



# ESSM Today

## ESSM NEWSLETTER

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# Welcome Address

I am delighted to welcome you to this **second 2015** issue of the ESSM newsletter. We have great things coming soon in our society.

We would like to congratulate again all ESSM members & staff for the great meeting held in Copenhagen, and specially thanks to the local chairmen **Dr. Sonksen & Fode**, for the great job they did. Madrid will welcome you next February for our annual meeting, as you probably know. All ESSM staff members, local chairmen, and scientific committee are working hard to have an outstanding event, so please "*start spreading the news*" between your colleagues & friends, to bring as much people as you could. The meeting contents, will be outstanding, the entire scientific team lead by **Dr. Albersen** are working really hard to get there.

In this issue, we have included an interesting interview with a pioneer and world-class expert in Sexual Medicine, **Prof. E. Meuleman**. We cover main topics-highlights presented at AUA 2015 New Orleans, presented by Dr. Trost along with our classic sections by my Associate Editors (**Dr. Mondaini, Angulo & Vozmediano**).

Also, we add two very interesting Key from Kols collaborations regarding Peyronie's Disease surgery done by **Dr. Egydio & Kuehhas**. I hope you will enjoy reading it.

Finally, I would like to thank you all for your continued support of our society and I look forward to seeing you in Madrid next February.

My very best  
Juan I. Martínez-Salamanca



# Interview with Prof. Meuleman

by Juan I. Martínez-Salamanca



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Prof. Meuleman is an internationally known figure and world-class leader in the field of Sexual Medicine. He is an outstanding contributor to the field of Sexual Medicine as a researcher, patient advocate, educator, innovator and author. Having you here it is a real pleasure and honor not only for me but also for all ESSM Members.

**JIMS: Prof. MEULEMAN could you make us a brief journey throughout your professional background?**

Starting in 1986 as a resident in training for urology my interest in male erectile dysfunction was triggered by my trainer Dr. Karl Delaere, who introduced a program of intracavernous self-injection with papaverin into the urology clinic in Heerlen, The Netherlands. In 1989, I moved to the Radboud University Medical Center in Nijmegen for my last year of training. There, Prof Frans Debruyne gave me the opportunity to extent my clinical research into the pathophysiology and diagnosis of erectile dysfunction, resulting in the publication of my thesis "Recent progress in the diagnosis of erectile dysfunction", in which I describe the methodology of penile duplex ultrasonography and cavernosometry in 1991. What followed was the era of international ED-research, fueled by the interest of pharmaceutical companies to develop an oral erectogenic agent. This also led to the maturation of the International Society of Impotence research and corpus cavernosum revascularization founded in 1978 by the late Adrian Zorngiotti in New York. The ED-hype culminated in 1998 with the launch of Viagra, precisely at the time that I was host-

ing the world meeting on impotence research in Amsterdam. The meeting was attended by more than 1800 participants. Under the guidance of the late Mr Robert von Hinke Kessler and with the aid of the financial benefits of the meeting, the society was transformed into a professional organization and was renamed in the International Society of Sexual Medicine (ISSM). I had the honor to serve ISSM as a treasurer for 6 years until 2006.

In the beginning of 2000 I realized that there is more than male ED in the world of sexual medicine and expanded my clinical and scientific interest into the field of andrology including reproductive medicine and men's health.

Since 2005 I'm appointed at the VU University Medical Center in Amsterdam as a professor of andrological urology and program director of the urology residency training program.

**JIMS: During you dilated career, which has led to the passage from "Andrology" to "Sexual Medicine", and what do you prefer "Sexual Medicine" or "Men's Health"?**

As a young urologist I focused my research completely on erectile dysfunction. Driven by clinical practice – patients who consulted me – I expanded my scientific interest and expertise into the broader field of male reproduction, sexual medicine and men's health. In other words: Andrology. Thus, sexual and reproductive health meet each other in men's health.

**JIMS: What do you think the role of the urologist should be in the management of male infertility? And what are our major challenges?**  
In The Netherlands, reproductive medicine is organized in a multidisciplinary team consisting of a gynecologist, urologist, embryologist, endocrinologist, geneticist and ethicist. In other words the urologist needs to be a teamplayer. The urologist has a specific role in case of anatomical or functional disorders of the male genital tract and azoospermia.

As a major challenge I see the preservation and transplantation of spermatogonial stemcells in prepubertal boys with an oncological problem who need chemotherapy.

**JIMS: Prof. Meuleman, PDE-5 Inhibitors (Tadalafil) have been recently approved in U.S. for patients with ED & LUTS, which do you consider being the ultimate role of this drug in all treatment options of this group of patients?**

ED and LUTS are both symptoms of the urogenital aging process. For the short term PDE-5 inhibitors, especially the long-acting ones such as tadalafil may be used for symptom relief. Thus, PDE-5 inhibition may postpone further deterioration of urogenital function, it can not reverse the process of urogenitale aging. In that respect I would put my money on life-style modification programs especially in men – and this is the majority – with co-morbidity such as the metabolic syndrome.

**JIMS: In the field of Peyronie's Disease, what do you think are the main challenges to achieve?**

Peyronie's disease is a condition of the tunica albuginea that is linked to aging and genetic factors. In most men it is associated not only with localized plaques that cause deformity but also with generalized fibrosis of the tunica leading

## Interview with Prof. Meuleman

to penile shortening. With respect to treatment, many modalities have been experimented with during the last 3 decades to resolve the plaques, most with little to zero effect. Recently, injectable collagenase clostridium histolyticum (Xiaflex®) has been approved by the FDA for Peyronie's disease. The substance is injected into the plaques in 6 treatment cycles of 2 weekly injections followed by a program of penile stretching and remodeling.

In a recent large randomized controlled trial in which 8 times collagenase was injected in the plaque, followed by manual remodeling of the penis, the average improvement of the curvature was 34% (on average 14,8 degrees less deviation). The Peyronie's disease symptom-burden score appeared to improve significantly. The question is whether men with severe curvature are sufficiently satisfied with this relatively modest improvement in curvature and if injection with collagenase may prevent surgical treatment. Once the deformity has stabilized and the patient's sexual function is impaired, I would suggest surgery. Either a plication-technique or

a grafting technique, depending on the severity of the malformation and the length of the penis.

**JIMS: Prof. MEULEMAN, regarding the latest controversy about Testosterone replacement therapy & cardiovascular risk, what is your personal opinion about that?**

In this respect I want to highlight three studies. First of all an open-access study of Lin Xue et al presenting data from a met analysis. The conclusion is "that the effect of testosterone on cardiovascular events varies with the source of funding. Overall and particularly studies not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular events". Another study in NEJM shows that "the application of a testosterone gel in older men with limitations in mobility and chronic disease is associated with increased risks of cardiovascular adverse events". And finally, the experience from a registry of low T centers is that testosterone is safe in young men who do not have significant risk-factors. The general picture I draw from

these publications is that it is safe in younger men without risk-factors and that one should be cautious in older frail men.

**JIMS: And last but not least, which do you consider the most important challenges for our specialty (Sexual Medicine) and for our society (ESSM) in the next 5 years?**

The greatest challenge for sexual medicine and ESSM is to survive in an era where the interest of the pharmaceutical industries in sexual medicine is declining and health authorities are inclined to subsidize new developments in oncology and cardiovascular medicine much more than quality of life issues such as sexuality. Therefore, the best way forward is to focus on prevention of sexual dysfunction and life-style modification.

**It was a great pleasure to interview you; I am convinced that your points of view, fruits of a lifetime devoted to your work, will be highly appreciated by our readers. Thanks once again.**

## AUA 2015 New Orleans: Take Home Messages. Sexual Function / Dysfunction

by Landon Trost



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Sexual medicine was well represented at the 2015 American Urologic Association Annual Meeting held in New Orleans, Louisiana, USA. There were over 100 podiums and posters and greater than 60 lectures, plenaries, courses, videos, and guidelines presented.

### ERECTILE DYSFUNCTION

#### Penile Ultrasound

- ▶ **Abstract 43-02** – The location of ultrasound probe placement on the penis had a significant impact on outcomes. The more distal the probe was placed, the higher the arterial insufficiency noted. Similarly the more distal the probe was placed on the penis the rate of venoocclusive dysfunction declined.
- ▶ **Abstract 43-07** – Vascular risk factors did not predict hemodynamic results on penile ultrasound.

- ▶ **Abstract 43-09** – If a patient did not achieve an erection which matched the stretched penile length at the time of ultrasound, this independently predicted venoocclusive dysfunction.
- ▶ **Abstract 43-18** – Audio and visual stimulation did not impact the total erectile rigidity or number of intracavernosal injections required to achieve a rigid erection prior to ultrasound.



## AUA 2015 New Orleans: Take Home Messages. Sexual Function / Dysfunction

### Zen Trial

- **Podium 40-01** – Follow-up data was provided on the Zen Trial for endovascular stenting of penile arterial insufficiency. Outcomes noted that >4 point improvements on the International Index of Erectile Function occurred among 60% of patients at three years compared to 70% of patients at six months. This trial has been prematurely halted by the sponsoring company for various reasons including significant difficulty in patient accrual.

### Shockwave Therapy

- **Podium 45-10** – A summary of eight studies reporting outcomes of shockwave therapy demonstrated very low rate of adverse events (0.2-0.4%; skin rash, penile dysesthesias). The patients from all trials demonstrated significant improvements in erectile function, which were maintained at 12 months.
- **Poster 52-06** – Low intensity shockwave therapy in diabetic rats was reported and noted equivalent improvements to PDE5 inhibitors. Combination therapy of shockwave and PDE5 inhibitors resulted in better outcomes than either therapy alone.
- **Podium 36-09** – Shockwave therapy was performed in type one diabetic rats and noted restoration of endothelium and smooth muscle content.

### Penile Prostheses

- **Podium 02-03** – Positive cultures from non-clinically infected penile prostheses were more common in uncoated devices compared to coated prostheses (35% versus 13%).
- **Podium 26-02** – Outcomes of cultures performed at the time of penile prosthesis revision or salvage surgery were reviewed. Among the cases, 38% had no growth, 43% gram-positives, 12% gram-negatives, 9% anaerobes, and 7% Candida species.
- **Podium 48-02** – Outcomes of a subcoronal incision approach to placement of a penile prosthesis were reviewed. Among 105 men undergoing the procedure, 75% were satisfied at three months and 3% experienced an infection.

### Basic Science

- **Podium 36-02** – Reviewed remodeling and calcium content in cardiac and pudendal arteries. Similar findings were identified in both sets of arteries, which fails to support the arterial size hypothesis of why erectile dysfunction proceeds cardiovascular dysfunction.
- **Podium 36-04** – Demonstrated increases in tumor necrosis factor alpha following nerve crush in rats. This podium also significantly demonstrated a preservation of sympathetic fibers and impairment of parasympathetic fibers following crush.
- **Poster 52-03** – Demonstrated that neural pericytes function as a cellular regenerator, which may offer a new target for erectile dysfunction therapy.
- **Podium 36-05** – Pioglitazone enhanced survival of the pelvic nerve ganglion following nerve crush in an animal model, suggesting its role as a neuroprotective agent.

### PEYRONIE'S DISEASE

#### AUA Guideline 2015

- A new guideline statement was released on Peyronie's Disease. Three statements were made on the importance for history and examination as well as role for intracavernosal injections with or without penile ultrasound. Physicians were counseled to only treat the condition if they had the tools and experience necessary to treat the condition adequately.
- Physicians were recommended to discuss all adverse events with each therapy and to utilize nonsteroidal anti-inflammatory drugs for pain as needed.
- Clinicians were recommended against certain therapies including vitamin E, tamoxifen, procabazine, omega-3 fatty acids, or vitamin E with L-carnitine. Electromotive therapy with verapamil, radiotherapy, and shockwave therapy for treatment of curvature or plaque size were also recommended against.
- Collagenase clostridium histolyticum was recommended as a possible treatment with modeling for men with 30–90° curvature and intact erectile function. Intralesional interferon

and verapamil were also considered as options for treatment.

- Surgery was indicated for men with stable disease and erectile function responsive to medications. Plication and incision/excision and grafting our option in cases of adequate penile rigidity.
- A penile prosthesis is indicated in men with erectile dysfunction unresponsive to pharmacotherapy.

### Other Peyronie's Disease

- **Podium 48-01** – Reviewed the incidence of Peyronie's disease following prostatectomy. Among 276 men, 17.4% developed Peyronie's disease within three years, with the majority (9.8%) occurring within the first year.
- **Podium 48-03** – Reviewed outcomes of using collagen fleece as a grafting material in 290 men undergoing incision in grafting for Peyronie's disease (follow-up 37 months). Outcomes demonstrated improved erectile function in 23% and unchanged erectile function in 66%. Decreased glanular sensation was noted in 7% with an overall increase in penile length of 0.7 cm.

### Trauma

- **Poster 18-19** – Reported retrospective outcomes of men undergoing repair of penile fracture at seven European sites. Results demonstrated worsened erectile function at one and three months among men surgically treated greater than eight hours after the initial presentation to the emergency room.

### Female Sexual Function

- **Podium 48-07** – Reviewed data from partners of men enrolled in the IMPRESS I and II collagenase trials. Thirty women had questionnaires obtained and demonstrated that treatment with collagenase significantly improved the functionality of the penis as noted by the partners. Also the sexual dysfunction in the female partner improved from 75% before treatment to 33% after treatment.

# Key from Kols: The Modified Sliding Technique (MOST) for penile length and girth restoration in patients with severe erectile dysfunction by Paulo H. Egydio and Franklin E. Kuehas



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According to current guidelines on erectile dysfunction (ED), the implantation of a penile prosthesis is the ultimo ratio for the treatment of therapy resistant ED. In a significant subset of patients with ED penile length loss is already an issue preoperatively. Patients with Peyronie's disease report in up to 80% of cases subjective penile length loss due to their underlying condition (1). The treatment of prostate cancer with radical prostatectomy (2) or androgen suppression (3) with or without radiation therapy (4) is also associated with penile length loss. A Nesbit procedure (5) as well as fibrotic changes due to recurrent priapism (6) have also been reported to result in reduced penile length.

Since a simple implantation of a penile prosthesis will result in additional penile length loss (7), the question arises what should be done with patients who suffer from therapy resistant ED and complain about significant loss of penile length. It is well known that reduced penile length and girth as well as the inability to participate in sexual intercourse may lead to severe emotional challenges, dissatisfaction, and decreased quality of life in a high percentage of men (8).

Therefore, patients with severe ED and significant penile shortening could be candidates for more aggressive surgical procedures, beyond the routine insertion of a penile prosthesis in order to restore their original penile length and girth.

Publications on circular and longitudinal tunica albuginea incisions with grafting to restore penile length and girth and concomitant penile

prosthesis insertion have shown promising results (9,10). Rolle et al (11) published the so-called "sliding technique" which is also a safe and valid therapeutic option for this subset of patients. The length gain with either of the two procedures ranges between 2–5 cm. However these approaches have one problem in common they are time-consuming procedures. Extended operative time is a potential risk factor for penile prosthesis infection. Therefore extended procedures should be avoided to reduce the risk of infection of the implant.

We recently published our experience with a modification of the "sliding technique" (11), which aims to reduce operative times, infection risk and costs associated with this type of surgery (12). The "modified sliding technique (MOST)" consists of three key elements: 1) the sliding manoeuvre for the restoration of penile length, 2) potential complementary longitudinal ventral and/or dorsal tunical incisions for the restoration of penile girth, and 3) the closure of the newly created tunical defects using Buck's fascia, rather than a graft.

143 patients underwent the MOST procedure. Malleable penile prostheses were used in 133 patients and inflatable penile prostheses were inserted in 10 patients. The median follow-up was 9.7 months (range, 6–18 months). Mean penile length gain was 3.1 cm (range, 2–7 cm). No penile prosthesis infection caused device explantation. The average IIEF score increased from 24 points at baseline to 60 points at the six-month follow-up. The average operative time for restoring penile length and girth with concomitant prosthesis implantation was 93 min for malleable prostheses (range,

64–22 min) and 121 min for inflatable prostheses (range, 100–164 min), which is a marked improvement compared with other series dealing with the treatment of ED and penile length and girth restoration (9–11).

The MOST technique is a safe and effective procedure to restore penile length and girth, as the elimination of grafting reduces the operative time, consequently decreasing the cost of surgery and potentially also the risk of infection. Therefore, any patient with severe ED who is a candidate for penile prosthesis implantation should be evaluated for subjective penile length reduction before the surgery, as penile prosthesis implantation with concomitant penile length and girth restoration is associated with higher patient satisfaction.

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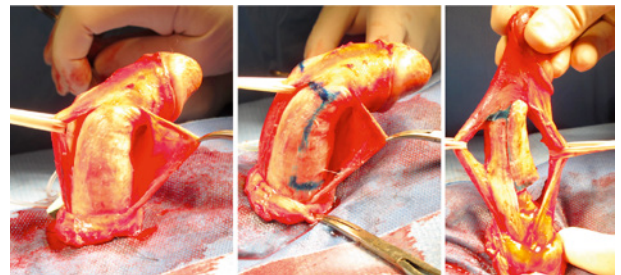
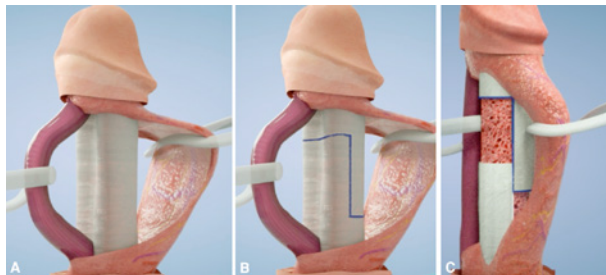
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**Fig. 1**

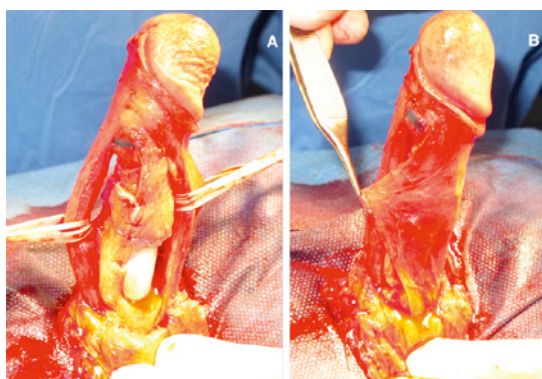
**Illustration of the preparation of the modified sliding technique:**

- A – Mobilization of the urethra and the neurovascular bundle through two longitudinal paraurethral incisions on Buck's fascia  
 B – Marking of the "sliding edges"  
 C – The penis is stretched to its maximum length, limited only by the elasticity of the neurovascular bundle and the urethra



**Fig. 2**

- A – Insertion of a penile prosthesis;  
 B – Coverage of the tunical defect with Buck's fascia only.





# Have you read? Best of the Best: Basic Research

by Javier Angulo



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## Peyronie's disease – Inhibiting the TGF- $\beta$ 1 pathway in fibroblasts

**Effect of Smad7 gene overexpression on TGF- $\beta$ 1-induced profibrotic responses in fibroblasts derived from Peyronie's plaque.**

*Choi MJ, Song KM, Park JM, Kwon MH, Kwon KD, Park SH, Ryu DS, Ryu JK, Suh JK.*

Asian J Androl – doi: 10.4103/1008-628X.142130 2014 Dec 5 [Epub ahead of print].

Although aetiology of Peyronie's disease (PD) is not completely elucidated, it seems to involve an inflammatory process in tunica albuginea. In this sense, overexpression of profibrotic cytokines contributes to the development of the plaque. The cytokine most consistently associated with the pathogenesis of PD is transforming growth factor- $\beta$ 1 (TGF- $\beta$ 1). In fact, injection of TGF- $\beta$ 1 in the penis of the rat causes a pathological process resembling some characteristics of PD in humans while expression and activity of TGF- $\beta$ 1 and its downstream effectors, Smad2 and Smad3 is increased in human PD plaques and fibroblasts derived from human PD plaques. Although some members of the family of proteins Smad are key participants in fibrotic process induced by TGF- $\beta$ 1 activation, other members have inhibitory activity on this process. This is the case for Smad7 which has been shown to antagonize TGF- $\beta$ 1-induced alterations in models of fibrotic pathologies.

The work by Choi and collaborators aimed to evaluate the overexpression of Smad7 in human fibroblasts derived from PD plaque as a strategy to overcome the pro-fibrotic phenotype induced by exposure of these cells to TGF- $\beta$ 1.

They isolated and cultured fibroblast obtained from surgical specimens of human PD plaque tissues. The cells were transfected with a vector including the Smad7 gene or by the vector alone. The changes in phenotype caused by exposure to TGF- $\beta$ 1 were evaluated in the two types of transfected cells.

The increased production of extracellular matrix proteins, collagen I and collagen IV induced by TGF- $\beta$ 1 in human PD fibroblasts was markedly inhibited by overexpression of Smad7 protein. A key point in the generation of fibrotic events is the transformation of fibroblast into myofibroblasts, which are thought to be responsible for fibrotic response. The phenotypic change identifying this transformation is the expression of the contractile protein  $\alpha$ -actin. TGF- $\beta$ 1 exposure induced expression of  $\alpha$ -actin in PD fibroblasts, consistent with the known involvement of TGF- $\beta$ 1 in transformation into myofibroblast phenotype. Overexpression of Smad7 reduced the expression of  $\alpha$ -actin, suggesting the inhibition of myofibroblast appearance among PD fibroblast culture. Smad7 upregulation also caused a reduced expression of cyclin D1, a positive cell cycle regulator and an increase in apoptosis of PD fibroblasts. The inhibitory effects of Smad7 are likely mediated by the interference with downstream effectors of TGF- $\beta$ 1 since its overexpression inhibited phosphorylation (activation) and nuclear localization of Smad2 and Smad3 induced by TGF- $\beta$ 1. Finally, Smad7 overexpression stimulated the expression of poly (ADP-ribose) polymerase-1 (PARP-1) that terminates transcription mediated by Smad proteins.

The authors conclude that the increased expression of Smad counteracts the extracellular matrix deposition induced by activation of Smad2/3 that drive the myofibroblastic differentiation triggered by TGF- $\beta$ 1. These inhibitory effects on fibrotic phenotype of PD fibroblasts would potentially combat the development and progression of PD plaque. However, although differentiation of tunical fibroblasts into myofibroblasts has been

shown as a high throughput method for screening potential candidate drugs for the treatment of PD, the **validation of this target (Smad7) in in vivo models of PD seems to be required**. In this sense, cell transfection with Smad7 gene appears as a way of therapy that presents practical difficulties. In this context, some pharmacological approaches (sesamin, abnormal savda munziq, resveratrol) have been shown to produce antifibrotic effects by up-regulating Smad7 expression. This could be considered for evaluation in PD. On the other hand, the local **administration should also be considered since Smad7 overexpression is related to pathological situations like Crohn's disease** (N Engl J Med 2015, 372:1104-12). An additional question to answer is if overexpression of **Smad7 would target only incipient stages of PD or could be beneficial in stable plaques**, maybe in combination with collagenase administration.

## Diabetic ED – Bypassing NO deficiency

**Beneficial effect of the soluble guanylyl cyclase stimulator BAY-41-2272 on impaired penile erection in db/db-/- Type II diabetic and obese mice.**

*Nunes KP, Teixeira CE, Priviero FB, Toque HA, Webb CB.*

J Pharmacol Exp Ther 2015, 353: 330-9.

Diabetes is not only associated with a threefold increase in the risk of suffering ED but also to a poorer response to conventional oral treatment for ED (i.e. PDE-5 inhibitors). Penile arteries and corpus cavernosum from diabetic men display an exacerbated impairment of endothelial and nitric relaxations that is related to a highly defective NO/cGMP pathway. This would explain why PDE-5 inhibitors, which act by potentiating the endogenous NO/cGMP signaling fail to produce a therapeutic response as good as that achieved in patients with less impacted NO/cGMP pathway. Among the mechanisms leading to a so impaired NO/cGMP pathway in diabetes, the reduction of NO bioavailability due



## Have you read ? Best of the Best: Basic Research

to excessive presence of reactive oxygen species (ROS) outstands.

In this study, Nunes and collaborators evaluate the effects of the soluble guanylyl cyclase (sGC) stimulator, BAY-41-2272 on cavernosal function and oxidative stress in corpus cavernosum in mice with type 2 diabetes and obesity. The mouse model used consisted of animals (db/db) that lack leptin receptor which results in the development of type 2 diabetes and obesity after 1–2 months of age. They determined in 14–16 weeks old diabetic db/db and their lean, non-diabetic (db/+) littermates functional responses of corpora cavernosa, systemic metabolic parameters and antioxidative status as well as cGMP content, superoxide generation and NADPH expression in corpus cavernosum.

This murine model of type 2 diabetes and obesity is associated with an impairment of endothelium-dependent and neurogenic relaxations in corpus cavernosum, a profile of cavernosal alteration consistently observed in diabetic models and humans. In contrast, relaxation induced by an NO-donor or the sGC stimulator in corpus cavernosum of db/db-/-mice is not altered. Treatment with mid-high nanomolar concentrations of BAY 41-2272 improves endothelium-dependent relaxation to acetylcholine and neurogenic relaxation induced by electrical field stimulation (EFS) in corpus cavernosum from diabetic/obese mice. In fact, the sGC stimulator increases duration of relaxant response to EFS in corpus cavernosum from both diabetic/obese and non-diabetic/lean animals. In addition to increase cGMP content in corpus cavernosum, treatment with BAY 41-2272 potentiates the cGMP accumulation induced by EFS and the NO-donor, sodium nitroprusside. Positive effects on NO/cGMP pathway by BAY 41-2272 are related to the down-regulation of the expression of the NADPH oxidase subunits gp91<sup>phox</sup>, p22<sup>phox</sup> and p47<sup>phox</sup> which are all up-regulated in corpus cavernosum from db/db-/-mice. Furthermore, consistently with NADPH oxidase down-regulation, BAY 41-2272 effectively coun-

teracts the increase in superoxide generation produced in corpus cavernosum from diabetic/obese mice.

The profound reduction of NO bioavailability seems to be the key factor in cavernosal dysfunction in diabetes. The results by Nunes and collaborators support this idea and provide evidence of the positive effects of **acting downstream of NO activity**. This is because of the preservation of diabetic cavernosal smooth muscle to relax when exogenous NO is provided to activate sGC or when sGC is directly stimulated. **Acting at this step of the pathway the defective NO availability could be overcome**. Additionally, the potentiating effects in cGMP accumulation caused by co-administration of BAY 41-2272 and the NO-donor or the NO derived from EFS suggest that BAY 41-2272 would **interact with NO to produce a robust stimulation of sGC**. This would account for the beneficial effects of the sGC stimulator on functional responses driven by physiological/pharmacological NO generation in corpus cavernosum from diabetic mice. However, potentiation of NO-mediated relaxation could be contributed by an additional mechanism suggested in this study. It is well established the pathophysiological role of reactive oxygen species (ROS) and, specifically, superoxide anion in the defective bioavailability of NO found in cavernosal tissue from diabetic animals and humans. In this sense, BAY 41-2272 is able to **antagonize the elevation of superoxide caused by diabetes/obesity** in cavernosal tissue, probably by down-regulating the expression of NADPH oxidase, an enzyme with outstanding participation in the generation of superoxide in cavernosal tissue and other vascular territories. The present work does not clarify if **this additional mechanism is specific for BAY 41-2272 or attributable to any sGC stimulator through the increased production of cGMP**.

Other open question would be related to the possible therapeutic advantage of combining PDE-5 inhibition with sGC stimulation in this model and

the impact on systemic hemodynamics. Finally, the interpretation of the present results should consider the fact that this is not a type 2 diabetes model but a type 2 diabetes and obesity model. Although obesity and type 2 diabetes are closely related conditions and both impact erectile function, the specific contribution of obesity to cavernosal dysfunction could influence the application of the results to type 2 diabetes in the absence of obesity.

### Diabetic ED – Hypoxic preconditioning for cell therapy

**Hypoxia precondition promotes adipose-derived mesenchymal stem cells based repair of diabetic erectile dysfunction via augmenting angiogenesis and neuroprotection.**

Wang XY, Liu CL, Li SD, Xu Y, Chen P, Liu Y, Ding G, Wahafu W, Hong BF, Yang MH.

PLoS One 2015, 10: e0118951.

Along last 10 years, a large number of studies have provided evidences supporting the ability of stem cells to recover erectile function in different animal models of ED. From embryonic to adult stem cells from different tissue sources, the implantation of these cells has shown certain degree of recovery/preservation of erectile function. Although neurogenic ED after cavernous nerve injury has been the main focus for cell therapy, other ED models involving different aetiologies such as diabetes have shown therapeutic response to cell implantation. However, further research to enhance the efficacy of cell therapy is being afforded.

Wang and co-workers have evaluated the hypoxic preconditioning as a way to enhance the efficacy of adipose-derived mesenchymal stem cells (ADSC) in reversing ED in diabetic rats. They have chosen the very well know model of type 1 diabetes induced in rats by a single injection of streptozotocin. The treatments were started 8 weeks afterwards, a time known to be enough to produce vascular alterations and ED. However,

## Have you read ? Best of the Best: Basic Research

the study used only rats that exhibited impaired erectile responses to subcutaneous injection of apomorphine at this time. Then, they compared the efficacy of intracavernosal injection of ADSC cultured under normoxic standard conditions (20% O<sub>2</sub>) to ADSC cultured in gas controlled chamber under 1% O<sub>2</sub> conditions for 24h, as a way to induce hypoxia precondition, in improving erectile responses and cavernosal histology in diabetic rats. Outcome was evaluated 4 weeks after injection.

The ADSC obtained from rats of the same strain were characterized by detecting the expression of stem cell markers in its surface and by the ability to undergo adipogenic and osteogenic differentiation. The improvement of erectile responses in diabetic rats receiving intracavernosal injection of ADSC with hypoxic preconditioning was superior to that obtained with injection of normoxic ADSC. This could be related to the in-

crease in expression of angiogenic (HIF-1 $\alpha$ , VEGF, angiopoietin-1, FGF-2), neurotrophic (BDNF, GDNF) and regenerative (SDF-1, CXCR4) factors induced by hypoxia in cultures of ADSC, which could explain the elevated survival of ADSC in cavernosal tissue 4 weeks after injection when these cells were cultured in hypoxic conditions. The greater improvement of erectile function achieved with ADSC injection after hypoxic precondition was also associated with less fibrosis and immune cell infiltration in cavernosal tissue as well as with increased expression of endothelium and smooth muscle markers.

The study by Wang and collaborators suggests that a relatively easy manipulation of the stem cells culture consisting of **hypoxic preconditioning before their intracavernosal injection may enhance the therapeutic efficacy in reversing ED in diabetic rats**. In fact, other manipulations of stem cells have been proposed

to enhance its efficacy in improving erectile responses in ED models, from gene delivery of neurotrophic or vasoactive factors, and clonal selection to the addition of adequate matrix. However, several issues should be outweighed considering the use of cell therapy in each specific type of ED. Although cavernous nerve injury (after prostatectomy for instance) involves a punctual insult that, if solved, it will not be persistent, diabetic ED represents a very different situation. Most of studies evaluating cell therapy do not contemplate the termination of the therapeutic effect of stem cell injection in ED models where the pathogenic mechanism of ED is persistent such as in diabetes. One would think that, **if diabetic condition is still present, further injections of ADSC would be required**. This is an interesting startpoint to analyze in future research the **time-course of the effects of cell therapy** in these types of ED models.



# ESSM

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## The ESSM School of Sexual Medicine 2015

16–25 October 2015  
Budapest, Hungary

[www.essm.org](http://www.essm.org)

# Have you read? Best of the Best: Clinical

A brief summary of the best papers and abstracts published in the main journals related to Sexual Medicine by **Nicola Mondaini**



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## Erectile dysfunction

### Efficacy of Avanafil fifteen minutes after dosing in men with erectile dysfunction: A randomized, double-blind, placebo-controlled study

*Hellstrom WJ et al:* J Urol. 2015 Jan 12.

To examine the therapeutic effects of avanafil 15 minutes after dosing in men with mild to severe ED. This randomized, double-blind, placebo-controlled 12-week study (4-week run-in; 8-week treatment period) randomized men to placebo (n=145), avanafil 100 mg (n=147), or avanafil 200 mg (n=148) on demand. The primary efficacy variable was the per-subject proportion of sexual attempts within the treatment period in which subjects obtained an erection sufficient for vaginal penetration within approximately 15 minutes after dosing (measured by stopwatch) that enabled successful completion of sexual intercourse (Sexual Encounter Profile question 3 [SEP3]). Significantly greater mean per-subject percentages of successful intercourse attempts within approximately 15 minutes after dosing were observed for avanafil 100 mg (mean, 25.9%, LS mean [SE], 24.7% [2.9]) and 200 mg (mean, 29.1%, LS mean [SE], 28.2% [2.9]) vs placebo (mean, 14.9% LS mean [SE], 13.8% [2.9],  $p=0.001$  and  $p<0.001$ ). After treatment, a statistically significant difference between avanafil and placebo in the average per-subject proportion of successful intercourse attempts (SEP3) was noted as early as 10 minutes in the 200 mg group and 12 minutes in the 100 mg group. Treatment-emergent adverse events included headache, upper respiratory tract infection, and nasal congestion; most were mild or moderate in severity. Treatment with avanafil produced ef-

ficacy, compared with placebo, within approximately 15 minutes of dosing, and a statistically significant treatment difference in the percentage of successful sexual attempts was demonstrated as early as 10 minutes after treatment.

### Priapism impact profile questionnaire: Development and initial validation

*Burnett AL et al:* Urology. 2015 Apr 8

To create and evaluate a psychometric instrument that measures the impact of experiencing priapism from the patient perspective. The research protocol consisted of several phases as follows: (1) generating items, (2) composing a patient questionnaire, (3) administering the questionnaire to patients with both active and remitted ( $\geq 1$  year without priapism episodes) histories of priapism, (4) performing internal consistency and criterion-oriented validity analyses in correlation with clinical histories and erectile function assessment tools, and (5) ascertaining psychometric properties of the instrument. The final instrument comprised a 12-item Priapism Impact Profile (PIP) questionnaire, representing the following 3 domains adversely impacted by priapism: Quality of life (QoL), sexual function (SF), and physical wellness (PW), with higher scores indicating inferior experience in respective domains. Internal consistency reliability coefficients for the total PIP score and the 3 domain scores were  $>0.75$ . Fifty-four patients (mean age,  $31.7 \pm 11.4$  years) completed the questionnaire. Patients with active priapism (n = 42) had higher total, QoL, SF, and PW scores than those with priapism remission (n = 8;  $P < .05$ ,  $P < .05$ ,  $P = .09$ , and  $P < .01$ , respectively). Patients with a history of recurrent priapism episodes  $>2$  hours in duration had higher total, QoL, SF, and PW scores than those with "very minor" priapism recurrences ( $\leq 2$  hours in duration;  $P < .01$ ,  $P < .05$ , and  $P < .001$ , respectively). Patients with "mild-to-moderate" to "severe" erectile dysfunction had higher total, QoL, SF, and PW scores than those with no or "mild" erectile dysfunction ( $P < .05$ ,  $P = .14$ ,  $P < .01$ , and  $P = .25$ ,

respectively). The PIP questionnaire is a novel psychometric instrument that offers a means to quantify the adverse health impact of the patient's experience with priapism

## Psychology

### Sexuality and romantic relationships in young adult cancer survivors: Satisfaction and supportive care needs

*Geue K et al:* Psychooncology. 2015 Mar 31.

In recent years, psycho-oncology has focused more and more on adolescents and young adults with cancer (AYA). Many studies have concentrated on fertility issues in AYAs, but romantic relationships and sexuality have only been researched to a limited extent. This cross-sectional study examined AYAs' quality of relationships and sexuality satisfaction thereby identifying sex differences. Ninety-nine cancer patients (N = 33 males) diagnosed between 15 and 39 years who were in a romantic relationship at the time of the survey completed questionnaires on their relationship (Partnership Questionnaire), sexuality (Life Satisfaction Questionnaire), and sexuality needs (Supportive Care Needs Survey). Test for mean differences and regression analyses to determine associated variables were performed. Seventy-six percent of AYAs (N = 75) rated their relationship quality as high. About 64% of patients reported having less sexual intercourse since diagnosis, more women than men (72% vs. 45%;  $p = .011$ ). The need for support was strongest for changes in sexual feelings (N = 38; 38.3%). Duration of relationship ( $\beta = -0.224$ ), being on sick leave ( $\beta = 0.325$ ), and satisfaction with sexuality ( $\beta = 0.409$ ) were associated with satisfaction with relationship ( $R^2 = 0.256$ ). Satisfaction with sexuality ( $R^2 = 0.344$ ) was regressed on physical function ( $\beta = 0.419$ ), satisfaction with relationship ( $\beta = 0.428$ ), and male gender ( $\beta = -0.175$ ). Sexuality need ( $R^2 = 0.436$ ) was associated with fatigue ( $\beta = 0.232$ ) and satisfaction with sexuality ( $\beta = -0.522$ ). Although they reported high satisfaction with their relationships, AYA patients experienced sexual problems and



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need support with sexual issues. As a substantial proportion of patients felt stressed because of sexual changes, communication and interventions addressing post-cancer sexuality, particularly in women, are indicated.

### FSD

#### **Advances in pharmacotherapy for treating female sexual dysfunction**

*Nappi RE1, Cucinella L. Expert Opin Pharmacother. 2015 Apr;16(6):875-87.*

'Female sexual dysfunction' (FSD) is an umbrella term comprising a range of common disorders, including hypoactive sexual desire, reduced subjective and/or physical genital arousal (poor sensation, vasocongestion, lubrication), sexual pain and inability to achieve orgasm/satisfaction, which are multidimensional by nature and often coexisting. Psychological and contextual factors have a significant influence on organic components of sexual response and behavior and a tailored medical approach to sexual symptoms is inevitably limited. The paper reports the most recent advances in pharmacotherapy for women taking into account the biopsychosocial model. Hormone therapy, including estrogens, testosterone, tibolone and dehydroepiandrosterone, are discussed in term of efficacy and safety in postmeno-

pausal women both for female sexual interest/arousal disorder (FSIAD) and genito-pelvic pain/penetration disorder. Ospemifene, a selective estrogen receptor modulator, approved to treat dyspareunia at menopause, is also discussed. Data on psychoactive agents for treatment of FSIAD in premenopausal women are discussed, including the potential use of on-demand combined hormonal (testosterone) and non-hormonal (buspirone or sildenafil) treatments to address possible neurophysiological profiles of women. We are still waiting for an approved pharmacotherapy for FSD. This is not the result of gender inequality in sexual medicine, but it reflects the need of balancing benefits and risks in order to provide effective and safe treatments to women of any age.

### SURGERY

#### **Penile length is a very important factor for cosmesis, function and psychosexual development in patients affected by hypospadias: Results from a long-term longitudinal cohort study**

*Ciancio F et al: Int J Immunopathol Pharmacol. 2015 Mar 26.*

Few studies of long-term outcome of hypospadias treatment in terms of voiding, surgical complications, sexual functioning, intimate

relationships and cosmetic results have been investigated and contrasting results have been obtained so far. The aim of our study is to investigate the long-term outcome of urinary and sexual function, cosmesis and the quality of intimate relationships in a series of hypospadias. In this study, 42 patients who underwent surgery for hypospadias were prospectively followed for 15 years. Medical records provided the hypospadias data, the number of reconstructive operations and the reconstruction technique that was used. Patients underwent physical examination, including penile length measurement and completed International Prostatic Symptoms Score (I-PSS), International Index Of Erectile Function (IIEF 15) and the Penile Perception Score questionnaire (PPPS). Twenty patients agreed to participate in the study. At the enrolment, the median value of HOSE was 13, as regards PPPS, 18/20 (90%) were satisfied, while in 1998 only 80% were satisfied. No significant statistical difference has been reported from the results obtained at enrolment and those obtained at follow-up, in terms of PPPS ( $P = 0.81$ ), IPSS and IIEF-15. Penile length was 6.5 cm flaccid and 10.5 cm stretched. Our data show how cosmesis, function and psychosexual development for these patients are highly connected to surgical outcome, which is understood to be a decrease in penile size.

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## MEETINGS AND EVENTS CALENDAR 2015



**Dr. Raul Vozmediano-Chicarro**  
Associate Editor  
Section of Andrology  
Department of Urology  
Carlos Haya University Hospital  
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### August 2015

#### 19<sup>th</sup> Congresso Brasileiro de Reprodução Assistida

August 5–8, 2015

Location: Hotel Atlantico, Búzios, RJ, Brasil

Website: [www.sbra.com.br/](http://www.sbra.com.br/)

#### Society for Theriogenology Annual Meeting

August 5–8, 2015

Location: San Antonio, Texas, USA

Website: [www.therio.org/](http://www.therio.org/)

#### International Academy of Sex Research Meeting

August 9–12, 2015

Location: Toronto, Ontario, CANADA

Website: [www.iasr.org/CMS/node/3](http://www.iasr.org/CMS/node/3)

#### XIII Congreso de la Sociedad Latinoamericana de Medicina Sexual (SLAMS)

August 13–16, 2015

Location: Raddisson Montevideo Victoria Plaza Hotel, Uruguay

Website: [www.slams2015.org/](http://www.slams2015.org/)

#### Florida Society of Reproductive Endocrinology and Infertility Annual Meeting

August 15, 2015

Location: Boca Raton Resort & Club in Boca Raton, FL, USA

Website: [www.fsrei.org/2015-meeting](http://www.fsrei.org/2015-meeting)

#### The Annual Scientific Meeting of the Endocrine Society of Australia and the Society for Reproductive Biology

August 23–26, 2015

Location: Adelaide, Australia

Website: <http://esa-srb.org.au/>

### October 2015

#### 61<sup>th</sup> Meeting of Canadian Fertility and Andrology Society

October 1–4, 2015

Location: Halifax, NS, Canada

Website: [www.cfas.ca/](http://www.cfas.ca/)

#### ASHG 2015 65<sup>th</sup> Annual Meeting

October 6–10, 2015

Location: Baltimore, USA

Website: [www.ashg.org/2015meeting/](http://www.ashg.org/2015meeting/)

#### 35<sup>th</sup> Congress of the Société Internationale d'Urologie

October 15–18, 2015

Location: Melbourne, Australia

Website: [www.siu-urology.org/congress-2015](http://www.siu-urology.org/congress-2015)

#### ASRM 2015 – 71<sup>st</sup> Annual Meeting of the ASRM

October 17–21, 2015

Location: Baltimore convention center, Balt, USA

Website: [asrm@asrm.org](mailto:asrm@asrm.org)

### November 2015

#### VIII Congreso ASEBIR

November 18–20, 2015

Location: San Sebastián, Spain

Website: [www.congresoasebir.es/](http://www.congresoasebir.es/)

#### Reunión Bienal de la ALIRH 2015

November 19–21, 2015

Location: Lima, Peru

Website: [alirh.org](http://alirh.org)

### December 2015

#### ASCB 55<sup>th</sup> Annual Meeting

December 12–16, 2015

Location: San Diego, CA, USA

Website: [www.ascb.org/meetings/](http://www.ascb.org/meetings/)



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EUROPEAN SOCIETY  
FOR SEXUAL MEDICINE



## 18<sup>th</sup> CONGRESS OF THE EUROPEAN SOCIETY FOR SEXUAL MEDICINE

4 – 6 February 2016 | Madrid, Spain

[www.essm.org](http://www.essm.org)

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☐ Herewith confirms the payment of EUR 25,00 for the **ESSM membership FOR RESIDENTS IN TRAINING\*** cost for the year 2015

☐ Herewith confirms the payment of EUR 160,00 for the **ESSM and ISSM membership** cost for the year 2015

\* A letter of the Chairman of the Department is necessary

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# Preparation Courses and Exams

## ESSM/EFS Exams Preparation Courses – Madrid, Spain

31 January – 2 February 2016

► Fellow of the European Committee on Sexual Medicine ► EFS/ESSM Qualified Psycho/Sexologist

EFS/ESSM will offer examination preparation courses for practitioners intending to take the examination on 3 February 2016. The courses are intended for physicians with experience of specialist-level practice in Sexual Medicine who wish to increase their chance of passing the MJCSM exam and for psychologists who intend to apply for the EFS/ESSM qualification exam for Psycho-Sexologists.

Preparation courses will provide an overview of all subjects in the MJCSM curriculum of Sexual Medicine that may be included in the examination and an overview of the content of the syllabus for clinical sexologists. Furthermore, advice about exam-taking skills and practice in completing Sexual Medicine MCQ's will be given. The teaching faculty for the courses will include recognised experts in the field of Sexual Medicine.

**Registration Fee: EUR 300,00**

### CME Accreditation

Application will be made for CME recognition for these courses and the exam so that participants may gain CME credits.

## ECPS Exam 2016 – Madrid, Spain

3 February 2016

### Become an EFS and ESSM certified Psycho-Sexologist

The European Federation of Sexology (EFS) and the European Society for Sexual Medicine (ESSM) collaborate in order to provide competency certification to individual psycho-sexologists from around the world. This procedure was initiated in 2014, and is carried out once in every two years.

### Eligibility criteria

The candidate eligible to apply for the exam must demonstrate expertise in psycho-sexology and obtain proof of

- Psychology University degree (with license in country of practice) or
- Psychiatry degree or
- MD degree with psychotherapy training

and

Postgraduate training in sexology (providing certificate) including supervised relevant experience of at least 2 years (providing 2 letters of recommendation using preformat)

### Examination format

Competency on the curriculum shall be assessed through a written exam consisting of 100 multiple choice questions to be answered in 3 hours.

### Who can apply?

Applicants that meet the eligibility criteria of all nationalities, including countries outside the EU, may apply for the exam.

Information and an application form are available on the ESSM website:

[www.essm.org](http://www.essm.org)

The ESSM and EFS Syllabus on Clinical Sexology is the preparation material endorsed by the EFS and ESSM Psycho-sexology Accreditation Committee (EPSA Committee).

**Registration Fee: EUR 300,00**

## MJCSM Exam 2016 – Madrid, Spain

3 February 2016

### The Multidisciplinary Joint Committee on Sexual Medicine (MJCSM)

was established by the UEMS specialist sections of Urology, Obstetrics and Gynaecology, and Psychiatry, and functions, within the framework of their respective statutes and bylaws. Its principle objective is to guarantee and promote the highest standards of healthcare in the field of Sexual Medicine, by ensuring that training in Sexual Medicine in Europe is established at an optimal level. The MJCSM determines the standards for training and assessment in Sexual medicine.

### Eligibility

The exam is set under the auspices of the UEMS but physicians of all nationalities, including countries outside the EU, are allowed to take the exam.

### Examination format

The exam duration will be 3 hours and will include 100 MCQ's in 5 domains of Sexual Medicine.

### Who can apply?

Only registered medical practitioners, who are accredited as medical specialists in their country of practice, or who are General Practitioners with more than 5 years' clinical experience of unsupervised independent practice, are eligible to apply. Candidates need to fill out their cases in the logbook available at the MJCSM website. Two letters of recommendations will be needed.

Information and an application form are available on the MJCSM website:

[www.mjcsm.org](http://www.mjcsm.org)

The contents will be according to the curriculum of Sexual Medicine defined by the MJCSM. The content has also been described in an ESSM publication, The Syllabus of Sexual Medicine by the ESSM Educational Committee

**Registration Fee: EUR 400,00**

## Again in 2016 prior to the ESSM Annual Congress in Madrid, Spain

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31 January to  
2 February 2016

Preparation Courses for the exams to become  
EFS / ESSM Qualified Psycho/Sexologist  
Fellow of the European Committee on Sexual Medicine

3 February 2016

**EXAM DAY**

- EFS / ESSM Qualified Psycho/Sexologist
- Fellow of the European Committee on Sexual Medicine  
The Examination in Sexual Medicine under the auspices of the UEMS



Location: Madrid, Spain  
Exam Application deadline: 2 November 2015

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Get more information on page 15 and at [www.essm.org](http://www.essm.org) or [www.mjcsm.org](http://www.mjcsm.org)

## Announcement for the next Congress **18<sup>th</sup> Congress of the European Society for Sexual Medicine**

4 – 6 February 2016 | Madrid, Spain

[www.essm-congress.org](http://www.essm-congress.org)



**ABSTRACT DEADLINE: 15 October 2015** for Oral Presentations and Posters