592 A comparison of hexaminolaevulinate (hexvix®) fluorescence cystoscopy and white light cystoscopy for the detection of bladder cancer: Results of the HeRo observational study

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INTRODUCTION & OBJECTIVES: To evaluate the diagnostic accuracy of hexylaminolaevulinate (HAL) hydrochloride (Hexvix ®) PDD cystoscopy compared with standard white light cystoscopy in an observational, open-label, comparative, controlled (within patient), multicenter study that used this diagnostic tool on a regular basis in daily practice. Sensitivity, specificity, positive predictive value and negative predictive value with each method were calculated.

MATERIAL & METHODS: Between January 2010 and January 2011, 96 consecutive patients with suspected or confirmed bladder cancer were recruited for the HeRo observational, open-label, comparative, controlled (within patient) study done at 5 centers in Italy.
All patients had standard white light (WLC) followed by blue light cystoscopy (BLC). The presence and the number of positive lesions/suspicious areas compared to surrounding urothelium detected using WLC and BLC were recorded. Biopsies/resection of each positive lesion/suspicious areas were always taken after the bladder was inspected under WLC and BLC.

RESULTS: Overall, 234 suspicious lesions were detected in 96 patients; 108 (46.2%) were histologically confirmed to be bladder tumors/CIS. The sensitivity of BLC biopsies was significantly higher than for WLC technique ($p<0.00001$; 99.1% vs. 76.8%; Delta% 22.3; McNemar Test χ^2 20.346). The relative sensitivity of BLC versus WLC was 1.289 (CI 1.164-1.415) showing a superiority of BLC of 28.9% (CI 95% 16.4%-41.5%). The specificity of BLC biopsies was not significantly different compared to WLC ($p=0.445$; 36.5% vs. 30.2%; Delta% -6.3; McNemar Test χ^2 0.583). Positive predictive value per biopsy for BLC- and WLC- guided biopsies was 54.9% and 50.9%, respectively. Negative predictive value per biopsy for BLC- and WLC- guided biopsies was 97.4% and 64.8%, respectively. The false positive biopsy rate for BLC- and WLC- guided biopsies was 45.1% and 49.1%, respectively. The sequential design analysis shows that in 83 patients the correct diagnosis was reached both by WLC and by BLC. At contrary the correct diagnosis was reached by BLC alone and WLC alone, in 11 patients (11.5%) and in 2 patients (2%) respectively. Therefore BLC and WLC reached the correct diagnosis in 97.9% and in 88.5%, respectively. This difference was statistically significant ($P=0.0265$; Delta % 9.4; CI 95% 1.1- 17.7).

CONCLUSIONS: HAL hydrochloride PDD cystoscopy used on a regular basis in daily practice enhances the diagnostic accuracy of standard cystoscopy with an elevate negative predictive value for BLC compared to WLC permitting an improvement in patient prognosis.