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## UROLOGICAL ONCOLOGY

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### **Prevalence and risk factors of bisphosphonate-associated osteonecrosis of the jaw in prostate cancer patients with advanced disease treated with zoledronate**

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*Eur Urol.* 2008; 54: 1066-72

**Background:** In addition to other treatments, patients with prostate cancer (pCA) and bone metastasis receive bisphosphonates. Since 2003, a previously unknown side-effect of bisphosphonates-bisphosphonate-associated osteonecrosis of the jaws (BP-ONJ)-has been described, and frequency has since increased. An exact incidence is still unknown.

**Objectives:** The aim of this study was to assess the incidence and additional factors in the development of BP-ONJ.

**Design, Setting, and Participants:** From July 2006 to October 2007, patients with advanced pCA and osseous metastasis receiving bisphosphonate therapy in the Department of Urology or Haematology and Oncology at the Johannes-Gutenberg-University Mainz, Germany, received a dental examination. In all, 43 patients were included.

**Measurements:** Patients were checked for exposed bone, osteonecrosis, mucosal defects, inflammation, and oral hygiene. Further points were the applied bisphosphonate, co-medication, the duration of application, and possible trigger factors for BP-ONJ.

**Results and Limitations:** Eight of 43 patients developed BP-ONJ (18.6%). All patients had received zoledronate at least 14 times. Two patients had received bondronate, and one patient had received pamidronate before switching to zoledronate. All patients had had a previous tooth extraction or a denture pressure sore, and all patients had received additional chemotherapy and corticosteroids.

**Conclusions:** The reason for this relatively high incidence compared to other studies might be the prospective study design and thorough dental examination. In studies with such small numbers as have been published to date, nondetection or nonreported cases of BP-ONJ have an influence on the outcome. The incidence of BP-ONJ in patients with pCA might be an underestimated problem.

### **Editorial Comment**

Bisphosphonates are widely given in patients with a high risk for, or manifest, bone metastases. In most patients with advanced prostate cancer, this drug is considered standard therapy. Recently, the risk for developing dental complications became evident but neither the true incidence nor risk factors are known. This paper helps to clarify the situation.

Nearly 19% of patients from this uncontrolled series suffered from some sort of osteonecrosis. Most were highly pretreated with bisphosphonates and steroid and/or docetaxel therapy. Urologists should be aware

of this possible complication and should work closely together with experienced dentists. Special attention should be given to multimodally treated patients.

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**Long-term survival after gemcitabine and cisplatin in patients with locally advanced transitional cell carcinoma of the bladder: focus on supplementary treatment strategies**

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Eur Urol. 2007; 52: 478-86

**Objective:** The objective was to evaluate response and survival, as well as efficacy of subsequent supplementary treatment and follow-up strategy in patients with locally advanced transitional cell carcinoma of the bladder following combination chemotherapy with gemcitabine and cisplatin (GC).

**Methods:** A total of 84 patients with locally advanced (T4b, Nx, M0 or Tx, N2-3, M0) received GC. After chemotherapy, the strategy was close surveillance in patients with complete response, and supplementary radical cystectomy or radiotherapy whenever possible in patients with partial response.

**Results:** A total of 25 patients (29.8%) with complete response to chemotherapy were followed by close surveillance. This group achieved a median overall survival of 47.6 mo. Another 25 patients had partial response to chemotherapy. Of these patients, 16 had supplementary treatment, with 10 achieving “no evidence of disease” (NED). Thus, a total of 35 patients achieved NED with a median overall survival of 48.7 mo versus 10.2 mo in patients not achieving NED (hazard ratio=0.10; 95%CI, 0.05-0.20; p<0.0001). The rate of NED was higher in the group of patients who had a cystectomy compared with the group who received radiotherapy as supplementary treatment.

**Conclusions:** In patients with locally advanced bladder cancer, NED following chemotherapy alone or chemotherapy plus supplementary cystectomy or radiotherapy is essential to achieve long-term survival. Patients with a partial response should be offered radical cystectomy whenever possible, which seems to be superior to radiotherapy. Close surveillance may be an alternative to immediate cystectomy in patients with complete response following chemotherapy.

**Editorial Comment**

Patients with locally advanced bladder cancer cannot be cured by surgery or radiotherapy alone. Systemic cytotoxic chemotherapy is the only option here. In contrast to patients with visceral metastases, patients without distant metastases and locoregional disease form a group with rather favorable prognosis. A group of 84 patients with this disease was analyzed for long-term survival after Gemcitabine-Cisplatinum (GC) – based chemotherapy.

Median overall survival of the group was 16.3 months. There was a significant difference between patients who had no evidence of disease (NED) after GC or after GC and supplementary treatment (e.g. cystectomy) in comparison to those who had a partial response and underwent supplementary treatment. Median survival in the first and second groups was nearly 48 months whereas the third group had less than 12 months median survival. Patients who underwent cystectomy as treatment after GC significantly fared better than patients who received

radiotherapy. In conclusion, relative long-term survival is possible in this cohort of patients and multimodal treatment should aim at eradicating all disease possible.

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## NEUROUROLOGY & FEMALE UROLOGY

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### **Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 12-month results from a prospective long-term study**

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J Minim Invasive Gynecol. 2009; 16: 56-62

**Study Objective:** To assess efficacy of nonsurgical transurethral collagen denaturation (Renessa) in women with stress urinary incontinence (SUI) caused by bladder outlet hypermobility.

**Design:** Continuing, prospective, 36-month, open-label, single-arm clinical trial. Twelve-month results from intent-to-treat (ITT) analysis are reported. Canadian Task Force classification II-2.

**Setting:** Thirteen physician offices or ambulatory treatment centers.

**Patients:** Women with SUI secondary to bladder outlet hypermobility for 12 months or longer who failed earlier conservative treatment and had not received earlier surgical or bulking agent therapy.

**Interventions:** Women were treated as outpatients and received an oral antibiotic and local periurethral anesthesia before undergoing treatment with transurethral radiofrequency collagen denaturation.

**Measurements and Main results:** Voiding diaries and in-office stress pad weight tests yield objective assessments. Subjective measures include the Incontinence Quality of Life (I-QOL), Urogenital Distress Inventory (UDI-6), and Patient Global Impression of Improvement (PGI-I) instruments. In total, 136 women received treatment (ITT population). Patients experienced significant reductions versus baseline in median number of leaks caused by activity/day and activity/week ( $p < .0026$  for both), with 50% of patients reporting 50% or more reduction. Pad weight tests revealed that 69% of women had 50% or more reduction in leakage (median reduction 15.2 g;  $p < .0001$ ); 45% were dry (29% no leaks; 16%  $< 1$ -g leakage). Significant improvements occurred in median scores on the I-QOL (+9.5 [range -66.0 to 91.0];  $p < .0001$ ) and mean scores on the UDI-6 (-14.1 +/- 24.7;  $p < .0001$ ). Furthermore, 71.2% showed I-QOL score improvement, including 50.3% with 10-point or greater improvement, and 49.6% reported on the PGI-I that they were “a little,” “much,” or “very much” better. **Conclusion:** At 12 months, treatment of SUI with nonsurgical transurethral collagen denaturation resulted in significant improvements in activity-related leaks and quality of life.

### **Editorial Comment**

Authors report on the therapy of female stress urinary incontinence using transurethral radiofrequency (RF) collagen denaturation. This report entails the 12-month results from an ongoing 36-month intent to treat study. The authors identified the following: no significant adverse events; that the procedure was very well tolerated; and using this minimally invasive technique, results similar to transurethral bulking agents were obtained.