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### Neoadjuvant chemotherapy in bladder cancer: Is cistectomy mandatory in case of complete response?

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**Purpose:** To evaluate retrospectively the results of neoadjuvant chemotherapy (m-VAC) in bladder cancer. To discuss the possibility of avoiding cistectomy in case of complete response (CR).

**Methods:** Forty patients with bladder cancer (stages: 6 T1G3, 13 T2, 15 T3, 6 T4) were treated with m-VAC regimen (three cycles) and then restaged by CAT, cistoscopy and multiple biopsies. Cistectomy wasn't perfomed in case of CR, and CT was continued for three more cycles.

**Results:** 34/40 patients were evaluable for response. 12 complete responses (5/6 T1G3; 5/13 T2; 2/12 T3) and 8 partial responses (4/13 T2; 3/12 T3; 1/6 T4) were obtained. The 12 patients in CR didn't undergo cistectomy, and CR is confirmed in 8/12, after a median f.u. of 17 months (r: 7–46).

**Conclusions:** – Neoadjuvant m-VAC induced 35% CR + 23% PR. – In 2/3 of patients who didn't undergo cistectomy CR is confirmed after a medium term f.u.

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### The efficacy of gemcitabine in controlling pain and improving performance status in men with hormone-refractory prostate cancer (HRPC)

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**Purpose:** A previous phase II study of single-agent (Gemcitabine) GEMZAR® in men with HRPC and bidimensionally measurable disease demonstrated an objective response rate of 17%. This trial was then designed to test in symptomatic men with HRPC the effect of gemcitabine (1200 mg/m$^2$ weekly ×3 every 4 weeks) on Kamofsky Performance Status (KPS) and pain palliation.

**Methods:** A response in KPS was defined as an improvement of ≥20 points for at least 4 weeks and a response in pain was defined as a ≥50% decrease in analgesic consumption and an improvement of ≥20 points on the pain intensity scale using a visual analogue scale card (VASC).

**Results:** To date, 22 men have been enrolled, 2 being ineligible. The median age was 72 years and 50% of the men had a baseline KPS of 70. The median number of gemcitabine cycles was 2. Of the 20 eligible and evaluable patients, 4 (20%) met the criteria for achieving significant clinical symptomatic benefit. Overall, 2 men had stable serial serum PSA levels and 2 had a PSA decrease of at least 25%. Ten men had objectively measurable disease sites with 1 PR seen and 3 others having stable disease. Toxicity was mild with grade 3 anaemia, leukopenia, thrombocytopenia and nausea and vomiting seen in 12.5%, 25%, 6.3% and 4.8% of patients respectively.

**Conclusion:** Gemcitabine appears to have some modest anticancer activity in men with HRPC. This level of activity might be enhanced if the drug is combined with other active agent(s).

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### Transcatheter embolization *vs* surgical ligation in the treatment of bleeding bladder neoplasms

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**Purpose:** To evaluate effectiveness of transcatheter embolization for control of bleeding complicating bladder neoplasms as an alternative to surgical ligation of internal iliac arteries.

**Materials and Methods:** Between 1984 and 1994, arterial embolization was performed in 21 patients while 19 petients underwent surgical ligation of the internal iliac arteries. All patients had intractable hemorrhage from unresectable bladder carcinoma. Autoclots/Ivalon/Gelfoam were utilized for occlusion.

**Results:** Post embolization, bleeding was completely controlled in 16 (76%) patients and decreased markedly in 5 patients. Hemorrhage was stopped in 11 of 19 (58%) patients after surgical ligation.

Hematuria recurred in 9 of 21 (43%) after embolization and in 13 of 19 (68%) patients after surgical ligation during 0.5–6.5 mo. For treatment of recurrens medical therapy (16) and repeated embolization (6) were successful. The long-term survival depended on effectiveness of following treatment such us chemotherapy and/or radiation therapy.

**Conclusion:** Arterial embolization is more effective than surgical ligation for control of bleeding from bladder cancer.

## Renal and testicular cancer

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### Subcutaneous (SC) Interleukin-2 (IL-2) plus alpha interferon (IFN-α) and 5 fluorouracil (5 FU) in out-patients (pts) with metastatic renal cell carcinoma (MRCC). Scapp II trial

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**Purpose:** The aim of this study was to confirm through a French multicenter trial the efficacy of this association already published by Atzpodien.

**Methods:** Il-2 (Proleukin®) and IFNα (Roféron®) have been administered by SC route three days a week (W) during 8 W respectively at 18 MUI and 9 MU. 5 FU (750 mg) has been given every Monday by IV route

**Results:** 83 pts with MRCC were included in this trial. At the moment, 56 pts are evaluable. The dosage was decreased or the treatment interrupted for 26 pts (toxicity) and for 4 pts (progressive disease). 12 pts were in objective response (1CR), 16 pts with stable disease (SD). Toxicity was more important than in SCAPP I trial (IL-2 (SC) alone). OMS grade III and IV toxicities were observed. In this program responding pts and pts with stable desease received 2 W maintenance cycles every 6 W. The 20-month survival represent 60%. According to the statistical method (triangular test) used in this trial, this program was interrupted in August 96.

**Conclusion:** This SC schedule unlike the results published by ATZPODIEN shows that the treble combination 5 FU, IFNα, IL-2 has the same efficacy than IL-2 alone given by IV or SC route with more toxicity. Other programs recently published confirm these data. The definitive results will be presented in September.

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### A randomized clinical trial comparing SC Interleukin-2, SC Alpha-2A-Interferon, and IV bolus 5-fluorouracil against oral tamoxifen in progressive metastatic renal cell carcinoma patients

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In various clinical phase II studies, Interleukin-2 based chemo-immunotherapy has produced objective tumor regressions in selected patients with progressive metastatic renal cell carcinoma. We conducted a prospectively randomized trial to compare outpatient SC Interleukin-2, SC Alpha-2a-Interferon, and IV bolus 5 fluorouracil against oral tamoxifen.

**Patients and Methods:** Of a total of 78 pts (59 male; 19 female; median age, 58 years; range, 34 to 80 years), 41 pts were randomized to receive 8 week cycles of SC Interleukin-2 (10 MIU/m2 BID days 3, 4 and 5 of weeks 1 and 4; and 5 MIU/m2 days 1, 3 and 5 of weeks 2 and 3), SC Alpha-2a-Interferon (6 MIU/m2 day 1 of weeks 1 and 4 and days 1, 3 and 5 of weeks 2 and 3; and 9 MIU/m2 days 1, 3 and 5 of weeks 5–8), and IV bolus 5-Fluorouracil (1000 mg/m2 once weekly, weeks 5–8); 38 pts received oral tamoxifen (45 mg/m2 BID, weeks 1–8). Pts were stratified according to known clinical predictors (J Urol 155: 19, 1996) to allow for equal risk distribution in both treatment arms.

**Results:** Therapeutic efficacy was evaluated on an intention to treat basis. Among 41 pts receiving out-patient SC Interleukin-2, SC Alpha-2a-Interferon, and IV bolus 5-FU, there were 7 complete responders (lung, lymph nodes, bone), and 9 partial responders (lung, liver, lymph nodes, adrenals, and others), with an overall objective response rate of 39% (95% confidence interval, 24%–55%). In contrast, tamoxifen produced no objective remissions in a total of 37 pts (95% confidence interval, 0%–9%). According to Kaplan-Meier, overall survival and progression free survival from start of therapy were significantly improved in pts receiving chemo-immunotherapy when compared to pts who were treated with tamoxifen (overall survival: median not reached after 42 months vs median