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# ROLE OF IMMUNONUTRIENTS IN CLINICAL OUTCOMES AMONG PATIENTS UNDERGOING RADICAL CYSTECTOMY: A NON-RANDOMIZED EXPERIMENTAL STUDY

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**ABSTRACT**

***Objective:*** *To compare rate of postoperative outcomes in patients receiving immunonutrients undergoing radical cystectomy as compared to matched historical controls.*

***Methods****: This non-randomized clinical study included 60 individuals (30 controls and 30 cases) between the ages of 35 and 75 of either gender. Patients who received 10-day perioperative Immunonutrition in the form of an arginine-based preparation (Impact Sachet) [TM] were prospectively included and compared with a retrospective, matched control group who did not receive Immunonutrition. 30-day complication rates, length of hospital stay, return of activity, and return of bowel function were recorded for both groups and analysed to assess differences in outcomes using multivariable binary logistic regression.*

***Results****: The median age of the participants was 63 (±11.5 IQR) years, with the study population being 80% male and 20% female. 20 (33.3%) participants experienced complications. We observed no significant difference in postoperative complication rate nor Clavien complication grade between the two groups (p=0.314 and p=0.302, respectively). The average length of hospital stay was six days in the intervention group and 7.5 days in the control group (p=0.041). Similarly, the time to return to bowel function was five days in the intervention group and six days in the control group (p=0.034). According to the multivariable binary logistic regression analysis, female gender (OR: 0.029), length of hospital Stay (OR: 2.509), and duration of surgery (OR: 0.310) were significant predictors of postoperative complication rate.*

***Conclusion****: Perioperative immunonutrition in patients with invasive bladder cancer undergoing radical cystectomy was not significantly associated with decreased postoperative complication rate.*

***Keywords:*** *Radical cystectomy, perioperative immunonutrition, complication rate, non-randomized experimental study*

## INTRODUCTION

The mainstay treatment of muscular-invasive bladder cancer is radical cystectomy (RC) combined with lymph node dissection and urinary diversion [1,2]. However, postoperative complications are common, varying between 13% and 78% of patients based on existing literature [3–5]. Most complications are minor and are related to bowel function (e.g., ileus), infection, or are associated with wounds, whereas major complications are less common, appearing in up to 13% of patients. Consequently, mortality rates for RC are low at 0.8%–8.3%. Some of these complications, such as sepsis, delayed return of bowel function, and anastomosis leak, have been linked to the nutritional status of the patient [6].

Malnutrition is very common among hospitalized patients, especially among those with cancer, with prevalence reaching 71% [7]. Nutritional status is directly related to immune function and, if not addressed in the perioperative period, may lead to increased morbidity [8]. Therefore, it is important to assess and improve nutrition before planning a major elective surgery. Nutritional screening of these patients can be done using various tools such as the Mini Nutritional Assessment®, which is commonly used to screen for malnutrition in the general population as well in hospitalized patients [9].

Perioperative nutritional status can be improved with the supplementation of immunonutrients, including amino acids (particularly arginine), omega-3 fatty acids, nucleotides, and vitamins [10]. These micronutrients can be incorporated into enteral formulations administered during the perioperative period to enhance immune function. By modulating the balance of inflammatory mediators and promoting protein synthesis, these immunonutrients help to optimize the body's immune response [11]. For example, arginine has been shown to support the balance between Th1 and Th2 cells, as well as lower the level of IL-6, a proinflammatory cytokine, which may potentially reduce postoperative complications [11]. Oral Impact® (Nestlé), an enteral preparation that combines these essential micronutrients, has been approved for use in patients preparing for major oncological surgeries, with promising evidence suggesting a reduction in morbidity for those undergoing major abdominal procedures [12].

Arginine-based immunonutrition supplementation is generally safe and not associated with any serious adverse effects, making its use common in surgical practice [6,13,14]. Despite encouraging findings, the role of immunonutrition in the context of RC remains unclear, as numerous studies have supported a difference in postoperative outcomes, whereas others found no difference. In this study, we aimed to investigate the effect of Oral Impact® on postoperative outcomes among patients undergoing RC.

## Materials & Methods

### Patients and population

We conducted a non-randomized experimental study at a tertiary care hospital in Karachi, Pakistan, from 8th February 2023. During the study period, 38 patients underwent RC, out of which 30 patients matching inclusion criteria were included in the study. To compare outcomes, data for an additional **30 patients**, matching inclusion criteria, serving as the "controls," were collected retrospectively from medical records. All patients 35–75 years of age undergoing RC for primary bladder cancer were included in the study. Exclusion criteria comprised patients undergoing other concomitant surgeries, those with metastatic/recurrent cancer undergoing salvage cystectomy without bowel segment use for urinary diversion, functional class IV patients, and those who did not consent to participating in the study. The study was approved by the Ethical Review Committee of the University Hospital (**Reference Number:** 023-7965-24048, dated 08/02/2023).

All 60 patients received standard perioperative care. Additionally, 30 patients received immunonutrients in the form of Oral Impact® supplement thrice daily five days before and five days after the surgery, in addition to their regular diet. Data for the control group (n=30), who did not receive perioperative immunonutrition, were collected from medical records and matched to the study group based on age, gender, and disease status. Data for the intervention group were collected prospectively at three time points: preoperatively at admission, during the postoperative hospital stay, and up to 30 days postoperatively after discharge. For both groups, data were recorded using a pre-designed proforma, which included patients' demographic features, operative parameters, and postoperative outcomes.

**Statistical Analysis**

Data analysis was conducted using IBM's Statistical Package for the Social Sciences (SPSS) version 23. Patient outcomes were analyzed and compared, including length of hospital stay, return of bowel function, return of activity, and postoperative complications such as infection, bowel-related, and urinary complications using the modified Clavien–Dindo classification. All complications during the first postoperative month were recorded.

The primary outcome of the study was postoperative complication rate within 30 days. The secondary outcomes were differences in length of hospital stay, return of activity, and return of bowel function between both groups. The Shapiro–Wilk Test was employed to check for normality within continuous variables. Descriptive data were expressed in terms of mean ± standard deviation or median ± interquartile range (IQR) for continuous variables, and frequencies with percentages for categorical variables. The chi-squared test was used to determine the relationship between categorical variables, whereas the independent-sample *t*-test was used for numerical and categorical variables. Based on observed cell counts of <5 and lack of normality in some variables, Fischer's exact test and the Mann–Whitney U Test were used as alternatives to the chi-squared test and independent-sample *t*-test, respectively. Throughout all these analyses, $p < 0.05$ was considered statistically significant.

The link between independent variables and outcome (30-day postoperative complication rate) was established using univariate and multivariable binary logistic regression. Clinical plausibility and a *p*-value of < 0.25 on univariate regression was considered the cut-off for inclusion in the multivariable regression model. A *p*-value of <0.05 was considered statistically significant, with a confidence interval of 95%.

**Results**

Between **01 January 2021 and 30 June 2024,** a total of **78 patients** underwent radical cystectomy (RC) at the hospital. Of these, **60 patients** met the eligibility criteria and were enrolled in the study, comprising both prospective and retrospective cohorts. The study population included **48 men (80%)** and **12 women (20%)**, with a median age of **63 years (±11.5 IQR)**. The final analysis comprised 30 cases who received preoperative immunonutrition and 30 controls who did not (Table 1). Both groups matched well in terms of demographic parameters and operation characteristics. The median ages were 63 (± 12.5) years and 63 (± 9.8) years for the control and case groups, respectively. Both groups had similar sex-based distributions (76.7% male in the case group vs. 83.8% male in control group). However, among all the patient characteristics, hemoglobin levels and ASA classification were significantly different between the two groups; the case group had a significantly lower mean hemoglobin level of 11.2 mg/dL ($p$=0.006), and the majority of cases fell under ASA Class 3 (56.7% of the case group vs. 30.0% of the control group; $p$=0.024).

**Table 1:** Comparison of patient characteristics between case and control groups.

| Variable | | Case Group (n=30) | Control group (n=30) | *p*-value |
|---|---|---|---|---|
| **Age (years)** [a] | | 63 ± 12.5 | 63 ± 9.8 | 0.412 |
| **BMI** [a] | | 24 ± 4.0 | 23.9 ± 4.3 | 0.395 |
| **Hb*** [b] | | 11.2 ± 1.3 | 12.1 ± 1.4 | 0.006 |
| **Creatinine** [a] | | 1.3 ± 0.6 | 1.2 ± 0.5 | 0.517 |
| **Duration (hours)** [a] | | 5 ± 2 | 5.5 ± 1 | 0.081 |
| **Blood loss (mL)*** [b] | | 1255 ± 710 | 1300 ± 629 | 0.798 |
| **Gender** [c] **(n%)** | **Male** | 23 (76.6%) | 25 (83.3%) | 0.347 |
| | **Female** | 7 (23.3%) | 5 (16.6%) | |
| **Functional Class** [d] **n (%)** | **1** | 5 (16.6%) | 5 (16.6%) | 0.297 |
| | **2** | 22 (73.3%) | 24 (80.0%) | |
| | **3** | 3 (10%) | 1 (3.3%) | |
| **ASA** [c] | **1** | 0 (0%) | 0 (0%) | 0.024 |

| | | | | |
|---|---|---|---|---|
| | **2** | 13 (43.3%) | 21 (70.0%) | |
| | **3** | 17 (56.6%) | 9 (30.0%) | |
| **DM [c] n (%)** | | 16 (53.3%) | 22 (73.3%) | 0.130 |
| **IHD [c] n (%)** | | 6 (20%) | 6 (20%) | 0.786 |
| **CRF [c] n (%)** | | 6 (20%) | 6 (20%) | 1 |
| **Muscle invasion [c] n (%)** | | 24 (80%) | 21 (70.0%) | 0.493 |
| **Screening score [d] n (%)** | **Normal** | 23 (76.7%) | 24 (80.0%) | 0.315 |
| | **At Risk** | 7 (23.3%) | 5 (16.7%) | |
| | **Malnutrition** | 0 (0%) | 1 (3.3%) | |

Cases group (10-day perioperative immunonutrition with Oral Impact®) and control group (standard diet). The p-value of <0.05 is considered statistically significant.
BMI, Body mass index; Hb, Hemoglobin; ASA, American Society of Anesthesiology Classification System; DM, Diabetes mellitus; IHD, Ischemic heart disease; CRF, Chronic renal failure.
*Variables for which mean and standard deviation was reported based on normality testing as Mean ± SD.
[a]Mann–Whitney U test was used for the given variables.
[b]Independent-sample *t*-test was used for the given variables.
[c]Chi-squared test was used for the given variables.
[d]Fisher's exact test was used for the given variables.

There was no statistically significant difference in the overall postoperative complication rate between the immunonutrition group (n=12, 40%) and the control group (n=8, 26.7%) ($p$=0.314). Complication severity, graded according to the Clavien–Dindo classification, also showed no significant difference between the two groups ($p$=0.302).
In the control group, eight (26.7%) patients experienced postoperative complications. Of these, four patients had grade I complications, two patients had grade IIIa complications, one patient had grade IVa complications, and one patient had grade V complications (mortality) due to septic shock. In the immunonutrition group, 12 (40%) patients developed postoperative complications; these included seven patients with grade I complications, one patient with grade II complications, two patients with grade IIIa complications, one patient with grade IVa complications, and one patient with grade V complications (mortality) due to septic shock. Neither overall complication rate nor complication severity distribution demonstrated a significant difference between the groups (Table 2).

**Table 2:** Comparison of postoperative complications between case and control groups.

| **Variable** | | **Case group (n=30)** | **Control group (n=30)** | ***p*-value** |
|---|---|---|---|---|
| **Length of Hospital stay (days) [a]** | | 6 (± 3) | 7.5 (± 3) | 0.041 |
| **Return of activity (days) [a]** | | 2 (± 1) | 2 (± 1) | 0.17 |
| **Return of bowel function (days) [a]** | | 5 (± 2) | 6 (± 2) | 0.034 |
| **IO complications [c] n (%)** | | 1 (3.3%) | 0 (0%) | 1 |
| **30-day complications [b] n (%)** | | 12 (40%) | 8 (26.7%) | 0.314 |
| **Clavien grade [c] n (%)** | **1** | 1 (8.3%) | 4 (50%) | 0.302 |
| | **2** | 2 (16.7%) | 0 (0%) | |
| | **3** | 6 (50%) | 2 (25%) | |
| | **4** | 2 (16.7%) | 1 (12.5%) | |
| | **5** | 1 (8.3%) | 1 (12.5%) | |
| **30-day readmissions [c] (n%)** | | 3 (10%) | 4 (13.3%) | 1 |

[a]Mann–Whitney U test was used for the given variables.
[b]Chi-squared test was used for the given variables.
[c]Fisher's exact test was used for the given variables.
IO: Intra-operative complications.

For secondary outcomes, it was observed that there was a significant reduction in the length of hospital stay in patients with immunonutrition (case group) at 6 (± 3) days compared to those without (control group) at 7.5 (± 3) days ($p$=0.041). The median number of days to return of bowel function was lower in the intervention group at 5 (± 2) days compared to 6 (± 2) days in the control group ($p$=0.034).

The binary logistic multivariate regression analysis showed that significant predictors of 30-day postoperative complication rate included female gender (OR: 0.029; CI: [0.001–0.934]), length of hospital stay in days (OR: 2.509; CI: [1.272–4.949]), and duration of surgery (OR: 0.310; CI: [0.118–0.813]). The full list of predictors used is given in Table 3.

**Table 3:** Binary logistic multivariable regression analysis to find predictors of 30-day postoperative complication rates in those undergoing RC.

| | | |
|---|---|---|
| Age | | 1.059 [0.990, 1.133] * |
| BMI | | 1.098 [0.950, 1.270] * |
| Hb | | 1.124 [0.804, 1.571] |
| Gender | Female | 0.370 [0.072, 1.909] * |
| ASA | 3 | 1.600 [0.539, 4.751] |
| DM | | 1.636 [0.542, 4.937] |
| IHD | | 8.000 [1.823, 35.109] * |
| CRF | | 1.476 [0.401, 5.431] |
| Muscle invasion | Invasive | 0.900 [0.256, 3.162] |
| Screening score | Malnutrition | 0.000 [0.000] |
| Duration (hours) | | 0.677 [0.422, 1.087] * |
| Blood loss (ml) | | 1.000 [0.999, 1.001] |
| Blood transfusion (ml) | | 0.999 [0.998, 1.000] * |
| Group | Intervention vs. No intervention | 1.750 [0.586, 5.225] |
| | | |
| Gender | Female | 0.029 [0.001, 0.934] ** |
| Length of Hospital stay (days) | | 2.509 [1.272, 4.949] ** |
| Duration (hours) | | 0.310 [0.118, 0.813] ** |

BMI, Body mass index; Hb, Hemoglobin; ASA, American Society of Anesthesiology Classification System; DM, Diabetes mellitus; IHD, Ischemic heart disease; CRF, Chronic renal failure. *$p$<0.25 on univariate analysis, **$p$<0.05 on multivariable analysis

**Discussion**

Bladder cancer is the 9th most prevalent cancer globally, and in 2022, more than 220,000 people died from the disease. Bladder cancer has a global age standardized incidence rate (per 100,000 persons/year) of 9.5 for men and 2.4 for women, which is consistent with our data, as our sample population comprised approximately 80% male and 20% female patients [15]. According to GLOBOCAN, the incidence and mortality rates of bladder cancer are four times higher in men compared to women [16]. This is supported by the results of our multivariate analysis, which determined female gender to be a significant predictor for lower postoperative complication rate (female gender OR: 0.029; CI: [0.001–0.934]).

Previous literature surrounding the above-mentioned finding (i.e., female gender is a significant predictor of lower postoperative complication rates) shows contradicting evidence. In their retrospective review of 1,142 patients, Siegrist et al. discovered a significantly higher rate of perioperative complications in female patients, in addition to higher blood loss and transfusion rate. However, the study involved a longer study period of 90 days for postoperative complications and also identified that the female population in the study underwent significantly lower rates of node dissection and continent diversion, which may act as potential confounders [17]. However, two other studies have shown similar complication rates between men and women,

necessitating the need for future meta-analyses on this conflicting results [18,19]. Interestingly, a common theme throughout most prior studies has been higher blood loss and transfusion rates within the female population.

Research involving the use of perioperative immunonutrition and its effects on postoperative morbidity has shown variable results. Some randomized double-blinded clinical trials have shown no significant difference in complications, infections, or hospital stay in patients at nutritional risk undergoing major GI surgery [10]. In contrast, a 2007 meta-analysis involving 1,269 patients showed that perioperative immunonutrition had a positive impact on length of hospital stay but no effect on mortality [6]. A study similar to ours involving the use of Oral Impact® for patients undergoing RC showed a significant reduction in complication rate among those who had perioperative immunonutrition compared to those who did not [20]. The aforementioned study had a similar study design and sample size but did not employ regression statistical analysis techniques. Reduction in length of hospital stay was an outcome that was significantly reduced in those receiving nutritional supplementation in both studies and may be confirmed with a prospective, randomized study to validate the cost-effectiveness of immunonutrition use by lowering hospital stay duration.

Bertrand et al. showed that postoperative complication rate decreased from 76.7% to 40% in patients taking immunonutrients containing arginine [6]. Hamilton-Reeves et al. showed that participants receiving immunonutrition had improved balance between Th1 and Th2 cells, which led to a decrease in infection-related complications [13]. In contrast, Lyon et al. did not identify any difference between patients taking immunonutrients preoperatively and patients who did not [14]. However, the duration of immunonutrition varied between these studies, which could potentially serve as a confounder and requires further exploration to identify the optimal immunonutrient supplement regimen for RC patients.

Another significant predictor for perioperative complication rate that our study identified was the duration of surgery. Interestingly, longer duration of surgery (OR: 0.310; CI: [0.118– 0.813]) was a significant predictor of lower complication rates. A retrospective cohort study of 296 patients showed that the 90-day postoperative complication rate was higher in those with longer operation times [20]. However, the cutoff for long operation times was defined as >369 minutes, whereas the median duration (± IQR) for our dataset was 5 ± 1 hours. Our descriptive analysis did not show any significant difference in surgical duration between the case group and control group ($p$=0.081), suggesting that this variable is likely procedure-dependent and not modified by immunonutrition.

One limitation of this study was the lack of prospective randomization and the inherent bias of the cancer patient population at a tertiary cancer center. Furthermore, this was not a true prospective study, as the control group was composed retrospectively. However, unlike other similar studies, the preoperative immunonutritional status of the retrospective control groups was evaluated and its effects analyzed [20].

## Conclusion

This quasi-experimental study does not support the hypothesis that immunonutrition decreases postoperative complications and Clavien's complication grade. However, those provided with peri-operative immunonutrition did exhibit shorter hospital stay length and duration of return to bowel function. We also identified gender, duration of surgery, and length of hospital stay as significant predictors of 30-day postoperative complication rate in those undergoing RC. Additional prospective randomized placebo-controlled research is required to validate these results, enhance patients' postoperative outcomes, decrease related expenses.

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**Declaration of interest:**

The author(s) declare no financial, personal, or professional conflicts of interest that could have influenced the design, execution, analysis, or reporting of this study. Additionally, no funding was received from

external sources that could create a potential bias. The research and its findings are solely based on the data collected and analyzed, ensuring objectivity and integrity in the work presented.

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| **Patient Data** | | **Operative Data** | | **Outcome Parameters** | |
|---|---|---|---|---|---|
| Age | | Date of surgery | | 30 day complications, | |
| Gender | | Blood loss | | Clavien grade | |
| BMI | | Blood transfusion | | 30-day readmissions, | |
| Functional class | | Duration | | Length of hospital stay | |
| ASA | | Surgeon | | Return of activity, | |
| DM | | Intraoperative complication | | Return of bowel function | |
| IHD | | Hb drop | | | |
| CRF | | | | | |
| Hb | | | | | |
| Cr | | | | | |
| TNM stage | | | | | |
| Tumor type | | | | | |

**Appendix:**

Performa

| Cases | Historical Controls |
|---|---|