STATE OF THE ART LECTURE

Voiding Dysfunction After Stress Incontinence Surgery.

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Purpose: The purpose of this study was to determine which urodynamic (UDS) parameters were associated with the resolution of overactive bladder (OAB) symptoms after anterior pelvic organ prolapse (POP) repair.

Methods: All patients who underwent anterior POP repair with preoperative UDS evaluation and preoperative and postoperative Urogenital Distress Inventory (UDI-6) were eligible for the study. Two groups were stratified according to questions 1 and 2 of the UDI-6 to assess for OAB symptoms. Both groups had OAB symptoms prior to POP repair. Postoperatively, group A were “not at all” bothered by OAB symptoms. Group B were “slightly”, “moderately”, or “greatly” bothered by OAB symptoms. The preoperative UDS parameters were then analyzed.

Results: 45 patients met our inclusion criteria. 12 patients (26.7%) met criteria for group A and 33 patients (73.3%) met criteria for group B. Group A had an average Baden-Walker grade of 2.23 (SD 0.93) and group B had an average Baden-Walker grade of 2.21 (SD 0.90) for the anterior compartment. The average number of days the UDI-6 questionnaires were completed after surgery for group A and B were 321 and 270 days, respectively. The average preoperative and postoperative combined score of questions 1 and 2 of the UDI-6 for group A was 4.58 and 2.00, respectively. The average preoperative and postoperative combined score of questions 1 and 2 of the UDI-6 for group B was 5.15 and 4.58, respectively. The UDS parameter which was statistically different between group A and B was detrusor pressure (Pdet) at maximum flow (Qmax) at 28.40 vs. 18.35 cm H2O (p<0.05), respectively.

Conclusions: The only UDS parameter associated with resolution of OAB symptoms after anterior POP repair was Pdet at Qmax. We can speculate that this could be secondary to correction of anatomic obstruction after anterior POP repair. Further study is needed in a larger group of patients to confirm our findings.
DETRUSOR OVERACTIVITY ON URODYNAMICS PREDICTS PERSISTENCE OF URGENCY AFTER SLING PROCEDURE
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(Presentation to be made by Dr. Catherine Chen)

**Purpose:** Patients with mixed urinary incontinence benefit from sling procedures by treating the stress incontinence aspect of their disease. The purpose of this study is to evaluate how placing slings effects urinary urgency in patients with mixed urinary incontinence (MUI).

**Materials and Methods:** A retrospective database of patients who underwent all sling procedures from 2008-2014 from a single surgeon and at single institution was compiled. Patients who underwent any concomitant surgery for pelvic organ prolapse or urethrolysis were excluded. MUI, detrusor overactivity (DO) on urodynamic study (UDS), persistent urgency after surgical procedure, and patient global impression of improvement (PGI-I) scores were evaluated.

**Results:** A total of 172 patients had only sling procedures. Of this group, 111 had mixed urinary incontinence. In the MUI group, 67.5% had no prior surgeries for incontinence and 25% had detrusor overactivity on UDS. 73 patients had persistent urgency, 11 which had worsening of their urgency, 29 with no change and 33 with improvement. Overall, 64% (71/111) of patient with MUI had either resolution (n=38) or improvement (n=33) of their urge symptoms. In patients that have never had any prior procedures for incontinence, those who test positive for DO have a 79% lower probably of improvement in their post-op urgency (p=0.003). Despite the difference in improvement rates, there is no statistically significant difference in patient satisfaction. Overall, a PGI-I score of 1 or 2 was 90% (100/111) in the MUI population.

**Conclusions:** DO on UDS in patients with mixed urinary incontinence undergoing their first sling procedure indicates that those patients are less likely to have improvement of their urge symptoms. This finding likely indicates worse urge severity than in those patients where DO was not detected on testing. Despite this finding, overall patient satisfaction after their procedure remains high, likely due to the efficacy of the sling procedure eliminating the SUI component of their symptoms, thus providing adequate satisfaction in controlling their incontinence. The expected improvement in urge symptoms should also be communicated to patient in pre-operative counseling.

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precise characterisation of bladder innervation with 3D image reconstruction

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Introduction: Currently, there is no comprehensive model that provides a detailed three-dimensional view of bladder innervation. As such, we utilized 3D computer assisted reconstruction of cadaver histopathology to precisely define the relationship of bladder autonomic nerves to the lumen of the bladder.

Methods: We harvested the bladder and surrounding tissues from a male cadaver. To create a 3D model, the bladder lumen was filled with melted paraffin to a semi-distended condition. We created 23 axial cross sections at 3mm intervals and stained with S100. We created a high-resolution depiction of each cross section at magnifications of 0.3X-20X optical zoom. We imported the images into ImageScope (Vista, CA). We performed manual demarcation of the autonomic nerve supply of the bladder. We measured the distances between the autonomic nerves and the bladder lumen. Autonomic nerve tracings of each cross section were imported into SolidWords (Waltham, MA, USA) and 3D reconstructions of the anatomy were created.

Results: The autonomic innervation was concentrated in the posterior aspects of the bladder and was most pronounced at the bladder neck and trigone region. The mean distance between the autonomic nerve branches and the bladder mucosa was 1.15mm posteriorly versus 4.0mm anteriorly (0.27-2.87 vs. 2.03-6.20, p<0.001).

Conclusions: Novel 3D reconstruction of the bladder is feasible and will improve our understanding of human bladder innervation. Autonomic innervation is highly focused in the posterior aspect of the bladder and is dense at the bladder neck. The most superficial fibers vary in distance from the urothelium from 1.15-4.0mm.

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EXAMINATION OF THE SIGNIFICANT PLACEBO EFFECT IN THE TREATMENT OF INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME

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(Presentation to be made by Dr. Bosch)

Purpose: To examine the significant "placebo effect" in a randomized, double-blind, placebo controlled interstitial cystitis/bladder pain syndrome trial. Randomized clinical trials are the reference standard for therapeutic impact assessment. However, proving efficacy of treatments for interstitial cystitis/bladder pain syndrome with rigorous placebo-controlled trials is difficult due to a significant effect of the placebo intervention.

Materials and Methods: Interstitial cystitis/bladder pain syndrome patients were randomized to receive SQ adalimumab or SQ placebo every 2 weeks for 12 weeks and outcome measures were assessed.

Results: Of the 43 patients, 21 received adalimumab and 22 received placebo. Of the patients who received placebo, there was a statistically significant improvement demonstrated in the O'Leary-Sant Interstitial Cystitis Symptom and Problem Indexes of -8.1 (95% CI 3.0, 13.2), Interstitial Cystitis Symptom Index of -3.7 (95% CI 0.9, 6.5), Interstitial Cystitis Problem Index of -4.4 (95% CI 2.0, 6.8), and Pelvic Pain, Urgency, Frequency scale of -6.9 (95% CI 2.8, 11.0) at week 12 compared to baseline. Most of the significantly improved placebo patients felt their improvement was because they were more conscientious about following physician advice and feeling less stress while in the study.

Conclusions: Patients with moderate to severe interstitial cystitis/bladder pain syndrome had significant improvement after receiving only advice and support. This intervention is risk-free and inexpensive. Physicians should review standard advice with all interstitial cystitis/bladder pain syndrome patients before starting medical therapy.

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COMPARING THE VAGINAL WALL SLING WITH AUTOLOGOUS RECTUS Fascia AND POLYPROPYLENE SLING - A PILOT STUDY
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(Presentation to be made by Dr Myklak)

Introduction and Objectives: Since the 2011 FDA safety update on transvaginal synthetic mesh for treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI), many patients are hesitant to undergo synthetic mesh implantation. The use of autologous tissue for suburethral sling surgery may be indicated in patients who have experienced prior mesh complications or wish to avoid synthetic material. We aim to compare urinary symptoms and patient satisfaction in patients who received a vaginal wall sling, autologous rectus fascia, or synthetic pubovaginal sling.

Methods: Patients who underwent autologous or synthetic sling placement either with or without POP repair by a single surgeon were reviewed retrospectively. Pre- and postoperative voiding symptoms were obtained from medical records, and a telephone survey was performed to assess patients' current voiding symptoms. Objective outcomes included self-reported pad usage and subjective outcomes included overall satisfaction measured with a Likert scale (1=very dissatisfied, 5=very satisfied). Fisher’s exact test, Mann Whitney, and independent samples Kruskal Wallis test were used for statistical analysis, with significance at p<0.05.

Results: From May 2011 to June 2013, 105 patients underwent pubovaginal sling surgery (mean age 62.5 years, range 29-87). Of these, 67 patients (63.8%) completed a phone survey at a mean of 392 days postoperatively (range 40-796). Sixteen patients (23.9%) underwent vaginal wall sling, 19 (28.4%) underwent rectus fascia sling and 32 (47.8%) a synthetic sling. Of patients receiving a vaginal wall sling, 100% underwent concomitant prolapse surgery, most commonly for cystocele (96%). This was significantly greater than the patients undergoing prolapse surgery at the same time as autologous rectus sling (60.7%) or synthetic sling (32.7%), p<0.001. Patients receiving a vaginal wall sling (p=0.01) or synthetic sling (p=0.01) demonstrated a statistically significant decrease in pad usage from pre- to post-op, which did not reach statistical significance in autologous rectus fascia slings (p=0.15). Patient satisfaction did not differ by sling type (3.5 for vaginal wall, 4.0 for rectus fascia, 3.9 for synthetic sling, p=0.58).

Conclusions: Patients who received a vaginal wall sling were equally satisfied and reported a similar rate of improvement of SUI as patients treated with polypropylene sling in this pilot study. Vaginal wall sling may be an alternative for patients with SUI and a cystocele who wish to avoid synthetic mesh; however, larger samples in a prospective study are warranted.

Source of Funding: None
LONG-TERM OUTCOMES OF AUTOLOGOUS RECTUS FASCIA PUBOVAGINAL SLING IN STRESS URINARY INCONTINENCE
(Presentation to be made by Dr. E. Lee)

Purpose: Synthetic mid-urethral slings are no longer viewed as the only option for female stress urinary incontinence (SUI) due to issues relating to polypropylene mesh. There are a limited number of surgical treatment options for SUI, particularly for patients with recurrent SUI or mesh complications, and autologous rectus fascia pubovaginal slings (AFS) are one important option in the clinical toolbox. The objective of this study was to evaluate the long-term outcomes for AFS in patients with SUI.

Methods: A retrospective review of prospectively collected data of patients undergoing AFS surgery for SUI was performed. Patients were followed postoperatively with mailed questionnaires at 12 months, then yearly thereafter. The primary outcome was patient-reported dry rate as assessed by the response “not at all” to the Urinary Distress Inventory (UDI-6) questionnaire item 3 “Do you experience, and if so, how much are you bothered by urine leakage related to physical activity, coughing, or sneezing?” Secondary outcomes were patient-reported percent improvement and percent satisfaction.

Results: A total of 138 patients received AFS for SUI between 1999 and 2014. There were 82 patients with a minimum follow up of 12 months. Mean age was 60 (range 34-87) and 63% (52/82) had undergone previous anti-incontinence surgery. At an average follow-up of 6.1 years (range 1.4-11.0), the dry rate was 35% (28/79). In addition, average patient-reported improvement and satisfaction were 42% and 63% (n=31), respectively. Of the 82 patients, 17 (23%) experienced a total of 19 peri-operative complications, including 8 cases of retention (1 requiring urethrolysis), 3 wound infections requiring antibiotics, 2 UTIs, 2 transfusion, 1 sling exposure, 1 small seroma that was drained, 1 abdominal wall hematoma, and 1 case of pneumonia.

Conclusions: Success and satisfaction scores after AFS in patients with SUI make it one of the few viable non-mesh treatment options. Given the need for data on long-term outcomes for all anti-incontinence procedures, our results regarding outcomes for AFS are important for pre-operative counseling of patients.
SACROCOLPOPEXY WITH AUTOLOGOUS FASCIA
Judy M. Choi, Diana C. Kang, Leah Nakamura, Shlomo Raz

Introduction and Objective: Abdominal sacrocolpopexy (ASC) with mesh has been regarded as the most durable operation for advanced pelvic organ prolapse (POP). However, recent reports estimate that there is a 10.5% risk of mesh erosion at 7 years, with either symptomatic or anatomic failure in 34-48% of cases. There are few alternatives noted in the literature to manage severe mesh complications. We propose a novel technique using a patient’s own rectus fascia in lieu of mesh to perform ASC, in the setting of SCP mesh removal.

Methods: After IRB approval was obtained, a retrospective review was performed using medical records of patients referred to our tertiary care center for mesh complications following ASC from January 2012 to October 2013. All patients underwent complete ASC mesh removal transabdominally, with concomitant ASC with autologous fascia. A lower midline incision was used to remove the previous mesh, and a 10x2 cm segment of anterior rectus fascia was harvested longitudinally. The fascial segment was then configured into an “L”-configuration; the superior aspect was sutured to the sacral promontory, and the inferior portion was sutured to the vaginal cuff, both using #1 delayed absorbable sutures.

Results: 10 patients were included in the study. Mean age was 56.5 years. Mean BMI was 28.0 (22.8-38). Mean time from original SCP was 61.9 months (15-128 months). Prior SCP consisted of 7 open, 2 robotic, and 1 laparoscopic SCP. The original SCP was performed with polypropylene (n=4), Prolene (3), Mersilene (1), or Goretex (1) mesh, and all were placed with permanent sutures (Prolene, Gore-Tex, Ethibond). Presenting symptoms included dyspareunia (7), vaginal pain (5), vaginal bleeding (4), lower back pain (5), lower abdominal pain (5), hip pain (4), recurrent urinary infections (3), and defecatory dysfunction (4), as well as one rectovaginal fistula. On presentation, 3 had cystoceles, 2 had enteroceles, and 2 had rectoceles. Mesh could be palpated or seen on 5 patients. During the ASC with autologous fascia, mean EBL was 317 cc, and mean hospital length of stay was 7 days. All patients reported significant improvement of their original symptoms at follow-up (mean 180 days) without any recurrent POP.

Conclusions: This is the first report to address the simultaneous management of severe mesh complications from ASC, and POP following ASC mesh removal. Abdominal sacrocolpopexy using autologous fascia is a safe and feasible alternative to the traditional SCP using mesh, although greater follow-up time is necessary to assess its durability and outcomes.
PATIENT QUALITY OF LIFE AFTER REMOVAL OF VAGINAL MESH
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Introduction: Despite the growing number of vaginal mesh removal surgeries, very little is known about patient quality of life in terms of pain, incontinence, and sexual function after the mesh has been removed. We present the short and long terms results of patient satisfaction and outcomes after mesh removal surgery in our patient population.

Methods: A retrospective review was conducted of all vaginal mesh removal procedures performed at UCLA by 4 fellowship trained Female Urologists between 2006 and 2012. We included vaginal prolapse mesh, vaginal sling mesh, and sacrocolpopexy mesh removal. Six hundred and sixty-two patients were identified and sent surveys pertaining to their quality of life. The questionnaire included the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), Incontinence Symptom Score (ISS-8) questionnaire, a modified Stanford comparative pain scale, and a modified International Prostate Symptom Score (I-PSS). Patients were additionally asked where their pain was located on the body and whether they had any systemic symptoms related to mesh. Surveys were collected and reviewed.

Results: Two hundred and fourteen surveys were collected with a mean follow up rate of 32%. The mean patient age was 65 years old (range 35-92). Mean follow up time since surgery was 39 months (range 5 – 95 months). In terms of improvement after surgery, 55% of patients stated that they were “very much better” or “much better” and a further 22% stated that they were “a little better”. Seventeen percent stated that they were “much worse” or “very much worse” after the surgery. On the Stanford comparative pain scale 66% of patients rated their pain as mild (score 0-3) while 33% rated their pain as moderate to severe. 30% of patients stated that they had no pain. Many patients continued to have incontinence after the procedure although this was mostly irritative in nature: 64% complained of moderate to great bother due to frequency while a further 59% complained of moderate to great bother due to urgency. Twenty eight percent of patients complained of stress urinary incontinence at least once a day. In terms of sexual function, 49% of women responding complained of dyspareunia since their vaginal mesh removal.

Conclusions: The majority of vaginal mesh surgeries are elective in nature and usually occur in otherwise healthy patients. Vaginal mesh has the potential to cause prolonged and disabling pelvic pain, urinary incontinence, and sexual dysfunction despite subsequent mesh removal.
Purpose: In elderly men, urinary retention is often attributed to an enlarged prostate. However, the true etiology may be more complex, involving detrusor hypocontractility, bladder outlet obstruction, or a combination. As this subset of men has been incompletely examined in the past, we studied the urodynamic characteristics of men in urinary retention who presented to our institution.

Materials and Methods: We performed a three-year retrospective review of men in either overt retention (dependence on catheter drainage) or objective retention (an office ultrasound post-void residual greater than 500 ml with subjective incomplete emptying). Men with neurogenic voiding dysfunction or a history of prostate cancer were excluded. In addition to a pressure flow study, an isometric detrusor contraction pressure (Piso) was measured with the continuous occlusion test by gentle occlusion of the urethra during the mid-voiding phase.

Results: Sixty-seven men were identified with urinary retention and underwent multichannel videourodynamic examination. Median age was 68 years (range 35-89). Of these men, 84% presented in overt retention. The median maximum flow rate (Qmax) was 3 ml/s, with a median detrusor pressure at maximum flow (PdetQmax) of 54 cm H2O. The median Piso was 68 cm H2O, and the median detrusor reserve (Piso - PdetQmax) was 7 cm H2O. Outlet obstruction, defined as an Abrams-Griﬃths number greater than 40 was present in 60%. Detrusor hypocontractility, defined as a bladder contractility index (BCI) number less than 100, was diagnosed in 73% of men; however, when we used another indicator of hypocontractility (Piso less than 50 cm H2O), only 30% were classified as having weak bladders. Overall, 79% had a detrusor reserve less than 20 cm H2O, while only 21% had detrusor reserve > 20 cm water.

Conclusions: In our cohort, only 60% of men in urinary retention have urodynamic evidence of bladder outlet obstruction. Depending on how bladder contractility is measured, (BCI versus Piso) the rate of detrusor hypocontractility varies. The majority of men in retention have a low detrusor reserve. In light of the variable urodynamic findings in men with urinary retention, surgical intervention may not be the optimal solution in all cases.
DISPELLING A COMMONLY HELD BELIEF: DIABETIC SEVERITY DOES NOT INCREASE THE RISK OF URINARY INCONTINENCE IN WOMEN (NHANES 2001-2010)
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(Presentation to be made by Dr. Weinberg)

Purpose: It is commonly assumed that Diabetes mellitus type II (T2DM) is an important cause of urinary incontinence (UI). However, it is uncertain whether diabetes and markers of diabetic severity act as independent risk factors for incontinence. We investigated the associations among proxy measures of diabetic severity with stress and urge urinary incontinence (SUI, UUI) among women in a nationally representative U.S. data sample.

Material and Methods: We performed a cross-sectional analysis of female adult participants in the 2001-2010 National Health and Nutrition Examination Survey (NHANES). Urinary incontinence was ascertained by self-report. Diabetic severity was defined by calculated measures of glycemic control and insulin resistance (IR). We classified glycemic control using hemoglobin A1c (HbA1c) and fasting plasma glucose levels (FPG). Insulin resistance was estimated using fasting plasma insulin (FPI) levels and the homeostasis model assessment of insulin resistance (HOMA-IR) definition. Logistic regression models, adjusted for sociodemographic variables, common risk factors and comorbidities, were fitted for each measure of T2DM severity and the presence of SUI and UUI. Additional regression models were developed to characterize other independent risk factors for female SUI and UUI among community dwelling US women.

Results: The overall prevalence of SUI was 41%, and UUI was 25.4%. Compared to women with a normal HbA1c, participants with T2DM had a significant increased prevalence of both SUI (38.6% vs 52.5%) and UUI (21.7% vs 40.3%). However, measures of glycemic control and insulin resistance were not associated with an increased risk of either SUI or UUI in multivariable regression analysis. In multivariable analysis, independent risk factors for SUI included age, parity, BMI, hysterectomy, hypertension, post-menopausal status and functional mobility limitations. Independent risk factors for UUI included age, race, parity, BMI, post-menopausal status, and functional mobility limitations.

Conclusions: Contrary to popular beliefs and despite and increased prevalence of SUI and UUI among women with diabetes, a direct association between diabetic severity and UI risk does not exist. We highlight significant risk factors that are shared among women with either SUI or UUI (increasing age, BMI, parity and functional limitations).

Source of Funding: None
THE VIRTUE® SLING - A NEW QUADRATIC SLING FOR POST-PROSTATECTOMY INCONTINENCE - RESULTS OF A MULTINATIONAL CLINICAL TRIAL
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(Presentation to be made by Dr. Comiter)

Purpose: Innovations in sling design and technique have fostered an increased interest in sling surgery for the treatment of post-prostatectomy incontinence. To successfully perform male sling surgery, the surgeon must achieve proximal urethral relocation and/or bulbar urethral compression. The Virtue® (Coloplast, Humlebaek, Denmark) quadratic sling is a novel device that provides both proximal urethral relocation via a trans obturator component and perineal urethral compression via a superior prepubic component. Based upon evaluation of initial clinical results, a novel fixation mechanism was incorporated, to prevent early sling loosening. We report the one year results of the Virtue sling with fixation – and compare it to the results of the initial “unfixed” sling trial.

Materials and Methods: A prospective trial was performed to assess the efficacy and safety of the Virtue sling. Patients with at least 6 months of stress incontinence (proven urodynamically) following prostatectomy were enrolled. Brachytherapy, cryosurgery and external beam radiotherapy were not exclusion criteria unless they occurred within 6 months previously. Based on an FDA Guidance document, objective success was predefined as > 50% decrease in 24-hour pad weight, and subjective success as a score of “much” or “very much” better on the Patient Global Impression of Improvement. Subgroups were analyzed by baseline incontinence: mild (< 100 g), moderate (100-400 g) and severe (> 400 g). Following analysis of the one year data, a second clinical trial incorporating a novel “fixation” technique was performed, with similar outcome measures.

Results: In the initial cohort (N=98), objective success was realized in 61.3%, 55.1%, 53.8%, and 41.9% at 1.5, 3, 6, and 12 months, respectively. Subjective success was achieved in 56.4%, 46.6%, 48.1%, and 41.9% at 1.5, 3, 6, and 12 months, respectively. Median pad weight reduction was 51.1% at 12 months (203.0 g to 65.0 g), and varied with the degree of baseline leakage. In the fixation cohort (N=31), objective success was achieved in 85.2%, 71.4%, 64.3%, and 79.2% at 1.5, 3, 6, and 12 months, respectively (p< 0.01 vs baseline for each). Subjective success was achieved in 80.0%, 71.5%, 78.6%, , and 70.9% at 1.5, 3, 6, and 12 months, respectively (p< 0.01 vs baseline for each ). Median pad weight reduction was 88.3% at 12 months (147.0 g to 12.0 g), and efficacy was similar regardless of baseline incontinence. There were no cases of prolonged retention, and no severe adverse events.

Conclusions: The Virtue sling with fixation is a safe and efficacious treatment for PPI, with substantial improvement in subjective and objective measures of continence at 1 year postoperatively. Based upon suboptimal maintenance of continence with the unfixed device, the addition of a straightforward fixation technique mediated a substantial improvement in sling efficacy. The stable results over 1 year support the concept that fixation prevents early sling loosening, without adversely affecting bladder emptying.

Source of Funding: Coloplast (Clinical Trial)
POINT / COUNTERPOINT

Pelvic Floor Dysfunction.

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