Da Chien General Hospital

Radiation Oncology Department

Radiotherapy Protocol and Regimen for Breast Cancer

I. Aim: To let the general public be aware of breast cancer and it treatment choice and be inform on the protocol and regimen for radiation therapy of said condition.

II. Primary indication for radiation therapy:

1. Curative intent:

1. Post breast conservation surgery adjuvant therapy

a.No pre-OP adjuvant Chemotherapy:Clinical Stages DCIS, I, II, III。

b.With pre-OP adjuvant Chemotherapy: Clinical Stages I, II, III。

2.Post modified radical mastectomy adjuvant radiotherapy

a. Tumor of more than 5 cm(T3)

b.Positive axillary LN >4 (N2,N3)

c. Positive axillay LN 1-3 nodes(N1)：with high risk factor:

T2 and above,high grade, <50 year old, lymphovascular permeation

d. Close surgical margin.

3. Neoadjuvant radiotherapy of very large tumor

a. Local recurrent tumor without distant metastasis

2 . Palliative intent:

1. Brain, bone metastasis

2. Symptomatic local distant metastasis

III. Meidcal personnel involved.

3.1 Accredited radiation oncolgist: Responsible for the overall assessment of patient disease condition, and to formulate treatment strategy, planning and dosimety and monitoring of entire treatment course with assessment of treatment response and side effect and formulation of post treatment followup and assessment.

3.2 Accredited nursing personnel: Responsible for clinical assessment of patient daily status, and give necessary nursing care and instructions

3.2 Accredited medical physicist:Responsible for formulation of treatment plans and ensuring the accuracy and precision of the linear accelerators and plans dosimetry

3.3 Accredited radiotherapist：Responsible for fabrication of

immobilization devices, CT simulation, treatment verification films, portal films and accurate delivery of the radiation treatment and daily QA of treatment machines.

IV. General nomenclatures:

4.1 Gross Tumor Volume(GTV) delineate the tumor extent as shown in CT scan and high risk regions.

4.2 Clinical Target Volume(CTV) delineate the tumor including probable invaded regions

4.2 Planning Target Volume(PTV)：CTV including margin for random and systemic error involved.

4.3 centiGray (cGy)：radiation dose unit.

V. Main treatment protocol

5.1 Mannufacture of immobilization devices

5.1.1 Patient is made to lie down in supine position

5.1.2 Uses vacuum bag as immobilization device to ensure reproducibity and accuracy.

5.1.3 Head of patient tilted from the treated side with hand raise above head

5.1.4 Marking of the treatment center and the lateral side

5.1.5 Reconfirm the treatment center before commencing CT simulation

5.2 Commencement of CT simulation

5.2.1 Before commencing CT simulation, patient should be on the immobilization device and on treatment position.

5.2.2 Placement of CT fiducial to mark the center and lateral marking of patient

5.2.3 The region of interest in CT scan images should be confirm by radiation oncologist

(1) Involves the whole thorax, from to 5 cm below sternal notch

(2)Slice thickness should be between 3-5 mm.

5.2.4 After taking the CT simulation images, the data should be transfer to the radiation treatment planning computer.

5.3 Target Volume Definition and Radiation Therapy Planning:

VI. Treatment dose prescription and treatment delivery

6.1 Dose prescriptions

6.1.1 Daily dose：：180 cGy/fraction/day。

6.1.1.1 Overall dose

6.1.1.1.1 Main tumor 4500-5000 cGy

6.1.1.1.2 High risk region, boost electron therapy: 1000-1200 cGy 6.1.1.2 Normal tissue constraints:

6.1.1.2.1 Ipsilateral lung

6.1.1.2.1.1 V20 <15%

6.1.1.2.2 Contralateral lung

6.1.1.2.2.1 V5 <10%

6.1.1.2.3 Heart

6.1.1.2.3.1 Left breast V20 <5%

6.1.1.2.3.2 Right breast V20 0%

6.1.1.2.3.3 Average heart dose：ideal<400 cGy；<500 cGy is acceptable

6.2 Treatment delivery

6.2.1 high output medical linear accelator using 6 MV photons.

6.2.1.1 Initial confirmation of relevant data.

6.2.1.2 Take IGRT pictures.

6.2.2.2.1 Do image fusion to confirm the position of patient is the same as on pretreatment images

6.2.2.3 Actual delivery of IMRT or FIF radiation

VII. Treatment schema of breast ca treatment

Breast biopsy/OP→ Pre-R/T evaluation → Radiation delivery4500-5000 cGy/25-28 fractions(IMRT/IGRT)or (FiF/IGRT)

V111 Possible side effects and recommended management

Possible side effects: Possibility of side effects depends on the type of surgery done,chemotherapy given, the timing,radiation dose, treated area, initial disease staging, age of treatment and individual differences.

1, Acute side effects(within 3 months after radiation)

- Depending on the site of treatment: dermatitis, including change in color(from reddish to brownish discoloration, desquamation and bullae formation). Need medical care and preventions.
- Axillary operative wound pain: portion of patient exhibit and need medical treatment
- Breast edema: some patient may developed breast edema, resolve spontaneously.

2、Chronic side effects(occurs more than 3 months after radiation):

- Breast fibrosis and shrinkage。
- 2. Ipsilateral arm edema：usually less than15%
- 3. Involved side arm neuropathy：usually less than 5%
- 4. 4. Lung disease: Fibrosis or inflammatory changes, usually asymptomatic but may cause coughing and dyspnea.
- 5. Cardiac disease:Pericarditis or vascular change， use of

anthracycline chemotherapy drug can increase the frequency

6.

3. All treatment related side effect should be written in patient chart and also the treatment given and radiation dose given. The should be radiation treatment plans and summary in every chart.

4、Treatment of radiation induce dermatitis: Judicious use of topical medications

VIII.Post radiation treatment followup schema:

1. First 3 months, monthly followup, check tumor markers e.g. CA153,CEA etc and general evaluation.

2. After 3 months: Every 3 to 6 months followup， check necessary tumor markers and general evaluation

3, Repeat followup CT scan or CT_PET every3-6 months to evaluate tumor control.

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Da Chien General Hospital

Radiation Oncology Department

Radiotherapy Guidelines and Regimen for Rectal Cancer

- Introduction and rationale

  Colorectal cancer (CRC) is a common and lethal disease. Approximately 11004 new cases of large bowel cancer are diagnosed each year in Taiwan, of which 6277 were in male subjects and 4727 in female. Approximately 4400 Taiwanese die of colorectal cancer each year[1]. Although CRC mortality has been progressively declining since 1990 at a rate of about 3 percent per year, it still remains the third most common cause of cancer death in the Taiwan. Surgical resection is the primary treatment modality for CRC, and outcome is most closely related to the extent of disease at presentation. Screening with fecal occult blood testing, endoscopy, or radiology can lead to diagnosis at an earlier stage of disease and thereby reduce cause-specific mortality. Compliance with screening guidelines is improving but still relatively low; CRC continues to be diagnosed after the onset of symptoms in the majority of patients [2]. Radiotherapy is a major part of the treatment to improve tumor control rate.

I. Main Rationale: Post OP adjuvant IMRT/IGRT of rectal carcinoma has been in practice for a long time, with very good results and loco-regional control rate
II. Primary Indications:
   (1) Rectal cancer with at least regional LN mets or locally advance disease
   (2) With suspected microscopic residual tumor
   (3) Patient who refuse surgery is also a candidate for primary IMRT/IGRT with adjuvant chemotherapy
III. Post OP Adjuvant treatment for locally advanced disease:
   (1) With pathology reporting Ln mets
   (2) lymph node (+) or resection margin (+)
IV. Primary IMRT/IGRT for patient refusing to have surgery.

SOP for treatment planning:

1. Initial general evaluation and general data input
2. Pre-treatment health education and options elaboration.
3. Pre-treatment procedures:

3.1. Immobilization.
3.1.1. Vacuum immobilization mattress fabrication.
3.1.2. Patient in supine position.
3.1.3. Urinary bladder in normal status
3.2. CT scan images acquisition from CT simulators
3.2.1. Treatment center designation.
3.2.2. Laser positioning and initial scout film acquisition.
3.2.3. Designation of region of interest.
3.2.4. CT scan images acquisition.
3.2.5. Transfer of CT images to the treatment planning computer.
3.3. Computer treatment planning and dosimetry
3.3.1. Delineation of actual treatment center
3.3.2. Contouring of normal organs and tissue
3.3.3. Designation of CTV and PTV with appropriate margins

3.3.4. Computer treatment planning (IMRT or RapidArc)
3.3.5. Evaluation of initial treatment plans and plans selection.
3.3.6. Confirmation of treatment plans and QA of plans.
3.3.7. Doctor's approval and hardcopy prints of the decided plans
3.3.8. Signature of physicist and attending doctor of the selected plans.
3.4. Dose prescriptions:
3.4.1. Dose per fraction: 1.8-2.0 Gy/fractions daily
3.4.2. Total dose:
3.4.2.1. Primary tumor regions: 65-70 Gy
3.4.2.2. Adjacent regions: 50-60 Gy
3.4.2.3. Normal tissue constraint
3.4.2.3.1. Rectum
3.4.2.3.1.1. V65 < 17%
3.4.2.3.1.2. V40 < 35%
3.4.2.3.2. Small bowel
3.4.2.3.2.1. V65 < 5%
3.4.2.3.2.2. V40 < 10%
3.4.2.3.3. Femoral head
3.4.2.3.3.1. V50 < 5%
3.5. Treatment delivery
3.5.1. High dose rate computer assisted linear acceleration (10 MV)
3.5.2. Initial setup verification
3.5.3. IGRT
3.5.4. verification of treatment portal
3.5.5. Actual treatment delivery
4. Treatment schema for Primary IMRT/IGRT to patient refusing surgery.
4.1.1. Initial biopsy → General studies and evaluation → induction chemo-RT to 50-55 Gy/28-31 fractions → rest 1 weeks → second-look CT scan and replanning for phase 2 IMRT/IGRT or RapidArc boost: 15 Gy/8-9 fractions.
5. Follow-up regimens
5.1.1. Follow-up with CEA and CA19-9 every 3 months × 1 year, every 6 months × 2 year, then annually. CT abdomen and pelvis q 1–2 year.

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Da Chien General Hospital

Radiation Oncology Department

Radiotherapy Protocol and Regimen for Endometrial Carcinoma

I. Guidelines and protocol for radiation therapy of endometrial cancer

II. Scopes: Indicated for radical treatment of endometrial carcinoma

III. Meidcal personnel involved.

1. Accredited radiation oncolgist: Responsible for the overall assessment of patient disease condition, and to formulate treatment strategy, planning and dosimety and monitoring of entire treatment course with assessment of treatment response and side effect and formulation of post treatment followup and assessment.
2. Accredited nursing personnel: Responsible for clinical assessment of patient daily status, and give necessary nursing care and instructions
3. Accredited medical physicist:Responsible for formulation of treatment plans and ensuring the accuracy and precision of the linear accelerators and plans dosimetry
4. Accredited radiotherapist：Responsible for fabrication of immobilization devices, CT simulation, treatment verification films, portal films and accurate delivery of the radiation treatment and daily QA of treatment machines.

IV.Medical terms

4.1 FIGO Staging and TNM Staging

FIGO		TNM
	Primary tumor cannot be assessed	TX
	No evidence of primary tumor	T0
*	Carcinoma in situ (preinvasive carcinoma)	Tis
I	Tumor confined to corpus uteri	T1
IA	Tumor limited to endometrium or invades less than one-half of the myometrium	T1a
IB	Tumor invades one-half or more of the myometrium	T1b
II	Tumor invades stromal connective tissue of the cervix but does not extend beyond uterus**	T2
IIIA	Tumor involves serosa and/or adnexa (direct extension or metastasis)	T3a

IIIB	Vaginal involvement (direct extension or metastasis) or parametrial involvement	T3b
IVA	Tumor invades bladder mucosa and/or bowel mucosa (bullous edema is not sufficient to classify a tumor as T4)	T4

* FIGO staging no longer includes Stage 0 (Tis)

** Endocervical glandular involvement only should be considered as stage I

and not Stage II.

Regional Lymph Nodes (N)

FIGO		TNM
	Regional lymph nodes cannot be assessed	Nx
	No regional lymph node metastasis	N0
IIIC1	Regional lymph node metastasis to pelvic lymph nodes	N1
IIIC2	Regional lymph node metastasis to para-aortic lymph nodes, with or without positive pelvic lymph nodes	N2

Distant Metastasis (M)

FIGO		TNM
	No distant metastasis (no pathologic M0; use clinical M to complete stage group)	M0
IVB	Distant metastasis (includes metastasis to inguinal lymph nodes intraperitoneal disease, or lung, liver, or bone. It excludes metastasis to para-aortic lymph nodes, vagina, pelvic serosa, or adnexa)	M1

TNM STAGE

Stage	0	Tis	N0	M0
Stage	I	T1	N0	M0
Stage	IA	T1a	N0	M0
Stage	IB	T1b	N0	M0
Stage	II	T2	N0	M0
Stage	III	T3	N0	M0
Stage	IIIA	T3a	N0	M0
Stage	IIIB	T3b	N0	M0
Stage	IIIC1	T1-T3	N1	M0
Stage	IIIC2	T1-T3	N2	M0
Stage	IVA	T4	Any N	M0
Stage	IVB	Any T	Any N	M1

4.2 Clinical Target Volume (CTV) Involve gross tumor region with safe margin of 0.2-0.5 cm, including the following regions: presacral nodes, internal iliac nodes, external iliac node and distal common iliac noted and other regional nodes involved.
4.3 Planning Target Volume (PTV) Includes CTV with safe margins of 0.2-0.5 cm.
4.4 CentiGray (cGy): Unit of radiation dose.

5. Treatment Planning Procedures:

5.1 Prepare for immobilization：

5.1.1 Every patient will use s upine position

5.1.2 For reproducibility, we'll use 90 cm.long vacuum bag as primary immobilization device, covering the dorsal part of trunk and upper thigh

5.1.3 Lower extremities should be position without any stress to patient

5.1.4 Center marks at the region 5 cm below umbilicus

5.1.5 Before performing computed tomography simulation), patient should be informed to take low residue diets

5.2 CT simulation:

5.2.1 Patient is arrange in the treatment position at the CT simulation room

5.2.2 Center marks at skin is delineated and marked by indelible inks.

5.2.3 Scope of CT simulation:

(1) CT scan images include region at the L3 region to the region 5 cm below subpubic area.

(2) CT images slice thickness:3~5 mm

5.2.4 Transfer the acquire images to the Eclipse computer treatmetn planning system.

5.3 Delineation of target volume definition(CTV)and planning target volume(PTV):

5.3.1 Endometrioid carcinoma

5.3.1.1 Stage I Post OP staging and adjuvant treatment and radiation scopes:

		G1	G2	G3
IA	No risk factors	Regular followup	Regular FU brachytherapy	Regular FU brachytherapy
	With risk factors*	Regular FU brachytherapy	Regular FU brachytherapy and/or EBRT	Regular FU brachytherapy and/or EBRT
IB	No risk factors	Regular FU brachytherapy	Regular FU brachytherapy	Regular FU brachytherapy and/or EBRT

	With risk factors*	Regular FU brachytherapy and/or EBRT	Regular FU brachytherapy and/or EBRT	Regular FU brachytherapy and/or EBRT ,Chemotherapy

*High risk factors：Age >60, lymphovascular invasion, large tumor(>2cm), involved lower uterine regions.

5.3.1.2 Stage II、IIIA Post OP staging and adjuvant treatment and radiation scopes:

	G1	G2	G3
II	Intravaginal brachytherapy +pelvic EBRT	Pelvic EBRT + Intra vag. brachytherapy	Pelvic EBRT + Intra vag. brachytherapy ,Chemotherapy
IIIA	CCRT or Pelvic EBRT + Intra vag. brachytherapy	CCRT or Pelvic EBRT + Intra vag. brachytherapy	Chemo±Pelvic EBRT + Intra vag. brachytherapy± Chemo orPelvic EBRT + Intra vag. brachytherapy

5.3.1.3 Stage IIIB~IVB Post OP staging and adjuvant treatment and radiation scopes:

IIIB	Chemo±Pelvic EBRT
IIIC1	Chemo±Pelvic EBRT
IIIC2	Chemo±Pelvic EBRT
IVA、IVB	Chemo±Pelvic EBRT

(1)Post OP CTV includes vagina,common iliac lymph nodes,internal and external iliac lymph nodes. CTV of lymphatics should includes periarterial and perivenous LN, care should be given to overlapping regions, upper limit at L5/S1down to superior aspect of pubic bones.If there is uterine cervical invasion,CTVincludes LN at S1-S3presacral lymph nodes and soft tissue，if para-aortic lymph node are involve, CTV should includes this regions.

(2)PTV：CTV plus 0.2cm margins

(3)Post OP PTV will deliver 6120 cGy/34 fractions, once daily, 5 days a week. For bulky tumor additional1000 cGy.

(4)PTVdose presciptions:

a. Prescription dose to include 97% of PTV，<0.03 cc of PTV received

>105%of prescribe dose，<0.03 cc of PTVreceived <95%of prescribe dose.

(5)Vaginal brachytherapy(HDR):

a.Post pelvic EBRT : vaginal brachytherapy 500cGy x 6

b.Only Vaginal brachytherapy: 500cGy x 6

5.3.2Papillary serous, clear cell or carcinosarcoma

5.3.2.1 Stage IA A After staging debulking surgery:(No uterine wall invasion): Close followup or chemotherapy or tumor bed EBRT

5.3.2.2 Stage IA After staging debulking surgery:(with invasion of uterine wall): Chemotherapy，Pelvic tumor EBRT orwhole abdomen EBRT， brachytherapy

5.3.2.3 Stage IB and II After debulking surgery: Chemotherapy，tumor EBRT or whole abdomena EBRT，brachytherapy。

5.3.2.4 Stage III, IV After debulking surgery: Chemotherapy，whole abdomenal EBRT or localized EBRT to tumor region ，brachytherapy

5.3.2.5 Stage III, IV After debulking surgery:Post OP adjuvant chemotherapy.

5.4 Organ at Risks and their Dose Constraints：

5.4.1 Rectum

(1)Region of interest:Rectum lower margin should have 1 cm distance from PTV, including recto-sigmoid junctions.

(2)Dose constraint:

a. $V_{60\%} \leq$ 4000 cGy (60%of all rectal volume should have $\leq$ 4000cGy

b.Acceptable:$V_{60\%}$>4000cGy, but <4500cGy

c.Not acceptable:$\geq$ 0.03 cc rectal volume >6500 cGy and $V_{60\%}$>4500 cGy

5.4.2 Urinary Bladder

(1)Region of interest:Include all urinary tract and urinary bladder

(2)Dose constraint:

a. $V_{35\%} \leq$ 4500 cGy (35%of bladder volume should have $\leq$4500cGy

b. Acceptable:$V_{35\%}$>4500 cGy but <5000cGy

c. Not acceptable:$\geq$ 0.03 ccof bladder volume>6500 cGyand $V_{35\%}$>5000 cGy

5.4.3 Femoral Head

(1)Region of interest:bilateral femoral head

(2)Dose constraint: both head individually monitor

a. $V_{15\%}$ <3500 cGy (15%of femoral head dose should be <3500cGy

b. Acceptable:$V_{50\%}$ <3500 cGy

c. Not acceptable:$\geq$ 0.03 ccof femoral volume>6500 cGy and $V_{50\%}$>3500 cGy

5.4.4 Bowel

(1)Region of interest:Bowel margin should 2 cm above PTV, includes peritoneal margins

(2)ose constraint:

a. $V_{30\%} \leq$ 4000 cGy (30% bowel volumes≤4000 cGy

b. Acceptable: $V_{30\%}$>4000 cGy. but <4500cGy

c. Not acceptable:≥ 0.03 cc bowel volume >6500 cGy and$V_{30\%}$>4500 cGy

5.5 Treatment Verification

5.5.1 3DCRT and IMRT patient：Pre-treatment verification films and weekly verfication should be taken.

5.5.2 Image guided radiation therapyIGRT):For accuracy purposes, daily image guided radiotherapy should be carried out for all patient.

II. Delivery of Radiation to Uterine Endometrial Cancer Patient

1.Initial assessment for radiation therapy.

1.1 Initial assessment is base ofn clinical evaluation, physical examination findings, biochemical examination findings, imaging findings and pathological reports and will do initial staging of disease. If patient had surgical treatment, surgical and pathological finding will be included in the treatment decision process.

1.2 The final decision for treatment will be done by radiation oncologist and will accept recommendation from the multidisciplinary physician team.

2. Preparation for radiation therapy:

2.1 Patient will be inform by treating physician on the indication for radiation therapy.

2.1.1 If patient meet the indications for radiation therapy, or have undergone discussion by multidisciplinary meeting, and was informed by physician on the indication for treatment and possible side effects and also alternate treatment modality, then will arrange for radiation treatment planning.

2.1.2 If patient and family agrees to primary radiation therapy, then the treatment planning process and other pertinent information will be given.

2.2 Signing of informed consent:

2.2.1 Patient after careful explanation of disease and treatment process, agrees to treatment have to sign informed consent. “Da-chien General Hospital Radiation Therapy Informed Consent” forms.

2.2.2 If consent is signed by patient relative, his relation to patient should be indicated, and signature of consignee and patient thumb prints should be obtained. “Da-chien General Hospital Radiation Therapy Patient General Information” forms.

2.3 Pretreatment patient educations.

2.3.1 Inform case managers for patient pre-treatment education concerning radiation therapy and general cares.

2.3.2 Radiation oncologist nursing specialist will do department tours and other nursing care educations about radiation treatments.

2.4 Pre-treatment CT scan images acquisition and simulation.

2.4.1 For safety purposes, patient inform the department about any idiosyncracies or allergic history and signed“Da-chien General

Hospital Radiation Therapy Patient General Information”forms.

2.4.2 Before obtaining CT scan images, patient should signs “Da-chien General Hospital Radiation Therapy CT scan simulation consent forms”.

2.4.3 Attending physicial will prescribe the area and kind of immobilization needed for this radiation therapy course. Will signs the ”Da-chien General Hospital radiation treatment plans”.

2.4.4 Radiologist will arrange for immobilization and will do CT scan images acquisition with attending physician supervision.

2.4.5 The CT scan images is transfer to the radiation oncology “Eclipse” treatment planning systems databank.

2.5 Generation of Treatment Plans:

2.5.1 The attending physician should be responsible for drawing CTV, PTV. Organ at risk and dose prescription for each regions.

2.5.2 Medical physicist will generate several plans for selection by attending physician of the best treatment possible.

2.6 Completion of the whole treatment plans.

2.6.1 The attending physician would be responsible for completion of the whole radiation therapy chart and plans.

2.6.2 Contents of radiation therapy charts includes pathological reports and staging, past and present history, family history, system reviews, physical examination, biochemical studies and tumor markers status, and relevant radiation therapy data.

III. Radiation Therapy Procedures:

3.1 Confirm patient identity.

3.1.1 Patient identification system has dual confirmation system, on by insurance card and one by vebal confirmation of pateint name, if patient is staying at hospital to confirm by name tag and reciting patient name.

3.1.2 With patient consent, we'll take patient picture and will couple to their treatment plan for future referencing by radiation therapist.

3.2 Initial verification films

3.2.1 Radiation therapy will take verification film and assessment of congruity with initial simulation films. If fitting is good, then delivery radiation treatment.

3.2.2 Weekly review of verification film is done to confirm the accuracy of treatment delivery.

3.3 Clinical response and side effect assessments

3.3.1 Weekly clinical assessment of radiation tumor response and clinical side effects of radiation treatment, and recorded at the OPD SOAP and radiotherapy charts.

3.3.2 Weekly measurement and recording of TPR, body weight, and laboratory studies results including CBC+DC, platelet count, and clinical assessment of nutritional status and recorded in hospital chart.

3.4 Clinical Chart Round

3.4.1 Weekly new patient clinical chart round to assess accuracy of clinical records and discuss possible problems.

IV. Post Radiation Therapy Clinical Procedures

4.1 Nursing care education:

4.1.1 Registered radiation oncology nursing staff will give patient complete post treatment nursing care education and will give practical teaching.

4.1.2 Will arrange for time of next visitation.

4.2 Completion of radiation treatment summary records

4.2.1 Radiation treatment summary record will be responsibility of attending doctor and within 1 week post treatment.

4.2.2 Content of summary of radiation therapy completion notes.

- Patient's general data：name, sex, birhtday, age at time of treatment, patient chart number.
- Radiation therapy treatment equipments and department name,
- Start and end of radiation therapy,
- Name of the registered radiation oncologist,
- Treatment given (e.g. surgery, chemotherapy and radiation therapy and their sequencing,
- Region of treatment, either generalized or local boost therapy,
- Radiation treatment equipment (e.g. LINAC, IORT or brachytherapy)
- Technique of radiation therapy (e.g. IMRT, RapidArc, Stereotactic radiosurgery)
- Region of target delineation and their ICRU references and fractionation.
- Tumor characteristic: anatomical site and pathological classification
- Tumor staging: Initial tumor staging, pathological type and differentiation and recurrent tumor (present staging)

- Other pertinent clinical history, and patient performance status
- Other multimodal treatment given: surgery and date, systemic treatment, time and dates.
- Pertinent clinical information for radiosurgery treatment: Target delineation and volume, radiation dosage to volume of target, dose volume histogram, maximal and minimal dose to target volume, mean target dose.
- Record of daily radiation regimen: Did patient complete entire radiation treatment, assessment of response and side effects and treatment of side effects and post treatment important reminders, further followup regimen and other notices.

4.3 Followup regimen for cancer patient:

4.3.1 Initial post treatment followup: assess acute reaction and recovery status.

4.3.2 Base on the uterine endometrial cancer followup guidelines, we'll arrange for pertinent biochemical and tumor markers studies and imaging studies.

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Da Chien General Hospital

Radiation Oncology Department

Radiotherapy Protocol and Regimen for Nasopharyngeal Cancer

▪ Introduction and rationale

Nasopharyngeal carcinoma is the predominant tumor type arising in the nasopharynx, the narrow tubular passage behind the nasal cavity. It differs from other head and neck squamous cell carcinomas in epidemiology, histology, natural history, and response to treatment. Worldwide, there are 80,000 incident cases and 50,000 deaths annually [1]. Nasopharyngeal carcinoma displays a distinct racial and geographic distribution, which is reflective of its multifactorial etiology.

The incidence of nasopharyngeal carcinoma demonstrates a marked geographical variation. In the United States and Western Europe, it is rare, with an incidence of 0.5 to 2 per 100,000 [2-4]. In contrast, nasopharyngeal carcinoma is endemic in southern China, including Hong Kong, where the incidence may reach 25 cases per 100,000 per year. Intermediate risk regions include Southeast Asia, North Africa and the Middle East, and the Arctic. Populations that migrate from areas of high to low risk retain an elevated risk, although this risk typically diminishes in successive generations [3]. M:F ratio is 2-3:1.

I. Main Rationale: Nasopharynx is a very special region with difficulty encountered if surgery is contemplated.

II. Primary Indications:

(1) Definitive diagnosis of nasopharyngeal carcinoma

(2) Completed all pre-treatment workup and dental studies and care

III. CCRT is indicated with very strong evidence of improved tumor control and survival advantage.

SOP for treatment planning

1. Initial general evaluation and general data input
2. Pre-treatment health education and options elaboration.

3. Pre-treatment procedures:

3.1. Immobilization.

3.1.1. Head and neck thermoplastic mask fabrication

3.1.2. Patient in supine position.

3.1.3. Head and neck in standard position, with head on headrest and bite formulation.

3.2. CT scan images acquisition from CT simulators

3.2.1. Treatment center designation.

3.2.2. Laser positioning and initial scout film acquisition.

3.2.3. Designation of region of interest.

3.2.4. CT scan images acquisition.

3.2.5. Transfer of CT images to the treatment planning computer.

3.3. Computer treatment planning and dosimetry

3.3.1. Delineation of actual treatment center

3.3.2. Contouring of normal organs and tissue

3.3.3. Designation of CTV and PTV with appropriate margins

3.3.4. Computer treatment planning (IMRT or RapidArc)

3.3.5. Evaluation of initial treatment plans and plans selection.

3.3.6. Confirmation of treatment plans and QA of plans.

3.3.7. Doctor's approval and hardcopy prints of the decided plans

3.3.8. Signature of physicist and attending doctor of the selected plans.

3.4. Dose prescriptions:

3.4.1. Dose per fraction: 1.8-2.0 Gy/fractions daily

3.4.2. Total dose:

3.4.2.1. Primary tumor regions: 68-74 Gy/35-40 fractions

3.4.2.2. Adjacent regions: 60-63 Gy/35-40 fractions

3.4.2.3. Normal tissue constraint

3.4.2.3.1. Spinal cord

3.4.2.3.1.1. Dmax≦45 Gy (≦50 Gy in difficult cases) Priority 1

3.4.2.3.2. Brainstem

3.4.2.3.2.1. Dmax≦50 Gy (≦55 Gy in difficult cases) Priority 1

3.4.2.3.3. Lens

3.4.2.3.3.1. Dmax≦6 Gy Priority 2

3.4.2.3.4. Optic nerves/optic chiasm

3.4.2.3.4.1. Dmax≦50 Gy Priority 2

3.4.2.3.5. Eyes

3.4.2.3.5.1. Dmean≦35 Gy Priority 2

3.4.2.3.6. Parotid gland

3.4.2.3.6.1. Dmean≦26 Gy (at least 1 gland

3.5. Treatment delivery

3.5.1. High dose rate computer assisted linear acceleration (6 MV)

3.5.2. Initial setup verification

3.5.3. IGRT

3.5.4. verification of treatment portal

3.5.5. Actual treatment delivery

4. Planning Goals:

4.1. The prescription dose is the isodose surface that encompasses at least 95% of the planning target volume (PTV).

4.2. No more than 20% of any PTV will receive ≥ 110% of the prescribed dose.

4.3. No more than 1% or 1 cc of the tissue outside the PTVs will receive ≥ 110% of the dose prescribed to the PTV.

4.4. No more than 1% of PTV will receive ≤ 93% of the prescribed dose

5. Follow-up regimens

5.1.1. Follow-up with endoscopic examination and tumor markers studies with EBV titer every 3 months × 1 year, every 6 months × 2 year, then annually. CT head and neck q 1–2 year.

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Da Chien General Hospital
Radiation Oncology Department
Radiotherapy Regimen for Non-small Cell Lung Cancer (NSCLC)

▪ Introduction and rationale

When a patient presents with suspected non-small cell lung cancer (NSCLC), the diagnosis should be confirmed and both the histologic type and disease stage should be determined. The disease stage is a measure of the extent of disease, which is used to determine prognosis and guide management. All patients with suspected NSCLC should undergo a history, physical examination, laboratory testing, and computed tomography (CT) of the chest with intravenous contrast. Most patients require additional imaging. The purpose of the evaluation is to identify a target lesion for tissue sampling. The sampling target should be the lesion that will establish the highest disease stage, assuming that the lesion is not inaccessible or particularly high risk. If initial tissue sampling provides inconclusive results or the clinical stage of disease remains unclear, then a second procedure may be indicated. There is usually enough information to determine the disease stage once the history, physical examination, laboratory testing, imaging, and tissue sampling are complete. Staging is based upon the tumor node metastasis (TNM) staging system for NSCLC. Tumor node metastasis (TNM) staging system for non-small cell lung cancer.

I. Main Rationale: Non-small cell carcinoma can be treatment by surgery followed by post OP adjuvant EBRT, of can be treated as primary CCRT. Depending on the disease status of patient.
II. Primary Indications:
    (1) Relative advance lung cancer with definitive LN mets
    (2) In conjunction with chemotherapy as primary treatment
    (3) Patient refused radical surgery
    (4) Palliative treatment of mets
III. Post OP Adjuvant treatment for locally advanced disease:
    (1) Patient with pathologically proven microscopic residual tumor
    (2) Patient with positive margins.
IV. Treatment for palliation of metastatic symptoms

SOP for treatment planning:

1. Initial general evaluation and general data input
2. Pre-treatment health education and options elaboration.
3. Pre-treatment procedures:

3.1. Immobilization.

3.1.1. Vacuum immobilization mattress fabrication.

3.1.2. Patient in supine position.

3.1.3. Special accessory if needed

3.2. CT scan images acquisition from CT simulators

3.2.1. Treatment center designation.

3.2.2. Laser positioning and initial scout film acquisition.

3.2.3. Designation of region of interest.

3.2.4. CT scan images acquisition.

3.2.5. Transfer of CT images to the treatment planning computer.

3.3. Computer treatment planning and dosimetry

3.3.1. Delineation of actual treatment center

3.3.2. Contouring of normal organs and tissue

3.3.3. Designation of CTV and PTV with appropriate margins

3.3.4. Computer treatment planning (IMRT or RapidArc)

3.3.5. Evaluation of initial treatment plans and plans selection.

3.3.6. Confirmation of treatment plans and QA of plans.

3.3.7. Doctor's approval and hardcopy prints of the decided plans

3.3.8. Signature of physicist and attending doctor of the selected plans.

3.4. Dose prescriptions:

3.4.1. Dose per fraction: 1.8-2.0 Gy/fractions daily

3.4.2. Total dose:

3.4.2.1. PreOP tumor regions: 45-50 Gy

3.4.2.2. Post-OP adjuvant dosage: 50-60 Gy + Boost to primary residual regions: 10-12 Gy

3.4.2.3. Normal tissue constraint

3.4.2.3.1. Spinal Cord

3.4.2.3.1.1. V45 Gy <33%

3.4.2.3.2. Normal lung

3.4.2.3.2.1. V20 < 37%

3.4.2.3.3. Heart

3.4.2.3.3.1. V60 < 33%

3.4.2.3.3.2. V45 < 67%

3.4.2.3.4. Esophagus

3.4.2.3.4.1. V34 < 50%

3.4.2.3.5. Brachial Plexus

3.4.2.3.5.1. V45 <50%

3.5. Treatment delivery

3.5.1. High dose rate computer assisted linear acceleration (6 MV)

3.5.2. Initial setup verification

3.5.3. IGRT

3.5.4. verification of treatment portal

3.5.5. Actual treatment delivery

4. Treatment schema for palliative therapy

4.1.1. Initial verification of mets regions → Palliative-EBRT to 30 Gy/15 fractions

5. Follow-up regimens

5.1.1. Follow-up with tumor markers status, e.g. CEA; SCC etc. and chest X-ray every months × 3 months, every 6 months × 2 year, then annually. CT chest q 3-6 months.

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Da Chien General Hospital

Radiation Oncology Department

Radiotherapy Protocol and Regimen for Prostate Cancer

I. Main Rationale: To propose a guideline and general principle for treatment of prostate cancer.To educate the general public the process of treatment for prostatecancer patient and give them idea on the guiding principle behind treatment decisions, and have accurate information for their decision making

II. Primary Indications:

(1) curative intent

(a) primary radiotherapy

1. Depending on the risk and recurrence rate：very low, intermediate, high,very high and N 1.
2. Post OP adjuvant radiotherapy

1、 Radical prostectomy with followup risk factors:

i. positive or close margin
ii. Gleason's score=8-10
iii. positive LN, N1
iv. detectable PSA
v. extracapsular extension, T3a)
vi. seminal vesicle invasion, T3b)

3. Salvage radiotherapy

1、 Radical prostectomy involving following status:

i. recurrence
ii. PSA >0.2 ng/mLor at least 2 studies with high PSA-biochemical failure

(2) palliative intent

4. With distant metastasis, e.g.bone mets and pain.

III. Personnel involved:

3.1 Certified radiation oncologist:responsible for diagnosing disease, formulating treatment strategy, target delineation, monitors entire treatment process and responsible for disease followup.

3.2 Certified oncology nurse:Responsible for clinical care, educating patient on disease and general nursing cares

3.3 Certified medical physicist: Help radiation oncologist on initial setup and running of treatment planning and dosimetry for the patient.

3.4 Certified radiation therapist: responsible for fabrication of immobilization, CT simulation, taking onf verification and simulation film and actual daily delivery of radiation treatment.

IV. Definition of terms

4.1 Gross Tumor Volume (GTV) includes all visible tumor at CT scan images.

4.2 Clinical Target Volume(CTV)：includes all possible clinical tumor involvement, visible or inferred.

Planning Target Volume(PTV)：Includes CTV plus margin to cover for uncertainties, including motion and systemic errors.

4.3 CentiGray (cGy) unit use for dose prescription.

V. SOP for treatment:

1 Initial general evaluation and general data input

5.1 Pre-treatment health education and options elaboration.

5.2 Pre-treatment procedures:

5.3 Immobilization.

5.3.1 Vacuum bag for body immobilization.

5.4 CT scan images acquisition from CT simulators

5.4.1 Treatment center designation.

5.4.2 Laser positioning and initial scout film acquisition.

5.4.3 Designation of region of interest.

5.4.4 CT scan images acquisition.

5.5 Transfer of CT images to the treatment planning computer.

5.6 Computer treatment planning and dosimetry

5.6.1 Delineation of actual treatment center

5.6.2 Contouring of normal organs and tissue

5.6.3 Designation of CTV and PTV with appropriate margins

5.7 Computer treatment planning (IMRT or RapidArc)

5.8 Evaluation of initial treatment plans and plans selection.

5.9 Confirmation of treatment plans and QA of plans.

5.10 Doctor's approval and hardcopy prints of the decided plans

5.10.1 Signature of physicist and attending doctor of the selected plans.

VI. Dose prescriptions:

6.1.1 Dose per fraction: 1.8-2.0 Gy/fractions daily

6.1.2 Total dose:

6.1.2.1 Primary tumor regions: 68-74 Gy/35-40 fractions

6.1.2.2 Adjacent regions: 60-63 Gy/35-40 fractions

6.1.3 Normal tissue constraint

6.1.3.1 Rectum

6.1.3.1.1 V50 <50%

6.1.3.1.2 V60 <35%

6.1.3.1.3 V65 <25 %

6.1.3.1.4 V70 <15%

6.1.3.2 Bladder

6.1.3.2.1 V65 <50%

6.1.3.2.2 V70 <35%

6.1.3.2.3 V75 <25%

6.1.3.2.4 V80 <15%

6.1.3.3 Penile body

6.1.3.3.1 Mean dose to 95% of gland <5000 cGy

6.1.3.3.2 D90% <5000 cGy

VII Treatment delivery

7.1 High dose rate computer assisted linear acceleration (6 MV)

7.2 Initial setup verification

7.3 IGRT

7.3.1 verification of treatment portal

7.4 Actual treatment delivery

7.5 Treatment Schema for primary EBRT;

Patient refuse to have surgery--> Biopsy --> General Evaluation--> Delivery of IMRT/IGRT (7500-8100 cGy/41-45 fractions.

VIII. Possible side effect and management:

7.1 Side effects of prostatic carcinoma EBRT: the frequency and severity depends on the technique of radiation, dose, scope, disease staging, age of patient and indiviual differences.

7.1.1 Acute reaction(Within 3 months post treatment)

Depending on the scope of treatment: Mainly ileitis, cystitis, dermatitis; other reaction include poor appetite, diarrhea, abdomenal discomfort, frequent bowel movement,urinary frequency, dysuria, anal pain. Condition will become ameliorated after 2-4 weeks time.

7.1.1.1 Management of condition: consults physician and will give medications.

7.1.2 Chronic reactions(> 3 months post treatment)

7.1.2.1 Hemorrhagic proctitis: Happen in <20% of cases.

7.1.2.2 Hemorrhagic cystitis: Happen in <5% of cases.

7.1.2.3 Radiation proctitis：Happen in <5% of cases.

7.1.2.4 Bipedal edema：Happen in <5% of cases.

7.1.2.5 Ureteral fibrosis：Happen in <5% of cases.

7.1.2.6 Loss of sexual function:According University of Chicago studies，Post treatment 1,20,40,60 months, loss of sexual function occur in 96%、75%、59%、53%。

7.1.3 Treatment of side effect is given by attending physician according to the conditions.

VIII Post treatment followup

8.1 First 3 months, monthly followup and check PSA、CEA level.

8.2 After 3 months, followup every 3 to 6 months and monitor tumor markers.

8.3 Followup CT scan or MRIC studies every 3-6 months.

8.4 Treatment of any residual side effect or any other conditions.

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Da Chien General Hospital

Radiation Oncology Department

Radiotherapy Protocol and Regimen for Uterine Cervical Cancer

I. Guidelines and protocol for radiation therapy of uterine cervical cancer

Indications for radiation therapy:

1.1 Patient with uterine cervical cancer with curative intent

1.2 Patient treatment will be based on decision of multidisciplinary consensus.

1.3 Patient whose case has not enter multidisciplinary meeting, but meets the criteria of protocol and guidelines for uterine cervical cancer.

1.4 Radiotherapy for palliative purpose of advance uterine cervical cancer including paraaortic LN, neck LN and bone and other organ mets.

1.5 Palliative radiotherapy for other metastatic disease or on patient who had previous EBRT history.

II. Radiation therapy dosimetry.

2.1 Post OP radiation dose:

2.1.1 Post OP radiation with clear margins: Dose of 5040 cGy, 180 cGy/fractions

2.1.2 Post OP radiation with surgical margin affected: Dose of 6120 cGy, 180 cGy/fractions

2.2 Primary IMRT/IGRT for patient without surgery:

2.2.1 Primary IMRT/IGRT dose of 6120 cGy, 180 cGy/fractions concommittant with chemotherapy regimen.

2.3 RapidArc boost therapy or remote controlled brachytherapy

2.3.1 For primary IMRT/IGRT aside from external treatment needs locoregional RapidArc boost with dose of 3060 cGy/17 fractions or Remote Afterloading Brachytherapy using HDR Ir-192 source to perform intracavitary brachytherapy, with dose of 500 cGy/fraction x 6 fractions to locoregional area.

2.4 For operated patient, RapidArc boost therapy or remote controlled brachytherapy

2.4.1 RapidArc boost therapy of 3060 cGy/17 fractions to vaginal cuff regions or brachytherapy to the vaginal cuff for dose 500 cGy/fractions x 6 fractions.

III. Radiation treatment area:

3.1 Gross Target Volume (GTV)

3.1.1 Tumor volume including the area cover by visible tumor at the CT scan images, as contoured by radiation oncologist

3.1.2 PET-CT images showing regions of pelvic LN with tumor invasion and metastasis, for possible boost therapy

3.2 Clinical Target Volume (CTV)

3.2.1 – Involve GTV region with safe margin of 0.2-0.5 cm, including the following regions: presacral nodes, internal iliac nodes, external iliac node and distal common iliac noted and other regional nodes involved.

3.3 Planning Target Volume (PTV)

3.3.1 Includes CTV with safe margins of 0.2-0.5 cm.

3.4 Image Guided Radiation Therapy: to take KV images to ensure the accuracy of radiotherapy therapy regimen.

IV Treatment plans evaluation

4.1 Using Dose Volume Histogram (DVH)to evaluate dose distribution in the irradiated regions.

4.2 Planning Target Volume (PTV)dose prescriptions.

PTV $D_{95} \geqq$ Prescription dose.

4.3 Clinical Target Volume (CTV) dose prescriptions.

CTV $V_{100\%} \geqq 95\%$.

4.4 Gross Tumor Volume (GTV) dose prescriptions.

GTV $V_{100\%} \geqq 99\%$.

4.5 Normal tissue dose constraints:

4.5.1 Rectum: $D_{max} \leqq 6000$ cGy.

4.5.2 Bladder: $D_{max} \leqq 6500$ cGy.

4.5.3 Femoral head: $D_{max} \leqq 5000$ cGy.

4.5.4 Small Bowel: $D_{max} \leqq 4500$ cGy.

V. Radiation techniques：

5.1 Internsity modulated radiation therapy (IMRT)and Image Guided Radiation Therapy (IGRT)。

5.2 three-dimendional computer generated radiation treatment planning (3D CRT)

II. Delivery of Radiation to Uterine Cervical Cancer Patient

1.Initial assessment for radiation therapy.

1.1 Initial assessment is base ofn clinical evaluation, physical examination findings, biochemical examination findings, imaging findings and pathological reports and will do initial staging of disease. If patient had surgical treatment, surgical and pathological finding will be included in the treatment decision process.

1.2 The final decision for treatment will be done by radiation oncologist and will accept recommendation from the multidisciplinary physician team.

2. Preparation for radiation therapy:

2.1 Patient will be inform by treating physician on the indication for radiation therapy.

2.1.1 If patient meet the indications for radiation therapy, or have undergone discussion by multidisciplinary meeting, and was informed by physician on the indication for treatment and possible side effects and also alternate treatment modality, then will arrange for radiation treatment planning.

2.1.2 If patient and family agrees to primary radiation therapy, then the treatment planning process and other pertinent information will be given.

2.2 Signing of informed consent:

2.2.1 Patient after careful explanation of disease and treatment process, agrees to treatment have to sign informed consent. “Da-chien General Hospital Radiation Therapy Informed Consent” forms.

2.2.2 If consent is signed by patient relative, his relation to patient should be indicated, and signature of consignee and patient thumb prints should be obtained. “Da-chien General Hospital Radiation Therapy Patient General Information” forms.

2.3 Pretreatment patient educations.

2.3.1 Inform case managers for patient pre-treatment education concerning radiation therapy and general cares.

2.3.2 Radiation oncologist nursing specialist will do department tours and other nursing care educations about radiation treatments.

2.4 Pre-treatment CT scan images acquisition and simulation.

2.4.1 For safety purposes, patient inform the department about any idiosyncracies or allergic history and signed “Da-chien General Hospital Radiation Therapy Patient General Information” forms.

2.4.2 Before obtaining CT scan images, patient should signs “Da-chien General Hospital Radiation Therapy CT scan simulation consent forms”.

2.4.3 Attending physicial will prescribe the area and kind of

immobilization needed for this radiation therapy course. Will signs the ” Da-chien General Hospital radiation treatment plans”.

2.4.4 Radiologist will arrange for immobilization and will do CT scan images acquisition with attending physician supervision.

2.4.5 The CT scan images is transfer to the radiation oncology “Eclipse” treatment planning systems databank.

2.5 Generation of Treatment Plans:

2.5.1 The attending physician should be responsible for drawing CTV, PTV. Organ at risk and dose prescription for each regions.

2.5.2 Medical physicist will generate several plans for selection by attending physician of the best treatment possible.

2.6 Completion of the whole treatment plans.

2.6.1 The attending physician would be responsible for completion of the whole radiation therapy chart and plans.

2.6.2 Contents of radiation therapy charts includes pathological reports and staging, past and present history, family history, system reviews, physical examination, biochemical studies and tumor markers status, and relevant radiation therapy data.

III. Radiation Therapy Procedures:

3.1 Confirm patient identity.

3.1.1 Patient identification system has dual confirmation system, on by insurance card and one by vebal confirmation of pateint name, if patient is staying at hospital to confirm by name tag and reciting patient name.

3.1.2 With patient consent, we'll take patient picture and will couple totheir treatment plan for future referencing by radiation therapist.

3.2 Initial verification films

3.2.1 Radiation therapy will take verification film and assessment of congruity with initial simulation films. If fitting is good, then delivery radiation treatment.

3.2.2 Weekly review of verification film is done to confirm the accuracy of treatment delivery.

3.3 Clinical response and side effect assessments

3.3.1 Weekly clinical assessment of radiation tumor response and clinical side effects of radiation treatment, and recorded at the OPD SOAP and radiotherapy charts.

3.3.2 Weekly measurement and recording of TPR, body weight, and laboratory studies results including CBC+DC, platelet count, and clinical assessment of nutritional status and recorded in hospital chart.

3.4 Clinical Chart Round

3.4.1 Weekly new patient clinical chart round to assess accuracy of clinical records and discuss possible problems.

IV. Post Radiation Therapy Clinical Procedures

4.1 Nursing care education:

4.1.1 Registered radiation oncology nursing staff will give patient complete post treatment nursing care education and will give practical teaching.

4.1.2 Will arrange for time of next visitation.

4.2 Completion of radiation treatment summary records

4.2.1 Radiation treatment summary record will be responsibility of attending doctor and within 1 week post treatment.

4.2.2 Content of summary of radiation therapy completion notes.

- Patient's general data：name, sex, birhtday, age at time of treatment, patient chart number.
- Radiation therapy treatment equipments and department name
- Start and end of radiation therapy
- Name of the registered radiation oncologist
- Treatment given (e.g. surgery, chemotherapy and radiation therapy and their sequencing
- Region of treatment, either generalized or local boost therapy
- Radiation treatment equipment (e.g. LINAC, IORT or brachytherapy)
- Technique of radiation therapy (e.g. IMRT, RapidArc, Stereotactic radiosurgery)
- Region of target delineation and their ICRU references and fractionation.
- Tumor characteristic: anatomical site and pathological classification
- Tumor staging: Initial tumor staging, pathological type and differentiation and recurrent tumor (present staging)
- Other pertinent clinical history, and patient performance status
- Other multimodal treatment given: surgery and date, systemic treatment, time and dates.
- Pertinent clinical information for radiosurgery treatment: Target delineation and volume, radiation dosage to volume of target, dose volume histogram, maximal and minimal dose to target volume, mean target dose.
- Record of daily radiation regimen: Did patient complete entire radiation treatment, assessment of response and side effects and treatment of side effects and post treatment important reminders, further followup regimen and other notices.

4.3 Followup regimen for cancer patient:

4.3.1 Initial post treatment followup: assess acute reaction and recovery status.

4.3.2 Base on the uterin cervical cancer followup guidelines, we'll arrange for pertinent biochemical and tumor markers studies and imaging studies.