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## **Conflicts of Interest:** Nil

## Abstract

**Purpose**: To know the complications of conscious sedation in cervical cancer patients treated with cobalt (CO60) based Intra-cavitary brachytherapy (ICBT) and to assess pain on visual analogue scale (VAS).

**Material and methods**: Cobalt 60 based intra-cavitary brachytherapy application was performed with conscious sedation in 45 carcinoma cervix patients and postprocedural pain was assessed with VAS at every 30 minutes interval for six hours along with other complications.

**Result**: Pain was well controlled (means VAS 5.0) in all patients with maximum VAS 10 and tramodol was received as rescue analgesic. Common complication was grade 1 & 2 bradycardia in 7 patients; and grade 1 hypertension in 7 applications; no patients found Gr 3 or 4 hypertension, Hypotension in 11 Patients (Gr1 in 6).

**Conclusions**: Conscious sedation is an alternate fast and safe option to perform intra-cavitary brachytherapy applications (Cobalt 60) in the patients of cervix cancer.

**Keywords**: Intra-cavitary Brachytherapy, Conscious Sedation, Cervix Cancer

## Introduction

India accounts for one fifth of the global burden of cervical cancer and this is the second most common malignancy among females<sup>1</sup>.

The concurrent external beam radiotherapy (EBRT) followed by intracavitary radiotherapy (ICBT) is proved as the main treatment therapy <sup>2-5</sup>

ICBT plays very important role in the management of gynecological cancers<sup>6</sup>. It is a means to deliver the required dose of brachytherapy to cervix and parametrium with relative sparing of the adjoining normal structure<sup>7</sup>.

According to American brachytherapy society guidelines<sup>8</sup>, brachytherapy should be done under general anesthesia (GA) as it provides good analgesia and muscle relaxation but it has shown to be associated with higher complications (hypotension, bradycardia etc.)<sup>9</sup>. To facilitate this procedure under GA is very time consuming specially in such Institute having heavy

patients load or less manpower. Sometimes it is very difficult to manage complications too of GA as well as co-existing disease itself and as per protocol these patients have to undergo pre-anaesthetic examination and clearance.

On the other side, ICBT in conscious sedation 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>10</sup>.

Our center is one of the centers in India where new registration of patients suffering with cervix cancer is very high (average 1200 patients/ year with age of 30-60 years).

So the aim of this study is to assess pain, sedation and other complication with conscious sedation and easiness of ICBT application in cervical cancer patients treated with  $CO^{60}$  based ICBT.

## **Materials and Methods**

This study was conducted prospectively on 45 patients of cervical cancer with stage  $IB_2$  to IIIB posted for ICBT application. The Definitive & conventional EBRT was prescribed with dose 45-50 Gy in 25 fractions by Cobalt 60 teletherapy machine. ICBT was started after 1 week of EBRT completion. Total three sessions of ICBT @ 7 Gy /session was delivered maintaining of a gap of 72 hours between two sessions.

The all procedures were done in lithotomy position. Fletcher suit type of applicators was used and dose delivery equipment was HDR remote after loading brachytherapy unit. After placement of Fletcher suite applicator, the orthogonal view was reconstructed and treatment planning was done on treatment planning system. Dose prescription was specified to point "A". Multiple points consistent with ICRU 38 were located and used for treatment planning and dose optimization to point A, bladder and rectum<sup>11</sup>.

Patient kept overnight fasting before bringing in OT and vitals was noted and premedicated with inj. Ondansetron 4mg i.v. and inj. Diclofenac 75mg i.v. slow 30minutes before procedure and then Inj. Midazolam 0.5-8 mg (median 2.5mg) slow i.v. infusion. Post procedure pain in moderate conscious sedation was assessed using VAS every 30 minutes for 6 hrs and sedation as described by American society of anaesthesiologists<sup>12</sup> Visual Analogue Scale<sup>13</sup>

| Pain intensity | Word scale        |
|----------------|-------------------|
| 0              | No pain           |
| 1-2            | Least pain        |
| 3-4            | Mild pain         |
| 5-6            | Moderate pain     |
| 7-8            | Severe pain       |
| 9-10           | Excruciating pain |

When pain score >3 supplementary, Inj. Tramadol 2mg/kg intravenous was given as rescue analgesic and if there is more severe pain inj fentanyl  $1-2\mu g/kg$  was supplemented.

Complications were recorded regularly up to 6 hours of the applications and grading of complication was done according to the common terminology criteria for adverse events (CTCAE) 5.0 guideline<sup>14</sup>.

### Results

#### **Patient characteristics**

Most patients belonged to stage II. (Table I)

Total 6 parameters were analyzed i.e., Dose to point  $A_{1,}$ Dose to point  $A_{2,}$  Bladder max dose( $B_{max}$ ), Rectal max dose( $R_{max}$ ), maximum VAS score and grades of complications.

## Max VAS score in conscious sedation

Most common Maximum VAS score was 5 in 12 applications while second most score was 4 in 9

applications. The mean of maximum pain score was 5.0 and similarly the median was 5.0. (Table IV). In two procedures mild to moderate pain was managed by inj Tramodol 2mg/kg while more (VAS>7) was managed by inj Fentanyl (50 µg increment).

#### **Complications with grade**

Most common complication was grade1 and grade 2 bradycardia (in 7 out of 45 applications), hypertension (grade 1 in 7 applications), Hypotension (gr 1 in 6 and Gr 2 in 5 patients) was manageable with fluid administration and ventricular dysrhythmia (grade 1 in 2 applications) (Table V). All were transient not required any medication except one patient required inj atropine 0.6mg).

### Dose to point A

The Dose range of Point A was from 6.0 to 7.0 Gy in majorities of applications (93%, 42 out of 45). The average doses were 6.82Gy and 6.83 Gy for Point A1 and A2 respectively. (Table II)

#### Bladder max and rectal max dose distribution

The Bladder max ranges from 24-108% (1.68-7.56 Gy). Similarly, the rectal max ranges from 30-95% (2.1-6.65Gy). (Table III)

#### Discussion

Total 45 ICRT applications were performed and the dose of 7 Gy was prescribed to target point A in each application. Overall dosimetric dose distribution was well and satisfactory.

The max bladder dose was ranges from 24-108% (1.68-7.56 Gy) of the dose prescribed to point A. While the max rectum dose were ranges between 30-95% (2.1-6.65Gy).

In Bhanabhai et al study<sup>15</sup>, 57 procedures of ICRT were done with conscious sedation. The mean and median pain scores during the procedures were 1.4 and 1.1 respectively. Brief moments of moderate to severe incidental pain were noted at the time of certain events during procedure-specifically during insertion and removal of ovoids and tandem applicator. The maximum pain score during entire procedure ranged from 0 to 10 (median: 4.7). No significant cardiovascular events were noted.

In our study, the mean and median pain scores during the procedures were 1.22 and 1 respectively. Maximum pain was noted at the time of insertion and removal of ovoid and tandem applicator similar to Bhanabhai et al<sup>15</sup>. There pain was managed by inj. Tramodol 2mg/kg wt and in only two patients it was supplemented with inj. Fentanyl  $100\mu g$  and after the procedure was completed. The cardiovascular complication –hypotension, bradycardia were transient and not required any management

#### Conclusion

Conscious sedation is an alternate fast and safe option to perform intracavitary brachytherapy in carcinoma cervix patients at higher workload department. It has good pain control and lack of fatal cardiovascular adverse events and without compromising dosimetric distribution. With this technique it will reduce workload of post-operative ward as well as.

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#### Legend Tables

Table 1: Showing patient characteristics.

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| Sno. | Attributes                          |    |
|------|-------------------------------------|----|
| 1.   | Median age (years)                  | 45 |
| 2.   | FIGO stage (no. of patients)        |    |
|      | Ι                                   | 13 |
|      | II                                  | 22 |
|      | III                                 | 10 |
| 3.   | Median EBRT dose (Gy)               | 50 |
| 4.   | Median duration of treatment (days) | 60 |

| 5. | ICRT  |    |
|----|---|----|
|    | Average applicator insertion time in OT (minutes) | 30 |
|    | Dose per fraction (Gy)                            | 7  |
|    | Median length of uterine cavity (cm)              | 6  |
|    | Median ovoid size                                 | 5  |

Table 2: Showing target Point A dose distribution.

| Target dose range (Gy) | Distribution at Point A1 | Distribution at Point A2 |
|------------------------|--------------------------|--------------------------|
| 5.5-6                  | 03                       | 03                       |
| 6-6.5                  | 10                       | 09                       |
| 6.5-7                  | 32                       | 33                       |

Table 3: Showing bladder max dose Distribution

| Dose range (% to dose received at point A) | Bladder <sub>max</sub> | Rectum max |
|--|------------------------|------------|
| 21-40                                      | 11                     | 7          |
| 41-60                                      | 15                     | 16         |
| 61-80                                      | 13                     | 16         |
| 81-100                                     | 5                      | 6          |
| 101-120                                    | 1                      | 0          |

Table 4: Showing max pain score recoded up to 6 hours.

| No. of procedures | Max VAS score |  |  |
|-------------------|---------------|--|--|
| 2                 | 0             |  |  |
| 2                 | 1             |  |  |
| 4                 | 2             |  |  |
| 5                 | 3             |  |  |
| 9                 | 4             |  |  |
| 12                | 5             |  |  |
| 3                 | 6             |  |  |
| 2                 | 7             |  |  |
| 4                 | 8             |  |  |
| 0                 | 9             |  |  |
| 2                 | 10            |  |  |

Table 5: Showing maximum grade of complications recoded up to 6 hours

| Complication |   |   | Gra | ade |   |   |
|--------------|---|---|-----|-----|---|---|
|              | 1 | 2 | 3   | 4   | 5 |   |
| Hypotension  | 6 | 5 | 0   | 0   | 0 |   |
|              |   |   |     |     |   | L |

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|-------------------------|---|---|---|---|---|--|
| Bradycardia             | 5 | 2 | 0 | 0 | 0 |  |
| Hypertension            | 7 | 0 | 0 | 0 | 0 |  |
| Ventricular dysrhythmia | 2 | 0 | 0 | 0 | 0 |  |
| Laryngo spasm           | 0 | 0 | 0 | 0 | 0 |  |