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Correlation between calculated and measured creatinine clearance in head and neck cancer patients undergoing concurrent chemoradiation

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ABSTRACT

Background: Cisplatin based chemoradiation forms the standard treatment for locally advanced head and neck malignancies. Cisplatin is notorious for its potential nephrotoxicity. Renal function assessment is crucial in determining the eligibility or the need for dose modification of potentially nephrotoxic drugs in clinical practice. measuring Glomerular Filtration Rate (GFR) is a uniformly accepted index of renal function. Even though the most common method of GFR assessment is 24 hour urine collection for evaluation of creatinine clearance, most of the time this test is inconvenient for the patient. This test may also overestimate GFR due to renal tubular secretion of creatinine. So, attempts have been focused on formulas that estimate GFR without collecting the patient's urine. In this scenario the most common formulas used by laboratories to predict GFR are the Cockcroft and Gault (CG) formula. In high volume centers and especially in resource constrained setting it will be difficult to get 24 hour measured CCT before each cycle of chemotherapy. Also in order to ensure proper 24 hour urine sample collection the ideal choice would be to do it in an inpatient setting. But it is impractical in a busy department and with limited resources. In our center we do 24 hour urine CCT as baseline before the start of cisplatin chemotherapy. The aim of this study was to find out the correlation between measured creatinine clearance and calculated creatinine clearance in patients with head and neck malignancy treated with cisplatin chemo radiation for locally advanced head and neck malignancy treated 1st January 2015 to 31st December 2019 at a tertiary cancer center in South India.

Methods: This was a retrospective study done in head and neck cancer patients being planned for concurrent chemoradiation. Medical records were reviewed and necessary data was collected. Demographic det ails,stage,site,histology,serum creatinine,body weight and measured creatinine clearance was recorded from the medical records and lab reports. Calculated Creatinine clearance was obtained from the Cockcroft and Gault formula. Pearson correlation test was used to find out the correlation between the two variables and Bland Altman plot was used to find out the level of agreement.

Result: A total of 104 patients were analyzed. The mean age of the study population was 56 years. 92 (88%) were males and 12 (12%) were females. Oral cavity (42%) was the most common site followed by oropharynx. Majority of the patients had stage IV B (44%) disease. Moderately differentiated squamous cell carcinoma (66%) was the most common histopathological subtype. The mean creatinine value was 0.79. he mean Body Mass Index was 20.50. he mean creatinine clearance that was calculated by Cockcroft & Gault equation was 81.1 (SD=23.03) ml/min compared to 102.56 (SD=38.91) ml/min estimated by 24-hour urine collection. The measured creatinine clearance and the calculated creatinine clearance showed a moderate level of correlation(r=0.561 and p<0.0001). he Bland Altman plot showed that there is good level of agreement between two measurements.

Conclusion: This study showed moderate correlation between creatinine clearance calculated by Cockcroft & Gault equation and 24-hour urine collection in head and neck cancer patients. If the calculated creatinine clearance is less than the cutoff, then a measured adequate creatinine clearance should be obtained before deciding on the chemotherapy. ince our study showed good correlation between measured and calculated CCT we plan to get a measured CCT before the start of chemotherapy and to get calculated CCT before each subsequent cycles.

Keywords: Ag NPs decorated TiO_2 NTs; Colon cancer cells (SW480 cells); Green laser exposure (@532 nm); NIR laser exposure (@808 nm)

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INTRODUCTION

The annual incidence of head and neck cancers worldwide is more than 550,000 cases with around 300,000 deaths each year [1]. There is a male preponderance with Male to female ratio ranging from 2:1 to 4:1. bout 90% of all Head and Neck cancers are Squamous Cell Carcinoma histology (HNSCC). HNSCC is the 6th leading cancer by incidence in the whole world. Most head and neck cancer arises in the epithelial lining of the oral cavity, oropharynx and hypopharynx [2,3]. These cancers are strongly associated with environmental and certain lifestyle risk factors like tobacco and alcohol consumption. The five-year overall survival rate of patients with HNSCC is about 40%-50%depending on the stage. Treatment for locally advanced HNSCC usually involves multimodality therapy with surgery radiation and chemotherapy.

Chemo radiation in head and neck malignancy is used either as definitive treatment in laryngo pharyngeal cancers or as adjuvant therapy after primary surgical resection. s per literature radical chemo radiation is an effective option and leads to an improvement of the Overall Survival (OS) of around 5% [4]. isplatin has emerged as one of the most active and most widely studied chemotherapy agents in the management of squamous cell carcinoma of the head and neck. After two randomized landmark clinical trials, the standard treatment for patients with postoperative high-risk LA-SCCHN has been chemo radiotherapy with 3-weekly cisplatin at dose of 100 mg/m^2 [5,6]. Clinical benefit was estimated to be an

approximately 10% absolute survival benefit and a 30% decrease in risk of death compared with radiation alone [7]. The standard concurrent schedule uses cisplatin 100mg/m^2 dose given on day 1,day 22 and day 43 of the radiation schedule or at a dose of 40mg/m2 as weekly regimen. Chemo radiotherapy with weekly cisplatin at 40 mg/m^2 is an established standard treatment for locally advanced nasopharyngeal carcinoma [8] and cervical cancer [9]. Carboplatin has radio sensitizing properties similar to cisplatin, but carboplatin can be administered with minimal hydration and causes less nausea.

Cisplatin (cis- diamminedichloroplatinum (II), CDDP) is an antineoplastic drug used in the treatment of many solid-organ cancers, including those of the head, neck, lung, testis, ovary, and breast. Cisplatin treatment is often associated with severe adverse effects, mainly as a consequence of its cytotoxic effects on healthy tissue cells while toxicities include ototoxicity, gastro toxicity, myelosuppression, and allergic reactions, the main dose-limiting side effect of cisplatin is nephrotoxicity. Typically, the onset of renal insufficiency begins several days after the dose of cisplatin. This is evidenced as increases in the serum creatinine and blood urea nitrogen concentrations. The urine output is usually preserved (non-oliguric) and the urine may contain glucose and small amounts of protein, indicative of proximal tubular dysfunction. Hypomagnesemia is also common, particularly after repeated doses of cisplatin, even in the absence of a fall in the glomerular filtration rate. Nephrotoxicity is of particular significance; even with the accompanied use of diuretics and pre-hydration [10,11], nephrotoxicity is still a dose-limiting adverse effect [12]. The baseline renal parameters should be normal for starting the patient on chemotherapy with cisplatin. Creatinine clearance is the measure of renal function and it can be found out in many methods. Given that treatment with cisplatin-based chemotherapy is critical for optimal survival outcomes in patients with head and neck cancer, methodologies for determining CrCl and/or eligibility criteria deserve additional examination.

Prior to the administration of the potentially nephrotoxic agent cisplatin, careful evaluation of the renal function in particular, the glomerular filtration rate, is usually required. This is measured in terms of Creatinine Clearance Test (CCT). egarding Glomerular Filtration Rate (GFR) determination, there are many methods that are widely used. The generally accepted gold standard used for Glomerular Filtration Rate (GFR) assessment is through the clearance of 99mTC-DTPA [13-15]. However, this approach is cumbersome, difficult and time consuming; it is not practical for routine clinical use. 24-hour urine creatinine clearance, practically recommended for clinical use but the Glomerular Filtration Rate (GFR), may be erroneous in poorly trained patients which can result in either inadequate or excess 24-hour urine volume. The most convenient way to determine Glomerular Filtration Rate (GFR) is through calculation from one of the following equations such as Cockcroft-Gault [16], Modification of Diet In Renal Disease (MDRD)[17] and Jelliffe [18]. These equations are based on stable serum creatinine. Cockcroft & Gault equation is the most convenient and being widely available used to estimate Glomerular Filtration Rate (GFR) which is based on serum creatinine.

At present, our institute uses 24 hour urine creatinine clearance to estimate creatinine clearance in patients planned for chemo radiation. If the 24 hour urine creatinine clearance is 60ml/mt or above then those patients will receive cisplatin chemotherapy. If it is below 60 ml/mt patients are treated with carboplatin based chemoradiation. The aim of this study is to evaluate the correlation between creatinine clearances calculated by Cockcroft & Gault equation and 24-hour urine collection in head and neck cancer patients.

METHODOLOGY

In head and neck malignancies concurrent chemo radiation is given in the adjuvant setting like in postoperative cases with high risk pathological features such as margin positive disease or node positivity with extra capsular extension. This is applicable to primary oral cavity malignancies. In case of laryngopharyngeal malignancies standard treatment is concurrent chemoradiation. he decision for taking a patient for radical or palliative intent treatment is taken after tumor board discussion as per our hospital policy. This depends on the patient's age, performance status, comorbidities and disease related factors like tumor stage, extent and type of tumor. Once the patient is planned for chemoradiation treatment we usually proceed with a planning CT scan for radiation treatment planning. All patients are immobilized in a custom made thermoplastic shell. Planning CT scans are taken at 2.5mm intervals from vertex to the sternal angle. Images are then exported on to the treatment planning system and contouring of the target volume and the organ at risk volume was done as per the RTOG standard contouring guidelines [19] by the Radiation Oncologist. Radiation physicist then makes the treatment plan based on prescription dose and respecting the tolerance limit of organ at risks. The oncologist will approve the plan once it is final and satisfies the standard acceptance criteria. This radiation plan will then undergo quality check before it is delivered to the patient. Once the plan passes the quality check criteria treatment is executed for patients.

For locally advanced head and neck malignancies we go for concurrent chemoradiation. The chemotherapy agent is cisplatin which is given at a dose of 40mg/m^2 once weekly. Because of its nephrotoxic potential before administering cisplatin a baseline renal function test and measured creatinine clearance is done. The patients were orientated to rid themselves of the first urine on the first day of the test and then to collect all the voided volume of the next 24 hours in appropriate containers. The urine collected in the morning of the following day was included in the total volume. This orientation was given by the Doctor and the Oncology nurse. Calculated creatinine clearance was obtained from the Cockcroft and Gault formula.

Inclusion criteria

All cases of head and neck malignancies who were planned for concurrent chemotherapy and whose creatinine values were available were included in the study.

Exclusion criteria

Case records with missing data and those patients who had radiation alone without chemotherapy were excluded

from the study. All the patients satisfying the inclusion criteria were included in the study. The data pertaining to patients were derived from record review of case records, radiation and chemo charts and lab reports available in the Medical Records Department of MCC. Data obtained from the medical records included age, sex, height, body weight, race, SCr and corresponding Blood Urea Nitrogen (BUN), and value of creatinine for each urine collection. Measured Creatinine clearance was recorded from lab reports.

Measured Creatinine Clearance Calculation (MCC)

Serum creatinine and weight was obtained. Patients were instructed to collect the 24 hour urine sample by a specialist oncology nurse. he determination of the urine and serum creatinine was done by standard autoanalyzer techniques (VITROS dry analyzer FS).

The measured creatinine clearance was calculated using the conventional formula =

$$\frac{\text{U (urine creatinine)} \times \text{volume (urine)}}{\text{Serum creatinine}}$$

Calculated Creatinine Clearance (CCC)

Numerous formulas have been developed to estimate GFR or creatinine clearance from serum creatinine and other sources. One widely used formula for predicting creatinine clearance was proposed by Cockcroft and Gault and is being used in our institution

Calculated creatinine clearance was calculated as per cockcraft and Gault's formula =

$$\frac{(140\text{-age}) \times (\text{weight in kg})}{72 \times \text{serum creatinine}}$$

This will be then corrected by a decrease of 15% for women.

All patients had this determination prior to the initiation of chemotherapy. A creatinine clearance value of 60ml/mt was used as a cut off for modifying the chemotherapy. hose patients whose creatinine values were 60 or above were eligible for cisplatin based chemotherapy. Those who had creatinine clearance of less than 60 the concurrent agent used was Carboplatin. Those with creatinine clearance values less than 30 were treated with radiation alone without concurrent chemotherapy.

Prior to administration of cisplatin chemotherapy we give antiemetic protocols consisting of Aprepitant,Ondansetron,Dexona and Ranitidine. Pre Chemotherapy hydration schedule is being followed which consists of one liter of normal saline with potassium chloride 20 mEq plus magnesium sulfate 2 g over 1 h. Cisplatin is given in 500 mL NS over 30 minutes to 1 hour. This is then followed by post chemo hydration schedule consisting of one liter NS with 20 mEq potassium chloride and 2 g magnesium sulfate over 1 hour. For those eligible for carboplatin based chemotherapy,dose is calculated as per Area under curve(AUC) of 2. arboplatin is administered as IV in 100 to 250 mL NS over 30 minutes.

During radiation treatment patients will be monitored weekly and concurrent chemotherapy will be given if the blood counts and renal function tests and serum electrolytes are within normal limits. Il patients received radiation treatment using Volumetric Arc Modulated Radiotherapy(VMAT) technique. ose for definitive radiation treatment was 69.3Gy in 33 fractions as one fraction daily and five fractions a week. or postoperative radiation treatment the prescribed dose was 60 to 66 Gy in 30 to 33 fractions. Toxicities during radiation treatment was recorded using Common Toxicity Criteria For Adverse Events (CTCAE version 4.0).

Statistical analysis

All data were entered in microsoft excel. Statistical analysis was done by Statistical Package for Social Sciences (SPSS) software version 20.0. escriptive statistics were expressed as proportion and continuous variables were expressed as median (interquartile range). correlation between two methods of Creatinine Clearance Calculation (MCC and CCC) was performed using Pearson correlation coefficient. The differences between the two methods were compared through Bland Altman regression analysis.

RESULTS

A total of 104 patients were included in the study. The mean age of the study population was 56 years.

Baseline characteristics

There were 92 males and 12 females. Oral cavity was the most common site (42%) followed by oropharynx. ajority of the patients had stage IV B disease. Moderately differentiated squamous cell carcinoma (63%) was the most common histopathological subtype. The mean body weight was 52.4Kg. he mean BSA was 1.5. he mean creatinine value was 0.80. he mean Body Mass Index was 20.20 **Tab. 1.**

Measured CCT and Calculated CCT

The mean creatinine clearance that was calculated by Cockcroft & Gault equation was 81.1 (SD=23.03) ml/min compared to 102.56 (SD=38.91) ml/min estimated by 24-hour urine collection **Tab. 2.**

Agreement between MCC AND CCC

Fig. 1. shows the scatter diagram of calculated creatinine clearance and measured creatinine clearance of 104 patients. Using a creatinine clearance of 60 ml/min as a threshold, **Fig. 1.** is divided into four quadrants. In quadrant I, both the CCC and the MCC were below 60, the threshold, while in quadrant II both values were above this cutoff. In either case there would be agreement on the chemotherapy modification protocol. In quadrant 1 we had 8 samples where the MCC and CCC were both below 60. n quadrant 11 there were 81 samples and both MCC and CCC were above 60. oth these quadrants had similar agreement regarding chemotherapy protocol. In quadrant 111 there were 11 samples and the MCC was more than 60 but CCC was below 60. n quadrant III the MCC would exceed the CCC; thus, if the CCC alone were used, a chemotherapy change would be affected. On the other hand, in quadrant IV there were 4 samples and CCC exceeded MCC and the opposite situation could occur. If we use cutoff for modification of chemotherapy of 60 ml/min, only 1.4.% of the patients would have received treatment adjustments inappropriately, by using the estimated creatinine clearance alone.

Tab. 1. Baseline characteristics.

Gender	Male	88%
	Female	12%
Age	Age (years; mean ± SD, range)	56.4 ± 9.04 (24–70)
Diagnosis	Carcinoma oral cavity	42%
	Carcinoma Oropharynx	31%
	Carcinoma Hypopharynx	15%
	Carcinoma Larynx	11%
	Carcinoma Nasopharynx	1%
Histology	WD SCC(Well differentiated squamous cell carcinoma)	18%
	MDSCC(Moderately differentiated)	63%
	PD SCC(Poorly differentiated)	16%
	Differentiation unknown	3%
Stage	STAGE III	26%
	STAGE IV A	30%
	STAGE IV B	44%
Body weight	(kg; mean ± SD, range	52.49 ± 10.56 (30–86)
BSA	(m^2; mean ± SD, range)	1.51 ± 0.16 (1–2)
Plasma creatinine	(mg/dL; mean ± SD, range)	0.8 ± 0.22 (0.4–1.8)
Body Mass Index(BMI)	(mean ± SD, range)	20.2 ± 4.30 (12–47)

Tab. 2. Measured and calculated CCT.

Creatinine clearance	Mean	Range
24 hour measured CCT	102.56 (38.91)	25-244
Calculated CCT	81.1 (23.03)	34.9-153.6

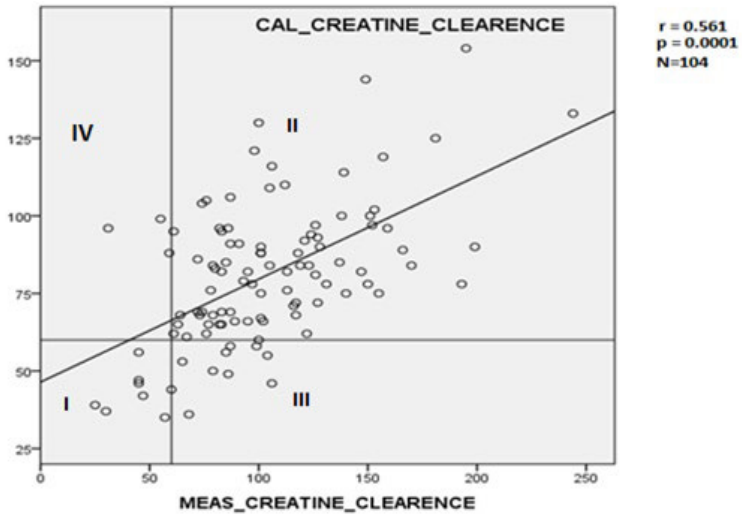

Fig. 1. Scatter diagram of MCC and CCC of 104 patients of head and neck malignancies.

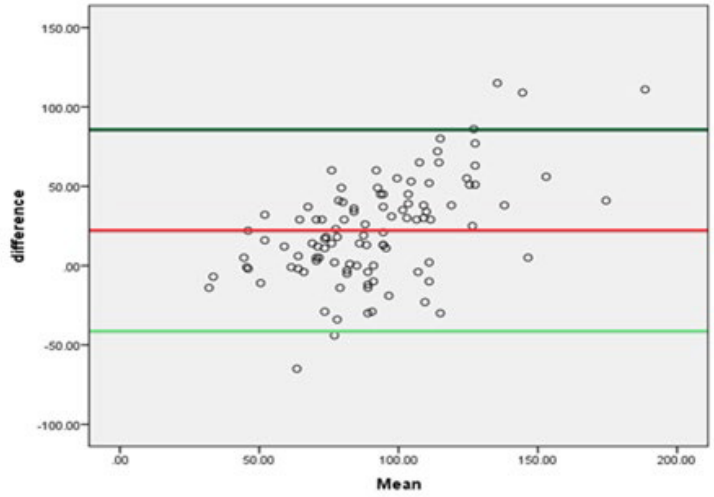

Fig. 2. Bland-Altman plot of 104 patients of head and neck malignancies.

Level of agreement

In the **Fig. 2.** Bland Altman plot was constructed to assess the level of agreement between the two methods The resulting graph is a scatter plot XY, Y axis shows difference between the two measurements (MCC-CCC) and X axis represents the average of two measurements. The three lines in **Fig. 2.** represent mean differences and the rest two lines are limits of agreement.. This showed that most of the points lie within the limits which indicates that there is agreement between two measurements. Using the Pearson test there was moderate level of correlation between the two values with r=0.561 and p<0.0001

DISCUSSION

Prior to the administration of a nephrotoxic drug, the most important estimate of renal function remains the glomerular filtration rate evaluated generally by a urinary creatinine clearance. Usually, a 24- hr collection is used. However, shorter timed collections may be acceptable [20]. In our institute we follow 24 hour urine sample collection. n determining the clearance, one needs not only the serum creatinine but also the urine volume and urine creatinine. Several methods have been reported in literature for finding out the measured creatinine clearance. stimated Glomerular Filtration Rate (GFR) through the clearance of 99mTC-DTPA15, the standard method, is very costly; invasive tests that require the administration of exogenous substances, catheterization and frequent blood draws and are not practical for routine use.

Estimating Glomerular Filtration Rate (GFR) by determining creatinine clearance based on 24-hour urine collection and Cockcroft & Gault equation has shown good correlation with 99mTC-DTPA in a previous study. Kung F, et al. [21] firstly reported comparison of kidney function in patients with ovarian cancer and treated with chemotherapy by Cockcroft & Gault equation and measurement of 24-hour urine creatinine clearance and regression analysis showed a moderate correlation between these two methods. Fotopoulos A, et al. [22], compared six radionuclidic and non-radionuclidic methods for assessment of glomerular filtration rate (GFR) in patients with chronic Renal failure Correlation coefficient of creatinine clearance calculated by Tc99 DTPA and 24-hour urine collection was 0.91 and correlation of creatinine clearance calculated by Tc99 DTPA and Cockcroft & Gault equation was 0.79. hey concluded that the radionuclidic methods in patients with chronic renal failure are reliable and reproducible, closely resembling those of inulin clearance. Among all radionuclidic methods, (99m) Tc-DTPA showed the best correlation. Barraclough K, et al. [23] studied in HIV-infected adults and reported correlation coefficient of 0.77 between creatinine clearance calculated by Cockcroft & Gault equation and Tc-99m Pentetate. The correlation coefficient was 0.63 between creatinine clearance estimated urine 24-hour creatinine clearance and Tc-99m Pertetate in a study by Gerber DE, et al. [24] who demonstrated that in a group of primary CNS lymphoma patients treated with high-dose methotrexate. Their study shows Pearson Correlation coefficient (r)=0.49 (P<0.0001) between creatinine clearance calculated by Cockcroft & Gault equation and 24-hour urine collection. The average MTX dose determined based on measured and calculated creatinine clearance was significantly correlated (r =0.72, P<0.0001). Our study compared creatinine clearance calculated by Cockcroft & Gault equation and urine 24-hour creatinine clearance instead of other equations such as Modification of Diet in Renal Disease (MDRD) and Jelliffe because most of the pharmacokinetic studies with chemotherapeutic agents were performed using the Cockcroft-Gault equation. The original article by Cockcroft DW, Gault MH, creatinine clearance was calculated by lean body weight. Actual body weight was used in our study because in our daily practice we used actual body weight to simplify the calculations.

In a study conducted by Chambers JT, et al. [25] in 84 patients with advanced ovarian cancer, even in the postoperative state, an evaluation of renal function with a calculated creatinine clearance prior to chemotherapy was sufficient and correlated well with measured creatinine clearance. The calculated creatinine clearance in our study was shown to have a moderate correlation with the measured creatinine clearance(p value 0.0001). hese findings in a group of patients with head and neck have implications for cost containment, if urine creatinine clearance is not needed in addition to the serum creatinine to assess renal function. Thus we suggest having a baseline measured creatinine clearance by 24 hour urine collection method and we can subsequently monitor the patients with calculated creatinine clearance alone during chemotherapy.

In a study conducted by Davila E et al. [26] in patients receiving cisplatin chemotherapy the timed urine specimen was compared with estimated creatinine clearance The correlation between creatinine clearances calculated by both methods was excellent (r=0.684, P less than.001). n our study there was moderate level of correlation with r=0.561. n a study by Haim N, et al. [27] a good correlation between Estimated Creatinine Clearance (ECC) and the standard Measured Creatinine Clearance (MCC) was found with r=0.78.

In our study patients while doing measured CCT patients were given instructions and the urine collections were done on an outpatient basis. his is in contrast to several studies where 24 hour urine collection was done in inpatients. n a study conducted by Lavelle RI, et al. [28] of hospitalized elderly adults, measured CrCl *via* urine collection was not found to correlate well with estimates of CrCl as determined *via* estimated CCT.

The drawbacks of our study is its retrospective nature and we did not compare creatinine clearance calculated by Cockcroft & Gault equation with standard method 99m TC-DTPA that is not practically used in our institute and we did not compare toxicity of patients between these two methods. lso our study was limited by the small number of patients. Gold standard "inulin" *in vitro* GFR measurement was not available for comparison. Further larger studies are required to confirm this correlation and comparison of toxicity in patients after using these two methods should be analyzed to show clinical significance.

Our study is relevant in large volume centers especially in resource constrained setting where doing measured 24 hr urine collection may not be feasible prior to every cycle of chemotherapy. ince our study showed good correlation between measured and calculated CCT we plan to get a measured CCT before the start of chemotherapy and to get calculated CCT before each subsequent cycles.

CONCLUSION

This study showed moderate correlation between creatinine clearance calculated by Cockcroft & Gault equation and 24-hour urine collection in head and neck cancer patients. urthermore, it is recommended to have a baseline creatinine clearance by 24 hour urine collection and subsequently can be monitored with calculated CCT alone. If the calculated creatinine clearance is less than the cutoff, then a measured adequate creatinine clearance should be obtained before deciding on the chemotherapy schedule.

ETHICAL STATEMENT

Ethical clearance was obtained from the Institutional Review Board of Malabar Cancer Centre for conducting this retrospective study.

AUTHOR CONTRIBUTION

Dr Joneetha Jones conceptualized and designed the study. Ms Hima Sasikumar helped in data collection. Dr Arun P Narendran prepared the the original draft. Statistical analysis was done by Mrs Binu Anilkumar. r Vinin N V and Dr Geetha M provided valuable inputs towards designing the manuscript. Dr Greeshma, Dr Nabeel and Dr Akhil helped in manuscript preparation. All authors read and approved the final version of the manuscript.

CONFLICTS OF INTERESTS

The authors declare no conflicts of interest.

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