



INTRAVESICAL MITOMYCIN C VERSUS GEMCITABINE INSTILLATION IN THE TREATMENT OF LOW-RISK NON-MUSCLE INVASIVE BLADDER CANCER: AN ANALYTICAL STUDY

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ABSTRACT **Background:** Non-muscle invasive bladder cancer (NMIBC) is a common urological malignancy with a high risk of recurrence and progression. Intravesical instillation of chemotherapeutic agents such as mitomycin C and gemcitabine has been widely used for adjuvant therapy in low-risk NMIBC patients after complete Transurethral bladder tumor resection. This study aims to compare the efficacy and safety of intravesical mitomycin C and gemcitabine instillation in the management of low-risk NMIBC. **Methods:** A retrospective analytical study was conducted on a cohort of low-risk NMIBC patients who received intravesical chemotherapy at our institution between January, 2018 and March 2022. Data including tumor characteristics, recurrence rates, progression rates, and adverse events were collected and analyzed. Statistical method such as chi-square test was employed to assess the differences between the two treatment groups. **Results:** Our analysis included a total of 26 low-risk NMIBC patients, with 14 patients receiving intravesical mitomycin C and 12 patients receiving gemcitabine instillation. The mean follow-up duration was 12 months. There were no significant differences in patient demographics and baseline tumor characteristics between the two groups. In terms of efficacy, the recurrence rate in the mitomycin C group was 28.6% compared to 25% in the gemcitabine group ($p = 0.6$). The progression rate was 7.14% in the mitomycin C group and 8.33% in the gemcitabine group ($p = 0.9$). Cox regression analysis adjusted for potential confounders confirmed that there was no statistically significant difference in recurrence and progression rates between the two treatment groups. Regarding safety, adverse events such as dysuria reported in 35.7% of patients in the mitomycin C group and 16.6% in the gemcitabine group ($p < 0.05$) and increased frequency of urination reported in 42.9% of patients in mitomycin C group and 16.6% patients in the gemcitabine group ($p < 0.001$). Most adverse events were mild and transient, with significant lower incidence of side effects in gemcitabine groups. **Conclusion:** In this analytical study, we found no statistically significant differences in recurrence, progression rates between intravesical mitomycin C and gemcitabine instillation in the treatment of low-risk NMIBC. Gemcitabine has better safety profile. Further prospective randomized controlled trials are warranted to validate these findings and establish optimal treatment protocols for low-risk NMIBC.

KEYWORDS : Non-muscle invasive bladder cancer, intravesical chemotherapy, mitomycin C, gemcitabine, recurrence, progression, safety.

INTRODUCTION

Non-muscle invasive bladder cancer (NMIBC) constitutes a significant proportion of bladder cancer cases, characterized by a relatively favorable prognosis but a high risk of recurrence and progression^[1]. As a result, the management of NMIBC remains a clinical challenge, necessitating effective adjuvant therapies to reduce the likelihood of disease recurrence and progression^[2,3].

Intravesical instillation of chemotherapeutic agents has long been a cornerstone in the management of NMIBC, particularly for low-risk patients^[4]. Among the agents employed, mitomycin C and gemcitabine have gained prominence for their potential in reducing tumor recurrence and maintaining bladder function^[5,6]. Despite their widespread use, there is an ongoing debate regarding the comparative efficacy and safety of these agents in the management of low-risk NMIBC.

This retrospective analytical study seeks to contribute to this ongoing debate by comparing the outcomes of intravesical mitomycin C versus gemcitabine instillation in a cohort of low-risk NMIBC patients. Our primary objectives are to assess the differences in recurrence and progression rates between the two treatment groups and to evaluate the safety profiles associated with each agent.

METHODS:

Study Design And Patient Population:

This study is a retrospective analytical study conducted at Stanley medical college between January, 2018 and March, 2022.

Inclusion criteria:

Low-risk NMIBC patients who received single dose of either mitomycin C or gemcitabine intravesical instillation as adjuvant therapy.

Exclusion criteria:

High-risk NMIBC patients, patients with a history of previous bladder cancer treatment, and those lost to follow-up.

Data Collection:

Demographic information, tumor characteristics, treatment protocols, and follow-up data were collected from medical records.

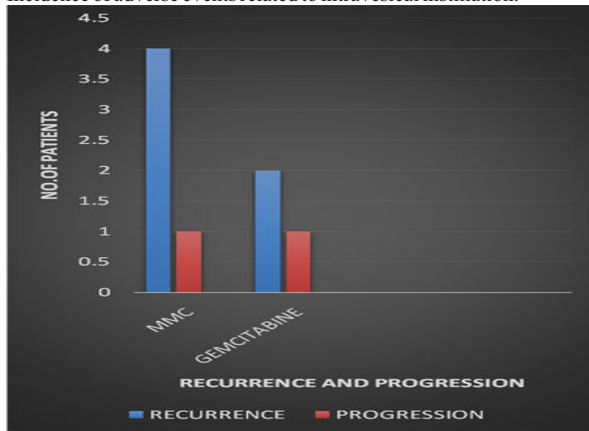
Outcome Measures:

Primary Outcome: Recurrence rate defined as the presence of histologically confirmed tumor recurrence during the follow-up period.

Secondary Outcome: Progression rate defined as the transition from non-muscle invasive to muscle-invasive bladder cancer.

Safety Outcome:

Incidence of adverse events related to intravesical instillation.



Statistical Analysis:

Descriptive statistics for patient characteristics were reported as mean for continuous variables and frequencies (percentages) for categorical variables.

Chi-square tests were used to compare categorical variables between the mitomycin C and gemcitabine groups.

Cox regression analysis adjusted for potential confounding variables was employed to assess the differences in recurrence and progression rates between the treatment groups.

A p-value less than 0.05 was considered statistically significant.

RESULTS:

A total of 26 patients of low-risk NMIBC patients were included in the analysis, with 14 patients receiving mitomycin C and 12 patients receiving gemcitabine instillation. The mean follow-up duration was 12 months.

There were no statistically significant differences in patient demographics and baseline tumor characteristics between the two treatment groups.

Efficacy Outcomes:

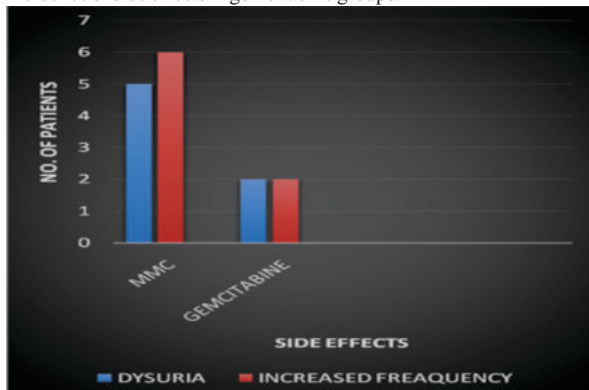
Recurrence Rate: 4 patients (28.6%) in the mitomycin C group versus 3 patients (25%) in the gemcitabine group (p = 0.6).

Progression Rate: 1 patient (7.14%) in the mitomycin C group versus 1 patient (8.33%) in the gemcitabine group (p = 0.9).

Cox regression analysis adjusted for potential confounders confirmed that there was no statistically significant difference in recurrence and progression rates between the two treatment groups.

Safety Outcomes:

Adverse Events: Adverse events such as dysuria was reported in 5 patients (35.7%) in the mitomycin C group and in 2 patients (16.6%) in the gemcitabine group (p <0.05) and increased frequency of urination was reported in 6 patients (42.9%) in the mitomycin C group and in 2 patients (16.6%) in the gemcitabine group (p <0.001). Most adverse events were mild and transient, with significant lower incidence of side effects in gemcitabine groups.



DISCUSSION:

This retrospective analytical study provides valuable insights into the comparative efficacy and safety of intravesical mitomycin C and gemcitabine instillation in the treatment of low-risk NMIBC. Our findings suggest that there are no statistically significant differences in recurrence and progression rates between the two treatment groups. Furthermore, both agents demonstrate acceptable safety profiles, with most adverse events being mild and transient. Gemcitabine has statistically better safety profile than Mitomycin C.

These results contribute to the ongoing discussion surrounding the optimal management of low-risk NMIBC. However, the retrospective nature of this study poses inherent limitations, including selection bias and the potential for unmeasured confounders. Therefore, prospective randomized controlled trials are warranted to validate these findings and guide clinical practice more definitively.

CONCLUSION:

In this analytical study, we found no statistically significant differences in recurrence, progression rates between intravesical mitomycin C and gemcitabine instillation in the treatment of low-risk NMIBC. Gemcitabine has better safety profile. Further prospective randomized controlled trials are warranted to validate these findings and establish optimal treatment protocols for low-risk NMIBC.

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