REPEAT USE OF BLUE LIGHT CYSTOSCOPY WITH HEXAMINOLEVULINATE FOR PATIENTS WITH UROTHELIAL CELL CARCINOMA

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Purpose: Hexaminolevulinate hydrochloride (HAL) with blue light cystoscopy (BLC) is approved by the U.S. Food and Drug Administration as an adjunct to white light cystoscopy (WLC) for the detection of urothelial cell carcinoma. In this study we examine the tolerability of the repeat use of WLC+BLC. Materials and

Methods: We retrospectively reviewed the records of all patients who underwent WLC+BLC with HAL during a 34-month period at two institutions. We compared the incidence of adverse events (AEs) after initial and subsequent procedures. We grouped, graded and assigned degree of attribution for all AEs. We compared the incidence of AE after first versus subsequent use.

Results: 181 patients underwent a total of 271 WLC+BLC. Of those 181 patients, 118 (65%) underwent WLC+BLC only 1 time. The other 63 (35%) patients underwent WLC+BLC 2 or more times: 44 (24%) of them 2 times, 18 (10%) of them, 3 or more times. We noted 89 AEs out of 271 procedures (33%), of which 66 (74%) occurred after the patient's 1st WLC+BLC; 14 (16%) after 2nd and 9 (10%) after 3rd or more. We found no statistically significant difference in frequency of AEs between those patients undergoing 1st versus 2nd WLC+BLC (P=0.134). In comparing the frequency of specific categories of AEs after first versus second WLC+BLC with HAL, there was no significant difference between the rates of specific AEs (Table 1). 89% of all adverse events were genitourinary in nature including dysuria, hematuria and bladder spasms. Four patients had hypersensitivity reactions including 1 with eye swelling, 1 with vision changes, 1 with penile swelling and 1 with rash. There was no statistically significant difference noted in the frequency of grades of AEs in patients undergoing 1st versus 2nd WLC+BLC with HAL (P=1.000) We observed one grade 3 and no grade 4 or 5 AE. There was no statistically significant difference in the frequency of each attribution rating between 1st versus 2nd WLC+BLC with HAL (P=0.250). None of the AEs were classified as probably or definitely related to HAL.

Conclusion: In this retrospective study we found no statistically significant difference in the frequency, grade or attribution of AEs between 1st versus 2nd use of WLC+BLC with HAL.

Table 1
Frequency of adverse events by CTCAE organ class

CTCAE organ class	WLC+BLC with HAL: 1 (n=181)	2 (n=63)	3+ (n=18)	Total n(%) (n=271)	P-value[1]
Genitourinary	59	11	9	79 (89)	0.092[2]
Neurological	2[a]	0	0	2 (2)	--
Gastrointestinal	1[b]	0	0	1 (1)	--
Cardiac	1[c]	0	0	1 (1)	--
Immunological	1[d]	3[e]	0	4 (5)	0.625
Unexpected postoperative hospital admission	2	0	0	2 (2)	--
Total Adverse Events n(%)	66 (36)	14 (22)	9 (44)	89	0.134[3]

[1] McNemar's test comparing 1st versus 2nd WLC+BLC in patients undergoing 2 or more WLC+BLC with HAL.
[2] Chi-squared value unable to be calculated as frequency of incidence is 0.
[3] McNemar's test comparing total AEs between 1st, 2nd and 3rd or more WLC+BLC with HAL.
a: transient ischemic attack and dizziness. b: nausea c: angina d: eye swelling
e: penile swelling; vision changes; pruritic rash
BLC=blue light cystoscopy; CTCAE = Common Terminology Criteria for Adverse Events; HAL = Hexaminolevulinate Hydrochloride; WLC = white light cystoscopy

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