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Abstract: To determine the optimum dosage and instillation time for water-soluble polyvinylpyrrolidone (PVP)-hypericin for photodynamic diagnosis of bladder cancer and to monitor its use in regard to patient safety. Forty patients with a cystoscopically suspected bladder neoplasm were enrolled in this prospective phase IIA study. Different combinations of PVP-hypericin dosage (225 μg and 75 μg and instillation time (120, 60, 30, 15 min) were used to evaluate the optimal conditions. After a run-in cohort of five patients to validate the test method, each group comprised seven patients. All intravesical lesions were documented, and their fluorescence characteristics were recorded. Dose finding was the primary, safety the secondary end point. Fluorescence intensities for the first two groups (225 μg PVP-hypericin for 120 and 60 min, respectively) were not different. For group three (225 μg for 30 min), both specific fluorescence and background noise were reduced. A shorter instillation time (225 μg for 15 min) or lower dose (75 μg for 30 min) was considered insufficient for lesion identification. A dose of 225 μg PVP-hypericin instilled for 30 minutes was determined as appropriate for the detection of lesions. Of the total 93 identified lesions, 62 were detected with both white light and fluorescence, 25 were seen with blue light only, and six with white light only. It was possible to identify additionally two
carcinoma in situ, eight pTa, and one pT1 lesions with PVP-hypericin and blue light. PVP-hypericin was safe and well tolerated. The optimum combination of dosage of PVP-hypericin and its instillation time was established and will be used to determine sensitivity and specificity of PVP-hypericin cystoscopy in a larger multicenter phase IIB study. The preliminary data of this study hint to a higher sensitivity of hypericin-assisted fluorescence cystoscopy.