Comparison of Conventional External Radiotherapy and Stereotactic Radiotherapy in the Treatment of Pituitary Adenoma

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Objective: *To compare the results of pituitary adenoma treated with conventional external beam radiotherapy (EBRT) versus stereotactic radiosurgery and stereotactic radiotherapy (SRS/SRT).*
Method and Material: *Data of patients with pituitary adenoma treated at Radiotherapy and Oncology unit, Ramathibodi Hospital between 1990 from 2003 were retrospectively collected and analyzed. Twenty-two patients were treated with EBRT and 51 patients were treated with SRS/SRT.*
Results: *The 5-year overall survival and local control rates were not different between the EBRT and SRS/SRT group (91% vs 100%, p = 0.10; 95% vs 96%, p = 0.33). The 5-year freedom from newly initiated hormonal replacement was 50% in EBRT and 75% in SRS/SRT group (p = 0.38).*
Conclusion: *At a similar outcome but with lower expense of resources, EBRT should be considered an acceptable radiation technique for patients with pituitary adenoma, especially in developing countries such as Thailand.*

Keywords: *Adenoma, Pituitary neoplasms, Radiosurgery, Radiotherapy, Stereotaxic techniques*

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Pituitary adenomas are the most common tumors near the sella and represent approximately 14% of all intracranial tumors[1]. Radiotherapy is an accepted treatment of pituitary adenomas following subtotal resection, persisting hormonal overproduction, recurrence of disease, and is a primary treatment when surgery is contraindicated or when macroadenoma is inoperable. There are various radiation techniques in treating pituitary adenoma. The prior and long-lasting radiation technique is called conventional external beam radiation therapy (EBRT) and the newly developing radiation technique is called stereotactic radiation. This is the technique that administer precisely directed, high-dose irradiation while minimizing radiation dose to surrounding normal tissue. The terminology used in stereotactic irradiation can be confusing. The term stereotactic radiosurgery (SRS) is used for irradiation in a single session or fraction, while stereotactic radiotherapy (SRT), is used for irradiation in multiple fractions. An advantage of SRS/SRT over EBRT is SRS/SRT technique produce a more rapid dose fall-off to minimize the dose to surrounding critical structures with the possibility of increasing the dose to the tumor, but at the expense of more resources. It would be interesting to assess the outcome of EBRT and SRS/SRT. If EBRT is effective and safe, it might be more cost-effective compared with the advanced techniques. The present retrospective analysis of two sequential series revealed comparative results of pituitary adenomas treated with EBRT and SRS/SRT in terms of overall survival, local control, and late complications.

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Method and Material

The medical records of 73 pituitary adenoma patients treated at Radiotherapy and Oncology Unit, Ramathiboidi Hospital between September 1990 and October 2003 were retrospectively reviewed. During this period, 22 patients were treated with EBRT and 51 patients were treated with SRS/SRT technique. Of these, 12 received SRS and 39 received SRT. The patient characteristics were similar in both groups, with the exception of type of tumor, for which SRS was significantly preferred in functioning tumors and as primary radiotherapy. Table 1 and 2 summarizes the patient characteristics in both groups.

Radiotherapy techniques

In the EBRT group, all 22 patients were treated with 1.8-2 Gy daily fractions by the Linac system (6 or 10 MV CLINAC 2100C, Varian Medical system, Palo Alto, CA, USA) or by the Cobalt 60 system (Theratron 780C, Atomic Energy of Canada Limited, Ottawa, Canada). The median tumor dose was 54 (46-60) Gy in 30 (23-33) fractions. In one patient treated with radiotherapy alone, dose 60 Gy was given. In the SRS/SRT group, all 51 patients were treated with the LINAC system (6MV dedicated LINAC, Varian, Palo Alto, CA; with XKNIFE planning system version3&4, Radionics, Boston, MA). Before treatment, all patients were evaluated by a multidisciplinary board consisting of neurosurgeons, radiation oncologists, endocrinologists, and neuroradiologists. Written informed consent was obtained before the treatment.

Clinical and hormonal evaluation

After treatment, the patients were clinically evaluated every 1-6 months. MRI and endocrinologic examination were performed at varying intervals depending on the physicians and the patients' status.

The tumor control was evaluated in terms of freedom from recognizable re-growth of the tumor on various imaging studies or a recurrence of the clinical symptoms that required additional surgical intervention. The criteria for hormonal normalization was a serum prolactin level below 20 ng/mL for prolactinoma, a serum growth hormone level below 5mIU/L for growth hormone (GH) producing pituitary adenoma and a daily urine-free cortisol level below 90 mg for adrenocorticotrophic (ACTH)- producing tumors.

A complete hormonal response was defined by the complete normalization of the hormonal level. Complications of treatment were the late severe complications that occurred as the results of radiation including brain necrosis, hypopituitarism, optic neuropathy, and second malignancy.

Statistical method

The Statistical Package for the Social Sciences (SPSS V11.5) was used for statistical analysis. The primary endpoints to be compared between both groups were overall survival, tumor control, and late complications rate calculated according to the Kaplan-Meier method[2]. Time points were calculated from the date of the initiation of EBRT or SRS/FSRT. The log-rank test was used to compare survival curves. Unpaired t-test was used to test the difference between means and Chi-square test or Fisher's exact test was used to test the difference between proportions for patients characteristics of the two groups. A p-value of less than 0.05 was considered statistically significance different.

Results

Overall survival

The median follow-up time was 4.6 years (range, 0.6-9.7 years) in the EBRT group and 4.7 years (range, 1.5-7.4 years) in the SRS/FSRT group. There were two deaths in the EBRT group, one from cerebrovascular accident, and another one from pancreatic CA. No patient died because of tumor progression. Consequently, the 5-year overall survival was 91% in the EBRT group and 100% in the SRS/SRT group ($p = 0.10$) (Fig. 1).

Tumor control

The five-year overall tumor control rate was 95% in the EBRT and 96% in the SRS/SRT group ($p = 0.33$) (Fig. 2). In the EBRT group, there was one local failure with recurrent visual symptoms at 6 years after EBRT and was salvaged by surgery. In the SRS/SRT group, there were two patients with ACTH secreting adenomas who had local failure, one had endocrinologic and radiologic recurrence at 15 months after SRS and subsequently had received surgery followed by FSRT. Another one had endocrinologic recurrence at 20 months after SRT that required additional bilateral adrenalectomy. There has been no further recurrence to date for the patients who underwent a salvage operation.

Hormonal response

Hormone normalization at three years was achieved in 72% after EBRT and 61% after SRS/SRT

Table 1. Patient characteristics between EBRT and SRS/SRT

Characteristic	EBRT	SRS/SRT	p-value
Number of patients	22	51	
Gender			0.07
Male	8 (36%)	29 (57%)	
Female	14 (64%)	22 (43%)	
Median age (years)	37.5 (16-66)	47 (17-65)	0.65
Type of tumor			0.78
Nonfunctional adenoma	11 (50%)	30 (59%)	
GH secreting	2 (9%)	14 (27%)	
Prolactin secreting	6 (27%)	2 (4%)	
ACTH secreting	3 (14%)	5 (10%)	
Presenting symptom			0.85
Visual disturbance	15 (53%)	29 (57%)	
Headache	7 (24%)	2 (4%)	
Hormone disturbance	5 (17%)	18 (35%)	
Any mass effect	1 (3%)	2 (4%)	
Incidental finding	1 (3%)	0	
Surgery			0.32
Postoperative RT	21 (95%)	46 (90%)	
RT alone	1(5%)	5 (10%)	
Previous radiation	0	6 (12%)	0.03
Median tumor volume (ml)	No record	10 (0.46-37.7)	

Test of difference between mean (Independent t-test), $p < 0.05$
Test of difference between proportions (Chi-square test), $p < 0.05$

Table 2. Patient characteristics between SRS and SRT

Characteristic	SRS	SRT	p-value
Number of patients	12	39	
Gender			0.42
Male	7 (58%)	22 (56%)	
Female	5 (42%)	18 (44%)	
Age (years) (median)	43.5 (17-65)	47 (23-67)	0.78
Type of tumor			0.012
Nonfunctional adenoma	2 (18%)	28 (70%)	
Growth hormone secreting	7 (64%)	7 (17%)	
Prolactin secreting	0 (0)	2 (5%)	
ACTH secreting	2 (18%)	3 (8%)	
Presenting symptom			0.32
Any mass effect	0 (0)	2 (5%)	
Visual disturbance	2 (18%)	27 (67%)	
Headache	0	2 (5%)	
Hormone disturbance	9 (82%)	9 (23%)	
Surgery			0.02
Postoperative RT	8 (73%)	38 (95%)	
RT alone	3 (27%)	2 (5%)	
Previous RT therapy	1 (16)	5 (84)	0.84
Median tumor volume (ml)	1.6 (0.7-10.8)	11.9 (0.5-37.7)	0.71

Test of difference between mean (Independent t-test), $p < 0.05$
Test of difference between proportions (Chi-square test), $p < 0.05$

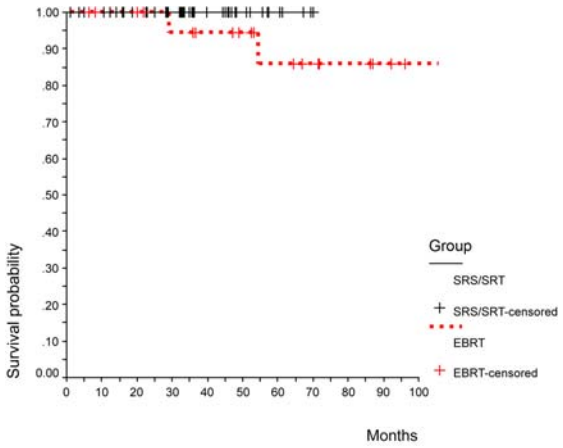

Fig. 1 Overall survival between EBRT and SRS/SRT

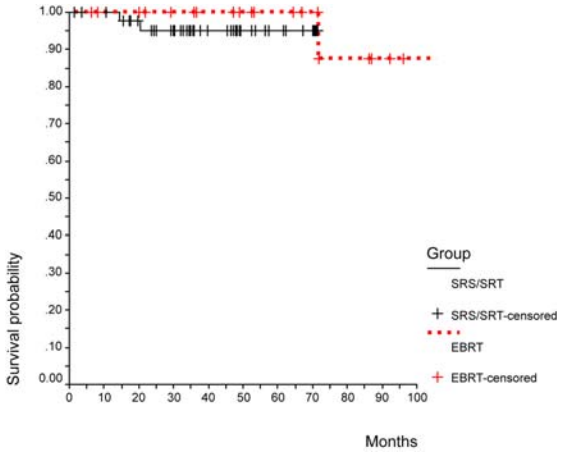

Fig. 2 Overall tumor control between EBRT and SRS/SRT

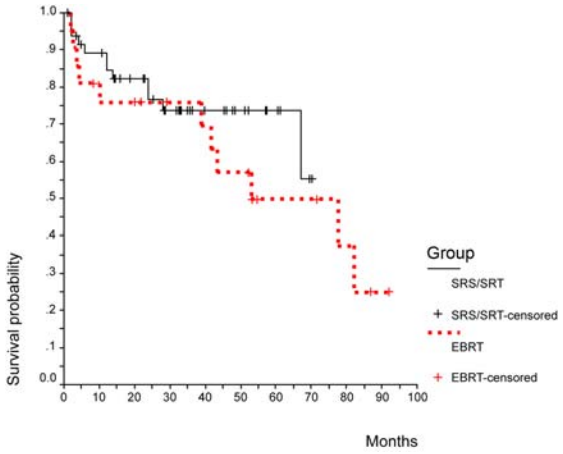

Fig. 3 Freedom from newly initiated hormonal replacement between EBRT and SRS/SRT

(75% for SRS and 50% for SRT). Five (71%) of the 7 GH secreting tumors had serum GH level returned to normal within 1 year after SRS. However, it took about 3 years to achieve normal serum GH levels by EBRT. The changes of GH levels following SRS were considered earlier than those with EBRT. The hormonal response of cortisol levels showed a pattern similar to the response in both the SRS and EBRT groups. Nobody had hormonal recurrence since normalization.

Late radiation complications

The incidence of newly developed hypopituitarism trend to be higher in the EBRT group than in SRS/SRT group, but the differences were not statistically significant. The 5-year freedom from newly initiated hormonal replacement was 50% in EBRT and 75% in SRS/SRT group (Fig. 3). The severe late radiation toxicity, such as brain necrosis, visual impairment, or radiation-induced tumor, was not reported in the present study.

Discussion

There are many therapeutic options for treatment of pituitary adenomas including surgery, radiotherapy, and medical treatment. The result depends on various factors such as tumor size, invasiveness, location, direction of growth, or hormonal activity. Advanced transphenoidal surgery is established as one of the most reliable treatment modalities[3,4]. Radiotherapy is selectively used as postoperative treatment after subtotal removal, in recurrent tumors, in excessive hormonal secretion, and as primary treatment when surgery is contraindicated. In the present series, the authors compared two treatment radiation techniques between EBRT versus SRS/SRT. EBRT is prior and long-lasting technique, using 1.8-2 Gy, 5 days per week to the total dose of 45-55 Gy has been shown to achieve fairly good treatment outcomes both for the control of tumor growth and endocrinological symptoms, and several studies revealed 80-95% tumor control rate and 40-90% hormonal control rate[5-8]. However, the risk of radiation-induced hypopituitarism requiring permanent hormone replacement was relatively high, reaching 25-30%. In addition, rare but dramatic, late radiation toxicity such as temporal brain necrosis and optic neuropathy is also noted in a few percent[5,9]. The SRS/SRT technique is the newly developing radiation technique to administer precisely directed, high-dose irradiation that tightly conforms to an intracranial target to create a desired radiobiologic response while minimizing radiation

dose to surrounding normal tissue. SRS/SRT technique used in the treatment of pituitary adenomas has been increasing worldwide. At this time, there is no clear indication for selecting radiation technique in treating pituitary adenoma. The choice of radiation modality often depends more on availability, physician preference, and perceived differences in toxicity rather than any convincing difference in reported outcome. EBRT can be effective in control of hypersecretion and mass effects due to large or recurrent tumors. SRS remains an appropriate treatment for selected cases: specifically, the smaller, radiologically well-defined tumors located at a distance (3-5 mm) from the optic apparatus. SRT is widely applicable, even to large tumors in intimate relationship with the optic apparatus. In Ramathibodi Hospital, the Linac-based radiosurgery system unit was started in August 1997. Since then, the EBRT has been gradually replaced by SRS/SRT in treatment of pituitary adenomas. Therefore, a prospective comparative study of EBRT vs SRS/SRT for pituitary adenoma has now become difficult. The present series reports on treatment results of 51 patients with pituitary adenoma treated with SRS/SRT and retrospectively compared with 22 patients treated with EBRT at the same institution. For all types, the overall survival and local control rates were similar between the EBRT and SRS/SRT group (Fig 1, 2). Results of these patients were very similar to those reported in other series[10-18]. There were two deaths in the EBRT group, one from cerebrovascular accident (CVA) and another patient from pancreatic CA. Brada et al[19] found that patients with pituitary adenoma treated with surgery and postoperative EBRT had a significantly increased risk of CVA when compared to the general population. In this particular patient, however, he had risk factors for developing CVA including underlying hypertension and heavy smoking, so it is difficult to conclude the real cause contributing to his CVA. In another patient who died from pancreatic CA, it was suspected to be the multiple endocrine neoplasia type I (MEN-1) syndrome[20].

For functioning pituitary adenoma, one of the primary aims of the treatment is to control hormonal hypersecretion. The present study showed the hormone normalization at three years which was achieved in 72% after EBRT and 61% after SRS/SRT (75% for SRS and 50% for SRT), comparable with the other series[21-31] that reports SRS results equivalent to those of SRT and EBRT. Overall, the rate of endocrinological normalization was similar for SRS and EBRT, with a hormonal control rate of 50-70% after SRS and 40-90% after EBRT. The response seems to be greater with single-fraction and could result in a quicker normalization of hormonal levels. However, most of these studies did not define standard end point of hormonal control after radiation treatment at the same standard consensus criteria. Different criteria cause different results and would not reflect the same response of radiation to hormone normalization. Importantly, imprecise biochemical assessment (*i.e*, insufficiently sensitive hormone assays and lack of information regarding IGF-1 normal ranges) may contribute to the uncertainty in the literature regarding dose-response relations between biochemical activity and improvement in morbidity and mortality rates. The result of the present study was interpreted using the criteria applied from the standard consensus criteria and depending on the referring physician. The main reason that standard consensus criteria cannot apply for the present study because of retrospective nature with no standard data available in the medical records. The complete hormonal response analysis is difficult because the endpoint definition usually varied in ranges, and the pituitary adenoma kinetic response was very slow with longer follow up, which could lead to a better and complete response rate. It is also difficult to compare the rate of hormonal decline between SRS and conventional techniques because of the different pretreatment parameters such as pretreatment hormone level, type of tumor, tumor volume and radiation dose. Finally, the interpretation of the results between SRS/SRT and EBRT should be in caution because of the small number of the patients, patient selection, differing methods of reporting results, and retrospective nature. The following studies should be done prospectively to gain accurate and standardized results that are able to set more appropriate protocols for radiotherapy in the future.

With regard to late radiation complication, EBRT to the pituitary gland has been reported to result in hypopituitarism, visual loss, secondary tumor, and dementia[32,33]. The most commonly reported late morbidity of EBRT is hypopituitarism, with a broad range of 30-70%[34]. Visual loss and radiation induced neoplasm occur much less frequently. The incidence of optic pathway damage after EBRT was 1-3%. Pituitary adenoma patients had a reported cumulative actuarial risk of 2-2.7% at 10-30 years for the development of in-field radiation induced neoplasms[35]. Although formal cognitive function studies have failed to detect a definite impairment due to RT alone, high dose RT to significant volumes in the temporal and

frontal lobes has been commonly associated with late neurocognitive dysfunction. With single fraction radiosurgery, injury to the optic apparatus was dose dependent with a 27% risk for those receiving 10-15 Gy and little or none with dose below 10 Gy to the optic apparatus. Losa et al[36] reported no radiation-induced optic neuropathy after SRS. Mitsumori et al[27] noted an 18% incidence of brain necrosis with SRS that was not seen with SRT. An advantage of SRT over SRS was the decrease in normal brain complications when the treatment volume was large or near the critical structures. To date, no case of FSRT induced brain necrosis or optic neuropathy has been described. The most commonly reported late toxicity of SRS/FSRT was hypopituitarism. Based on the literature, the risk of partial hypopituitarism as a result of SRS/SRT showed very low rates compared with the EBRT. The incidence of partial hypopituitarism varied from 0- 40% in SRS series and 5-20% in FSRT series. The reason for this comparative low incidence is probably because the target is clearly outside the pituitary sellar resulting in protection of the pituitary gland and hypothalamus. In the present study, most patients had hypopituitarism as a result of tumor mass effect or by postoperative changes rather than direct radiation effects. The authors also noted a lower incidence of newly developed hypopituitarism after SRS/SRT, the 5-year freedom from newly initiated hormonal replacement of 75% in SRS/SRT group and 50% in EBRT but not significantly different ($p = 0.38$) (Fig. 3). There was no case of radiation-induced optic neuropathy, brain necrosis, or secondary tumor in the present report. A possible reason for our low complication rates in the SRS/SRT group might be the conservative dose used in SRS, the more use of SRT, and the relatively short follow-up time.

Conclusion

At a similar outcome but with lower expense of resources, EBRT should be considered an acceptable radiation technique for patients with pituitary adenoma, especially in developing countries such as Thailand.

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การศึกษาเปรียบเทียบการรักษาเนื้องอกที่ต่อมใต้สมองด้วยการฉายรังสีวิธีปกติ และ การฉายรังสีร่วมพิกัด

พุฒิพรรณ พัวทวีพงศ์, มัณฑนา ธนะไชย, สมใจ แดงประเสริฐ, จิรพร เหล่าธรรมทัศน์, วีระศักดิ์ ธีระพันธ์เจริญ, พรพรรณ ยงวิทิตสถิตย์

วัตถุประสงค์*: เพื่อเปรียบเทียบผลการรักษาเนื้องอกที่ต่อมใต้สมองด้วยการฉายรังสีวิธีปกติ และการฉายรังสีร่วมพิกัด*

วัสดุและวิธีการ*: ทำการเก็บข้อมูลผู้ป่วยเนื้องอกที่ต่อมใต้สมอง ที่หน่วยรังสีรักษาและมะเร็งวิทยา โรงพยาบาลรามาธิบดี จากเวชระเบียนย้อนหลัง ตั้งแต่ปี พ.ศ. 2537-2548 โดยมี 22 รายได้รับการฉายรังสีวิธีปกติ และ 51 รายได้รับ การฉายรังสีร่วมพิกัด*

ผลการศึกษา*: พบว่าไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างการฉายรังสีวิธีปกติ และ การฉายรังสีร่วมพิกัด ทั้งในด้านอัตราการอยู่รอดที่ 5 ปี (ร้อยละ 91และ ร้อยละ 100, p = 0.10) อัตราการควบคุมโรคเฉพาะที่ที่ 5 ปี (ร้อยละ 95 และร้อยละ 96, p = 0.33) และอัตราการปลอดจากการรับฮอร์โมนเสริม (ร้อยละ 50 และร้อยละ 75, p = 0.38)*

สรุป*: ด้วยผลการรักษาที่เท่าเทียมกัน แต่มีค่าใช้จ่ายที่น้อยกว่าในการฉายรังสีวิธีปกติ ดังนั้นการฉายรังสีวิธีปกติควรจะพิจารณาเป็นการฉายรังสีที่ยอมรับได้ในผู้ป่วยเนื้องอกที่ต่อมใต้สมองโดยเฉพาะประเทศที่กำลังพัฒนา เช่น ประเทศไทย*