

## Original Research Article

# The effect of general anaesthesia versus conscious sedation in dosimetric distribution of intracavitary radiotherapy in cervical cancer patients

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## ABSTRACT

**Background:** Majority of Indian patients presents in locally advanced stage and most of them treated by combination of external teletherapy and intracavitary brachytherapy (ICRT). Because of deficient infrastructure, the waiting period is generally long at existing cancer centers. Hence ICRT may be done in conscious sedation to treat more patients by avoiding time consuming general anaesthesia. The aim of this study is to know the effect of general anaesthesia vs. conscious sedation in dosimetric distribution in brachytherapy and its feasibility.

**Methods:** Total 80 ICRT applications were randomized to general anaesthesia (GA) and conscious sedation (CS) groups. Fletcher suit type of applicators was used and dose delivery equipment was cobalt 60 high dose rate remote after loading brachytherapy unit. In CS group, injection midazolam 0.5-8mg (median 2.5mg) in the form of slow i.v. infusion was used along with antiemetic support.

**Results:** Total 6 parameters were analyzed. e.g., Dose to point A1, Dose to point A2, Bladder max dose, Bladder mean dose, Rectal max dose and Rectal mean dose. The dose distribution was found similar both groups and it did not depend on type of anaesthesia.

**Conclusions:** The high volume centers of developing countries are most suitable candidate to opt conscious sedation to perform ICRT to treat more cancer cervix patients in same time frame.

**Keywords:** Cancer cervix, Conscious sedation, Intracavitary brachytherapy

## INTRODUCTION

Cancer cervix is the second most common in developing areas (445000 new cases each year) and it is also the third cause of cancer-related death in developing countries (230158 deaths) which means that more than 80% of the global burden occurs in developing areas.<sup>1</sup> Multiple randomized trials done in past proved that in early stages of carcinoma cervix surgery has equivalent treatment outcome as radiotherapy.<sup>2</sup> For advanced stages, i. e. from bulky stage IB2 and IIA to Stage IVA, external beam radiotherapy (EBRT), followed by intracavitary radiotherapy (ICRT) constitutes the main treatment.<sup>3</sup>

Concurrent weekly injection cisplatin 35-40mg/m<sup>2</sup> is given with EBRT from stage IB2 onwards.<sup>4</sup> ABS guidelines says that brachytherapy should be done under general anaesthesia (GA).<sup>5</sup> It provides good analgesia and muscle relaxation, although it has shown to be associated with higher complications (hypotension, bradycardia etc).<sup>6</sup> For general anaesthesia pre-anesthetic clearance is required. Institute with heavy burden of patients and less manpower, it is very time consuming. Sometimes it is very difficult to manage complications too.

The infrastructure is also deficient. Only 221 out of 500 cancer centers are equipped in nation.<sup>7</sup> Even, the patients

those attending equipped centers are also facing long waiting period for ICRT.<sup>8</sup>

On the other side, brachytherapy in conscious sedation (CS) is simple and convenient to practice, not requiring pre-anesthetic clearance but may cause pain, discomfort and poor muscle relaxation, which may lead to compromising dosimetry.<sup>8</sup> However, it may be very useful to treat more numbers of patients if adequate facilities are lacking in terms of infrastructure and many patients are waiting for ICRT.<sup>8</sup> So, the aim of this study is to know the effect of general anaesthesia vs. conscious sedation in dosimetric distribution in cervical cancer patients treated with ICRT.

## METHODS

This study was conducted prospectively on 80 applications of ICRT in carcinoma cervix patients with stage IB<sub>2</sub> to IIIB. EBRT dose 45-50 Gy in 25 fractions at the rate of 180-200 cGy per fraction treated 5 days per week over 5-6 weeks was given with concurrent chemotherapy if indicated. ICRT was started after 1 week of EBRT completion. The four sessions at the rate of 6 Gy/session was given with a gap of at least 72 hrs between each session. ICRT was done using Fletcher suit applicators and high dose rate remote after loaded brachytherapy unit with CO radionuclide source.<sup>60</sup> As per departmental guidelines informed consent of every patient was taken in written before brachytherapy. Those patients in post-op settings, re-irradiation and with inadequate vaginal space were excluded. Grouping was done at systemically odd and even basis in which all odd number patients was in group AG group and even number was in CS group. The patients were enrolled in between October, 2015 to November, 2015.

### Group AG

ICRT applications were 40. Before each ICRT, all patients were under gone pre-anesthetic clearance (PAC) and were admitted one day before of scheduled ICRT for preparation like overnight empty stomach and enema.

### Group CS

In this group, 40 ICRT applications were done in conscious sedation. Injection (inj.) midazolam 0.5-8mg (median 2.5mg) in the form of slow i.v. infusion was used along with antiemetic support and rescue for pain was injection tramadol 2mg/kg.<sup>9</sup> Since the procedures were done under mild sedation, so there was no need for PAC or patient staying empty stomach.

Post procedure rescue for pain in either group was injection tramadol 2mg/kg.

The rest of procedures were same in both the groups. Each Patient was positioned in lithotomy. Local examination was done to know the size and direction of

uterus, to assess the angle and length of the central tandem. Cleaning and draping of pelvic area was done using povidone iodine solution. A Foley's catheter was inserted into the urinary bladder and the balloon was inflated with 7 cc (according to ICRU 38) of diluted Urografin dye to identify the bladder reference points.<sup>10</sup> After serial dilation of the cervical os, the most suitable central tandem was inserted through the cervical os into the uterus such that keel was get fixed at the level of external os. The ovoids were placed in right and left vaginal fornix equidistant from the central tandem. The vagina was packed with gauze to further displace the bladder anteriorly and the rectum posteriorly to minimize the dose to these organs and to immobilize the applicators. An additional rectal marker was placed in rectum to identify the ICRU rectum points. With the help of reconstruction box, antero-posterior and lateral orthogonal X-rays were taken with C-arm X ray machine. Multiple points consistent with ICRU 38 were located and treatment planning was done. The dose was prescribed to point A and optimized for bladder and rectum reference points.

## RESULTS

Mostly patients were belonging to stage IIIrd. Total 56 patients were enrolled and randomized as odd and even basis to AG group and CS group respectively. Total 6 dose distribution parameters were analyzed. e.g. dose to point A1, dose to point A2, bladder max dose (Bmax.), bladder mean dose (Bmean), rectal max dose (Rmax) and rectal mean dose (Rmean) (Table 1).

**Table 1: Patient characteristics.**

Attributes	Group AG	Group CS
<b>Median age (years)</b>	49	50
<b>FIGO stage (no. of patients)</b>		
I	01	01
II	7	08
III	19	18
<b>Median duration of treatment (days)</b>	60	60
<b>ICRT</b>		
Average applicator insertion time in OT (minutes)	37	12
Dose per fraction (Gy)	6	6
Median length of uterine cavity (cm)	5	5
Median ovoid size	Medium	Medium

### Dose to point A1

In Group AG, the doses were at target A1 (point A to the right on x axis) ranges from 5.04-6.36 Gy and the average dose was of 5.69 Gy. In CS group, it doses were ranges from 4.91-6.92 Gy and the average dose was 5.92 Gy. The distribution was similar in both groups and P value was insignificant (0.327) (Table 2).

**Table 2: Target A1 dose distribution in group AG and CS.**

Target A1 dose	Group AG	Group CS
4.5-5	0	2
5-5.5	8	9
5.5-6	22	14
6-6.5	9	13
6.5-7	1	2

**Dose to point A2**

In Group AG, the doses were at target A1 (point A to the left on x axis) ranges from 5.06-6.44 Gy and the average dose was of 5.75 Gy. In CS group, it doses were ranges from 4.77-6.76 Gy and the average dose was 5.97 Gy (see table 3 & fig 2). The distribution was similar in both groups and P value was insignificant (0.640) (Table 3).

**Table 3: Target A2 dose distribution in group AG and CS.**

Target A2 dose	Group AG	Group CS
4.5-5	1	0
5-5.5	7	10
5.5-6	20	18
6-6.5	10	8
6.5-7	2	4

**Bladder max dose**

The Bmax dose in group AG ranges from 27.5-114.7 % (1.65-6.88 Gy) and in group CS, it was ranges from 21.2-111% (1.27-6.66 Gy) (Table 4).

**Table 4: Bladder max dose percent distribution in group AG and CS.**

Bladder max dose (%)	Group AG	Group CS
21-40	8	10
41-60	11	13
61-80	11	11
81-100	8	5
101-120	2	1

**Bladder mean dose**

The Bmean dose in group AG were ranges from 17.7-69.2% (1.07-4.14 Gy) and in Group CS, it ranges from 15.54-74.24% (0.93-4.45 Gy) (Table 5).

**Rectum max dose**

The Rmax dose in group AG were ranges from 26.2-90.4% (1.99-5.42) and in group CS, it ranges from 25.5-90% (1.53-5.45 Gy) (Table 6).

**Table 5: Bladder mean dose percent distribution in group AG and CS.**

Bladder mean dose (%)	Group AG	Group CS
0-20	3	3
21-40	21	20
41-60	14	16
61-80	2	1

**Table 6: Rectum max dose percent distribution in group AG and CS.**

Rectum max dose %	Group AG	Group CS
21-40	3	6
41-60	14	14
61-80	14	14
81-100	9	6

**Rectum mean dose**

The Rmean dose in group AG ranges from 32.5-77.73% (1.95-4.78 Gy) and in Group CS, it ranges from 21.07-79.16% (1.26-4.75 Gy) (Table 7).

**Table 7: Rectum mean dose percent distribution in group AG and CS.**

Rectum mean dose %	Group AG	Group CS
21-40	4	10
41-60	27	17
61-80	9	13

The radiation dose distribution at above six analyzed parameters was found approximately similar both groups and it did not depend on type of anaesthesia.

**DISCUSSION**

The developing countries are facing highest incidence and prevalence of cervical cancer. Majority of patients presented in locally advanced and they are the candidate for radiation treatment.<sup>1</sup> Because of limited infrastructure, the existing centers are heavily burdened. Hence, the patients those attending equipped centers are also facing long waiting period.<sup>8</sup> For example, India accounts one fifth of global burden of cervical cancer and 35% of existing radiation centers are lacking the brachytherapy facilities.<sup>7,11</sup> As ICRT is integral component of treatment and usually have to done under general anaesthesia. The overall duration of ICRT under anaesthesia is relatively longer due to extra time required for preparations and procedure. In this study, the average OT time for GA group is 37 minutes, while its 3 time less in CS group e.g., 12 minutes only. Hence, general anaesthesia consumes a significant proportion of OT time. This might overburden the recourses, resulting in further prolonging the waiting list and limiting the number of cases. It is generally assumed that lack of GA may result in inferior

dosimetry but the dose distributions as per parameters analysed are good and satisfactory in conscious sedation and are very comparable with general anaesthesia. Similar study was conducted by Sharma et al. In their study<sup>12</sup>, total 138 procedures were done, 69 in anaesthesia group (AG) and 69 in non-anaesthesia group (NAG). For each ICRT 7 Gy prescribed to point A. The mean dose to Bladder reference points in AG and NAG was 5.03Gy and 4.90 Gy, respectively (p value 0.6). The mean dose to rectal reference points in AG and NAG was 5.09 Gy and 4.90 Gy, respectively (p value 0.01). No significant difference in dose distribution in AG and NAG group. So, there was no significant difference in dose distribution of doses delivered to point A, bladder and rectal reference point in both groups. By extensive data analysis of our study, we recommend that the conscious sedation can be alternative to general anaesthesia to perform ICRT at high volume centers of developing countries to provide timely treatment to more patients in day and to exhaust long waiting list.

## CONCLUSION

Intracavitary brachytherapy in carcinoma cervix can be done under conscious sedation without compromising dosimetric distribution. The high-volume centers of developing countries are most suitable candidate to opt this technique to provide timely treatment to more patients in same time frame.

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