra-operative sling tension evaluation is difficult. Infra-vesicle obstruction and/or voiding dysfunction may occur as a result of tension at the time of sling placement, but may also occur due to tissue contraction and fibrosis as a reaction to secondary

scarring. Prosthetic mesh-related complications include vaginal extrusion with associated symptoms of vaginal bleeding, vaginal discharge, or pain in the sexual activity of the patient or her partner. Erosion of the urinary tract affects the bladder and/or urethra, evidenced by urinary frequency, urgency, dysuria, frequent urinary tract infections, or stones. Although some published studies have described persistent pain in the groin or thigh after placement of transobturator MUS, passing or transient pain is more common, occurring in 5% to 31% of patients. Other studies have reported pelvic pain and dyspareunia in 24% of patients after MUS placement, and can be a painful and irreversible complication[38,39]. The complication rate has been shown to vary according to the experience and the learning curve of the surgeon, this being a determining factor in these cases[40].

There is solid evidence[20,27] to support the use of MUS in more than 2,000 publications, which makes this treatment the most widely reviewed and evaluated procedure for female UI currently in use. These scientific publications studied all types of patients, including those with co-morbidities such as prolapse, obesity and other types of bladder dysfunction. However, it is acknowledged that any operation can cause complications. In the case of MUS, these complications include bleeding, bladder and bowel damage, difficulty in bladder emptying, mesh exposure and pelvic pain, which may all require repeated surgery, although this is infrequent. However, the results of one large multi-centre trial have confirmed excellent and equivalent results between a retro-pubic sling and a transobturator sling and the complication rate after MUS treatment was expected to be low[41]. The success of the treatment diminished over the five-year follow-up period for the retro-pubic and transobturator slings and did not meet the pre-specified equivalence criteria for retro-pubic slings, revealing only minor benefits. However, satisfaction with both types of meshes remained high. Women undergoing transobturator sling procedures reported sustained improvement in urinary symptoms and sexual function. Over time, new extrusions were carried out for both types of meshes, albeit at a similar speed[42]. In addition, long-term effectiveness of up to 80% has been demonstrated in studies that followed up patients for 17 years[43,44].

4.- POSITION OF OTHER SCIENTIFIC SOCIETIES

The majority of Scientific Societies involved in UI management claim that it is a highly prevalent condition with well-established diagnostic and therapeutic criteria. In the specific case of SUI, when surgery is indicated, treatment with MUS continues to be the first therapeutic option, supported by a large volume of evidence included in most international clinical guidelines.

The consensuses and opinions of different Scientific Societies are presented below:

4.1. SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR).

As the use of surgical meshes in urogynecologic surgery has become increasingly common, the adverse effects associated with their use, e.g. infections, tissue erosion, mesh exposure, retraction, pain and sexual dysfunction, have also increased. For this reason, the European Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to assess the health risks associated with the use of surgical meshes.

The SCENIHR examined various options for the treatment of pelvic floor dysfunctions, for which it studied available scientific literature and the guidelines published by scientific societies and health authorities, in addition to surgical and non-surgical treatments and different types of meshes. The resulting opinion focused on the health risks of meshes used in urogynecological surgery, the identification of groups of high-risk patients and evaluation needs.

The SCENIHR concluded that clinical results after mesh insertion depend on different factors, such as the properties of the materials, the design of the product, total mesh size, insertion route, the characteristics of the patients, associated procedures (e.g. hysterectomy) and the experience of the surgeon, all of which must be taken into account when choosing an appropriate therapy.

In assessing the health risks associated with synthetic meshes, a clear distinction must be made between the minor risks of mesh surgery for SUI and those associated with mesh surgery to treat POP.

In its conclusions, the SCENIHR supports the continued use of mesh surgery to treat SUI, provided it is performed by an experienced and appropriately qualified surgeon, since it is an accepted procedure with proven efficacy and safety in most patients with moderate or severe SUI.

However, the SCENIHR does not advocate the use of synthetic meshes vaginally for POP repair. As this type of surgery may have higher risks, it should only be used when other surgical procedures have failed or there are reasons to believe that they would not be effective.

The evaluation of the identified risks indicates that type-1 polypropylene meshes are the most suitable synthetic meshes for vaginal use and type-1 polypropylene and type-3 polyester meshes are best for abdominal insertion.

Patients should be selected and advised appropriately to achieve optimal results in all surgical procedures, especially those of this nature.

The SCENIHR recommends that the number of meshes should be limited in all procedures as much as possible and that a certification system should be established for surgeons, based on existing international guidelines, developed in cooperation with European surgical associations.

The definitive opinion, published in December 2015 after a public consultation on the preliminary opinion, presents the full evaluation and other details on the use of surgical meshes in urogynecological surgery. A dossier presenting a general and simplified overview of this aspect is also available[44].

4.2. EAU (European Association of Urology) - European Uroginaecological Association (EUGA)

In its consensus statement, the Association issued the following conclusions: When considering surgery for SUI, it is essential to evaluate the available options, which may include the synthetic mid-urethral slings (MUSs) using polypropylene tapes, colposuspension and autologous sling surgery. The use of synthetic MUSs for surgical treatment of SUI in both male and female patients has good efficacy and acceptable morbidity. Synthetic mesh for POP should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with adequate training who are working in multidisciplinary referral centres[45].

Patient recommendations: Synthetic slings can be safely used in the surgical treatment of SUI in both male and female patients. Patients need to be aware of the alternative therapy and potential risks and complications of this therapy. Synthetic mesh for treating prolapse should be used only in complex cases with recurrent prolapse in specialist referral centres.

This statement ends with the following recommendations: a) adequate training and certification; b) communication of the number of cases per year and their complications; c) existence of specialised centres for the treatment of complications; d) complete and adequate information to patients; and e) creation/modification of specific informed consent.

4.3. IInternational Urogynaecological Association (IUGA)

The International Urogynaecological Association in its Position Statement published in 2014 concluded that there is robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female SUI. These publications studied all types of patients, including those with co-morbidities such as prolapse, obesity and other types. It is, however, acknowledged that any operation can cause complications. For MUS these include bleeding, damage to the bladder and bowel, voiding difficulty, mesh extrusion and pelvic pain; all of these may require repeat surgery.

Nevertheless, the results refer to a low rate of complications and long-term effectiveness of up to 80%. As a result, IUGA supports the use of monofilament polypropylene MUS for the surgical treatment of female SUI. (Information available at: https://www.iuga.org/publications/position-statements).

4.4. 6th INTERNATIONAL CONSULTATION ON INCONTINENCE (ICI) (2017):

Recommendation on the use of MUS with the highest level of evidence "1" and grade of recommendation "A" as an effective treatment maintained over time. Low incidence of short- and long-term complications[46].

4.5. ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS (RANZCOG)

The position of the Australian College of Obstetricians and Gynecologists (available at:https://www.ranzcog.edu.au/mesh-resources) has been to initiate an open investigation on the use of meshes in the treatment of UI. In Australia, the use of meshes for POP treatment has been prohibited (information available on the following website: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions)

RANZCOG recommends that the use of meshes should not be prohibited in general, that risks should be assessed individually together with the risks of recurrence. It also considers that the government should finance research in this field.

4.6. CANADIAN ASSOCIATION OF UROLOGY

In its consensus document, this association establishes that when a surgical anti-incontinence procedure with transvaginal mesh is offered to a patient, the latter should be informed about potential specific complications of the procedure and specific complications of the mesh. The 2014 Health Canada Notice must be disclosed to patients (available at: Surgical mesh - (Complications associated with transvaginal implantation for the treatment of stress urinary incontinence and pelvic organ prolapse - notice to hospitals - recalls & alerts 2014.Healthy Canadians website.[Accessed March 5, 2015].www.healthycanadians.gc.ca.http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/39475a-eng.php. Published May 13, 2014).

Surgeons performing these procedures should have adequate training specific to SUI surgery and training specific to the sling technique used at their institutions.

They must be able to recognize, diagnose and treat possible complications related to the procedure[47].

4.7. AMERICAN ASSOCIATION OF UROLOGY (AUA)

The AUA fully agrees that physicians should analyse the specific risks and benefits of meshes before selecting synthetic mid-urethral sling procedures for the surgical treatment of female SUI. This statement coincides fully with the FDA's recommendations regarding informed consent prior to surgery. The AUA also agrees that surgeons intending to perform anti-incontinence mesh surgery should have rigorous training on the principles of pelvic anatomy and pelvic surgery, be properly trained in specific sling techniques and be able to recognise and manage complications associated with the placement of synthetic mesh slings[48].

4.8. AMERICAN UROGYNECOLOGIC SOCIETY (AUGS) AND THE SOCIETY FOR URODYNAMICS, FEMALE PELVIC MEDICINE AND UROGENITAL RECONSTRUCTION (SUFU). *Published January 2014; Updated June 2016/2019*

The polypropylene mid-urethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple outpatient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy, it has created an environment for a much larger number of women to have access to treatment. In the past, concerns over failure and invasiveness of surgery caused a substantial percentage of incontinent women to live without treatment. One of the unintended consequences of this polypropylene mesh controversy has been to keep women from receiving treatment for SUI. This procedure is probably the most important advancement in the treatment of SUI in the last 50 years and has the full support of our organizations, which are dedicated to improving the lives of women with UI.

A clear distinction must be made between meshes inserted vaginally for the treatment of POP and those placed sub-urethrally for the treatment of SUI. The key points of this statement are: polypropylene material is safe and effective as a surgical implant; suburethral slings are the most extensively studied anti-incontinence procedure, as the first-choice treatment for this pathology with an adequate level of security[48].

5.- CONCLUSIONS:

Position of the Ibero-American Society of Neurourology and Urogynecology (SINUG) in relation to the use of synthetic suburethral meshes for the surgical treatment of female stress incontinence.

In relation to the use of suburethral meshes for the surgical treatment of female stress incontinence, the Ibero-American Society of Neurourology and UroGinecology presents its vision in this communication, which is a summary of the document analysing the state of topic prepared by the Society. For more information on the subject, please consult the aforementioned document at www.sinug.org:

- The surgical procedure of choice for treating female stress urinary incontinence consists in the placement of a suburethral mesh in the mid urethra. A robust level of evidence is available to make this recommendation in relation to clinical efficacy (objective cure rates around 92%) and safety.
- Synthetic meshes for the surgical treatment of stress urinary incontinence are different to meshes used to treat pelvic organ prolapse in terms of surface area, location and placement/fixation systems, and therefore pose a different risk. When assessing the health risks of synthetic meshes, a clear distinction must be made between the minor risks of mesh surgery for SUI and those associated with mesh surgery to treat POP.
- The complications of surgery with meshes for stress urinary incontinence are related to inadequate training on the part of surgeons and inappropriate indications on surgical treatment, among other factors.
- A system needs to be established to certify that surgeons have sufficient knowledge in urogynecology, the skills required for this surgical technique (successful completion of the learning curve and number of operations performed per year) and the ability to resolve any complications deriving from this surgery.
- Data regarding the efficacy and safety of these surgical techniques performed with synthetic material should be based both on clinical trials with short- and medium-term results and on long-term follow-up, so databases should be created from cases registered for this purpose.
- The creation of a national mesh registry would be a useful tool, although this would be difficult to create and complete.

Final conclusion:

Urinary incontinence is a highly prevalent social problem and significantly deteriorates quality of life. Effective treatments are currently available, such as suburethral mesh placement, with low morbidity and adequate clinical safety.

BIBLIOGRAPHIC REFERENCES

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U et al. The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Neurourol Urodyn 2002; 21: 167-178

2. Cardozo L. New developments in the management of stress urinary incontinence. BJU Int 2004; 94 (Supl. 1): 1-3.

3. Rexach Cano L, Verdejo Bravo C. Incontinencia urinaria. Inf Ter Sist Nac Salud 1999; 23: 149-159.

4. Hunskaar S, Burgio K, Diokno AC, Herzog AR, Hjalmas K, Lapitan MC. Epidemiology and Natural History of Urinary Incontinence (UI). En: Incontinence 2nd Edition. Abrams P, Cardozo L, Khoury S, Wein A (Eds). Chp 3, pp. 165-202. Plymbridge Distributors Ltd., United Kingdom 2002.

5. Dugan E, Roberts CP, Cohen SJ, Presisser JS, Davis CC, Bland DR et al. Why older community-dwelling adults do not discuss urinary incontinence with their primary care physicians. J Am Geriatr Soc 2001; 49: 462-465.

6. Espuña Pons M. Incontinencia de orina en la mujer. Med Clin (Barc) 2003; 120: 464-472.

7. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trondelag. J Clin Epidemiol 2000; 53: 1150-1157.

8. Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. BJU Int 2004; 93: 324-330.

9. Nihira MA, Henderson N. Epidemiology of urinary incontinence in women. Curr Womens Health Rep 2003; 3: 340-347.

10. Lose G. The burden of stress urinary incontinence. Eur Urol Supplements 2005; 4: 5-10.

11. Grupo Español de Urodinámica y de SINUG. Consenso sobre terminología y conceptos de la función del tracto urinario inferior. Actas Urol Esp 2005; 29: 16-30.

12. Minassian VA, Drutz HP, Al-Badr A. Urinary incontinence as a worldwide problem. Int J Gynaecol Obstet 2003; 82: 327-338.
13. Kelleher C. Quality of life and urinary incontinence. En: Textebook of Female Urology and Urogynecology. Cardozo L, Staskin D (Eds). Chp 5: 47-58. Isis Medical Media Ltd, United Kingdom 2001.
14. Pascual MA. Prevalencia y calidad de vida. Prog Obstet Ginecol 2002; 45 (Supl. 1): 2-9.
15. Ertunc D, Tok EC, Pata O, Dilek U, Ozdemir G, Dilek S. Is stress urinary incontinence a familial condition? Acta Obstet Gynecol Scand 2004; 83: 912-916.
16. Abrams P et al Members of the Committees. Recomendation of the International Scientific Committee:Evaluation and treatment of urinary incontinence, pelvic organ prolapse and feccal nincontinence. In: Incontinence. Paul Abrams, Linda Cardozo, Adrian Wagg, Alan Wein, editors. International Consuktation in INcontinence. 6th edition, Tokyo. SEptember.2016.ISBN: 978-0-9569607-3-3.2017;2549-2605
17. Pesce F. Current management of stress urinary incontinence. BJU Int 2004; 94 (Suppl 1): 8-13.
18. Petros PE, Ulmsten U. An Integral Theory of Female Urinary Incontinence. Acta Scand O&G 1990; 153 (Supp), 69:1-79.
19.- Kenton K, Stoddard AM, Zyczynski H, Albo M, Rickey L, Norton P, Wai C, Kraus SR, Sirls LT, Kusek JW, Litman HJ, Chang RP, Richter HE. 5-year longitudinal follow up after retropubic and transobturator mid urethral slings. J Urol. 2015. Jan;193(1):203-10. doi: 10.1016/j.juro.2014.08.089. Epub 2014 Aug 23
20. Ford AA, Rogerson L, Cody JD, Aluko P, Ogah JA. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2017, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub4.
21. Tijdink, M, Vierhout ME, Heesakkers JP, Withagen MI. Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh. Int Urogynecol J. 2011; 22: 1395-1404.
22.- Keltie K, Elneil S, Monga A, Patrick H, Powell J, Campbell B, Sims AJ. Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women. Sci Rep. 2017 Sep 20;7(1):12015. doi: 10.1038/s41598-017-11821-w.
23. Falconer C, Soderberg M, Blomgren B, Ulmsten U.: Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women *Int Urogynecol J Pelvic Floor Dysfunct* 2001; 12 Suppl 2: S19-S23.
24. Amid Pk, Shulman Ag, Lichtenstein Il, Hakakha M.: Biomaterials for abdominal wall hernia surgery and principles of their applications. *Langenbecks Arch Chir* 1994; 379 (3): 168-171.

25.- Serati M, Braga A, Athanasiou S, Tommaselli GA, Caccia G, Torella M, Ghezzi F, Salvatore S. Tension-free Vaginal Tape-Obturator for Treatment of Pure Urodynamic Stress Urinary Incontinence: Efficacy and Adverse Effects at 10-year Follow-up. Eur Urol. 2017 Apr;71(4):674-679. doi: 10.1016/j.eururo.2016.08.054. Epub 2016 Sep 3.

26. Thomas T, Siff L, Jelovsek E, Barber M. Surgical Pain After Transobturator and Retropubic Midurethral Sling Placement. Obstet Gynecol. 2017; 130(1): 118.

27. Anger JT, Weinberg AE, Albo ME, Smith AL, Kim JH, Rodriguez LV. Trends in surgical management of stress urinary incontinence among female Medicare beneficiaries. Urology. 2009;74(2):283-7.

28.- Fusco F, Abdel-Fattah M, Chapple CR, Creta M, La Falce S, Waltregny D, Novara G. Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. Eur Urol. 2017 Oct;72(4):567-591. doi: 10.1016/j.eururo.2017.04.026. Epub 2017 May 4.

29. FDA. FDA public health notification: serious complications associated with transvaginal placement of surgerical mesh in repair of pelvic organ prolapse and stress urinary incontinence 2008. (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm.)

30. Slack 1. M, Ostergard D, Cervigni M, Deprest J. A standardized description of graft-containing meshes and recommended steps before the introduction of medical devices for prolapse surgery. Consensus of the 2nd IUGA Grafts Roundtable: Optimizing Safety and Appropriateness of Graft Use in Transvaginal Pelvic Reconstructive Surgery. Int Urogynecol J. 2010. Epub 3/07/2012.,

31. Jacquetin B., Cosson M. Complications of vaginal mesh: our experience Int Urogynecol J, 20 (2009), pp. 893-896.

32. Haylen B.T., Freeman R.M., Swift S.E., Cosson M., Davila G., Deprest J., et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Terminology and Classification of Complications Related Directly to the Insertion of Prosthesis (Meshes, Implants, Tapes) or Grafts in Female Pelvic Floor SurgeryNeurourol Urodyn, 30 (2011), pp. 2-12 Epub 12/22/2010.

33. Dwyer P.L., Riss P. The mesh debate. Int Urogyn J, 23 (2012), pp. 1-2.

34. Khanuengkitkong S, Lo T-S, Dass A. Delayed vaginal and urethral mesh exposure: 10 years after TVT surgery. Int Urogynecol J. 2012. Epub 06/27/12.

35. Mucowski S., Jurnalov C., Phelps J.Use of vaginal mesh in the face of recent FDA warnings and litigation. Am J Obstet Gynecol, 203 (2010), p. 103 e1-4.

36. Surgical mesh for stress urinary incontinence to be halted immediately in England. *BMJ* 2018; 362 doi: https://doi.org/10.1136/bmj.k3035. Use mesh implants for stress urinary incontinence only as last resort, says NICE).
37. Morling JR, McAllister DA, Agur W, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997©2016: A population-based cohort study. Lancet. 2017;389:629–40. https://doi.org/10.1016/S0140-6736(16)32572-7.
38. Schimpf MO, Rahn DD, Wheeler TL, Patel M, White AB, Orejuela FJ, El-Nashar SA, Margulies RU, Gleason JL, Aschkenazi SO, Mamik MM, Ward RM, Balk EM, Sung VW; Society of Gynecologic Surgeons Systematic Review Group. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol. 2014 Jul; 211(1):71.e1-71.e27. doi: 10.1016/j.
39. Oliveira LM, Dias MM, Martins SB, Haddad JM, Girão MJBC, Castro RA. Surgical Treatment for Stress Urinary Incontinence in Women: A Systematic Review and Meta-analysis. Rev Bras Ginecol Obstet. 2018 Aug;40(8):477-490. doi: 10.1055/s-0038-1667184. Epub 2018 Aug 24.
40.- Hilton P, Rose K. The "learning curve" for retropubic mid-urethral sling procedures: a retrospective cohort study. Int Urogynecol J. 2016 Apr;27(4):565-70. doi: 10.1007/s00192-015-2853-z. Epub 2015 Oct 2.
41. Richter HE, Albo ME, Zyczynski HM, Kenton K, Norton PA, Sirls LT, Kraus SR, Chai TC, Lemack GE, Dandreo KJ, Varner RE, Menefee S, Ghetti C, Brubaker L, Nygaard I, Khandwala S, Rozanski TA, Johnson H, Schaffer J, Stoddard AM, Holley RL, Nager CW, Moalli P, Mueller E, Arisco AM, Corton M, Tennstedt S, Chang TD, Gormley EA, Litman HJ; Urinary Incontinence Treatment Network. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med. 2010 Jun 3;362(22):2066-76. doi: 10.1056/NEJMoa0912658. Epub 2010 May 17.
42. Kenton KS. What Is New in Pelvic Organ Prolapse?: Best Articles From the Past Year. Obstet Gynecol. 2015 Nov;126(5):1102-5.
43. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J. 2013 Aug;24(8):1265-9
44. SCENIHR. Final opinion on the safety of surgical meshes used in urogynecological surgery; 2015. http://ec.europa.eu/health/ scientific_committees/emerging/docs/scenihr_o_049.pdf. http://ec.europa.eu/dgs/health_foodsafety/dyna/enews/enews.cfm?al_id=1656
45. Chappel, C., Cruz, F., Diffieux, X. et al. Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of

Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence. European Urology 72 (2017) 424–431. http://dx.doi.org/10.1016/j.eururo.2017.03.048)
46. Abrams P, Cardozo L, Wagg A, Wein A. INCONTINENCE. 6th Ed 2017. ICS. ISBN 978-0-9569607-3-3 p.p 1741.
47. Welk, B., Carlson, K., Baverstock, R. et al. Canadian Urological Association position statement on the use of transvaginal mesh. Can Urol Assoc J. 2017 Jun; 11(6Suppl2): S105–S107.doi: 10.5489/cuaj.4579
48. AUA position statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence (SUI) American Urological Association; [Accessed March 5,2016]. https://www.auanet.org/education/vaginal-mesh-for-pelvic-organ-prolapse.cfm.
49. AUGS/SUFU position statement on mesh midurethral slings for stress urinary incontinence. [Accessed June 5, 2016]. http://sufuorg.com/docs/news/augs-sufu-mus-position-statement.aspx.