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"COMPLICATIONS IN NON-MUSCLE INVASIVE BLADDER CARCINOMA PATIENTS UNDERGOING MOSCOW STRAIN INTRAVESICAL BCG IMMUNOTHERAPY –SINGLE CENTRE EXPERIENCE"

Urology

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ABSTRACT

Urothelial bladder carcinoma accounts for around 3.9% cases of all the male cancers in India. Non muscle invasive bladder carcinoma (NMIBC) is predominant group which constitute approximately three fourth of the urothelial bladder cancer. Intravesical BCG immunotherapy is the corner stone of today's NMIBC management. However, as with any other therapy it has its own complications and its interruption due to these adverse effects is a major cause of suboptimal efficacy. The aim of this study was to assess the complications of intravesical BCG therapy in NMIBC patients.

KEYWORDS

NMIBC, TURBT

INTRODUCTION

Bladder cancer is the most common malignancy of the urinary system and the ninth most common malignancy worldwide. After initial TURBT, various intra vesical agents are used to reduced recurrence in NMIBC patients but BCG is immunotherapeutic agent which prevent recurrence as well as progression. According to EAU guidelines, patients with intermediate-risk tumors should receive full-dose BCG or chemotherapy instillations for 1 year and for high-risk tumors full-dose BCG treatment for 1–3 years is recommended. BCG is the main stay treatment of high risk NMIBC, which has been in use since long time. Unfortunately, nearly 60–70% patients experience local or systemic side effects resulted from BCG and in about < 5% patients it can cause serious adverse complications.

Strain	Name	Supplier
Connaugh	TheraCys/ ImmuCyst	Sanofi Pasteur (Canada)*
Danish	Urovac/BCG-Onco	Green Signal Bio Pharma Private Limited GSBPL (India)
Japan	Immunobladder	Japan BCG Laboratory (Japan)
TICE	OncoTice	Organon-Merck (USA)
RIVM	BCG-Medac /Vejicur	Medac GmbH (Germany)
Russian	SII-Onco BCG	Serum Institute of India Pvt Ltd (India)

Note: *Production was definitely stopped and Connaugh strain is not available in the market

MATERIAL AND METHOD

AIM

Mixed design cohort study to know the various complications in NMIBC patients undergoing Moscow strain intra vesical BCG immunotherapy.

OBJECTIVES

To observe proportion of various complications like irritative voiding symptoms (frequency, urgency, nocturia, dysuria), fever, haematuria, Epididymo orchitis, prostatitis, balanitis, Arthritis, haemoptysis in NMIBC patients undergoing Moscow strain intra vesical BCG immunotherapy.

Study Design: Mixed design cohort study

Study Duration: 3 year (July 2021 to July 2024)

Inclusion Criteria: All the patients with NMIBC who underwent BCG immunotherapy at our institute.

Exclusion Criteria:

- Patients not willing to participate in the study
- Patient hyper sensitive to BCG.
- Immunocompromised patients.
- Incontinent patients (as they cannot retain BCG for desired period)

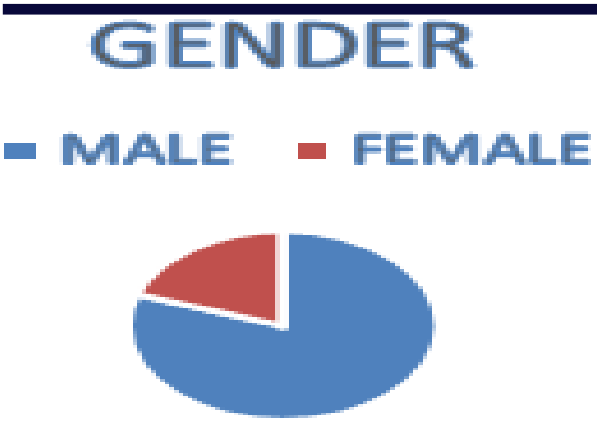
Sample Size:- 56

For Instillation, BCG powdered vaccine (80 mg) was reconstituted with 50 mL of saline and administered through a urethral catheter under gravity. Treatments was begun 2 to 4 weeks after tumor resection. In the event of a traumatic catheterization, the treatment was delayed for several days to 1 week, depending on the extent of injury. Retention time was 2HRS. All patients were advised to report immediately if they develop symptoms of BCG adverse effect or infection. We follow swog regimen weekly for 6 week in induction phase and 3 weekly instillation at 3rd month, 6 month, then every 6 month for 3 year.

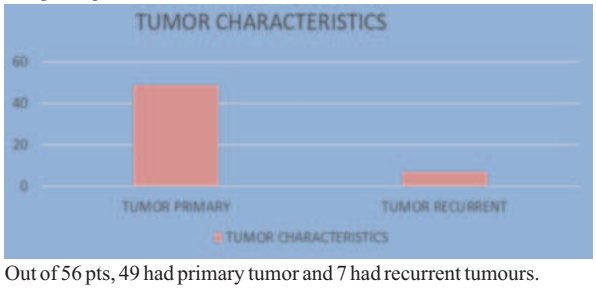
RESULTS

Age (years)	No. of patients	Percentage
<20	0	0
21-30	0	0
31-40	4	7
41-50	4	7
51-60	16	28
61-70	22	39
71-80	10	18

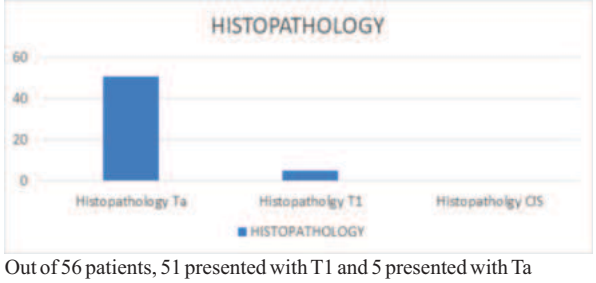
In our study most of the patients are in older age group mostly in sixth and seventh decade of life



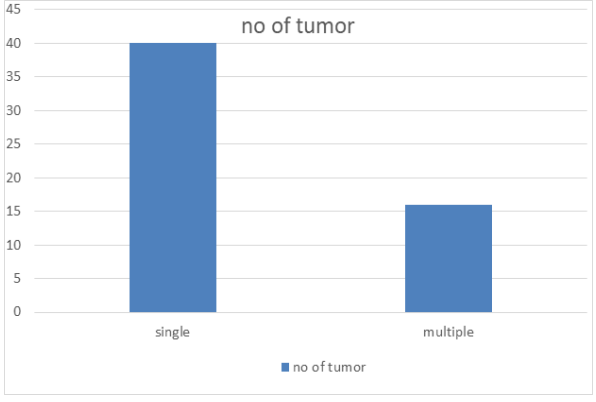
Total 56 patients were analysed, comprising 45 males and 11 females.



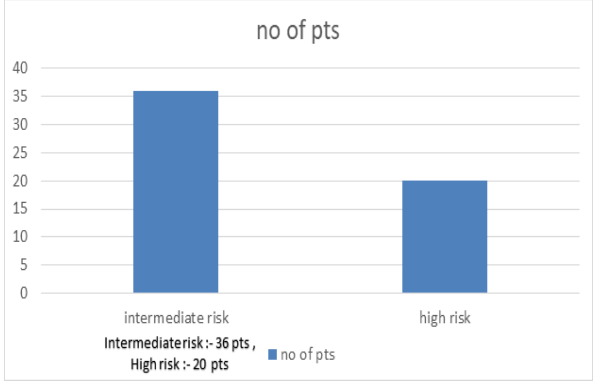
Out of 56 pts, 49 had primary tumor and 7 had recurrent tumours.



Out of 56 patients, 51 presented with T1 and 5 presented with Ta None of them presented with CIS



Out of 56, 16 patients had multiple tumor and 40 had single tumor.



COMPLICATION

Complications	No. of patients	Percentage
Irritative voiding symptoms	26	46
Fever	8	14
Hematuria	1	1.78
Balanitis	0	0
Prostatitis	0	0
Epididymo orchitis	0	0
Arthritis	0	0
Hemoptysis	1	1.78
TOTAL	36	60

In our study most of the patients presented with irritative voiding symptoms (46%) followed by fever (14%)

COMPLICATION

CLEVELAND CLINIC GRADE	No of patients	Percentage
GRADE 1 MILD: - symptoms <48hr, Irritative voiding symptoms, fever, haematuria	32	57%
GRADE 2 MODERATE: - symptoms >48hr, irritative voiding symptoms, fever, haematuria	3	5.3%
GRADE 3 SEVERE: - hemodynamic changes and persistent high-grade fever Allergic reaction-Joint pain, Rash Solid organ involvement-Liver, Lung, kidney	1	1.78%

Out of 56 patients, dose of bcg was reduced to half in 3 patients (5.3%) who developed grade 2 complications and bcg was stopped in 1 patient (1.78%) who developed grade 3 complications.

DISCUSSION

Intravesical bcg is the most effective adjunctive agent and remains as the standard of care in the management of superfcial bladder cancer. Although it is most effective in prevention of tumour recurrence and progression but it is also associated with significant adverse effects. The underlying pathogenic mechanisms of complications following bcg instillation remain not fully understood and on-going debate exists about whether it represents a form of hypersensitivity reaction or an active mycobacterial infection. This study aimed with bringing out the possible adverse effects associated with intravesical bcg.

Complication	In Our Study (56 patients)	Brausi Et All (1316 patients)	Vivek sharma et all (149 pts)
Irritative voiding symptoms	46 %	53.3%	26.17%
Fever	14 %	8.1%	4.02%
Hematuria	1.78 %	22.6%	0%
Balanitis	0 %	3%	1.3%
Prostatitis	0 %	2%	3.3%
Epididymo orchitis	0 %	1%	2.68%
Arthritis	0 %	1%	1.01%
Hemoptysis	1.78%	3%	2.01%
TOTAL	60 %	69.5%	58.3%

In comparision to other study, irritative voiding symptoms found most common complication followed by fever and systemic complication present in <5% of patients who undervent bcg immunotherapy.

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Conflicts Of Interst :- There are no conflict of interst.

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