

## EVALUATION OF A PERSONALIZED PROFORMA FOR ADMINISTRATION OF INTRAVESICAL BCG IN PATIENTS OF CARCINOMA BLADDER

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### ABSTRACT

**Background:** Carcinoma bladder is a common malignancy of the genitourinary tract and NMIBC is the most common presentation. The management involves TURBT followed by intravesical instillation of BCG in cases with intermediate and high risk of progression. The schedule of BCG instillation is long and difficult to follow with high dropout rates specially in patient of poor socioeconomic status. **Materials and methods:** We provided 30 patients with a personalized schedule of BCG administration and gave each patient a questionnaire regarding the ease of understanding of the schedule. **Result:** All 30 patients in the study reported that the schedule was easy to understand and follow. All patients also preferred to be given the entire schedule of BCG instillations at the beginning of the treatment. **Conclusion:** A personalized complete schedule for the administration of BCG therapy is easy understand and may reduce dropout rates.

**Keywords:** BCG, personalized, proforma, carcinoma, bladder

### INTRODUCTION

Carcinoma bladder is a common malignancy of the genitourinary tract with an increased incidence in smokers. In India, carcinoma bladder is the 9th most common malignancy with a contribution of 3.9% to all malignancies. (1) The spectrum of the disease ranges from papillary urothelial neoplasms to metastatic disease. However, the most common presentation is a non-muscle invasive disease with the most common histopathology being a transitional cell or urothelial carcinoma (>90%) (2). The primary modality of management of NMIBC is transurethral resection of bladder tumor (3). This is followed by a histopathological assessment and depending on the histopathology the subsequent treatment is decided.

Tumors with low risk of recurrence are managed by immediate intravesical instillation of mitomycin C while for intermediate and high groups only BCG therapy has shown benefit in both preventing

recurrence as well as progression. As per the SWOG regimen, BCG is administered intravesically with a 6-week induction course followed by three weekly instillations at 3, 6, 12, 18, 24, 30, and 36 weeks. The duration of this treatment is long and difficult to understand. The patient also has to undergo check cystoscopy at every 3 months for two years and 6 monthly till 5 years. This becomes cumbersome for both the clinician and the patient to manage without a pre-existing proforma.

We created a proforma for the assignment of dates for BCG instillation dates and gave it to 15 new patients and 15 old cases undergoing management of NMIBC. Both the clinician and the patients were then given questionnaires to assess the ease of understanding of the schedule and the responses of the two groups of patients were compared.

## MATERIALS AND METHODS

This prospective observational study was conducted from July 2019 to June 2020. All cases of NMIBC who underwent TURBT during this period and were eligible for intravesical BCG therapy according to the SWOG regimen were included in the study. We also included 15 other patients who were on intravesical BCG therapy and transferred their data from a dedicated register to the pre-prepared proforma. Patients operated during the study period were given a questionnaire at the beginning of the maintenance phase of BCG therapy i.e. at 3 months after TURBT. The patients already on BCG therapy were given the proforma and the evaluation was done at the time of the second dose of BCG therapy after being given the proforma. The responses of the patients were then tabulated and compared.

The inclusion criteria of the study were patients with NMIBC, tumor size less than 3 cm, histopathology of urothelial carcinoma with intermediate or high risk of recurrence, and patients motivated for follow-up. The exclusion criteria were muscle invasion on histopathology, patients with histopathology other than urothelial carcinoma, tumor size greater than 3 cm, and patients not motivated for follow-up.

## RESULT

During the study period, a total of 36 patients underwent TURBT. Of these 15 patients who underwent TURBT for bladder tumors had histopathology suggestive of intermediate (6) and high risk (9) of recurrence. Among these patients, 13 were taken on intravesical BCG therapy following a check cystoscopy after two weeks revealed no residual disease. Two patients had residual disease and were taken on BCG therapy following a repeat resection and a repeat cystoscopy confirming no residual disease. These patients were given printed proformas with pre-assigned dates for the instillation of intravesical BCG.

During this period 15 patients who were on BCG therapy before the study period began were also given the schedule and asked to follow it. These patients were given the questionnaire after one three week maintenance course and their answers were recorded. Thus, a total of thirty patients responses were recorded and analysed.

The questionnaire was taken by all 30 participants in the study and all of them completed the questionnaire.

All participants in the study reported that the schedule was easy to understand and had clarity

regarding the dates of follow-up. The patients who were already on BCG and were shifted to the group with pre-printed proformas reported increased clarity and ease of understanding regarding the dates of follow-up.

## DISCUSSION

Carcinoma bladder is one of the common malignancies of the genitourinary tract and is the most common tobacco related cancer of the genitourinary tract in India (4). It may present with a variety of presentations ranging from a papillary urothelial neoplasm to metastatic disease. However, the most common presentation is NMIBC (5). The management of NMIBC entails a TURBT followed by intravesical instillation which varies according to the risk of recurrence as defined by the EORTC risk tables probabilities of recurrence and progression (6). All low-risk tumors are managed by an immediate post-operative instillation of intravesical Mitomycin C. For tumors with intermediate risk of progression the management can either be intravesical BCG or intravesical chemotherapy. We prefer intravesical BCG as it is financially viable and most patients at our institute tolerate the treatment well. Treatment of urothelial carcinoma with a high risk of recurrence or progression as per the EORTC tables involves intravesical BCG administration (7). It is the only modality which has been proven to decrease the risk of both recurrence as well as progression of the disease (8).

The standard course of BCG immunotherapy consists of a six-week induction course followed by three weekly maintenance doses at 3, 6, 12, 18, 24, 30, and 36 months (9). The patients often complained of difficulty in understanding the schedule and had difficulty in remembering the dates of follow-up. This is specially difficult in patients with poor socioeconomic status. These patients often have greater difficulty in understanding the schedule and the duration of treatment. In our experience these patients are often lost to follow up and present at a later date with advanced disease. We created the proforma with a personalized schedule for each patient and evaluated the ease of understanding and the follow-up of these patients.

The use of technology in medicine is not a new idea. Softwares have been use in the last 25 years in hospitals at every level. They have often been used to make duty rosters of staff and to record data for research (10). We used software to design a proforma to determine the entire dosage schedule of administration of BCG and evaluated the patients

follow-up and ease of understanding. All patients were evaluated at the second visit and given a questionnaire regarding the ease of understanding and the clarity of the schedule.

All patients in the study reported that the pre-prepared personalized schedule given to them detailing the dates of all days of administration of intravesical BCG was easy to understand and follow. All patients in the study also preferred to be provided the entire schedule at the beginning rather than be informed of the next date of visit at each BCG instillation. 26 patients reported that the duration of the schedule (3 years) was quite long and difficult to maintain. All patients also reported that the visits are easy to be planned and continued with the entire schedule given to them in a personalized format. Even the patients with poor socioeconomic and literacy status reported that the entire schedule given as a proforma was easy to understand.

## CONCLUSION

The management of NMIBC with intravesical BCG instillation is a long and arduous process complicated further by the complexity of the schedule. The patients often have difficulty in understanding and following the schedule when given to them piecemeal at each visit. A personalized schedule given to each patient with the date and day of the visit is easy to understand and may lead to decreased dropout rates. All patients in our study reported increased ease of understanding. However, a longer study with more participants is required to evaluate the actual dropout rate and efficiency of providing a personalized schedule to each patient.

**Conflict of interest:** We have no conflict of interest.

**Ethical standards:** All ethical standards have been met.

## REFERENCES

1. Kurkure A. Cancer incidence and patterns in urban Maharashtra. Consolidated report of the population based cancer registries, Year. 2001.
2. Rabbani F, Cordon-Cardo C. Mutation of cell cycle regulators and their impact on superficial bladder cancer. *Urol Clin North Am.* 2000;27(1):83-102.
3. Palou-Redorta J, Rouprêt M, Gallagher JR, Heap K, Corbell C, Schwartz B. The use of immediate postoperative instillations of intravesical chemotherapy after TURBT of

NMIBC among European countries. *World J Urol.* 2014;32(2):525-30.

4. Yeole BB, Kurkure AP, Koyande S. Geographic variation in cancer incidence and its patterns in urban Maharashtra, 2001. *Asian Pac J Cancer Prev.* 2006;7(3):385.
5. Cassell A, Yunusa B, Jalloh M, Mbodji MM, Diallo A, Ndoeye M, et al. Non-muscle invasive bladder cancer: a review of the current trend in Africa. *World J Oncol.* 2019;10(3):123.
6. Sylvester RJ, van der Meijden AP, Oosterlinck W, Witjes JA, Bouffieux C, Denis L, et al. Predicting recurrence and progression in individual patients with stage Ta T1 bladder cancer using EORTC risk tables: a combined analysis of 2596 patients from seven EORTC trials. *Eur Urol.* 2006;49(3):466-77.
7. Urology EAo. Guidelines Non-Muscle-Invasive Bladder Cancer and Muscle-Invasive and Metastatic Bladder Cancer. 2018.
8. Böhle A, Bock P. Intravesical bacille Calmette-Guerin versus mitomycin C in superficial bladder cancer: formal meta-analysis of comparative studies on tumor progression. *Urology.* 2004;63(4):682-6.
9. Lamm DL, Van Der Meijden AP, Morales A, Brosman SA, Catalona WJ, Herr HW, et al. Incidence and treatment of complications of bacillus Calmette-Guerin intravesical therapy in superficial bladder cancer. *The Journal of urology.* 1992;147(3 Part 1):596-600.
10. Irvin SA, Brown HN. Self-Scheduling with Microsoft Excel. *Nurs Econ.* 1999 1999/07//:201.

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