

RADIATION THERAPY ONCOLOGY GROUP

RTOG 79-21

RANDOMIZED STUDY OF NEUTRON THERAPY

IN THE TREATMENT OF NON-RESECTABLE ADENOCARCINOMA OF THE PANCREAS

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SCHEMA

S
T
R
A
T
I
F
Y

1. Extent T1-3
T4 or N⁺
2. Location
Head
Body/tail
Diffuse

R
A
N
D
O
M
I
Z
E

Photon: 6400 rad photon/electron
in 6-1/2 - 7-1/2 weeks at 180-200
rad per fraction.

~~Mixed Beam: 3800 rad in 19
fractions photon/electron + 910 rad
(Fermi) in 13 fractions neutron
over 6-1/2 - 7-1/2 weeks.~~

NOT CTF

Neutrons: 2200 rad (Fermi) + 100
rad in 15 fractions two
fractions/week over 7 weeks.

A facility may randomize patients into two or three arms but all must choose the control photon arm.

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1.0 INTRODUCTION

Cancer of the pancreas, a relatively infrequent tumor in the early years of the century, has recently increased in frequency and now ranks fourth among the leading causes of cancer deaths accounting for 5.4% of all cancer mortality in the United States. About 85% of malignant pancreatic tumors are typically adenocarcinoma. Since the disease is relatively asymptomatic in its early stages, detection of early resectable pancreatic carcinoma is relatively uncommon and resectability rates seldom exceed 20%. Advanced and technically non-resectable tumors are generally identified because of late manifestations of the disease which include severe and persistent abdominal pain or obstructive jaundice of such severity as to necessitate surgical intervention. The prospect of five-year survival in patients treated by conventional means for carcinoma of the pancreas has remained at less than 2% for many years (1). Conventional surgical techniques are relatively ineffective, the immediate surgical mortality is high, and the five-year survival in the operable group is seldom more than 5%.

Moertel, et al. conducted a prospective, controlled, double blind study comparing conventional low-dose radiation therapy alone with conventional low-dose radiation therapy plus a three-day course of 5-Fluorouracil at the start of the radiation therapy program. When used with radiotherapy, 5-Fluorouracil was given as a three-day consecutive loading regime at the start of the treatment course. This was found to be tolerable. A modest but statistically significant increase was shown in mean survival (10.4 months for the 5-Fluorouracil group and 6.3 months for the placebo group)(2).

Metastases tend to occur late in the course of the disease and most deaths can be attributed to local extension of the tumor in the region of the pancreas. Conventional radiation therapy has been used mainly for palliation, and up to the present time attempts at radical radiation therapy have been ineffective because of the relative radioresistance of the tumor and difficulty in delivering high doses without injury to sensitive adjacent structures.

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Dobelbower, Strubler, and Suntharalingam postulated that higher radiation doses were necessary to control pancreatic cancer. They recently described a technique employing high-energy photons and electrons capable of delivering high doses to the pancreas, yet largely sparing the spinal cord, kidneys, liver and gut (3). In the course of 3 years' experience with Precision High Dose (PHD) Radiotherapy, 19 patients have been treated. Four of these patients are now alive with survival times (from diagnosis to death) of 19 months to 5 years. The median survival time is presently 12 months with 53% of patients surviving one year. The PHD radiotherapy was well tolerated in every case.

The possibility of palliative or curative irradiation of pancreatic carcinoma is severely constrained by adjacent organs which are intolerant of significant radiation injury. Proximity of the growth to the kidneys and bowel has necessitated that dosage in the target volume not exceed 5500 rad, appropriately fractionated, which is not curative for the relatively radioresistant adenocarcinomas of the gastrointestinal tract. Careful localization of the tumor by the placement of markers at the surgical exploration and the use of ultrasound and CT scanning techniques make it possible to plan dose distribution meticulously and avoid inclusion of significant volumes of kidney within the radiation field, so that somewhat higher doses could be delivered than would be possible without these aids. Nevertheless, irradiation of bowel is unavoidable and this imposes a major constraint on adequate irradiation of the pancreatic bed.

Radiobiological investigations indicate that well differentiated tumors of the gastrointestinal tract may be expected to respond better to High-LET radiation than to conventional photon beams. Initial trials at Hammersmith Hospital, London, have confirmed this expectation in relation to other well differentiated

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adenocarcinomas of the alimentary tract including carcinoma of the stomach (which presents a similar problem because of the location and proximity to the same normal structures), so that a trial of neutron beam therapy for carcinoma of the pancreas seems to be well justified.

Fifty patients with pancreatic carcinoma have been treated at Fermilab with 1950 neutron rad in 13 fractions. The treatment was well tolerated with no significant side effects, however, local control was not achieved in a majority of cases. Median survival was 7 months with 20% survival at 12 months. Autopsy results all showed persistent tumor. Because of this, the dose has been increased to 2250 neutron rad in 15 fractions. Six patients have been treated with this dose with no acute side effects.

1.1 General Outline.

This protocol is confined to non-resectable carcinomas of the pancreas but those that are limited in extent although locally advanced. Because of the relative resistance of this tumor to conventional radiation and the documented response of other GI carcinomas to neutron therapy, the use of neutron beams is proposed in this study. Because of the deep seated location of the pancreas and its proximity to the kidneys and spinal cord, carefully directed, multiple and wedged beams of high-energy neutrons, or mixed beams of neutrons and a low-LET modality (photons or electrons) will be used. These will be compared to a low-LET (photon/electron only) conventional treatment arm. Because the results reported with precision high dose radiotherapy are superior to other radiation regimes with or without chemotherapy, this has been adopted as the control arm. Eligible patients will be those with advanced, non-resectable primaries which can be encompassed by a 1700 cm³ target volume.

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2.0 OBJECTIVES

- 2.1 To evaluate the effectiveness of high-energy neutron beams alone or in combination with low-LET therapy in local control and in alleviating the symptoms of carcinoma of the pancreas.
- 2.2 To evaluate the degree of palliative relief attained, coding the severity and remission of specific symptoms.
- 2.3 To determine the duration of symptomatic remission.
- 2.4 To determine the time of onset, evolution and severity of radiation injury, if any, in surrounding normal tissues (notably bowel).
- 2.5 Estimation of the time of local recurrence or of the appearance of metastases, if any.
- 2.6 Determination of survival rates at 1, 2, 3 and 5 years.

3.0 PATIENT SELECTION

3.1 Eligibility Criteria.

Only patients who have been investigated and found to have unequivocal evidence of adenocarcinoma of the pancreas are acceptable. All patients shall have had a laparotomy and biopsy with histological proof of the disease. Wherever possible, radio-opaque markers (surgical clips) should be placed to outline the upper, lower and lateral extent of macroscopically observed disease. Demonstration of the extent of the tumor in the transverse section using either an ultrasound display or a CT scan, noting the relation of the tumor to the kidneys and to the spinal cord is recommended. Although locally advanced, tumors must be limited to target volume no greater than 1700 cm^3 (e.g., $13 \times 13 \times 10 \text{ cm}$). Palliative surgery (biliary bypass, for example) should have been done where indicated. All patients referred must be ambulatory and capable of outpatient visits to the neutron therapy facility and treatment in a standing position.

- 3.1.1 No evidence of distant metastases.
- 3.1.2 Ductal carcinoma, Stage T_{1-3} , T_4 or N^+ , biopsy proven (see Appendix I).
- 3.1.3 No previous chemotherapy or abdominal radiotherapy.

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- 3.1.4 Adequate marrow function, WBC $> 4,000/\text{mm}^3$, platelets $> 100,000/\text{mm}^3$.
- 3.1.5 Patients must be at least 10 days past major abdominal surgery.
- 3.1.6 All institutional, National Cancer Institute and Food and Drug Administration regulations requiring submission to the Institutional Human Experimentation Committee and the use of procedures for obtaining and recording informed consent will be followed. A patient may be removed from the study at any time if the study is not in the best interest of the patient; however, follow-up assessment forms must be submitted. A patient may withdraw voluntarily from the study at any time, as will be indicated in the consent form (see Appendix II).
- 3.1.7 Patients must sign an informed consent form.
- 3.2 Ineligibility Criteria.
 - 3.2.1 The presence of overt metastases demonstrable on chest x-ray, liver scan, or other clinical means.
 - 3.2.2 Patients with chronic kidney disease.
 - 3.2.3 Prior chemotherapy or abdominal radiation therapy.
 - 3.2.4 Previous or concurrent cancer except skin cancer unless disease-free 5 or more years.
 - 3.2.5 Acute intercurrent complications such as infections or post-surgical complications which would preclude radiation therapy.
 - 3.2.6 Islet cell carcinoma.
 - 3.2.7 Tumors requiring a target volume greater than 1700 cm^3 (e.g., $13 \times 13 \times 10 \text{ cm}$).

4.0 PRETREATMENT EVALUATION

4.1 History and Physical.

4.2 Surgery.

- 4.2.1 Laparotomy with biopsy and marking of gross margins of tumor, biliary and gastrointestinal bypass procedure as indicated.

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- 4.2.2 Inspection, biopsy and marking of regional nodes as indicated.
- 4.3 Pathological evaluation of biopsies of primary tumor and/or regional nodes.
- 4.4 Mandatory Laboratory Procedures.
 - 4.4.1 CBC (including platelets and differential).
 - 4.4.2 CEA.
 - 4.4.3 Alkaline phosphatase
 - 4.4.4 BUN.
 - 4.4.5 Blood sugar.
 - 4.4.6 Urinalysis.
- 4.5 Mandatory Imaging Procedures.
 - 4.5.1 Chest x-ray.
 - 4.5.2 Upper GI.
 - 4.5.3 IVP.
 - 4.5.4 Liver scan.
 - 4.5.5 Computer assisted tomography (CT scan) or ultrasonogram.

5.0 RANDOMIZATION

- 5.1 A facility may choose to randomize a patient into either two or three treatments but must include the photon control arm. This must be stated, in writing, prior to participation in the study.
- 5.2 When a patient has been fully evaluated and found eligible, the patient may be placed on study by calling RTOG Headquarters (215/574-3191 between 9:00 a.m. and 5:00 p.m., ET) and providing the following information:
 - 5.2.1 Protocol Name.
 - 5.2.2 Institution Referring Patient.
 - 5.2.3 Neutron Facility.
 - 5.2.4 Physician.
 - 5.2.5 Patient's Name.
 - 5.2.6 Stage (T_{1-3} vs T_4 or N^+).
 - 5.2.7 Tumor location (head vs body/tail vs diffuse).
- 5.3 A project case number and treatment will be assigned which will be confirmed by mail.

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6.0 TREATMENT

6.1 Target Volume.

The target volume will include the surgically outlined tumor with a 2 cm margin. This must not exceed 1700 cm³.

6.1.1 Planning. Individual plans will be executed for each patient, but in general the target volume is best treated by means of three converging fields. These include an anterior portal covering the anatomical projection of the pancreas and the entire tumor as outlined by the surgical markers with a 2 cm margin extending beyond all known disease. This will be supplemented by two lateral portals matching the anterior field in the craniocaudal extent and of a sufficient width to encompass the antero-posterior extension of the pancreas and the tumor. The posterior margins of the lateral fields will be tangential to the anterior vertebrae. To this end orthogonal x-rays and IVP (AP and lateral) will be used. If a horizontal neutron beam is to be applied, these films will be taken with the patient in the standing position. Wedge filters may be required on the lateral portals to match the body contours and the falling gradient in the anterior field.

6.1.2 Dose and Time. Treatment plans will be designed to deliver (photon-equivalent) doses of 6400 rad at 180-200 rad per fraction to the target volume but not exceeding 5000 rad to bowel outside the target volume, 2000 rad to the kidneys, 4000 rad to the spinal cord, or 3500 rad to more than half the liver. Neutron doses actually delivered will be approximately one-third of the photon dose (except liver where it will be approximately one-fourth). Treatment time will be 6-1/2 - 7-1/2 weeks. Neutrons

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will be given twice a week (15 fractions over 7 weeks). With the mixed beam option the low and high-LET components must be given concurrently (2 neutron fractions and 3 low-LET fractions each week). The following dosage scheme (+5%) will be delivered:

Facility	Neutrons Only	Photons Only	"Mixed" Photons	Neutrons
Fermilab	2200	6400	3800	910
Tamvec	2050	6400	3800	825
Gianta	2000	6400	3800	800
Seattle/Chicago	1775	6400	3800	715

6.1.3 Treatment Plans. Any treatment plan that adequately encompasses the target volume and sufficiently spares the surrounding normal tissue according to the doses specified in 6.1.2 is acceptable.

The target volume shall surround gross margins of tumor with a clearance of at least 2 cm. It is recommended that the left margin be 3 cm in order to encompass a greater volume of the pancreas, as pancreatic tumors are known to spread along the pancreas in an occult fashion. The entire pancreas may be included. Fields may be reduced to 1-2 cm margins after 4500 rad total equivalent dose. Field angling and shaping are encouraged to conform the high dose volume to the shape of the tumor and to avoid spinal cord, kidneys, liver, and gut. The entire target volume, however, must be no greater than 1700 cm³. Location of kidneys will be determined by lateral films during nephrogram phase of IVP. Spinal cord dose will be limited to 4000 rad equivalent (1200 rad neutrons or 500 rad neutrons + 2400 rad of the low-LET component) and the dose to the contralateral kidney will be limited to 2000 rad equivalent (one half the cord limits shown) at its midpoint. A 2 cm posterior margin may not be possible.

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6.1.4 Interruption of Treatment. A continuous course of radiotherapy should be maintained, if possible. However, if clinically indicated due to a patient's symptoms, a single break of 14 days (10 treatment days) may be given. Such an interruption should be added to the time indicated in 6.1.2 and will not be considered a major protocol deviation. If more than one interruption of treatment occurs or if a single interruption is greater than 14 days, treatment should continue at the discretion of the radiotherapist. Such a patient will remain on study with all RTOG forms required but this data will be analyzed separately.

6.2 Mixed Photons and/or Electron and Neutron Beam Option.

6.2.1 Any field arrangement may be used which delivers the specified dose to the primary target volume and limits the dose to normal structures as required.

6.2.2 If an anterior electron beam field is used, the energy of the electron beam may be reduced appropriately so that the 50% isodose line does not extend beyond the anterior limits of the body of the vertebrae or the anterior surface of the kidney.

6.2.3 An electron or photon dose of 3800 rad in 19-21 fractions will be delivered to the target volume in 6-1/2 - 7-1/2 weeks (concurrent with neutrons).

6.2.4 The neutron dose delivered to the target volume will be as in 6.1.2.

6.3 Neutrons as the Sole Radiation Modality.

6.3.1 Equipment will produce a d 1/2 of 10 cm or greater.

6.3.2 Anterior and two lateral wedged fields will usually be used.

6.3.3 No more than 30% of the tumor dose should reach the kidneys.

6.3.4 Minimal tumor doses will be as in 6.1.2 delivered in 6-1/2 - 7-1/2 weeks.

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- 6.3.5 Peak doses should not exceed the neutron doses in 6.1.2 by more than 20%.
- 6.3.6 Bowel outside the target volume is not to receive more than 1750 rad neutrons.
- 6.3.7 Spinal cord doses should not exceed 1200 rad neutrons.
- 6.3.8 More than half of the liver should not receive more than 900 rad.

6.4 Chemotherapy.

No chemotherapy will be used in this protocol.

7.0 PATHOLOGY

Representative slides and a copy of the pathology report must be submitted to RTOG Headquarters for review by the study pathologist.

8.0 PATIENT ASSESSMENTS

8.1 The purpose of patient follow-up assessments is to determine:

- 8.1.1 Patient survival time.
- 8.1.2 Quality of survival.
- 8.1.3 Tumor response. Primary tumor volume will be estimated using CT scans to determine maximum dimensions and dimensions at right angles. Third dimensions will be estimated when possible.
 - 8.1.3.1 Complete response (CR) - Complete disappearance of all measurable and palpable tumor.
 - 8.1.3.2 Partial response (PR) - Tumor shrinkage greater than 50% of the product of the perpendicular diameters of the two largest dimensions.
 - 8.1.3.3 Minor response (MR) - Tumor shrinkage greater than 25% but less than 50% of the product of the perpendicular diameters of the two largest dimensions.

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- 8.1.3.4 No change (NC) - 25% growth to 25% shrinkage of the product of the perpendicular diameters of the two largest dimensions.
- 8.1.3.5 Progressive disease (PD) - Growth of tumor greater than 25% of the product of the perpendicular diameters of the two largest dimensions. If response cannot be measured by the above, patients will be scored on the basis of their symptoms.
- 8.1.4 Response of regional node metastasis.
- 8.1.5 Time and site of distant metastasis.
- 8.1.6 Time and site of local recurrence.
- 8.1.7 Acute and late response of normal tissue.
- 8.1.8 Patient functional status during survival.
- 8.2 Follow-up assessments should be scheduled within two weeks of the specified times and will be reported every two months after radiotherapy (the first day of definitive treatment is considered Day 1) for the first year and every three months thereafter.
 - 8.2.1 Parameters to be recorded at each follow-up evaluation include:
 - 8.2.1.1 Medical history data including Karnofsky Status.
 - 8.2.1.2 Physical examination.
 - 8.2.1.3 Laboratory tests, as indicated.
 - 8.2.1.4 Imaging procedures, as indicated.

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8.3 Summary of Study Parameters.

<u>Parameter</u>	<u>Pre-Study</u>	<u>Weekly During Irradiation</u>	<u>Follow-Up*</u>
History & Physical Exam	x	x	x
WBC	x	x	x
HGB or HCT	x	x	x
Differential	x	x	x
Platelets	x	x	x
Alkaline Phosphatase	x		x
SGOT or SGPT	x		x
BUN	x		x
Urinalysis	x		
Blood Sugar	x		A
Chest x-ray	x		x
Upper GI	x		A
Liver Scan	x		
CEA	x		x
CT Scan	x	(optional)	A
IVP	x		

(A = As Indicated)

(* = Every two months for first year; every three months thereafter)

9.0 DATA COLLECTION

A copy of each study form must be submitted to RTOG Headquarters. Data will be recorded on standard forms to be supplied to each participating institution. The following records will be generated by the study team and participating institutions for storage, retrieval and analysis.

9.1 On-study form.

9.2 Treatment prescription.

9.3 Localization Films. Localization films of each field will be taken and sent to the RTOG office during the first week of therapy together with a copy of the treatment plan.

9.4 Treatment Summary Form.

9.4.1 Radiation therapy administered (type of energy, daily schedule of treatment, maximum dose, complications during radiation therapy, a description of the lesion at the end of treatment, patient's weight at the end of treatment, performance at end of treatment, complications following therapy and their management,

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copies of port films and isodose curves, etc.).
Isodose distributions should be attached.

9.4.2 Operative procedures and findings, if applicable
(extent of disease, presence of metastases, type and
extent of surgery performed, etc.).

9.4.3 Postoperative data (complications following surgery,
patient weight at time of discharge, performance at
time of discharge, etc.).

9.4.4 Drugs administered, if any (a description of type and
dose of any drugs administered, duration, and
purpose, including any chemotherapy administered in
the event of lack of tumor control).

9.5 Follow-Up Assessment Form (see Section 8.2).

9.6 Summary of Forms Submission.

Form

Due

On-study form

Within one week of randomization

Radiotherapy prescription

Copies of localization films

Pathology slides and report

Operative report

Treatment summary form

Within two weeks of completion of
radiotherapy

Copy of radiotherapy record

Copy of boost fields

Isodose distribution

Follow-up assessment

Within two weeks of times in 8.2

Death form

Within one month of death

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10.0 STATISTICAL CONSIDERATIONS

With the best current management, the median survival for patients with carcinoma of the pancreas is in the region of 8-12 months. This translates, assuming survival follows a negative exponential distribution, to a 5-year survival rate of 0-3%. The projections below are based on the belief that if the neutron therapy raises the 5-year survival to 10% (or a median survival of 18 months) the additional effort will have been justified. To be reasonably sure (i.e., > 90%) of detecting such an improvement, from 30-75 patients per arm will be required. The statistical comparison will be based on a 5% one-sided test of significance. Just how many patients will be required will depend on how fast they are accrued, and when the analysis is performed, as is demonstrated in the following table:

<u>Accrual Per Year</u>	<u>Years Of Accrual</u>	<u>Total Per Arm</u>	<u>Power (%) At End Of Accrual</u>	<u>Power 2 Yrs. Later</u>
20	3	30	72	87
	4	40	87	95
30	2	30	63	86
	3	45	86	96
	4	60	96	99
40	2	40	74	93
	3	60	93	99
	4	80	99	100
50	1	25	40	68
	2	50	82	94
	3	75	97	99

The above calculations are based on a comparison of either of the neutron therapy arms with the conventional therapy arm. If some institutions choose to study mixed beam therapy and others choose to study neutron-only therapy (with both sets of institutions studying conventional therapy), then if the comparison is of interest it will also allow an indirect comparison of the two neutron arms but with considerably less power.

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11.0 ADDITIONAL TREATMENT

Therapy is to be administered as detailed in Section 6.0.

Subsequent therapy shall proceed at the discretion of the patient's responsible physician. Indications for subsequent therapy and the therapy performed should be documented in the patient's follow-up records.

Patients in this study may have their radiation therapy modified or interrupted as dictated by the clinical indications or unusually severe radiation reaction not amenable to simple daily dose reduction or symptomatic treatment.

If the primary tumor is not controlled at the primary site, subsequent therapy should proceed at the discretion of the patient's responsible physician. Clinical evidence of lack of tumor control should be documented in the patient's follow-up records.

In the event that surgery or a biopsy is performed, the excised tissue or biopsy specimen should be carefully examined by a pathologist at the participating institution, with representative slides forwarded to RTOG Headquarters for review by the study pathologist.

REFERENCES

1. Levin, D.L., and Connelly, R.R.: Cancer of the pancreas. Available epidemiologic information and its implications. Cancer 31:1231-1236, 1972.
2. Moertel, C.G., et al.: Combined 5-Fluorouracil and supervoltage radiation therapy of locally unresectable gastrointestinal cancer. Lancet 2:865-867, 1969.
3. Dobelbower, R.R., Strubler, K.A., and Suntharalingam, N.: Treatment of cancer of the pancreas with high energy photons and electrons. Int J Rad Onc Biol Phys 1:141-146, 1975.

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APPENDIX I

STAGING OF CANCER OF THE PANCREAS

American Joint Committee for Cancer Staging and End Results Reporting (1977)

Primary Tumor (T)

- T_x Minimum requirements cannot be met.
- T₁ Tumor limited to pancreas, greatest diameter 0 to 2 cm.
- T₂ Tumor limited to pancreas, greatest diameter 2 to 6 cm.
- T₃ Tumor greater than 6 cm in greatest diameter.
- T₄ Tumor invading extrapancreatic contiguous structures by direct extension.

Nodal Involvement (N)

- N_x Minimum requirements cannot be met.
- N₀ No metastatic nodes.
- N₁ One regional group involved at laparotomy.
- N₂ Two or more regional groups involved at laparotomy.
- N₃ Clinical evidence of regional node involvement (no laparotomy).
- N₄ Involvement of juxtaregional nodes.

Distant Metastases (M)

- M_x Not assessed.
- M₀ No (known) distant metastases.
- M₁ Distant metastasis present.

Stage Grouping

None recommended at this time.

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