

Comparison of Thermoplastic Cast Versus Knee Wedge/Foot Rest Immobilization Technique in the Treatment of Carcinoma Cervix with Conformal Radiation Therapy

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Abstract: A total of 58 patients who underwent concurrent chemo-radiation for carcinoma cervix were analyzed for magnitude of variation in daily treatment position with two immobilization methods, and its impact on the dose delivered to the organs at risk. Assessment was done with the help electronic portal imaging devices (EPID). The main endpoints of the study were to quantify and compare the total isocentric displacement among the knee rest foot rest and thermoplastic cast groups, and to correlate the effect of isocentric displacement with dose volume changes. The EPIDs were compared with the DRR and set-up errors were noted in X (medio-lateral) Y (antero- posterior) and Z (cranio-caudal) axes. Any variations above the prescribed limits were corrected accordingly before treatment and variations were noted. The root mean square variation in thermoplastic cast group ranged from 0.93 mm to 4.61 mm in X axis, 1.28 mm to 8.07 mm in Y axis, 1.19 mm to 9.49 mm in Z axis. In knee rest foot rest arm these variations are 1.27 mm to 6.05 mm in X axis, 0.91 mm to 4.8 mm in Y axis and 1.09 mm to 5.3 mm in Z axis respectively. P value was significant in Y direction. The total vector error in thermoplastic cast group is 6.308 ± 2.17 , and for the knee rest foot rest group was 4.67 ± 1.48 . The p value obtained was 0.002, which was statistically significant in favor of knee rest foot rest arm. The bladder, rectum, bowel dose mean differences after isocenter displacement were not statistically significant in both arms.

Keywords: Carcinoma cervix, external beam radiation therapy, displacement, errors.

INTRODUCTION

Cervical cancer is the fourth most common cancer worldwide and second most common in developing countries [1]. The incidence is 9.9 and 15.7 per 1, 00,000 population in developed and developing countries respectively [1]. India accounts for one fourth of total cervical cancer deaths caused worldwide. Treatment for carcinoma cervix is surgery or chemo-radiation depending on stage. The standard treatment for carcinoma cervix from stage IB onwards is concurrent chemo- radiation as per national cancer institute (NCI) alert 1999 [2-6] and usually its External beam radiation followed by Brachytherapy.

Conventional radiotherapy based on bony landmarks has been used for decades and has produced reasonably good local control and overall survival rates. However various studies have shown significant anatomical variations between individual patients like different levels of bifurcation of abdominal aorta, altered sacral curvature etc. In an attempt to achieve superior tumor control and with advancement in both imaging modalities and radiation delivery techniques, computerized tomography (CT) scan based three-dimensional (3D) planning has replaced bony landmark based two-dimensional (2D) planning in most of the centers. Various studies have reported

significant improvement in tumor volume coverage and decrease in toxicities with the use of conformal radiation therapy. This is primarily because of ability of conformal therapy to provide tighter margins. The flipside of having tighter margins is that, it is highly dependent upon patient positioning. With the use of conformal radiation therapy, profound emphasis is to be given for patient immobilization and its reproducibility, as errors in patient positioning may leads to either under-dosing of target volume (TV) and/or overdosing of normal tissue. Set-up errors, are inevitable within the radiotherapy course. For patients with carcinoma cervix, the increase in set-up errors may eventually lead to higher local relapse and more severe radiation reactions.

Due to prolonged treatment period chances of set-up error occurrences are very high, so reproducibility of daily set up becomes necessary. Even with adequate immobilization techniques, set up errors are likely to occur, resulting in the geographic miss of the target or higher doses to the normal tissue. These set up errors are measured using verification methods such as portal imaging.

Nutting *et al.* in a randomized study for the use of a customized immobilization system in the treatment of prostate cancer with conformal radiotherapy had earlier assessed this aspect of radiotherapy planning process. Though the organ motion associated with localized prostate cancer can be much more pronounced, it is also found that early uterine cervical cancer can be

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equally mobile and also influenced by similar parameters such as bladder filling, rectal filling and bowel distensions. However, since we are trying to assess gross setup errors and the implications of the same, through portal imaging match of bony pelvic anatomy, the internal organ motion would not alter outcome in any primary cancer of the pelvis. It was found that the anterior rotation in conventional treatment position (CTP) was 0 ± 0.6 , and in immobilization system was found to be 0.2 ± 0.8 . The purpose of this study is to compare the setup reliability of two patient immobilization systems, the knee wedge/foot rest system and the thermoplastic cast system in patients with uterine cervical carcinoma receiving 3D conformal radiotherapy.

MATERIALS AND METHODS:

We set out to conduct this prospective randomised non-inferiority study to determine the implications of two different immobilization systems in uterine cervical cancer patients receiving radical radiation therapy at a tertiary cancer centre & medical teaching hospital in Bangalore for the period between 2014 to 2015. Institutional ethical committee clearance was obtained prior to commencement of this study as per protocol. In the present study, expecting similar results as that of the study mentioned earlier with a 95% confidence level, the sample size was estimated to be 43. Patients who were allergic to tattoo ink and orthopedic deformity were excluded from the study.

All eligible patients according as per the inclusion criteria were enrolled into the study. Informed consent for participation was taken. Baseline investigations were done as per institution protocol. The radiation therapy treatment consists of three steps,

- i. immobilization,
- ii. acquiring patient data for treatment planning, execution and
- iii. treatment verification

Patients were divided into two groups by a simple randomisation technique of numbered table method. First group were immobilized with aquaplast cast. The patients were taken to the mould room couch and made to lie down in the supine treatment position over the base plate & both arms were abducted overhead. The Orfit cast was dipped in water bath for few minutes till it softened which was pre-heated to a temperature of 60 to 70 degree Celsius. At this temperature, the

Aquaplast is soft and malleable. The cast is then placed over the patient on the site to be treated. Once the cast become rigid and takes the shape of the patient's body contour, tattoo marks were placed at the cranial & caudal end of the cast, to be able to identify the exact position in which the cast was prepared to allow for easy reproducibility during daily treatment.

The second group of patients were immobilized with knee wedge & foot rest immobilization device, which is made up of carbon fibre. This device mildly flexes the hip & knee joints as well as externally rotates the hip joint to allow for relaxation of the pelvic and lower limb muscles & joints, which will ensure reproducibility & reduce leg fatigue. Foot rest is to accommodate the foot of the patient with comfort, and aid in immobilization. Patients were positioned on the knee wedge foot rest immobilization system and then marks were made on the patient's skin where the edges of the device touch the patient's thigh and leg.

Once the patient is immobilized, the next step is to collect the patient's anatomical data by subjecting the patient to contrast enhanced computerized tomography scan, taking serial axial sections of 5 mm slices. All patients had a bladder protocol as per which, patient empties their bladder, and then drinks 500 ml of water 30 minutes before simulation. The same protocol will be followed everyday till completion of treatment. This was done to ensure differences in bladder filling would not compound the variations in treatment setup as well as to minimise the volume of bowel in the treatment field. Laser markings would be aligned, two lateral and one anterior. Markings were made over the orfit cast, where the positioning lasers intersect with each other. For knee wedge foot rest group, patients were aligned based on the intersecting lasers and markings were done over the patient's skin. These were then converted to permanent tattoo marks to allow for daily reproducibility. Simulation CT scan was done after applying the radiopaque markers as fiducials on these reference markings to facilitate visualization. The images were loaded in to the treatment planning system and delineation the organs at risk, namely bladder, bowel bag, rectum& bilateral femoral heads were done. The targets were delineated as clinical target volumes(CTV), of the nodal areas and primary disease. Then as per our departmental protocol, a planning target volume (PTV) of 7mm was given to account for day to day set-up errors. The plan is generated by the medical physicist.

Before starting treatment, reference markings on the patients are aligned to orthogonal lasers in

treatment room. Necessary movement, derived from the treatment planning system, were made to reach the treatment isocentre from the simulation position. This would be permanently inked on patient's skin and on the thermoplastic cast accordingly.

The electronic portal images (EPID) were used for position verification before treatment by matching to digitally reconstructed radiograph (DRR) generated from simulation CT data. As soft tissue visibility would not be possible in EPID's, bone matching would determine the verification of positional match on a daily basis. We did not account for organ filling/motion as a component of set-up error, as it was not within the scope of this study. Also, as we were using three dimensional conformal radiotherapy, internal organ motion & filling is not usually of concern as any movement due to these will still be encompassed by the treatment fields, as opposed to those of a more conformal technique such as IMRT/VMAT. EPIDs were obtained as per department protocol, with an orthogonal antero-posterior and lateral view being taken, while patient is on the couch in the treatment position. EPIDs were taken on the first three days and weekly there after till completion of the treatment. After the first 3 days, if the correction would exceed beyond the PTV margin and in the same direction regularly, then a couch shift would be assigned and the re-confirmed to negate the systematic error. If the same happens after the first week, then the protocol is to do 3 consecutive day EPID's and then correcting the random error, if any. Any displacement of treatment field isocenter from that of simulated image, as determined by EPID images are recorded in each axis. Though rotational readings could be measured, they were not taken into account, as the treatment couch at our center is not equipped to apply this correction. The mean isocenter displacement is calculated in X axis for medio-lateral direction Y axis for antero-posterior direction and Z axis for cranio-caudal direction. For both groups, the total isocenter displacement were calculated geometrically. The displacements in each direction will be tabulated and collated for each patient for both groups. Also, to establish the effect of isocentric displacement on dose volume characteristics, the average readings for each patient would be first determined. Then, a separate plan would be generated on initial simulation CT scan using this data, to determine the changes in target volume and organs at risk dose volume indices. As systematic errors (those seen in first week) are more pronounced & commonly occurring, re-planning was done taking

only the first week data in to account. Random errors (those seen after first week of therapy) were much less frequent and hence did not warrant a replanning exercise.

Statistical Methods

To know significant difference between paired set of measurements, the test is called paired t test. It is applied to paired data of independent observation observations from one sample only when each individual gives pair of observations. Paired t test was used to compare the error values in each axis and total vector error between the knee rest foot rest arm. The Mann Whitneys test was used to compare the mean dose difference to the OARs between the two arms

RESULTS

The subjects of the study were females with age ranging from 30-75 years and all of them had uterine cervical cancer of Stage IIA to IIIB. In our study of 57 carcinoma cervix patients, 29 were treated with orbit cast and 28 were treated with knee wedge/foot rest device. The root mean square variation in orbit cast group ranged from 0.93 mm to 4.61 mm in X axis, 1.28 mm to 8.07 mm in Y axis, 1.19 mm to 9.49 mm in Z axis. In knee wedge/foot rest arm, these variations are 1.27 mm to 6.05 mm in X axis, 0.91 mm to 4.8 mm in Y axis and 1.09 mm to 5.3 mm in Z axis respectively. The mean and standard deviation in orbit cast group in X axis is 2.57 ± 1.096 mm, 4.493 ± 1.7581 mm in Y axis, 3.173 ± 1.875 mm in Z axis.

In the knee wedge/foot rest arm, the mean and standard deviations are 3.0304 ± 1.2035 , in X axis, 2.1793 ± 0.9520 in Y axis, 2.589 ± 1.006296 in Z axis respectively.

Table 1: Knee Wedge/Foot Rest vs Thermoplastic Cast: Variation in each Axis

	Thermoplastic cast	Knee wedge/foot rest	P value
X axis	2.575 ± 1.096	3.0304 ± 1.2035	$p=0.140$
Y axis	4.493 ± 1.758	2.1793 ± 0.9520	$p < 0.0001$
Z axis	3.173 ± 1.875	2.589 ± 1.006296	$p = 0.15$

P values were not significant in X (medio-lateral direction) or the Z (cranio-caudal direction) axes. It was found to be significant in Y axis (antero-posterior direction), with a p value of less than 0.0001.

Table 2: Knee Wedge/Foot Rest vs Thermoplastic Cast in Total

Thermoplastic cast	6.308± 2.17
Knee wedge/foot rest	4.67± 1.48
P value	0.002

As shown in the Table 2, if we take the variation in total the variation is significant when thermoplastic cast is compared to knee wedge/footrest immobilisation.

The bladder, rectal and bowel doses were calculated after giving the correction to the isocenter as per the EPID readings. This was done to just ascertain the possible difference that might have cropped up based on the variation in setup, keeping in mind that the internal organ based variations which occur daily, cannot be accounted for while replanning on the simulation CT scan. The bladder dose mean difference was -9.8 ± 1.33 in thermoplastic cast group & -0.51 ± 1.52 for the knee wedge/foot rest group, with a p value of 0.125. The rectal dose mean difference was -0.696 ± 1.51 in cast group and -1.30 ± 1.70 in knee wedge/foot rest group, with a p value of 0.596. The bowel dose mean difference was 0.716 ± 3.66 in the thermoplastic cast group and 0.094 ± 2.77 in the knee wedge/foot rest group, with a p value of 0.304. In all cases these values were not statistically significant.

DISCUSSION

Daily set up errors are an inherent part of conventional fractionated radiation therapy. Set up errors during radiation therapy for pelvic malignancies are perhaps larger than for any other site in the body. These large errors not only have the potential to alter day to day dose delivery to the target, but accounting for these large errors by applying bigger margins can offset the dosimetric advantage of highly conformal treatment modalities like IMRT, Rapid arc (VMAT) etc. A failure in delivering prescribed radiation doses to the target volume can ultimately lead to a lower cure rates. It has been widely observed that immobilization

devices are important in positioning reproducibility. In this study, the relative impact of thermoplastic orfit cast and the knee wedge/foot rest systems, on the reproducibility during uterine cervical cancer radiotherapy was evaluated.

Most of the studies in this regard are on prostate malignancies, but in contrast we have applied it in uterine cervical malignancy. As mentioned earlier, we have tried to ascertain the broad immobilization related issues related to any pelvic malignancy and focused on gross errors as opposed to internal organ related errors. As both are pelvic structures and since in our country cancer of the uterine cervix is more prevalent, this study is of significance.

In the study done by Cristopher Nutting *et al.* [7], in patients of carcinoma prostate receiving conformal radiotherapy, the use of immobilization system was prospectively analyzed. They evaluated the impact of customized immobilization system on field placement accuracy, simulation and treatment delivery time, radiographer convenience and patient acceptability. Despite the minor increment of patient comfort using immobilization system, the study did not prove any enhancement in treatment accuracy. With a lower total vector error value, the knee wedge foot rest system had smaller over all isocenter shifts than the thermoplastic cast system, making it more reproducible. Research has shown that rigid leg immobilizer systems are more reproducible than rigid pelvic abdominal ones. Study done by Fiorino *et al.* [8], showed that when considering average isocenter shift, improvements are observed using leg immobilization compared to other rigid immobilization like alpha cradle at pelvic level. The result of these analysis, showed that in patients immobilized for the pelvis from the waist to the upper thigh showed a significantly higher number of major shifts with respect to patients immobilized from the knees to the feet in postero-anterior direction and lateral direction. The two systems gave comparable results for the error in cranio-caudal direction. In our study we found that both thermoplastic cast group and knee wedge group didn't show any statistically

Table 3: OAR doses in Comparison with Knee Rest and Foot Rest

OAR doses	Thermoplastic cast	Knee wedge/foot Rest	P value
Bladder dose mean difference	-0.98 ± 1.33	-0.51 ± 1.52	P=0.125
Rectal dose mean difference	-0.696 ± 1.51	-1.30 ± 1.70	P=0.596
Bowel dose mean difference	0.716 ± 3.66	0.094 ± 2.77	P=0.0304

significant difference in error in either cranio-caudal or lateral direction, however the knee wedge/foot rest group showed decreased error formation in antero-posterior direction. The result of the study done by Fiorino *et al.* is comparable with our study, as our study also found decreased error in the antero-posterior direction in knee wedge/foot rest group which was statistically significant. It was not significant in cranio-caudal direction in concordance with Fiorino *et al.*

Bel *et al.* [9], investigated the set up accuracy in the conformal treatment of prostate cancer, verifying the possibility of an offline procedure for correcting systematic set up errors. Systematic errors were in particular found to be generally dominant with largest incidence in the postero-anterior direction. In our study too, the incidences of error were largest in postero-anterior direction, especially in thermoplastic group. It was significantly reduced by using knee wedge/foot rest system. An important question that comes up is why does leg immobilization work so well? It can be explained that, leg position is a parameter of paramount importance while positioning the patients supine. In particular, a comfortable leg immobilization (flexion at hip & knee with associated external rotation of the hips) reduces patient's rotations at hip level, which may cause a shift of the skin tattoos of the lateral ports and may result in apparent in PA shifts. Instead pelvic immobilization device was found to be quite uncomfortable for the patient in this aspect, especially in those who are obese.

Malone *et al.* [10], in a prospective comparison of three systems of patient immobilization for prostate radiotherapy, compared the set up reliability of three patient immobilization devices. A rubber leg cushion, the alpha cradle and the thermoplastic Hip fix device in patients receiving conformal radiotherapy for prostate cancer were compared. The Hip-fix was found significantly superior to the other two devices in reducing mean set up errors in all axes. The average field-positioning error with the Hip-fix ranged from 1.9 mm to 2.6 mm for all axes, whereas the deviations for the other two systems ranged from 2.7 to 3.4 mm. They concluded that, there was a significant difference in performance of each immobilization device. Hip-fix was consistently more reliable in reducing setup errors than the other two devices. These results were comparable to our study, in which we have reported that thermoplastic cast immobilization system has shown inferior results compared with knee wedge/foot rest immobilization system. The total vector error also was

more in thermoplastic cast group and was statistically significant. However we need to keep in mind that in the study done by Malone, thermoplastic Hip-fix group had immobilized the patients in prone position & the other two arms used supine position. They have commented that they wanted to explore the potential advantage of prone position for conformal radiotherapy. Ideally, the study should have evaluated each of these immobilization systems in similar conditions, to allow for a direct comparison as was done in our study.

Peter white *et al.* [11] has done a similar study, in which they compared two systems of patient immobilization devices for prostate radiotherapy. They compared the reproducibility of patient positioning with Hip-fix system and whole body alpha cradle used for the treatment of localized prostate cancer. The total vector values were 5.1 and 2.8 mm for Hip-fix and whole body alpha cradle systems respectively. The total vector error associated with the whole body alpha-cradle system was found to be significantly less than Hip-fix system. In our study, the total vector error values obtained for thermoplastic cast immobilization device is 6.308 ± 2.17 , and for knee wedge/foot rest is 4.67 ± 1.48 . It is statistically significant in favor of knee wedge/foot rest. Also, there were lesser error values shown by thermoplastic cast in terms of deviation in medio-lateral axis, and greater error values in cranio-caudal axis. But these values were not statistically significant. However, knee wedge/foot rest system has shown significantly lesser error values in the antero-posterior direction in comparison with thermoplastic cast ($p < 0.0001$). This result could also be attributed to the weight loss during the radiation therapy period, as these patients are prone to develop diarrhea and vomiting and associated with anorexia. These results are in contrast with the results obtained by the study done by Peter *et al.* in that the whole body alpha cradle system was found to be better than thermoplastic cast in terms of reproducibility in the cranio-caudal direction.

A comparison of 4 different kinds of patient immobilization in prostate cancer patients receiving conformal radiation therapy was done by Song *et al.* [12]. In this study, four immobilization systems were compared among each other and also with no immobilization. There was no significant difference among the groups in the overall movement, but there were significant differences when assessed specifically in the vertical and lateral directions. The aquaplast immobilization had the smallest movement probability

in the vertical and antero-posterior directions, but it had the largest movement probability in the lateral direction. Although there was decreased movement seen in the antero-posterior direction with the aquaplast, this was not significant. These results are in contrast with the present study, as the thermoplastic cast arm has shown decreased error in the lateral direction only, even though it was not significant. Also, antero-posterior movement was significantly greater with our patients in comparison with other arm. However, Song *et al.* observed significantly lesser antero-posterior movement with aquaplast cast. Again the use of concurrent chemo-radiation in uterine cervical cancers, results in patients developing diarrhea and anorexia during third and fourth weeks of radiation. This may contribute to weight loss during the radiation treatment course, which may not be a confounding factor in prostate cancer treatment. These factors contributed to variations during RT in spite of effective immobilization. Additionally, the bladder protocol followed in our department prior to radiation may affect the patients and make them more uncomfortable once they develop acute cystitis changes, especially inside a rigid thermoplastic cast. This also may contribute to the total error developed by the thermoplastic cast system.

Most of the studies so far were done in prostatic malignancies & to the best of our knowledge, this study is the only study done in uterine cervical malignancy treated with 3DCRT technique. As our study showed that the knee wedge/foot rest system was better than the thermoplastic system, there is an added advantage that the same knee wedge/foot rest system can be reused for many patients. However, we need to keep in mind that our sample size was small and we have utilized two-dimensional verification system, such as EPID, for verification

CONCLUSION

Knee wedge/Foot rest system is better than the thermoplastic cast system in terms of

- Lesser error in A-P direction
- Reduced total vector errors.

When these errors were compared with mean dose difference to OARs, obtained by a re-planning process on the simulation scan, it was not found to be statistically significant. Hence we would like to conclude that, Knee wedge/Foot rest system is better than thermoplastic cast system for the process of

immobilization in uterine cervical malignancies. Since this study was based on 2D image verification, further studies may need to be conducted using three dimensional imaging such as Cone beam CT scan (CBCT or kVCT).

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