Debates on Bladder Cancer

Debates on Bladder Cancer 2011; 3:2

Bladder Cancer highlights from the EAU Congress and AUA Annual Meeting 2011

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Abstract
In 2011, the EAU Congress in Vienna from 18-22 March and the AUA Annual Meeting in Washington D.C. from 14-19 May shed light on different topics concerning bladder cancer. We would like to discuss some of the studies and their results presented at these ambitious scientific conventions.

Key words: bladder cancer, AUA annual meeting Washington D.C., EAU Congress Vienna, urothelial cancer

DETECTION AND SCREENING

HUBER et al. (AUA #1241) initiated a prospective study for early diagnosis of bladder cancer with former exposure to aromatic amines. The study was named "UroScreen". The tests UroVysion, NMP22 and urine cytology for bladder cancer were investigated to ascertain predictive values. 1611 active and former chemical workers at the age of 58 (25-86) years underwent 7252 preventive medical check-ups. With one positive urine based tumour marker test cystoscopy was recommended. Urine cytology was positive in 15 checkups, UroVysion was positive in 81 checkups and NMP22 was positive in 225 checkups. UroVysion in combination with cytology and/or NMP22 were positive in 27 checkups.
All in all, 1 positive tumour marker test was registered in 348 checkups. 230 patients voluntarily underwent additional cystoscopy, in which 12 bladder carcinomas (2 CIS, 5 pTa, 2 pT1, 1 pT1+CIS, 1 pT2, and 1 pT3b) and 2 bladder papillomas were detected. Only 5 bladder cancers (2 pTa, 2 pT1, 1 pT1+CIS) and another papilloma were detected in subjects in whom cytology, UroVysion, and NMP22 were negative. As a result of this, Huber et al. postulated a diagnostic validity of tumour marker tests for early diagnosis of bladder cancer in asymptomatic persons with high risk for bladder cancer. The study group particularly emphasized that the combination of cell-based (UroVysion, cytology) and protein-based (NMP22) markers may improve the sensitivity and specificity of urine-based tumour markers when screening high-risk populations for bladder cancer.

VOLPE et al. (AUA #1250) investigated the diagnostic accuracy of fluorescent cystoscopy with Hexaminolevulinate for non-muscle invasive bladder cancer (NMIBC). 65 patients with suspicious primary or recurrent bladder tumour were included in this study. After intravesical instillation of

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invited June 26th 2011
accepted Octobre 11th 2011
published Octobre 12th 2011

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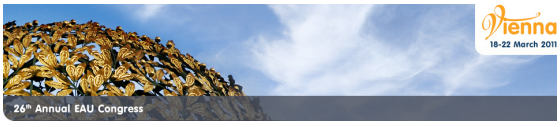
Hexaminolevulinate 85 mg one hour before the procedure, white light cystoscopy (WLC) was performed, followed by blue light cystoscopy (BLC). A total of 256 bladder lesions were discovered, of which 219 were malignant and 37 benign. 97% (213/219) of the malignant results were detected by blue light cystoscopy (BLC) whereas 67% (147/219) were detected by white light cystoscopy (WLC). BLC had highest diagnostic advantage for carcinoma in situ (100% vs. 25%) and for lesions at the bladder dome (100% vs. 53%). Minimum one CIS, dysplastic or papillary lesion could be observed in 24 out of 65 patients by BLC after WLC. The subset analysis did not show any decrease of detection rate of BLC in patients who have undergone previous endovesical treatment (97.6% vs. 98.3%), with false detection rates equally not increasing (14.3% vs. 14.2%). When considering their results, the authors asserted a higher level of diagnostic accuracy for BLC compared to WLC in the diagnosis of NMIBC.

NON-MUSCLE INVASIVE BLADDER CANCER

O' BRIEN et al. (EAU #435) investigated the recurrence rate of bladder tumour after photodynamic blue light (B/L) transurethral resection of bladder tumour (TURBT) with Hexaminolevulinate (HAL) compared to white light (W/L) TURBT in newly presenting bladder cancer. This prospective randomised trial included 249 patients with suspected NMIBC from 2005-2010. B/L was performed in 129 cases, W/L in 120 cases. After the respective procedure, single shot intravesical Mitomycin C (MMC) was instilled. Collectively, a total of 207 out of 249 (83%) patients showed cancer histopathologically, of whom 187 (89%) were diagnosed with NMIBC (B/L 99; W/L 85). After 3 months, recurrence was seen in 17/94 (18%) of the B/L arm and 14/82 (17%) of the W/L arm (p=0.86). Recurrence after 12 months was detected in 10/66 (15%) of the B/L series vs. 12/61 (20%) in the W/L series (p=0.50). In conclusion, the authors did not find any significant difference in recurrence between the B/L arm and the W/L arm in three and 12 months after TURBT. The study group recommended the development of novel treatment strategies, which could be used in improved diagnostic tools like photodynamic diagnosis in order to reduce the recurrence rate in NMIBC.



ONISHI et al. (AUA #1649) compared continuous saline bladder irrigation (CSBI) and MMC/ Cytosine arabinoside instillation after TURBT in patients with newly diagnosed NMIBC. A population of 200 patients underwent TUR, followed by CSBI. 75 patients with intermediate-risk NMIBC received intravesical chemotherapy with Mitomycin C and Cytosine arabinoside after TUR for one year. The patients were classified into three groups according to risk level. In addition, freedom from bladder cancer recurrence was calculated. The low risk group consisting of 62 patients had a recurrence free rate with 87.5% after 1 and 3 years, and 84 % after 5 years; the intermediate risk series with 123 patients had a recurrence free rate of 72% after 1 year, 64% after 3 years, and 58% after 5 years and the high risk group with 15 patients had a recurrence free rate of 61.5% in the first year, 38.5% after 3 and 5 years. The CSBI series showed no significant changes in recurrence free rate, in the period of first recurrence after TURBT (13.9 months vs. 16 months) and in the frequency of recurrence (1.9 times vs. 2.2 times) compared to the intermediate risk patients with intravesical chemotherapy. In fact, the subjects with intravesical instillation of MMC and Cytosine arabinoside showed a significant higher tumour progression rate (16% vs. 9%). The Japanese study group described an advantage for CSBI after TUR for patients with low-risk and intermediate-risk NMIBC. Moreover, the authors assumed easy administration for CSBI,

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accepted Octobre 11th 2011
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with a lack of toxicity and a benefit according to recurrence, progression and cost savings compared to intravesical chemotherapy with MMC and Cytosine arabinoside.

MORALES et al. (AUA #1650) presented preliminary results from a phase-3 open-label single-treatment arm multicentre study on a second-line therapy for patients with NMIBC. The subjects were all refractory to BCG therapy after TUR and at high risk of progression with NMIBC. The study group initiated and analysed a bladder sparing method with Mycobacterial Cell Wall-DNA Complex (MCC). A total of 129 patients with high-grade urothelial carcinoma (papillary NMIBC and /or carcinoma in situ CIS), who didn't respond to one or more cycles of BCG were included. 91 patients (70.5%) had CIS with or without papillary tumours and 38 patients (29.5%) had only papillary tumours. These patients were treated with 8 mg MCC in 6 weekly intravesical instillations followed by 3 once-weekly instillations at 3, 6, 12, 18 and 24 months after TUR. The overall one-year disease-free survival (DFS) rate was 25.0% with a median DFS interval of 177 days. Patients with CIS showed DFS rate of 21% after one year, patients with papillary tumours exhibited a one-year DFS rate of 35.1%. Haematuria and urinary tract infection were seen in two subjects and were considered as a potential adverse reaction to the therapy. The study group concluded that MCC is responsive in patients with BCG-refractory NMIBC and could represent an alternative to cystectomy for these patients.

BENDARY et al. (AUA #1655) compared the efficacy and safety of intravesical instillation of Gemcitabine versus BCG in treatment of NMIBC after TURBT. The study included 80 patients with primary Ta-T1 Transitional Cell Carcinoma (TCC) without CIS. The subjects were randomised into two groups, with each group receiving either BCG or Gemcitabine after TUR. The end points were recurrence rate, progression rate and safety during and after the follow-up of 18 months. In the Ta series, recurrence was seen in 26% of the BCG-group and in 22% of the Gemcitabine-group (p=0.92). Tumour progression appeared in one case in each group. 33% of the patients in the BCG group and 27% of the Gemcitabine group showed recurrence in the T1 population (p=0.66). Progression in this population was detected in 9.5% of the BCG-series and 9.1% in the Gemcitabine-series (p=1.0). The overall recurrence rate was 30% for the BCG-collective compared to 25% for the Gemcitabine-collective (p=0.61). Overall progression rate was equal in both of the groups (p=1.0). Dysuria was seen in 35% of the BCG-group and in 12.5% of the Gemcitabine-group (p<0.05). Urinary frequency was registered in 45% of the BCG group compared to 10% in the Gemcitabine group (p<0.05). In their analysis of the results, Bendary's study group reported equivalent results between Gemcitabine and BCG in the therapy of NMIBC after TUR with regard to recurrence and tumour progression. However, the authors attributed a better safety profile and a minimal toxicity to Gemcitabine.

JO et al. (AUA #1658) investigated the efficacy of additional post-TUR-MMC-instillation on patients treated with BCG compared to post-TUR-BCG-instillation-therapy only patients. In this double arm study, 162 patients with high risk NMIBC were included between 2000 and 2007. These patients underwent TUR and BCG instillation. A total of 76 of the 162 patients received additional immediate post-TUR-MMC-instillation. The other 86 patients received post-TUR intravesical BCG only. The BCG-MMC group showed a lower recurrence rate (26% vs. 49%, p=0.003) and longer time to recurrence (24.9 months vs. 21.8 months, p=0.293) compared to the BCG-only group. The 5-year recurrence free survival was also higher in the BCG-MMC series (p=0.003). No differences concerning stage at recurrence were visible in either group. As for reducing the recurrence rate and time to recurrence, the authors postulated an advantage for

Forum Verlag Dr. Wolfgang Otto • Postfach 10 07 28 • D-93007 Regensburg

invited June 26th 2011
accepted Octobre 11th 2011
published Octobre 12th 2011

immediate additional post-TUR-MMC-instillation for patients with high risk NMIBC.

PALOU et al. (EAU #434) presented their data including 1039 patients with various forms of bladder sparing management in histopathologically T1G3 bladder cancer. In this study, the authors retrospectively analysed results of the following post-TUR therapy options in patients: 1) only TUR without BCG, 2) Re-TUR only without BCG, 3) BCG Connaught 27mgrs induction course, 4) BCG Connaught 81mgrs induction course, 5) BCG Connaught 81mgrs induction course + maintenance. Patients with TUR only showed progression rate of 36.1% (p=0.01), recurrence rate of 66.6% (p<0.001) and disease specific survival of 27.8% (p<0.003). In subjects with Re-TUR only without BCG, progression rate of 26.79% (p<0.001), recurrence rate of 71,2% (p<0.001) and disease specific survival of 15.7% (p<0.091) were revealed. The bladder tumour progression rate was 15% (p=0.0003) in BCG 81 induction course and maintenance compared to 20% (p=0.24) in BCG 81 induction course and 29% in BCG 27 (p=0.009). Recurrence rate was 29% (p<0.001) in BCG 81 induction course and maintenance compared to 38% (p=0.047) in BCG 81 induction course and 47% (p=0.003) with BCG 27. Cancer specific survival was 9.4% (p=0.003) in BCG 81 induction course and maintenance, 11.7% (p=0.780) in BCG 81 induction course and 15% (p=0.211) in BCG 27. The authors concluded that patients undergoing BCG 81 induction course and maintenance after TUR had the best outcome on T1G3 non-muscle invasive bladder cancer with regard to recurrence, progression and disease specific survival.

OSMAN et al. (AUA #1744) scrutinized the diagnostic potential of narrow-band imaging (NBI) in post-TUR in patients with superficial bladder tumours. Between January and June 2010, post-TUR-NBI was performed on 52 patients. All lesions that were visible in TUR were also detected by NBI. All in all, 52 lesions were revealed, of which malignancy was reported in 33 cases. NBI discovered a total of 8 lesions overlooked in cystoscopy. 2 of these overlooked lesions were malignant and 6 benign. The sensitivity of routine cystoscopy and NBI were 94% and 100%, respectively. The positive predictive value of cystoscopy and NBI was 58% and 63% respectively. The authors describe limited diagnostic potential for NBI in the detection of additional malignant lesions post-TUR, which were overlooked by routine cystoscopy due to inferior positive predictive value.

BLASQUEZ et al. (AUA #1750) investigated the role of specimen weight after TUR, as an additional independent morphological factor to tumour size and tumour multiplicity, for the risk of recurrence and progression of NMIBC. From 1999-2007, a population of 423 patients were subjected during a median follow-up of 58 months. The pathological reports yielded the specimen weight of 100 out of 423 patients, with a median weight of 7.5 g (0.7g-70g). The recurrence rate in this group was 26% per year and 53% after five years. The progression rate was 5% per year and 8% after five years. There were no differences in this group with regard to grade, stage or presence of CIS from the rest of the series. Also, no differences were detectable between rate of recurrence and progression in this group and the overall series. The statistical analyses showed weight of resection as an independent variable for recurrence (p=0.007) at a cut-off value of 4g in the ROC curve and with an increased risk of relapse HR 2.6 (95% CI 1.3-5.2). Taking their results into consideration, the authors attributed tumours larger than 4g a 2.6 times higher risk of recurrence than tumours with lower weight.

LAMMERS et al. (EAU #428) investigated the influence of smoking behaviour on the development of recurrence and progression of NMIBC after TUR. 730 patients (587 male, 143 female) underwent TURBT and were randomized in a trial comparing three schedules of adjuvant intravesical Epirubicin therapy. 87% of the male study population

Forum Verlag Dr. Wolfgang Otto • Postfach 10 07 28 • D-93007 Regensburg

invited June 26th 2011
accepted Octobre 11th 2011
published Octobre 12th 2011

smoke (or used to smoke) cigarettes, compared to 60% of the women (p<0.001). After a follow up of 5 years, 47% of the current or ex-smokers were recurrence free while 62% of the non-smokers were recurrence free (p=0.007). With regard to gender, 60.2% of the women and 46.6% of the men were recurrence-free (p=0.011). Moreover, the authors describe smoking behaviour as a risk factor for recurrence (p=0.031), whilst gender was not statistically significant (p=0.094). Post follow up, 93.6% of the women and 94.7% of the men were progression-free (p=0.237). Smoking behaviour did not influence the 5-year progression-free survival (p=0.092). The study group concluded that smoking cigarettes has a significant impact on developing recurrence of NMIBC after TUR.

STRÖCK et al. (EAU #430) evaluated the necessity of follow-up cystoscopy on patients who showed a minimum tumour-free period of 5 years after BCG treatment.
A population of 190 patients was divided in two groups. Group 1 with a total of 73 patients showed histopathologically TaG1-G2, group 2 with a total of 117 patients showed TaG3/Cis/T1. The median tumour-free period was 105 months (range 62-225) in both groups. In the first group, 5 out of 73 patients had recurrences (6.8%). 13 out of 117 patients in the second group had recurrences after a tumour-free period of 63-133 months. The Kaplan-Meier estimated risk for recurrence was 11% at 10 years and 18% at 15 years. As such, the study group recommended lifelong follow-up cystoscopy for patients with BCG-treated bladder cancer, regardless of initial grade and stage.

JAHNSON et al. (EAU #431) investigated the adherence to guidelines of treatment with adjuvant instillation of BCG after TUR in NMIBC. A population of 4091 patients of the Swedish Bladder Cancer Register from 1997-2006 with T1 bladder cancer on the use of BCG were included in the study. 3149 (74%) of the subjects were male, 942 (26%) were female. The mean age was 72 years. A total of 24% received BCG. This percentage slightly increased over the years (1997-2000 18%; 2001-2003 27%; 2004-2006 41%). Thus, the authors ascribed an association of cancer specific survival with BCG treatment and tumour grade in this series. The study group specifically found a lack of BCG treatment in low-volume hospitals, which registered less than 10 patients with T1 tumours per year. Jahnson et al. concluded that bladder cancer treatment should be undertaken in higher volume hospitals, e.g. with 10 or more T1 tumours per year, in order to improve adherence to guidelines and treatment results.

RUKIN et al. (EAU #536) presented data of their investigation with flexible cystoscopy and Holmium: YAG laser, performed under local anaesthesia for the treatment of superficial bladder carcinoma. A total of 126 patients, were included in this study, undergoing 210 individual procedures. 68% of the patients showed pTa bladder cancer, 24% pT1. The median number of tumours treatments per flexible cystoscopy was 1 (1-6), with a mean tumour size of 7mm (2-40mm). The local tumour recurrence rate was 12.5%, most of which could be resected in a further laser session. A total of 32% of the patients developed further superficial bladder cancers at different sites within the bladder during follow up. 80% of these patients were treated successfully with repeated laser treatment. Only one patient needed general anaesthesia. With the minimal level of complications and an overall level of patient satisfaction of 100%, the authors recommended Holmium: YAG laser treatment in combination with flexible cystoscopy and local anaesthesia for treating superficial bladder cancer. Furthermore, they hypothesised that laser treatment at time of tumour detection spares patients a second hospitalisation for subsequent treatments.

WONG et al. (EAU #537) evaluated clinical outcome and cost-effectiveness of flexible cystoscopy laser ablation with photodynamic diagnosis (PDD/blue light) and white light in the treatment of transitional cell

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carcinoma (TCC) of the bladder. The study group compared local anaesthesia outpatient treatments to general anaesthesia inpatient procedures. A total of 39 selected patients with a high risk for general anaesthesia and previous tumour histology ranging from pTaG1 to pT1G3 underwent laser ablation after local anaesthetic gel instillation. For 13 out of the 39 patients, the treatment was performed using PDD (HexVix). More than 50% of the patients had greater-than-or-equal to >3 co-morbidities, mean age was 78 years. All of the patients tolerated the procedure well, nominating 0-2 on the visual analogue scale. Moreover, the hospitalisation length was less than 2 hours compared to 3.8 days for inpatient procedures (p=0.0085). Furthermore, no statistical difference was seen in recurrence rates between outpatient laser ablation and inpatient procedures (p=0.0568). Equally, no statistical difference was observed concerning the laser ablation being performed with or without PDD (p=0.4112). The study group calculated that the procedural cost of outpatient laser ablation was £469 (white-light) or £761 (PDD) compared with £1375 (white-light) or £1742 (PDD) for inpatient procedures. Analysing their findings, the study group recommend laser ablation as treatment for TCC of the bladder in elderly patients with co-morbidities and heightened risk or general anaesthesia risk. The study group demonstrated a comparable oncological outcome between inpatient and outpatient procedures and cost-effectiveness for laser ablation.

MUSCLE-INVASIVE BLADDER CANCER

YOUSSEF et al. (AUA #1400) evaluated the association of the expression of the cell cycle-related molecular markers p53, p21, p27, Cyclin E and Ki-67 with pathologic features and clinical outcomes of patients with squamous cell carcinoma of the urinary bladder treated with radical cystectomy. In this study, 152 patients were included, of whom 81% had bilharziasis. The presenting stage of the patients was histopathologically from pT2 upwards, the presenting grade was grade II or less. The authors registered altered Cyclin E expression with stage (p=0.02), altered p21 with grade (p=0.02) and altered p27 with lymphovascular invasion (p=0.02). Altered p53 expression was the only marker associated with an increased risk of disease recurrence (p=0.05) and bladder cancer specific mortality (p=0.05) in all patients. Thus, the authors showed altered cell cycle molecular markers on squamous cell carcinoma of the urinary bladder with p53 to be a prognostic factor in patients undergoing radical cystectomy with regard to disease recurrence and bladder cancer specific mortality.

BASTIAN et al. (EAU #866) presented data from a multi-centre study on the association between the extent of pelvic lymphadenectomy and cancer-specific survival in patients with lymph node (LN) negative urothelial carcinoma of the bladder undergoing radical cystectomy. 1291 patients who had undergone a radical cystectomy were included and the number of removed lymph nodes and presence or absence of lymphovascular invasion was recorded. A significant enhancement of the cancer-specific survival (CSS) could be seen for a lymph node count of 16 by using multivariable Cox regression models for different numbers of removed LNs. After 5 years, CSS rates of patients with lymphadenectomy less than 16 LN was 72%, compared to CSS rates of 83% on patients with greater-than-or-equal to 16 removed LN (p=0.01). Hence, the authors attributed an improved oncological outcome to a removal of higher LN count.

MAYR et al. (EAU #45) evaluated the correlation of four comorbidity indices – Adult Comorbidity Evaluation – 27 (ACE-27), the age adjusted Charlson Comorbidity index (aCCI), the Eastern Cooperative Oncology Group (ECOG) and the American Society of Anaesthesiologists score (ASA), and age,

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gender and Body Mass Index (BMI) -with perioperative mortality after radical cystectomy for Urothelial cancer (UC) of the bladder. 618 patients were included between 2005 and 2010. All four comorbidity indices, together with age, gender and Body Mass Index (BMI) showed associations with perioperative mortality after radical cystectomy. However, the ASA-score showed a significant association in perioperative mortality (p=0.00385), whilst aCCI (p=0.0536), ACE-27 (p=0.061) and ECOG (p=0.442) jointly could not demonstrate any significance. Thus, the authors summarized that the American Society of Anaesthesiologists score (ASA) is an independent prognostic factor for perioperative mortality after radical cystectomy.

TISCIONE et al. (EAU #759) presented their data on rare histological variants of urothelial bladder cancer at radical cystectomy specimen analysis. In this retrospective study during 2000-2009, 66 uncommon pathological variants of bladder cancer have been detected and reviewed: a total of 41 squamous cell carcinoma, 8 micropapillary carcinoma, 4 clear cell carcinoma, 3 adenocarcinoma, 2 small cell carcinoma, 2 of sarcomatoid differentiation, 3 lymphoepithelioma-like, 1 giant cell and 2 undifferentiated carcinoma. All in all, 1 pT1, 14 pT2, 2 pT2 with CIS, 29 pT3a, 5 pT3b, 15 pT4, and 5 N1, 7 N2, 2 N3 were detected. At a mean follow-up period of 97.6 months (from 10 to 114), 19 subjects were alive without disease, 5 patients were alive with disease progression and 42 died for disease (survival mean time 9.7 months). The authors could report that squamous cell carcinoma is the most common variant of bladder cancers and correlates with higher grade and stage. A poorer prognosis was ascribed to cases of bladder cancer with sarcomatoid differentiation. Clear cell carcinoma and micropapillary carcinoma were associated with better prognosis. The authors recommended a high index of clinical suspicion for aggressive disease in patients presenting with either urothelial cancer with divergent differentiation or non-urothelial histology after pathological analysis after TURBT.

EHDAIE et al. (AUA #1593) compared the clinical outcomes of pure squamous cell carcinoma (SCC) and urothelial carcinoma with squamous differentiation (SD) in patients treated with radical cystectomy. 2506 patients who underwent radical cystectomy and bilateral pelvic lymph node dissection were subjected. A total of 78 patients were registered with pure SCC, whereas 67 patients showed SD. The median follow-up for patients who were still alive at the time of the last follow-up was 44 months. There were 104 deaths in total of which 60 were cancer specific. At 4 years, patients with pure SCC and SD had a CSS probability of 42% and 58% respectively. OS (overall survival) and CSS among patients with pure SCC and SD were similar (OS: HR 1.10 (95%CI 0.75, 1.62) p=0.6; CSS HR 1.43 (95%CI 0.86, 2.38) p=0.17). Upon univariate analysis, positive surgical margins were significantly associated with increased risk of cancer-specific death (p<0.001) and overall death (p<0.001) in patients with pure SCC. In patients with SD, pathologic stage (p=0.01) and vascular invasion (p=0.037) were found to be significantly associated with an increased risk of overall death and pathologic stage (p=0.005) and neo-adjuvant chemotherapy (p=0.040) were associated with increased risk of cancer-specific death. Hence, the authors denied any notion that CSS and OS differed by SD. Furthermore, the study group ascribed neo-adjuvant chemotherapy as giving an improved CSS in patients with SD. The authors attributed pathological stage as a prognostic factor for oncological outcome in patients with SD, whilst surgical margins are associated with CSS and OS in patients with pure SCC.

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Conflicts of interest

The authors declare that there are no conflicts of interest.

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