This section presents a small sample of the Pelvic Floor Digest, an online publication (www.pelvicfloordigest.org) that reproduces titles and abstracts from over 200 journals. The goal is to increase interest in all the compartments of the pelvic floor and to develop an interdisciplinary culture in the reader.

FORUM

An introduction to genes, genomes and disease. Hall PA, Reis-Filho JS, Tomlinson IP, Poulson R. The Journal of Pathology EPUBDATE: 2009-12-05. The human and other genome projects and subsequent resequencing programmes have provided new perspectives on the nature of the gene and how genes function. The complexity of the eukaryotic nucleus and the diversity of genetic regulatory mechanisms is central to understand how genes function, as well as the recognition of gene dosage issues. This introduction to the 2010 Annual Review Issue, Genes, Genomes and Disease, provides overviews of these areas and then considers their relevance to a range of human diseases.

One example on how colloidal nano- and microparticles could contribute to medicine. Peteri-Cartelle J, Rodriguez-Pedreira M, Zhang F et al. Nanomedicine. EPUBDATE: 2009-12-05. Nanomedicine is a popular keyword in the media, although everyone seems to associate it with different visions, hopes and even fears. This article from the point of view of a materials scientist, indicates what new materials will be possible, how they will be designed and which properties they could offer for diagnosis and treatment, from the point of view of a medical doctor it indicates which properties are actually desired and what materials are hoped for practical applications. Although sophisticated materials will be available in the future, they do not automatically match the requirements and demands of clinicians.

Stem Cells: a review and implications for urology. Yu RN, Estrada CR. Urology. EPUBDATE: 2009-12-08. The promise of stem cells is to provide a source of non-diseased material for the generation of patient-specific cells or tissue for replacement and reconstruction. The future of reconstructive surgery will surely incorporate a number of stem cell based technologies in revolutionary ways that may improve and extend lives. However, the ultimate clinical applicability of the different types of stem cells will depend on a complex synthesis of further basic research, future clinical trials, and ethical and regulatory reconciliation.

1 THE PELVIC FLOOR

Effectiveness of EUS in drainage of pelvic abscesses in 25 consecutive patients (with video). Varadarajulu S, Drelichman ER. Gastrointestinal Endoscopy. EPUBDATE: 2009-12-08. EUS is a minimally invasive, safe, and effective technique that affords long-term benefit for patients undergoing pelvic abscess drainage. In patients with an abscess that measured less than 8 cm in size, two 7F transrectal stents were deployed. In patients with an abscess that measured 8 cm or more in size, an additional 10F drainage catheter was deployed. Treatment was successful in 24 (96%) of 25 patients. The mean duration of the postprocedure hospital stay was 3.2 days. At a mean follow-up of 189 days (range 93-817), all 24 patients were doing well without abscess recurrence.

Management of hemorrhage in severe pelvic injuries. Jeske HC, Lardorfer R, Krappinger D et al. The Journal of Trauma Injury, Infection, and Critical Care. EPUBDATE: 2009-12-10. Major pelvic trauma results in high mortality. No standard technique to control pelvic hemorrhage has been identified. Of 1,476 pelvic fracture patients, 45 were included, 1 died, 2 underwent emergency laparotomy with pelvic packing, 42 underwent angiographic embolization before or after a TC scan. Application of a clinical algorithm focusing on basic radiologic diagnostics, external fixation, and early angiographic embolization was effective and safe to rapidly control hemorrhage in hemodynamically unstable trauma patients with pelvic fractures.

2 FUNCTIONAL ANATOMY

Virtual pelvic anatomy simulator: a pilot study of usability and perceived effectiveness. Peyton Hassinger J, Dozios EJ et al. Journal of Surgical Research. EPUBDATE: 2009-12-05. A three-dimensional (3-D) pelvic anatomy teaching module derived from human magnetic resonance and computerized tomography images was used as a simulator for surgical education for medical students and surgery residents. Fifty percent of participants to the evaluation felt the module needed a higher level of anatomic detail.

[Functional anatomy of the pelvic floor.] You R, Costa P, Haub F, Delmas V. Progrès en Urologie. EPUBDATE: 2009-12-09. The levator ani muscle is the major component of the pelvic floor, it is formed essentially by type I fibers with high oxidative capability and presence of slow myosin as in postural muscles. The aerobic metabolism makes it susceptible to injury caused by eccentric contraction and mitochondrial dysfunction. The pelvic floor is innervated by the 2nd, 3rd, 4th anterior sacral roots. The perineum includes the musculosfascial structures under the L4: ventrally the striated urethral sphincter and the ischio-cavernous and bulbospongious, caudally the fatty tissue filling the ischioanal fossa. Pelvic fascia covers the muscles; it presents reinforcements: the urovescical and cardinal ligaments, the arcus tendineus fascia pelvis (ATFP) and the arcus tendineuslevator ani (ATLA). The combined action of all these anatomical structures anteriorly form the perineal “hammock”, medially the urovescical and cardinal ligaments, posteriorly the rectovaginal fascia and the perineal body. The angles formed by the pelvic viscers with their evacuation ducts participate to the pelvic statics and during the pelvic dynamics these angles change due to the action of the musculosfascial structures.

HRT and mRNA expression of estrogen receptor coregulators following exercise in postmenopausal women. Diel-Honwight CM, Spektor TM, Rice JC, Schroeder ET. Medicine & Science in Sports & Exercise. EPUBDATE: 2009-12-03. The use of hormone replacement therapy (HRT) is a potential treatment to relieve symptoms of menopause in postmenopausal women, however, the effects on skeletal muscle are unclear. A single bout of maximal exercise enhances estrogen receptor transcriptional activity with a greater response.

3 DIAGNOSTICS

[Evaluation of two classifications systems for pelvic prolapse on dynamic MRI.] Novellas S, Mondot L, Bajghi A et al. Journal de radiologie. EPUBDATE: 2009-12-03. To determine the usefulness of two classification systems for pelvic prolapse detection and staging on MRI based on different anatomical landmarks, a prospective study of 30 patients with symptoms of pelvic prolapse was performed, the first using the pubococcygeal, the second the midpubic line. The classification system based on the pubococcygeal line appeared more reliable and simple for the evaluation of pelvic prolapse on MRI.

X-ray microcomputed tomography as a tool for the investigation of the biodistribution of magnetic nanoparticles. Rahn H, Odenbach S. Nanomedicine. EPUBDATE: 2009-12-05. Computed tomography studies the inner structure of opaque samples using the material-dependent attenuation of x-rays. Microcomputed tomography improves the spatial resolution to a few micrometers. An example for the application of x-ray microtomography is the study of the 3D biodistribution of magnetic nanoparticles in tumoral tissue after minimal invasive cancer therapy, which is one of the crucial factors for this kind of therapy.
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[Alternatives to colonoscopy and their limitations.] Chaput U, Oudjit A, Prat F, Chaussade S. Presse Médicale EPUBDATE: 2009-12-08. Conventional optical colonoscopy’s morbidity and poor acceptability have led to the development of alternative techniques. Colo-TC has the best recognized performance (sensitivity 85% and specificity 97% for the detection of polyps>9 mm), but because of its irradiating nature MRI would be preferable: work on the topic is less abundant at the moment. Capsule endoscopy (the Pill-cam) for the colon is promising (sensitivity 64%, specificity 84%, positive predictive value 60%, negative predictive value 86% for detecting polyps>6mm). Improvements for standard colonoscopy (Aer-O-Scope, Invrescope, CathCam colonoscopy) are in their infancy.

4 PROLAPSES

[Risk factors and prevention of genitourinary prolapse.] Ragni E, Lousqy R, Costa P et al. Progrès en Urologie. EPUBDATE: 2009-12-09. Vaginal delivery increases the risk of prolapse (proof level 1), though the Cesarian section cannot be considered a completely effective preventative method (proof level 2). The pregnancy itself is a risk factor for prolapse (proof level 2). Certain obstetrical conditions contribute to the alterations of the perineal floor muscle: a foetus weighing more than 4 kilos, the use of instruments at birth (proof level 3). If the risk of prolapse increases with age, infiltration with hormonal factors is important (proof level 2). The role of hormonal replacement therapy remains controversial. Antecedent pelvic surgery has also been identified as a risk factor (proof level 2). Acquired factors as obesity, intense physical activity, constipation, increase the risk (proof level 3).

[Update on the epidemiology of genital prolapse]. Lousqy R, Costa P, Delmas V, Haab F. Progrès en Urologie. EPUBDATE: 2009-12-09. The prevalence of pelvic organ prolapse (POP) varies between 2.9 and 11.4% in questionnaire-based studies. Aging is significantly associated with the prevalence and severity of POP. Pelvic disorders are a health economic challenge for the future due to the longer life expectancy of women and to an increasing demand for a better quality of life.

[Urodynamic and prolapse.] Hermieu JF. Progrès en Urologie. EPUBDATE: 2009-12-09. With urogenital prolapses bladder outlet obstruction and stress urinary incontinence are common findings. The diagnosis of stress urinary incontinence is made by physical examination, urodynamic tests are crucial to decide the most appropriate treatment for each individual patient. Despite some technical limitations, we recommend that a proper urodynamic investigation should be performed before any surgical intervention for urogenital prolapse.

[The role of ultrasound in the exploration of pelvic floor disorders.] Lapray JF, Costa P, Delmas V, Haab F. Progrès en Urologie. EPUBDATE: 2009-12-09. Pelvic and endovaginal ultrasounds should be systematic. Perineal and introital dynamic ultrasound allows the appreciation of the bladder neck and urethral mobility, certain complications with suburethral tape and pelvic mesh, post-miotic residual. Endoanal ultrasound is the first line morphological examination of the anal sphincter.

[Non surgical treatment of prolapse.] Conquy S, Costa P, Haab F, Delmas V. Progrès en Urologie. EPUBDATE: 2009-12-09. In case of stage 1 prolapses or surgical contra-indication, some non surgical treatment can be proposed: there is no proof of efficacy of hormonal treatment. Pessaries give 58 to 80% satisfaction, vaginal discomfort being improved by local estrogenotherapy. Pelvic floor training in moderate prolapse can be useful. Prevention includes careful delivery management, struggle against overweight, carriage of weight, chronic cough, etc.

Risk factors for mesh erosion 3 months following vaginal reconstructive surgery using commercial kits vs. fashioned mesh-augmented vaginal repairs. Finamore PS, Echols KT, Hunter K et al. International urogynecology journal and pelvic floor dysfunction. EPUBDATE: 2009-12-05. To establish retrospectively the overall graft erosion (exposure of any mesh upon visual inspection of the entire vagina) rate in a synthetic graft-augmented repair 3 months postoperatively, 124 grafts were evaluated. The overall erosion rate was 11.3%. There was a significantly lower erosion rate when using “commercial kits” vs. traditional repairs (1.4% vs. 23.6%).

Effects of colpocleisis on bowel symptoms among women with severe pelvic organ prolapse. Gutmans RE, Bradley CS, Ye W. International urogynecology journal and pelvic floor dysfunction. EPUBDATE: 2009-12-05. Most bothersome bowel symptoms resolve after colpocleisis, especially obstructive and incontinence symptoms, with low rates of de novo symptoms. This was demonstrated in 152 women evaluated with the Colorectal-Anal Distress Inventory (CRADI) and the Colorectal-Anal Impact Questionnaire (CRAIQ).

[Should a hysterectomy be carried at the same time as surgery for a prolapse by vaginal route?] Debodinance P, Fattar B, Lacot JP. Progrès en Urologie. EPUBDATE: 2009-12-09. Hysterectomy during vaginal surgery for prolapse is indicated for major hysteroccele or in case of concomitant uterine pathology. The anatomical and physiopathological facts are in favour of uterus or cervix preservation that does not modify the anatomical results of prolapse surgery. If a mesh is used, uterine or cervix preservation reduce the chance for a vaginal erosion. The sexual consequences, aside the narrow vaginal tube, are more psychological than objectively proved. The wish of pregnancy in young patient must leads to conservative procedures with sacrofixation (Richter or Richardson) better than cervix ablation (Manchester procedure).

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5 RETENTIONS
Efficacy of traditional Chinese medicine for the management of constipation: a systematic review. Lin LW, Fu YT, Dunning T et al. Journal of alternative and complementary medicine. EPUBDATE: 2009-12-05. In this Cochrane review of 137 controlled studies, traditional Chinese medicine interventions (Chinese herbal medicine, acupuncture) appear to be useful to manage constipation. Significant positive results were found in 15 high-quality studies. However there was heterogeneity in diagnostic procedures and interventions, hence the results should be interpreted cautiously.

Sexual abuse: a strong predictor of outcomes after colectomy for slow-transit constipation. O’Brien S, Hyman N, Osler T, Rabinowitz T. Diseases of the Colon & Rectum, EPUBDATE: 2009-12-08. Patients undergone subtotal colectomy and ileorectal anastomosis for slow-transit constipation at a university hospital from 1991 to 2006 were questioned about a history of anal and vaginal sexual abuse and 13 out of 15, all women, highly satisfied with the results of their surgery, came for assessment; 8 (62%) reported a history of sexual abuse, 7 (58%) both anal and vaginal. The history of sexual abuse resulted a strong predictor of more functional diagnoses, more precoluntary operations, and more postcolectomy medical care for abdominal complaints.

Botox treatment for vaginismus. Pacik PT. Plastic and Reconstructive Surgery. EPUBDATE: 2009-12-03

Stapled transanal rectal resection for obstructed defecation: a cautionary tale. Titu LV, Riyad K, Carter H, Dixon AR. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08. Stapled transanal rectal resection can be performed on a day-case basis with 77% of patient satisfaction. However major complications were seen in 7%: fecal urgency, reported by 46%, persisted at six months in 11%; 5% patients reported severe postoperative pain.

6 INCONTINENCES
Defects on endonal ultrasound and anal incontinence following primary repair of fourth-degree anal sphincter rupture: a study of the anal sphincter complex and puborectal muscle. Sakse A, Secher NJ, Ottesen M, Starck M. Ultrasound in obstetrics & gynecology. EPUBDATE: 2009-12-03. In a 1-year follow-up period after primary suture of fourth-degree anal sphincter rupture, the frequency of anal incontinence was 67%. No clear association was seen between incontinence and sphincter defects detected on ultrasonography. There was an association between the angle of the puborectalis muscle and the extent of ultrasound defects.

Retention test in sacral nerve stimulation for fecal incontinence. Michelsen HB, Maeda Y, Lundby L et al. Diseases of the Colon & Rectum, EPUBDATE: 2009-12-08. Though sacral nerve stimulation is an established treatment for fecal incontinence, the mechanism of its action remains obscure. It does not alter the ability to retain rectal content and further studies are needed to investigate the reasons why it may be successful.

Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence. Heymen S, Scarlett Y, Jones K, Ringel T, Drossman D, Whitehead WE. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08. Biofeedback was more effective than pelvic floor exercises alone in producing adequate relief of fecal incontinence symptoms in patients for whom conservative medical management had failed.

Factors associated with percutaneous nerve evaluation and permanent sacral nerve modulation outcome in patients with fecal incontinence. Govaert B, Melenhorst J, Nieman FH, Bols EM, van Gemert WG, Baeten CG. Diseases of the Colon & Rectum, EPUBDATE: 2009-12-08. Older age, repeated procedures, and a defect in the external anal sphincter are factors that may indicate lower chances of success for test stimulation but do not exclude patients from sacral nerve modulation treatment. Although assessed in a selected patient group, no factors were predictive of the outcome of permanent stimulation.

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Encouraging results obtained, in agreement with most recent literature, show that endoanal injection of bulking agents is effective in treating mild to moderate fecal incontinence. This procedure is minimally invasive, repeatable, not associated with major complications and is feasible in an outpatient regime. Moreover the good patient compliance associated with favorable cost-benefit analysis requires further studies with a longer term follow-up to assess bulking agents as the first line treatment for mild to moderate fecal incontinence non-responsive to medical therapy.

REFERENCES

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Anterior sphincteroplasty for fecal incontinence: a single center experience in the era of sacral neuromodulation. Oom DM, Gosselink MP, Schouten WR. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08. It has been reported that patients with external anal sphincter defect may also benefit from sacral neuromodulation. The success of this technique raises the question whether anterior overlapping sphincteroplasty still deserves a place in the surgical treatment of fecal incontinence. This study investigated the outcome of anterior sphincteroplasty in a series of 172 patients after a median follow-up of 111 months. Results were acceptable to excellent in 60% of patients, especially in those under the age of 50 years at surgery.

Myoblasts differentiated from adipose-derived stem cells to treat stress urinary incontinence. Fu Q, Song XF, Liuo GL, Deng CL, Cai L. Urology. EPUBDATE: 2009-12-09. Adipose-derived stem cells have the ability of differentiating into multiple lineages, including myoblasts. This ability to induce myoblasts can be used to treat stress incontinence, with the advantages of minimal invasion and faster recovery as proved in 20 female incontinent rats.

7 PAIN
Efficacy of montelukast, a leukotriene receptor antagonist, for the treatment of dysmenorrhea: A prospective, double-blind, randomized, placebo-controlled study. Fujihara HA, Komma R, Netsa S et al. European Journal of Obstetrics & Gynecology and Reproductive Biology. EPUBDATE: 2009-12-01. Montelukast is a clinically reasonable management option to consider before prescribing an hormonal agent, it may be effective in alleviating pain associated with dysmenorrhea in some women. It is safe and does not influence hormonal levels.

Increased cold-pain thresholds in major depression. Schwier C, Klem A, Böötger MK, Bär KJ. Journal of Pain. EPUBDATE: 2009-12-01. Patients suffering from major depressive disorder show a decreased sensitivity for external or skin surface pain, eg, for heat or electrical stimuli, as compared to healthy controls.

Effect of meal ingestion on ileocolonic and colonic transit in health and irritable bowel syndrome. Deitteren A, Camilleri M, Burton D et al Digestive Diseases and Sciences. EPUBDATE: 2009-12-02. Postprandial symptoms in irritable bowel syndrome (IBS) have been associated with increased bowel contractility. This study shows that ileocolonic transit immediately after eating is higher in IBS diarrhea predominant (IBS-D) patients than in the healthy controls, whereas colonic transit is blunted in IBS-C (constipation predominant).

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Electrodermal measures of Jing-Well points and their clinical relevance in endometriosis-related chronic pelvic pain. Ahn AC, Schuyer R, Conboy L et al. Journal of alternative and complementary medicine. EPUBDATE: 2009-12-05. Electrodermal measures at Jing-Well acupuncture points, “indicator” points located at the tips of fingers and toes, are significantly associated with clinical outcome in 14 adolescent women (ages 14-22) with laparoscopically diagnosed endometriosis and chronic pelvic pain.

8 FISTULAE
Do we need new surgical techniques to repair vesico-vaginal fistulas? Zambon JP, Batezini NS, Pinto ER et al. International urogynecology journal and pelvic floor dysfunction. EPUBDATE: 2009-12-02. The urogenital fistula continues to be a devastating distressful problem. Hysterectomy is the major etiology. Complex vesicovaginal fistula repair may need tissue interposition by vaginal or abdominal approach and depends on the surgeon’s experience and local factors like size, location, and previous radiotherapy. Using traditional approaches is possible and reasonable to treat any sort of vesicovaginal fistula.

Endoscopic repair of post-traumatic fistulae of posterior urethra using hyaluronic acid dextranomer. Appignani A, Bertocci M, Prestipino M. Urology. EPUBDATE: 2009-12-08. A prostatic urethral fistula, developed from an abscess after an intervention to correct a pubic symphysis fracture was repaired with a minimvasive endourologic procedure, using the hyaluronic acid dextranomer, commonly used in vesicoureteral reflux treatment.

Assessment of the efficacy of the rectovaginal bulb fistula plug for the treatment of ileal pouch-vaginal and rectovaginal fistulas. Gonsalves S, Sagar P, Lengyel J et al. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08. The Surgisis Biodesign rectovaginal bulb fistula plug with a total of 20 plug insertions was used in 5 patients with rectovaginal fistulas and 7 ileal pouch-vaginal fistulas. At a median follow-up of 15 weeks, 58% had been successfully treated. All plug failures were the result of dislodgement of the plug. There was no morbidity.

9 BEHAVIOUR, PSYCHOLOGY, SEXOLOGY
Female sexual dysfunction. Clayton AH, Hamilton DV. Obstetrics and Gynecology Clinics of North America. EPUBDATE: 2009-12-01. Sexual dysfunction is influenced by a variety of factors: medical, psychiatric, cultural, and stage of life. A variety of treatment modalities exist, though current research has not yet provided Food and Drug Administration approved therapies for sexual disorders in women.

Intimate partner violence. Zolotor AJ, Denham AC, Weil A. Obstetrics and Gynecology Clinics of North America. EPUBDATE: 2009-12-01. A knowledge of patients’ intimate partner violence victimization may help physicians develop a better understanding of patients’ presenting symptoms and health risks associated with this common problem that takes on many forms, including psychologic/emotional, physical, and sexual abuse, and affects many women.

When depression complicates childbearing: guidelines for screening and treatment during antenatal and postpartum obstetric care. Macik M, Marcus SM, Heringshausen JE et al. Obstetrics and gynecology clinics of North America. EPUBDATE: 2009-12-01. One in 5 women experience an episode of major depression during their lifetime. Management of depressed peripartum women includes care of a growing fetus or breastfeeding infant. The treatment is complex and requires input from a multidisciplinary team (obstetrician, psychiatrist, and pediatrician).

[Prevalence of erectile dysfunction in patients consulting urological clinics: the ENJEU survey (one day national survey on prevalence of male sexual dysfunction among men consulting urologists).] Droupy S, Giuliano F, Cuzin B. Progrès en Urologie. EPUBDATE: 2009-12-01. This first survey in French urologists’ community emphasizes the high prevalence male sexual dysfunctions including erectile dysfunction for inpatients visiting their urologists. Despite declared urologists’ interest for male sexual dysfunction, the discrepancy between the high prevalence of erectile dysfunction and the low rate of patients consulting for this condition probably explains the low rate of patients using treatments.

Laparoscopic radical cystectomy. The new gold standard for bladder carcinoma? Castillo OA, Vitagliano G, Vidal-Mora A. Archivos Españoles de Urología. EPUBDATE: 2009-12-04. Laparoscopic radical cystectomy is associated with diminished operative bleeding, time to oral intake and hospital stay. It is a reproducible technique but it demands a very long learning curve.

Penile foreign bodies. Pastor Navarro H, Donate Moreno MJ, Segura Martin P et al. Archivos Españoles de Urología. EPUBDATE: 2009-12-05. Penile foreign bodies are placed for a wide variety of reasons, but primarily for erotic or self-arousal purposes, rarely this is due to an accident. The consequences can be mild or very severe, resulting in penile amputation. These cases can be successfully treated with a urethral diverticulum and/or penile prosthesis.

Does vaginal size impact sexual activity and function? Schäufel MO, Harvie HS, Omotosho TB et al. International urogynecology journal and pelvic floor dysfunction. EPUBDATE: 2009-12-05. Vaginal size does not affect sexual activity or function. Total vaginal length and genital hiatus were assessed using the POPQ exam and the Female Sexual Function Index (FSFI) in 505 women. They did not differ between women with normal FSFI scores and those with sexual dysfunction.

10 MISCELLANEOUS
Sustained efficacy and immunogenicity of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine: analysis of a randomised placebo-controlled trial up to 6.4 years. Lancet. EPUBDATE: 2009-12-08. 560 women were included in the vaccine group and 353 in the placebo group. Vaccine efficacy against incident infection with HPV 16/18 was 95.3% (95% CI 87.4-98.7) and against 12-month persistent infection was 100% (81.8-100). Vaccine efficacy against CIN2+ was 100% (51.3-100) for lesions associated with HPV-16/18 and 71.9% (20.6-91.9) for lesions independent of HPV DNA. Up to 6.4 years an excellent long-term efficacy, high and sustained immunogenicity, and favourable safety was demonstrated.


Paget disease of the vulva: a study of 56 cases. Shaco-Levy R, Bean SM, Vollmer RT et al. European Journal of Obstetrics & Gynecology and Reproductive Biology. EPUBDATE: 2009-12-09. The records of 56 patients with vulvar Paget disease, a rather controversial issue, were reviewed. Only rarely it results in a patient’s death, but recurrences are common and can be noted many years after the initial treatment. In general stromal invasion is not associated with worse prognosis. Intra-operative frozen section analysis of the margins as well as initial radical surgery does not reduce recurrence rate. Radiation therapy given to five patients who either had multiple positive surgical margins or experienced disease recurrence and refused additional surgery resulted in complete response with no further recurrences.