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A Relative Investigation among Hypofractionated Radiotherapy and Conventional Fractionated Radiotherapy in the Locoregional Control of Carcinoma of the Cervix

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Abstract: ***This study was undertaken to know the effect of hypofractionated radiotherapy by comparing this with the effect of conventionally fractionated radiotherapy in the locoregional control of carcinoma of cervix stage IIa, IIb, IIIa, and IIIb along with the screening the early complication of radiation therapy. A total number of 60 patients of squamous cell carcinoma of the cervix were elected to host the experiment, divided into two groups with an equal number named Control group and Case group. The Control group was treated with conventional therapy of 60 Gy in 30 fractions in 6 weeks. The case group was treated by hypofractionated therapy of 60 Gy in 18 fractions in 6 weeks. The objectives of the study were to observe the local response and early complication of radiation toxicities in both groups of patients. In the control group, p/v findings were (observed after 6wks from the completion of radiation treatment), where complete response 16(53.3%) and partial response were followed by stage IIa 10(33.3%) and stage IIb 04(13.3%). In the case group, complete responses were 11(36.7%) partial response were followed by stage IIa 11(36.7%) and stage IIb 8(26.7%). But statistically, the difference in outcome was not significant. (X=1.077, df=01, p=0.299). No significant differences were observed between control and case groups, regarding the adverse effects of radiotherapy (P>0.05). Regarding locoregional control of carcinoma cervix, statistically, the difference of outcome was not significant between control and case population (P>0.05). Considering all the parameters, it is concluded that – Effects of radiotherapy in terms of locoregional control and adverse effects in patients treated with hypo fractionated radiotherapy appears comparable to that of conventional fractionation.***

Keywords: Cervical cancer; hypofractionated radiotherapy; conventional fractionated radiotherapy

I. INTRODUCTION

Since cancer is one of the prime causes of ubiquitous deaths according to WHO guidelines 2006, more than 70% of demises ensue in low and middle revenue countries having limited cure facilities. Being the second most common cancer, cervical cancer considers overall 15% of all female cancer which is very familiar with female cancer victims in Bangladesh [1-4]. A report of Dhaka Medical College and Hospital's Gynecology Unit asserted about 1.47% of cervical cancer survivors, where another survey claimed cervical cancer is 26% among all female cancers [5-10]. Even the neighboring country India witnesses death ranging from 35 - 45 years due to cervical cancer. The death ratio is nearly 30 per hundred thousand along with 120 thousand new cases every year [2,11,12]. WHO indicates some key reasons behind the mortality rate in developing countries such as, lack of awareness, poor screening processes and limited medical services [1,13]. Though cervical cancer becomes more common among women in developing countries (approximately 20-30%) than in developed countries (nearly 4-6%) [14], However, cervical carcinoma is generally radio responsive and curable disease at early stages. But It continues to be the mainstay of the therapy especially when the disease is beyond stage II a. A number of factors may influence the choice of local treatment, including tumor size, stage, histological features, evidence of lymph node involvement, risk factors for the complication of surgery or radiation and patient preference. However, as a rule, intraepithelial lesions are treated with superficial ablative technique; micro invasive cancers invading less than 3 mm (stage IA1) are managed with conservative surgery. Early invasive cancers (stage IA2 and IB1 and some small stage IIa tumors) are merged with radical surgery or radiotherapy and locally advanced cancers (stage IB2 to IVa) are managed with radiotherapy. Radiotherapy is the primary local treatment for most patients with locoregionally advanced cervical carcinoma [15-20]. The general rule for radiotherapy in carcinoma of the cervix is that the intracavitary brachytherapy element is used to treat primary cancer and external radiotherapy to the pelvis to treat the nodes [21].

Due to the limitation of brachytherapy, carcinoma cervix is treated only by telepathy here in our facility. External beam irradiation is used to deliver a homogeneous dose to the primary cervical tumor and to potential sites of regional spread. In our densely populated country, the number of radiotherapy centers is minimal. Large numbers of carcinoma cervix patients are coming regularly to the center for their treatment. When they are treated by conventional radiotherapy, existing centers cannot provide them. If we treat the patient by hypofractionated radiotherapy we can provide a large number of patients for radiotherapy. If the effect is similar it should be the main regimen for carcinoma cervix patients.

Conventional external beam radiation delivers a dose of 2 Gy per fraction with pelvic portals with anterior and posterior two opposing field techniques. Time: dose and fractionation schedules have been altered in an attempt to improve the probability of local control. Various altered fractionation schedules include hypofractionation, rapid fractionation split course regimen and hyperfractionated accelerated hyperfractionation [22-27]. A rest period of a few weeks between two phases of treatment is given but this causes a repopulation of cancer cells. Long treatment time reduces loco-regional control and accordingly the final outcome, terms as Acceleration using a split will follow in our study [28-33]. The basic aim of hyperfractionation is to further separate early and late effects. The overall treatment time remains conventional at 6 to 8 weeks, but since two fractions per day are used, the number of fractions is doubled to between 60 to 80. The dose must be increased since the dose per fraction has been decreased. The intent is to further reduce late effects while achieving the same or better tumor control and the same or slightly increased early effects [34-38]. Hypofractionated radiotherapy delivers a high dose per fraction (333 Gy) daily for 3 days in a week. As the number of days of coming for radiation treatment reduced, the beneficial effect of this reduction is maintained by giving a high dose per fraction.

Alteration in the fractionation has been attempted mainly to improve the local control at the same time decreasing the normal tissue complication. Carcinoma cervix stage IIa, IIb and III includes a heterogeneous group of patient of the small volume of disease to extensive disease [39].

The influx of patients requiring radiation therapy during the period of the study led to the need to introduce hypofractionated radiotherapy in order to maximize the use of the only functioning teletherapy facility in this region (North Bengal).

An analysis of the results of all the patients of carcinoma cervix stage IIa, IIb, IIIa and IIIb who will receive hypofractionated external beam radiation therapy will be carried out with an aim to assess the efficacy of hypofractionated radiotherapy, regarding the local control of the disease and early complications related to the treatment. So, we planned to study the role of hypofractionated radiotherapy by comparing this treatment with conventionally fractionated radiotherapy in the management of carcinoma of the cervix in our population.

II. MATERIALS and METHODS

A total number of 60 patients were nominated for the study and spared them equally in two groups (Control and Case) to run this prospective study. All the patients irrespective of age attending the department of radiotherapy, Rajshahi Medical College Hospital, Rajshahi were examined. Those who were fulfilling the inclusion and exclusion criteria including in this study. Each group includes four stages of IIa, IIb, IIIa, and IIIb. The selection procedure went through by the following criteria.

1) Patients are diagnosed clinically and histologically confirmed for carcinoma of the cervix.
2) According to the Federation of Gynecology and Obstetrics (FIGO), staging stage II to stage III are included in both groups.
3) Patients who did not receive any treatment previously for this disease process.

There were few exclusion criteria were followed in the selection process,

a) Patients of stage I carcinoma cervix.
b) Patients who were operated (total abdominal hysterectomy).
c) Patients who have taken neoadjuvent chemotherapy.
d) Patients who have been treated previously by radiation therapy.
e) Aged above 60 years.
f) UICC grade more than 3.

An eighteen months long prospective study had been done which went through sample selection, data collection, and interpretation, following up the patients and analyzing those accumulated data. The investigation was done by the Department of Radiotherapy at Rajshahi Medical College Hospital, Rajshahi (RMCH).

A. The procedure of Data Collection

All selected patients were interviewed personally with a detailed history of every individuals were documented in a prescribed data collection sheet. A thorough clinical examination (general, local and systemic) was done for each patient including the P/V examination. Relevant laboratory investigations, such as complete blood count, blood grouping, kidney function test, X-ray chest P/A view, USG of the whole abdomen and histopathology were done. The clinical staging was done according to the FIGO classification.

All patients were treated with standard pelvic portals with anterior and posterior field techniques. The dose per fraction was 333 cGy per day for the case group 3 days in a week for 6 weeks and for the control group it was 200 cGy per day for 5 days in a week for 6 weeks. In patients from both groups were treated by cobalt 60.

B. The procedure of Data Assessment

Patients were examined during radiation therapy for acute genitourinary, gastrointestinal, and skin reactions. Patients were treated symptomatically. During treatment planning the required information is such as; total dose to the target volume, number of fractions, dose per fraction, the overall time for treatment, number of fractions in a week, dose specification point. After verification of field arrangements and inspection of the dose distribution, the treatment prescription was finalized. Treatment volume was decided approximately 1 – 2 cm generous margin around the target volume. The treatment area was marked on the skin with gentian violet placing the patient on the table. The patient's position was done properly. Patients of both the groups were reviewed every week up to the completion of treatment and findings of acute reactions were recorded in the documented sheet. All the observations and results were then documented on the master sheet respectively. The results were then statistically analyzed by using SPSS (Statistical Package for Social Science).

III. RESULTS

A total number of 60 patients of squamous cell carcinoma of the cervix were nominated and divided into two equal groups of Control and Case groups. Among them, the mean age of controls was 46.53 ± 8.27 years (range: 35- 65 years) and the case group was 47.00± 9.09 years (range: 30-75 years). During the radiotherapy sessions, several effects were observed between both Control group and Case group patients with P/V bleeding, P/V discharge including other side effects (e.g. weakness, lower abdominal pain) and post-radiotherapy follow-up screening data are mentioned below in Fig 1, 2 and 3.

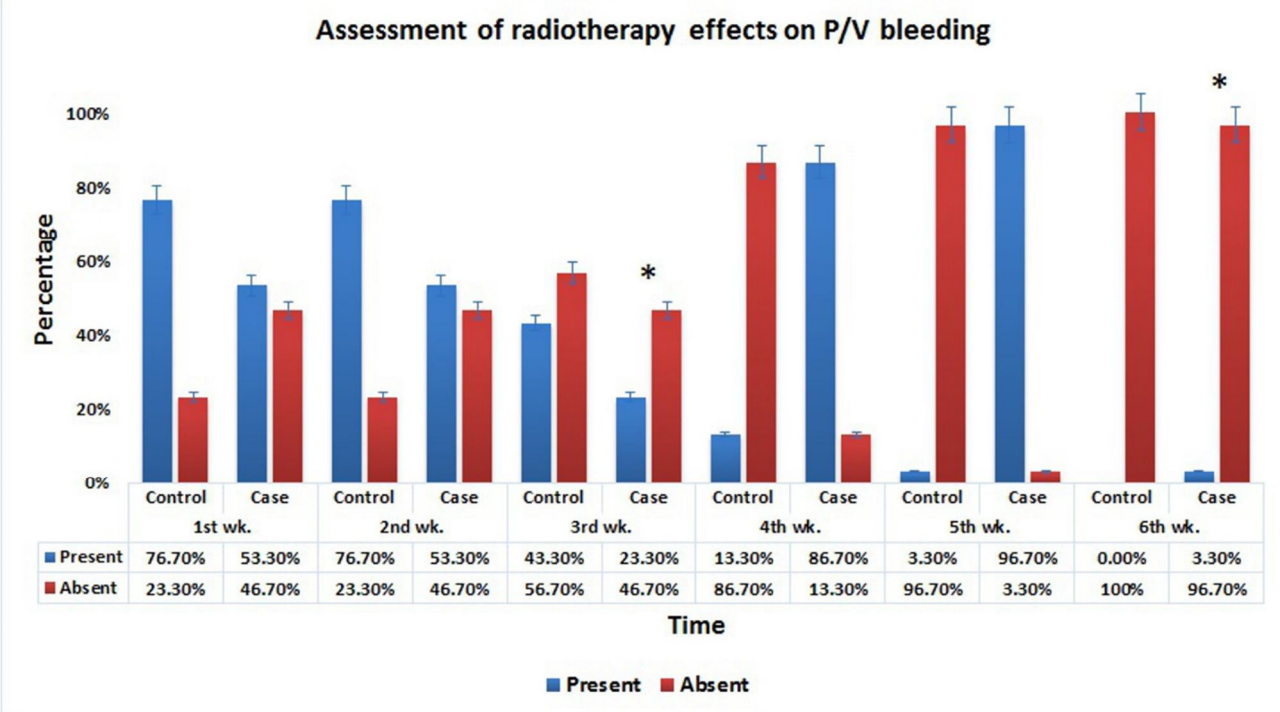

Fig 1. Assessment of radiotherapy effects on P/V bleeding, showing a comparison of the effect on P/V bleeding during therapy and it was found that there was Absent significant difference of effect on P/V bleeding between control and case group. A T-test on the mean episode on 3rd wk. & 6th wk. showed Absent significant difference P>0.05 (*). Here, no. of Control= 30 and no. of Case= 30.

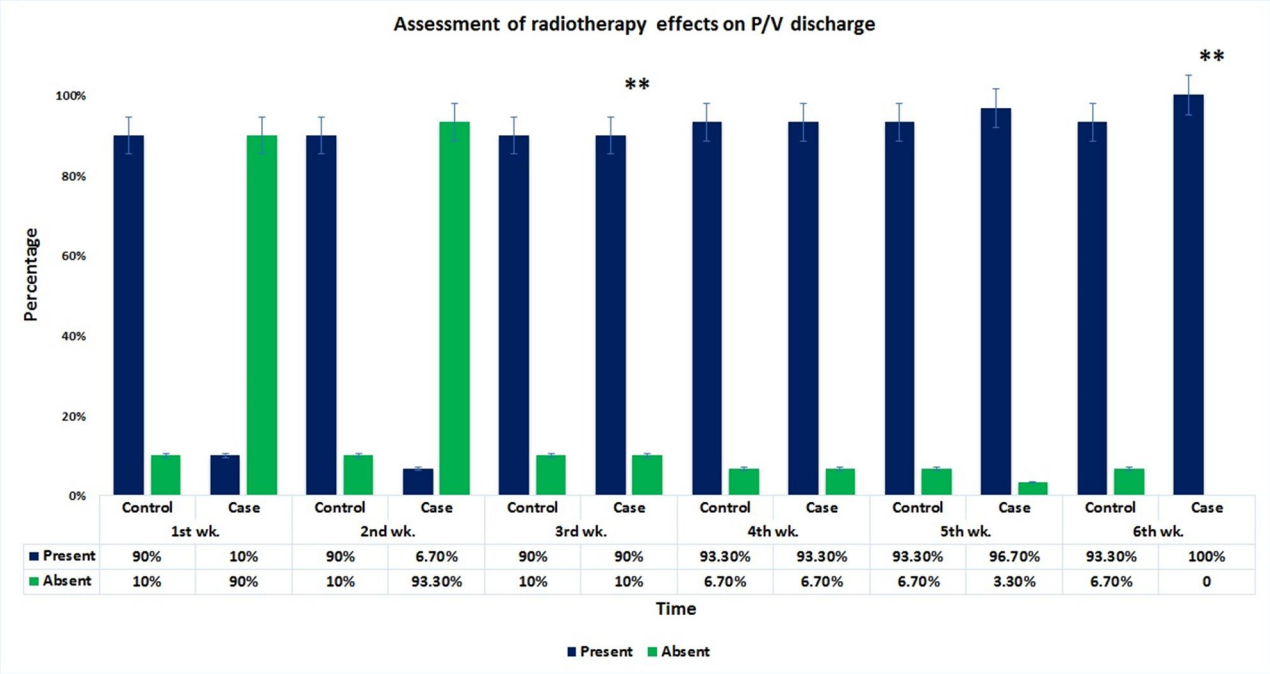

Fig 2. Assessment of radiotherapy effects on P/V discharge, showing a comparison of the effect on P/V discharge during therapy and it was found that there was Absent significant difference of effect on P/V discharge between control and case group. A T-test on a mean episode on 3rd wk. & 6th wk. showed Absent significant difference P>0.05 (**). Here, no. of Control= 30 and no. of Case= 30.

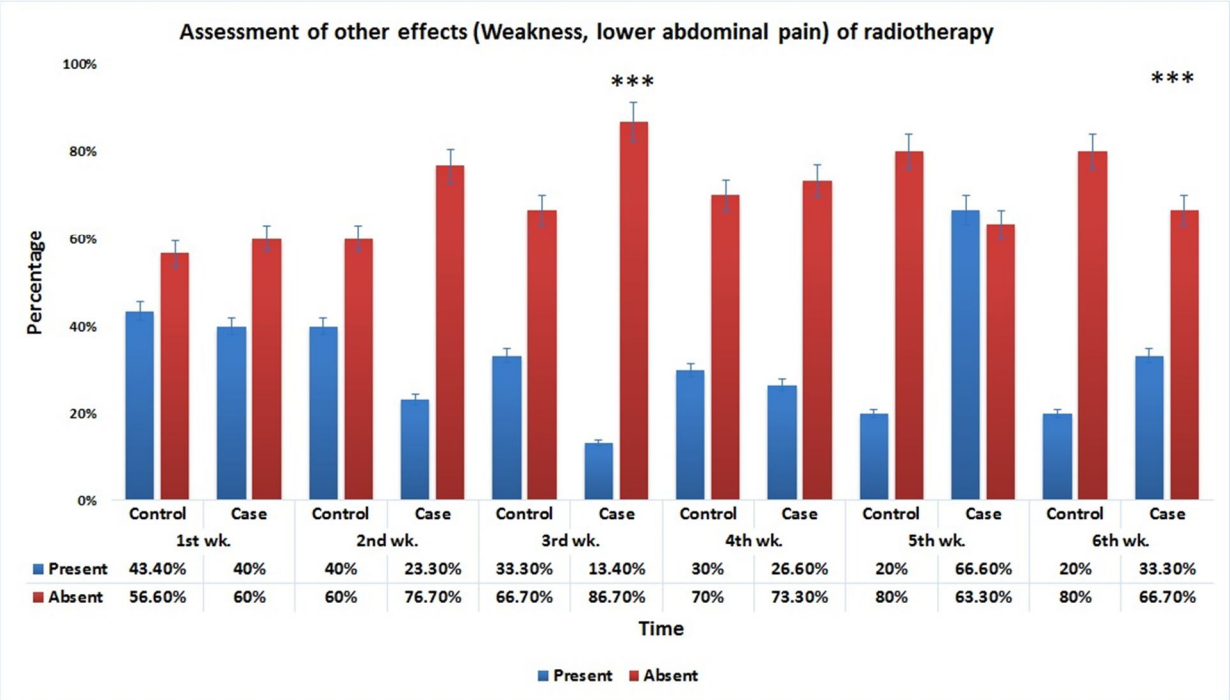

Fig 3. Assessment of other effects (Weakness, lower abdominal pain) of radiotherapy, showing comparison of other radiotherapy effects during therapy and it was found that there was Absent significant difference in other radiotherapy effects between control and case group. A t-test on the mean episode on 3rd wk. & 6th wk. showed Absent significant difference P>0.05 (***). Here, no. of Control= 30 and no. of Case= 30.

The radiotherapy therapy session of cervical carcinoma ended after 6 weeks, showing P/V findings were observed with a complete response –16 (53.3%) followed by stage IIa 10 (33.3%) and stage IIb 04 (13.3%) in the control group. In the case group, P/V findings were complete response 11 (36.7%), followed by the partial response, stage IIa 11 (36.7%) and stage IIb 8 (26.7%) mentioned in Fig 4. But statistically, the difference in outcome was not significant. (x^2=1.077, df =01,p=0.299).

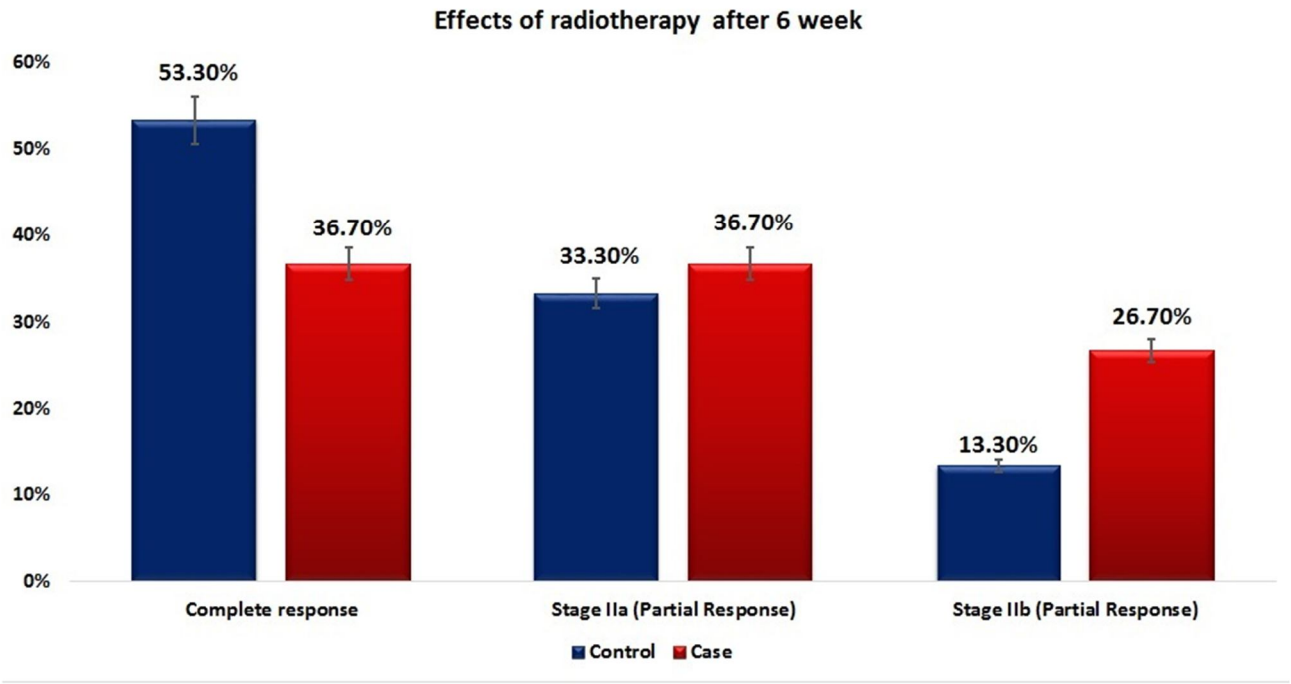

Fig 4. Effects of radiotherapy after 6 week

Fig 5. shows most of the carcinoma of the cervix were under stage IIb 20(66.7%) and 22(73.3%) in control and case group respectively, followed by stage IIIa 6(20%), 02(6.7%) and stage IIa 03(10%), 04(13.3%) and stage IIIb 01(3.3%), 02(6.7%) in both control and case group. Here, no. of Control= 30 and no. of Case= 30.

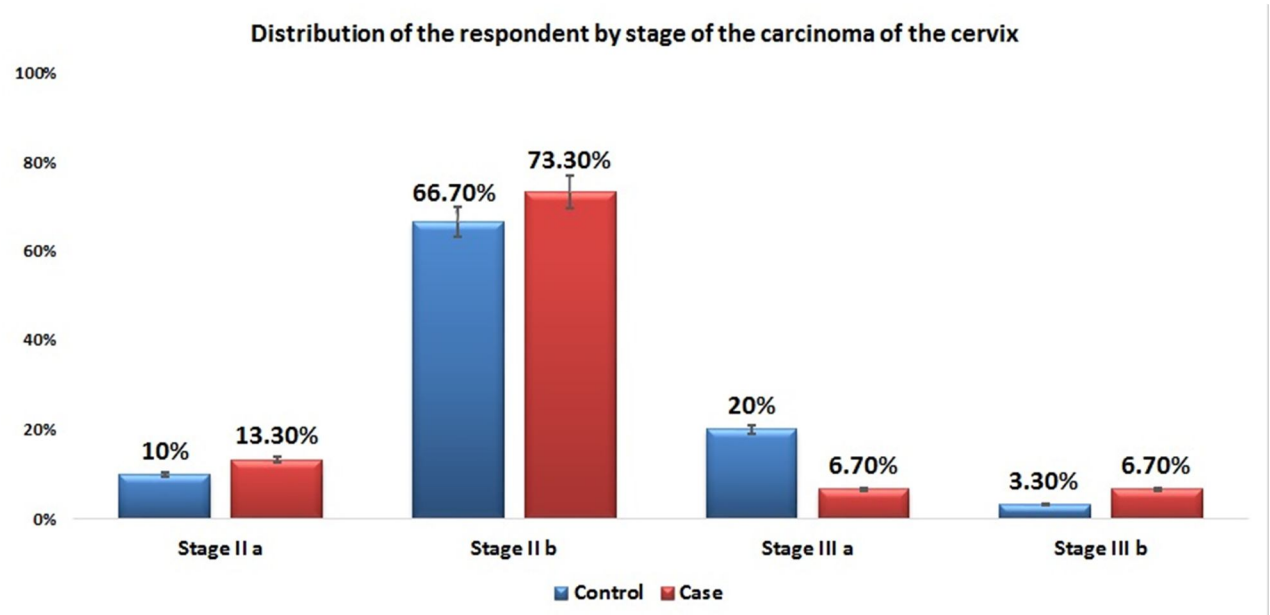

Fig 5. Distribution of the respondent by stage of the carcinoma of the cervix

IV. DISCUSSION

This study was undertaken to know the effect of hypofractionated radiotherapy by comparing with conventionally fractionated radiotherapy in the locoregional control of carcinoma cervix stage IIa, IIb, IIIa and IIIb also to see the early complication of radiation therapy.

A total number of 60 patients of squamous cell carcinoma of the cervix were included in this case. Among them, 30 were in the control group and another 30 patients were in the case group. The mean age of the patients of the control group was 46.53±8.27 years (range: 35-65) and in the case group were 47 ± 9.09 years (30-75). In comparison, Mary et al was recruited in a total of 62 patients with advanced carcinoma cervix IIIb, among them 37(60%) patients were treated with telecobalt while 25(40%) patients were treated with a linear accelerator. The mean age of the patients was 49 years (range 30-62 yrs). In another case Campbell et al, 2000, the number of patients was 480. They divided into conventional radiotherapy group (control n=250) and hypofractionated radiotherapy group (case n=230) [40].

In our study, the dose of radiotherapy in the control group (conventional) was 200cGy per fraction 5 days in a week over 6 weeks. The dose in the case group (hypofractionated) was 333cGy per fraction 3 days in a week over 6 weeks. In another case, cervical cancer patients in stage I, II, III on conventional Fractionated Radiotherapy (CFR) received tumor dose of 50 Gy in 25 fractions over 5 weeks (external radiotherapy) while stage IVa patients on CFR received 30Gy in 15 fractions over 3 weeks. Patients in stage I, II and III on hypofractionated (HF) received 50 Gy 15 fractions over 5 weeks, while stage IVa patients on HF received 30 Gy in 9 fractions over 3 weeks [40]. Mary et al, used the dose 300 cGy per fraction in the pelvic portal with anterior and posterior fields that were treated per day. The patients were treated for 5 days a week and the total dose delivered was 39 Gy in 13 fractions over 17 days. Hence in our cases, most of the carcinoma of the cervix in the control group were stage IIb 66.7%, stage IIIa 20%, stage IIa 10% and stage IIIb 3.3% and in the case group, the stage IIb 73.3%, stage IIa 13.3%, stage IIIa 6.7%, and stage IIIa 6.7% but Campbell et al, divided into his case group stage I 28%, stage II 38%, in stage III 24% and in stage IV 24%. In the control group 11% in stage I, 26% in stage II, 40% in stage III and 23% in stage IVa.

Conventional fractionation delivers 1.8 – 2 Gy per fraction 5 days a week. This fractionation scheme was developed because of tolerable acute reactions, acceptable delayed effects and reasonable local controls. In an attempt to improve the therapeutic ratio various fractionation schedules have been attempted. Hypofractionation has been used in various gynecological malignancies [41,42,43]. Lee et al studied 23 patients with stage III and IV head and neck Carcinomas treated with 44 – 52 Gy/11 – 13 fractions. The actuarial survival rate at 2 years was 45% and local control was 59%. Fraction size is the dominant factor in deciding the late effects. An increase in the dose per fraction also causes an increase in the late effects. In my case, the follow-up time was too short so late effect radiotherapy and survival of the patients could not observe.

In this case, in comparison, early radiation adverse effects were observed between the control and case groups, but there was no significant difference in the two groups. Early and late adverse effects of radiotherapy on the skin, anorexia, nausea, dysuria, P/V bleeding, P/V discharge etc. had no significant difference between control and case group.

In our case study, after 6 weeks, the follow-up with complete responses was 53.3%, followed by partial responses were stage IIa 33.3% and stage IIb 13.3% in the control group. But in the case group, 36.7% were complete responses followed by partial response were 36.7% stage IIa and 26.7% were stage IIb. Regarding locoregional control, statistically, no significant differences were observed between hypofractionated and conventional fractionated radiotherapy.

Campbell et al revealed that the complete response was seen in 96.8% of patients with stage I and 83.2% of those with stage IV, 76% stage III, and 56.2% stage IVa, in the case group. Local tumor control according to the clinical disease stage was 92.5% for stage I, 77% for stage II, 73.4% for stage III, and 52.7% for stage IVa in the case group. In the control group, local tumor control was 93.4% for stage I disease, 79.3% for stage II, 75.8% for stage III and 55.9% for stage IVa. There were no differences in the complete response to treatment or local tumor control in the two groups.

In another case, at six weeks after completion of radiation therapy, 85% of patients achieved a complete response, two patients had a partial response and two had no response while three patients had progressive disease on follow up. So, hypofractionated radiotherapy for advanced Carcinoma cervix stage IIIb gives survival comparable to that of conventional treatment. Though the acute, as well as late radiation, squeal seen to be higher. The percentage of patients developing severe radiation squeal is comparable to that of standard treatment [44].

A. Limitation of the study

In the present case, the follow-up time was only 6 weeks, so the late effect of radiotherapy and survival of the patients could not be ascertained.

V. CONCLUSIONS

This study was initiated to know the effect of hypofractionated radiotherapy by comparing this with the effect of conventionally fractionated radiotherapy in the locoregional control of carcinoma of cervix stage IIa, IIb, IIIa and IIIb to see the early complication of radiation therapy. There were 60 patients of squamous cell carcinoma of the cervix. The patients were divided into two groups, 30 patients in each group- The Control group was treated with conventional therapy of 60 Gy in 30 fractions in 6 weeks. The case group was treated by hypofractionated therapy of 60 Gy in 18 fractions in 6 weeks. In summary, No significant difference was observed between control and case groups, regarding the adverse effects of radiotherapy (P>0.05). Regarding locoregional control of carcinoma cervix, statistically, the difference of outcome was not significant between control and case population (P>0.05). The effects of radiotherapy in terms of adverse effects in patients treated hypofractionated radiotherapy appears comparable to that of standard fractionation.

VI. ACKNOWLEDGEMENT

This prospective study was performed at the Department of Radiotherapy, Rajshahi Medical College Hospital, Rajshahi, Bangladesh.

VII.AUTHOR CONTRIBUTIONS

Dr Rawshan Ara Khatun (RAK) designed the study and executed the experiments along with Dr Julekha Khatun (JK). Both RAK and JK analyzed the experimented data. RAK wrote the manuscript. Both authors approved the final version of the manuscript.

A. Conflicts of Interest

Authors declared that they have no conflict of interest.

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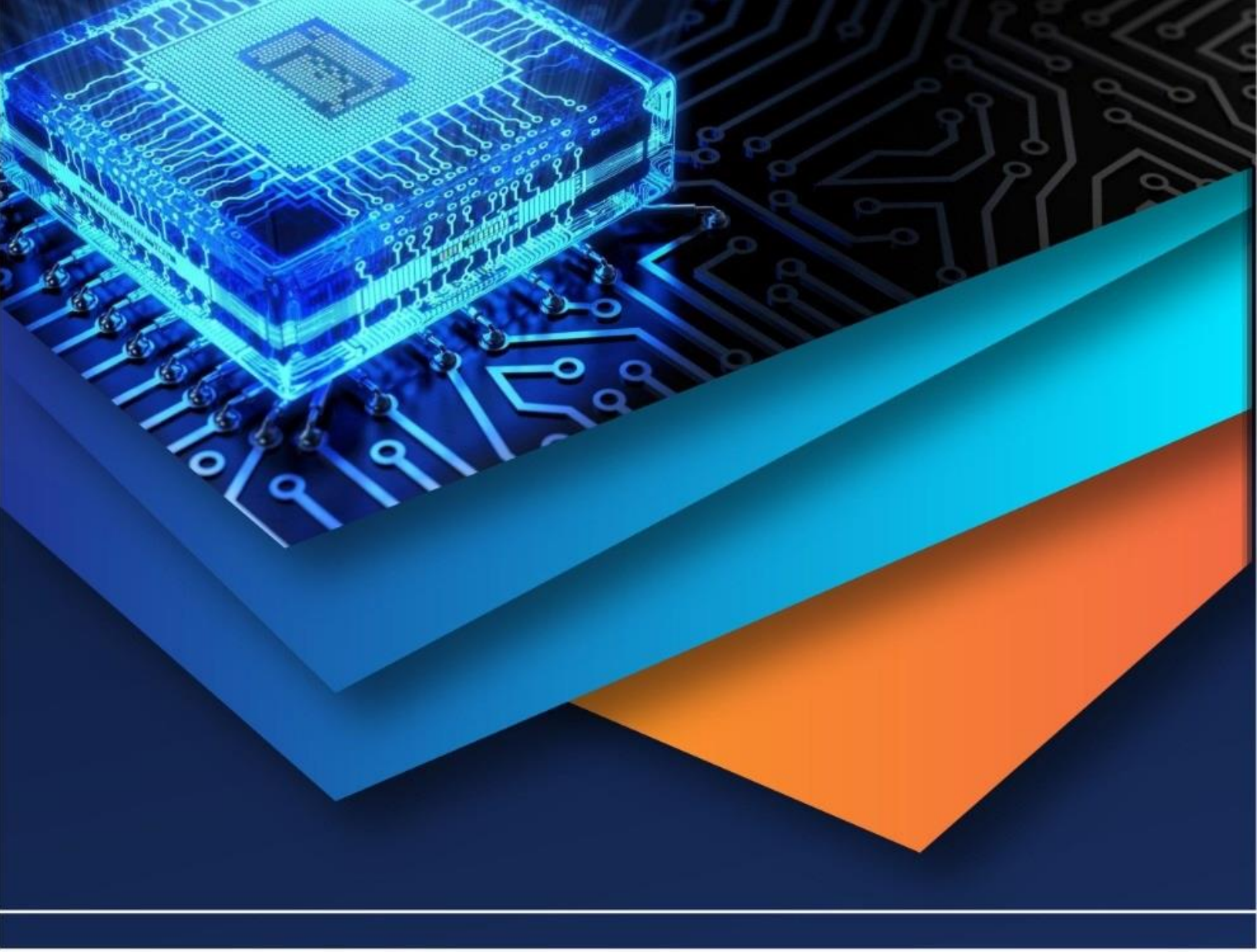

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