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ORIGINAL ARTICLE

Comparison of outcomes and safety of concurrent chemoradiotherapy with weekly cisplatin and paclitaxel verses cisplatin alone in locally advanced cervical cancer.

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ABSTRACT… Objective: To evaluate the outcome, survival and safety of weekly combination therapy with cisplatin and paclitaxel chemoradiotherapy in comparison with cisplatin alone in locally advanced cervical cancer. **Study Design:** Prospective study. **Setting:** Oncology Department of Nishtar Hospital, Multan. **Period:** May 2024 to May 2025. **Methods:** A total of 100 women with locally advanced epithelial cell cervical carcinoma, KPS score of ≥70 and normal bilirubin, urea, creatinine and nitrogen were selected. Patients were divided into control group and study group consisting of 50 patients each. Control group was administered 40 mg/m2 of IV cisplatin once a week with a maximum weekly dose of 70 mg. Study group was administered 50 mg/m2 paclitaxel and 30 mg/m2 cisplatin once a week. External beam radiotherapy was performed in all patients at the same time of chemotherapy targeting cancer site, internal and upper external iliac, uterus, presacral and common iliac lymph nodes. **Results:** At the last follow-up, 80% patients in control group and 88% in study group survived. 17 patients (34%) in control group and 10 (20%) in study group had a recurrence so the disease-free survival was 66% and 80%, respectively. 12 patients (24%) in control group had local recurrence and 5 (10%) had distant recurrence. 5 patients (10%) in study group had local recurrence and only one (2%) had distant recurrence. No treatment related deaths occurred but 14 patients (28%) in control group and 27 patients (54%) suffered grade 3 or 4 toxicities, the difference was significant (p=0.02). Significantly higher number of patients in study group had gastrointestinal toxicities than control group. **Conclusion:** Concurrent cisplatin and paclitaxel chemoradiotherapy had better outcomes with increased but manageable toxicities than cisplatin chemoradiotherapy alone.

Key words: Chemotherapy, Cisplatin, Radiotherapy, Safety.

INTRODUCTION

Cervical cancer is the fourth most common cancer in Asia with over 350k patients diagnosed each year and a 50% mortality rate.[1] Concomitant cisplatin chemotherapy and radiotherapy is the recommended treatment. However, it is mostly unsuccessful in eliminating cancer in 20-25% in pelvic region and 10-20% in metastatic regions.[2,3] A Cochrane meta-analysis reported the increased efficacy of radiotherapy alone as compared to concomitant chemoradiotherapy.[4]

Cisplatin and other agents have been tested for single or combination chemotherapy which improve survival outcomes in concurrence with radiotherapy. This approach has shown high success rates in lung cancer, head and neck cancers, etc.[5,6] Paclitaxel has also shown excellent results in breast cancers, lung cancer and ovarian carcinoma. Studies have also reported it radio sensitizing effect in carcinoma of cervix.[7] A combination therapy of cisplatin and paclitaxel has shown a remission rate of 36-46% in recurrent and metastatic cervical cancer.[8]

We conducted this study to evaluate the outcome, survival and safety of weekly combination therapy with cisplatin and paclitaxel chemoradiotherapy in comparison with cisplatin alone in locally advanced cervical cancer.

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METHODS

A prospective study was conducted in the Oncology Department of Nishtar Hospital, Multan from May 2024 to May 2025. A total of 100 women with locally advanced epithelial cell cervical carcinoma, KPS score of ≥70 and normal bilirubin, urea, creatinine and nitrogen were selected. Women with a history of metastatic cancer, metastatic cancer or lymph node involvement, contraindicatory to chemotherapy, underwent hysterectomy, pelvic radiotherapy or systematic chemotherapy were excluded. Study was approved by the ethical review board of hospital (Ref.No.18948/NMU-8/4/24) and patients were briefed about the procedure to obtain informed consent.

All patients were examined physically and microscopically with pelvic examination for cancer staging. Complete blood biochemistry, urinalysis, chest radiography, sonology, hemogram and abdominal and pelvic CT were performed. Involvement of rectum or bladder was confirmed by proctoscopy, cystoscopy, IV pyelography and urine cytology.

Patients were divided into control group and study group consisting of 50 patients each. Control group was administered 40 mg/m^2 of IV cisplatin once a week with a maximum weekly dose of 70 mg. Study group was administered 50 mg/m^2 paclitaxel and 30 mg/m^2 cisplatin once a week. Antiemetics and premedication were given before the procedure. Renal and liver function tests and complete hemogram was performed before each cycle.

External beam radiotherapy was performed in all patients at the same time of chemotherapy targeting cancer site, internal and upper external iliac, uterus, presacral and common iliac lymph nodes. A total dose of 50 Gray was given using four field box technique in 25 equal sessions. The procedure was paused if white blood cell count dropped below 3000/mm^3 and treatment was stopped for 1 week if any toxicity occurred. If Hb fell below 10 g/dL, blood transfusions were given. Low-dose intracavitary ^{137}Cs brachytherapy was administered at a maximum total dose of 85 Gray. The patients not eligible for brachytherapy were delivered 20 Gray supplemental radiotherapy in ten sessions above 2 weeks.

Treatment related toxicities were noted at every session and after treatment completion. Radiology related toxicities were assessed by RTOG acute morbidity criteria and hematological toxicities were documented under ECOG criteria. Follow-ups were scheduled for 6 weeks post treatment and then after every 3 months. Clinical response was recorded and biopsy was performed for evaluating local failure.

All data analysis was done by SPSS version 20. Survival was assessed by log rank test by plotting curves. P values were calculated on 2x2 tables on Fisher's exact test. The main endpoint was disease free survival and overall survival on follow-up. Disease free survival was from admission till recurrence, death or last follow-up. Overall survival from was admission to death or last follow-up. Local recurrence was found in vagina, pelvis or cervical area and distant recurrence was found in extrapelvic area. Secondary outcomes were toxicities in kidneys, GI tract, skin and hematology throughout the study and clinical local control at follow-up.

RESULTS

A total of 100 patients were enrolled with 50 treated with cisplatin plus paclitaxel chemoradiotherapy and 50 were treated with cisplatin alone chemoradiotherapy. There was no significant difference between baseline demographic, laboratory and tumor features among both groups.

Radiotherapy was given according to protocol and it was paused for 1 week in 8 (8%) due to grade 4 adverse effects where 6 patients were from study group and 2 patients were in control group. 14 patients were not eligible for brachytherapy among which 8 were from control group and 6 were from study group ($p=0.81$). The average duration radiotherapy was 8 weeks with 85 Gray as average dose.

Patients were followed upfor a maximum of 10

months with an average duration of 7 months. At the last follow-up, 80% patients in control group and 88% in study group survived. 17 patients (34%) in control group and 10 (20%) in study group had a recurrence so the disease-free survival was 66% and 80%, respectively. Survival curves showed no significant difference between groups with respect to overall survival but a significance difference for disease-free survival (p=0.06). 12 patients (24%) in control group had local recurrence and 5 (10%) had distant recurrence. 5 patients (10%) in study group had local recurrence and only one (2%) had distant recurrence.

No treatment related deaths occurred but 14 patients (28%) in control group and 27 patients (54%) suffered grade 3 or 4 toxicities, the difference was significant (p=0.02). Significantly higher number of patients in study group had gastrointestinal toxicities than control group (Table-II).

DISCUSSION

This study was conducted to compare the outcomes and safety of concurrent cisplatin and paclitaxel chemoradiotherapy vs cisplatin alone. The results showed a significant difference in complete response where control group showed better outcomes with increased but manageable toxicities than study group. These results are in compliance with previous studies.[9,10,11]

14 patients were not eligible for brachytherapy among which 8 (16%) were from control group which was higher than 6 patients (12%) from study group (p=0.81). This finding is similar to other studies. This may be because in these patients cervical dilation was not possible to place the thicker tandem even if they were eligible.

Features	Control Group (n=50)	Study Group (n=50)
Age		
30 years or younger	2 (4%)	-
31-40	8 (16%)	9 (18%)
41-50	18 (36%)	14(28%)
51-60	15 (30%)	18 (36%)
Older than 60	7 (14%)	9 (18%)
Karnofsky performance score		
70	4 (8%)	3 (6%)
80	29 (58%)	27 (54%)
90	18 (36%)	20 (40%)
Hemoglobin (g/dL)		
Less than 11	20 (40%)	20 (40%)
11-12	20 (40%)	17 (34%)
More than 12	10 (20%)	13 (26%)
Tumor growth pattern		
Ulcero-proliferative	35 (70%)	34 (68%)
Nodulo-proliferative	9 (18%)	11 (22%)
Nodulo-infiltrative	6 (12%)	5 (10%)
Type of carcinoma		
Squamous cell carcinoma	45 (90%)	45 (90%)
Adenosquamous	2 (4%)	2 (4%)
Adenocarcinoma	3 (6%)	3 (6%)
Tumor grading		
1	20 (40%)	20 (40%)
2	25 (50%)	22 (44%)
3	5 (10%)	4 (8%)
Tumor staging		
IIA	1 (2%)	-
IIB	23 (56%)	24 (58%)
IIIB	26 (42%)	26 (42%)

Table-I. Baseline patients data and tumor profile

Toxicities	Control group				Study group			
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 1	Grade 2	Grade 3	Grade 4
Hematological	21 (42%)	5 (10%)	1 (2%)	1 (2%)	20 (40%)	17 (34%)	1 (2%)	-
Cutaneous	10 (20%)	24 (58%)	8 (16%)	-	6 (12%)	24 (58%)	10 (20%)	-
Gastrointestinal	24 (48%)	13 (26%)	3 (6%)	1 (2%)	12 (24%)	19 (38%)	10 (20%)	6 (12%)

Table-II. Comparison of treatment related toxicities

The disease-free survival was significantly higher in study group i.e. 88% as compared to control group i.e. 66%. The same pattern was noted in proportion of overall survival i.e. 80% vs 88%, however, the difference was not significant due to limited number of patients.

Other studies assessing concomitant radiotherapy with cisplatin have shown comparable DFS, indicating the efficacy of treatment.[12,13,14] Since, radiotherapy was delivered by same procedure and dose in both groups, the higher DFS is accounted by the addition of paclitaxel in the treatment.

During the initial phase of treatment, study group showed higher incidence of toxicities as compared to control group. Gastrointestinal adverse effects started in the second session of chemotherapy and required frequent hospitalization in study group, however, symptoms could be managed by conservative methods. Both groups have same incidence of skin and hematological adverse effects. Treatment was paused more often in study group but average treatment duration did not differ significantly between both groups. The reason for this can be the higher number of patients eligible for brachytherapy in study group leading to shorter time for disease regression. Study group also have fewer recurrences. These results are similar to other studies.[15,16]

Our study has some limitations. We had a small sample size and a limited follow-up duration. The ineligibility of patients for brachytherapy may have influenced the results.

CONCLUSION

Concurrent cisplatin and paclitaxel chemoradiotherapy had better outcomes with increased but manageable toxicities than cisplatin chemoradiotherapy alone.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Aalia Bashir:** Proof reading.
2	**Anam Siddque:** Writing, data collection.
3	**Muhammad Junaid Hassan:** Analysis.