

Stereotactic Body Radiotherapy for Metastatic and Recurrent Soft Tissue Sarcoma

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Research

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Abstract

Background

Soft tissue sarcoma (STS) is a malignant tumor of highly heterogeneous mesenchymal origin. STS has a biologic pattern and clinical transformation with localized invasive growth and susceptibility to hematogenous metastasis. Metastatic and recurrent soft tissue sarcoma may be treated by local therapeutic options, including surgery and radiation therapy. This study evaluated the safety and efficacy of SBRT for metastatic and recurrent soft tissue sarcoma.

Methods

We performed a retrospective analysis of 37 STS patients with 58 lesions treated with SBRT from 2009-2019 at our institution. We analyze the local control (LC), overall survival (OS), progression free survival (PFS) and toxicity rates of the patients.

Result

The median follow-up was 20 months (range 2 to 120 months). One and two year LC rates were 75.3% and 55.2% [95% confidence interval (CI) 20–25 months]. Median OS was 24 months and the survival rates were 66.6%, 45% and 26.6% at 1, 2 and 3-year after SBRT. Median PFS were 11 months (95% CI 8–18 months). No acute or chronic grade \geq 3 toxicity was observed.

Conclusions

In patients with metastatic and recurrent STS, LC, OS and PFS were higher than expected. SBRT should be a proper treatment option for STS.

Background

Sarcomas are a rare and heterogeneous group of tumors—a general term for a class of mesenchymal solid tumors that can occur anywhere. In 2020, it was estimated that in the USA 13130 people would be diagnosed with STS and 5350 would die of these diseases^[2]. For 30 years, extended local resection and postoperative radiotherapy have remained the standard treatment for soft tissue sarcoma. An increasing number of trials on STS stereotactic body radiation therapy (SBRT) were published, with encouraging results in terms of local control (LC), toxicity and overall survival (OS)^[3].

Soft tissue sarcoma can occur anywhere in the body, most often in the extremities and trunk, and its local behavior is mainly longitudinal extension along the muscle cavity rather than direct invasion. Soft tissue sarcoma does not develop long term invasion of the lymph nodes adjacent to the draining area, a few histological subtypes may have a 15% probability of lymph node metastasis, while hematogenous dissemination is the route of widespread spread of the lesion, with the lung being the most common site of metastasis and approximately 80% of distant metastases occurring within 2-3 years of diagnosis. Treatment of recurrence and metastasis is still challenging, and radiotherapy may be an effective alternative strategy for patients in whom surgical resection is difficult or for those in whom surgery would result in serious complications.^[5-7]

Stereotactic Body Radiotherapy (SBRT) refers to the type of treatment under stereotactic control, in which a high dose of radiation is given to the target area in one or less concentrated doses. It plays an important role in the treatment of

tumors^[1]. SBRT is non-invasive and has a convenient segmentation plan that minimizes chemotherapy delays. In addition, SBRT uses rigorous fixation, advanced image guidance, and complex treatment planning and delivery systems, resulting in a highly conformal dose distribution that reduces treatment volume relative to conventional radiotherapy. This, in turn, allows each fraction to deliver large doses of radiation and increase the biologically effective dose (BED), as opposed to what traditional treatments can do^[4].

Thus, theoretically, SBRT is an attractive alternative to surgical resection, conventional radiotherapy or other palliative measures in certain patients with metastatic or recurrent soft tissue sarcoma. In the current study, we report our early institutional experience with SBRT in patients with soft tissue sarcoma.

Methods And Materials

Patients

We retrospectively searched our patient database for records of patients who received SBRT at our institution between 2009 and 2019. All patients were confirmed by biopsy pathology at the time of the first disease recurrence.

SBRT

The American Society of Therapeutic Radiology and Oncology and the American College of Radiology published guidelines for the implementation of SBRT, which is defined as "an external beam radiation therapy for the very precise delivery of high doses of radiation to extracranial targets in the body, using single doses or small fractions".^[8] Indications for the treatment were discussed at the multidisciplinary tumor board. Stereotactic therapy using the CyberKnife Radiation Therapy System. The planned target volume (PTV) was obtained by isotropic expansion of 2-7 mm around the macroscopic lesion (bulk tumor volume, GTV) outlined on a 1.0 mm thick simulated CT scan. The dose was opened to the outer line of the PTV and to the 75-85% isodose line. Different dose grading procedures were used. Efficacy was assessed using the revised solid tumor response assessment criteria (RECIST version 1.1,2009). Acute toxicity and late toxicity (within 3 months or after the end of treatment, respectively) were assessed using the Common Terminology Criteria for Adverse Events (CTCAE version 4.03,2010). Clinical assessment by physical examination and CT scan was performed at 3 and 6 months, followed by every 6 months until 5 years post-treatment or until disease progression.

Definition of the endpoints

Local failure (LF) was defined as a minimum 20% increase in the diameter of the treated volume. Local control rate (LC) was calculated for 58 lesions from the start of radiotherapy to LF or last follow-up. Overall survival (OS) was measured from the start of radiotherapy to death from any cause or the last follow-up visit.

Statistical analysis

LC PFS and OS rates for all patients were calculated from the date of the SBRT using the Kaplan-Meier method. Univariate analysis was performed using univariate analysis and a multi-logistic regression analysis to identify significant prognostic factors for LC PFS and OS. For all analyses, two-sided tests of significance were used with P values < 0.05 considered significant. All statistical analyses were performed using the Statistical Package for the Social Sciences (version 22.0; SPSS).

Results

Patient- and treatment-related characteristics

Between June 2009 and June 2019 37 patients with 58 lesions were treated in this study. As the table 1 shows, the mean age was 55 years (range, 19-82 years). The number of lesions at the first SBRT less than 3 and equal or more than 3 was 27(73%) and 10(27%). Together, the number of high differentiation, moderately differentiation and poor differentiation was 19(51%),4(11%) and 14(38%).

Table 1 Patient-related characteristics in STS patients treated by SBRT (per patient)

Patient-related variables (n = 37)	Patients, n	%
Age		
<60	18	49
≥60	19	51
Gender		
Male	25	68
Female	12	32
Pathological type		
leiomyosarcoma	3	8
Spindle cell tumor	6	16
Malignant fibroblastoma	8	22
fibrosarcoma	3	8
liposarcoma	4	11
Others	13	35
Grading		
high differentiation	19	51
Intermediate differentiation	4	11
low differentiation	14	38
Number of concurrent metastases at the time of first SBRT		
<3	27	73
≥3	10	27

Table 2 Treatment-related characteristics in metastases or local recurrences treated by SBRT (per treatment)

Treatment-related variables (n = 58)	Treatments, n	%
Site		
Head and neck	6	10
Lung	17	30
Chest	5	9
Abdominal pelvic	13	22
renal region	5	9
Vertebral body bone	10	17
limbs	2	3
Diameter		
<50mm	26	45
≥ 50 mm	32	55
BED		
<100Gy	29	50
≥100Gy	29	50

Abbreviations: BED: biologically equivalent dose. BED values calculate using $\alpha/\beta = 10$.

Table 3 The dosimetry index of the patients during Cyber-knife radiosurgery treatment

Item	CI	nCI	HI	Coverage (%)	PTV (cm ³)	Prescription dose (Gy)	fx	Isodose (%)
Range	1.00- 2.77	1.13- 2.93	1.10- 2.00	47.81- 99.75	2.02- 1878.09	20-75	1-10	50-88
Mean	1.31	1.61	1.39	82.52	307.03	44.81	4.33	73.26
Median	1.13	1.42	1.33	86.12	83.25	45	5	75

Abbreviations: Coverage: the coverage is volume of the tumor receiving greater than or equal to the prescription dose divided by the total volume of the tumor times 100; CI, conformity index; nCI, new conformity index; HI, homogeneity index.

Local control

Among the 58 lesions in the 37 patients in this study, the median local control time was 25 months and 95%CI was 20-25 months. A Kaplan-Meier plot for overall survival is shown in Fig. 2A. One year local control rate was 75.3% and

55.2% in 2 years. Among them, LC with low differentiation sarcoma was better than high differentiation ($P = 0.0201$), LC with tumor diameter less than or equal 5cm was better ($P = 0.0081$), and was independent of BED ($P = 0.0891$).

Overall survival

In this study, the median time of OS was 24 months, and 95%CI was 12.0-35.0 months. A Kaplan-Meier plot for overall survival is shown in Fig. 2A. 1-year OS was 66.6%, 2-years OS was 45%, and 3-years OS was 26.2%. Among them, OS was related to systemic status, and single lesion was better, $P = 0.0069$. Median OS of single lesion was 28 months, 95%CI was 21-75, 1-year and 3-year survival rates were 100% and 50.5%, respectively. The median OS of multiple lesions was 11 months, 95%CI was 4.00-26.00, and the 1-year and 3-years survival rates were 45.3% and 11.3% respectively.

Progression-free survival

A Kaplan-Meier plot for progression-free survival is shown in Fig. 3. 1-year PFS is 44.9% and 2-years PFS is 26.2%. The median PFS of single lesion was 15 months, 95%CI 8.00-31.00, and the 1-year and 2-years progression-free survival rates were 53.2% and 37.3%, respectively. The median PFS of multiple lesions was August, 95%CI 3.00-13.00, and the 1-year and 2-year progression-free survival rates were 26.6% and 0%, respectively. In addition, low-grade lesion PFS was superior to high-grade lesion PFS, $p = 0.0006$, low-grade median PFS was 25 months, 95%CI was 11.00-77.00, 1-year and 2-year progression-free survival rates were 76.9% and 57.7%, 1-year and 2-year progression-free survival rates were 8months 95%CI 4-10, 1-year and 2-year progression-free survival rates were 22.4% and 5.5%, respectively.

Univariate Analysis and A Multi-Logistic Regression Analysis

Univariate and multivariate regression analysis were used to determine which factors were associated with LC, OS and PFS. Multivariate analysis for LC was associated with pathological grade, tumor size, and number of tumors at the time of first SBRT treatment, but not with BED. In univariate analysis, it was only related to pathological grade and tumor size, but not to BED and the number of tumors at the time of first SBRT treatment. Univariate and multivariate analysis of OS and PFS were related to pathological grade and the number of tumors at the time of first SBRT treatment, but not to BED and tumor size.

Table 4 Univariate analysis of PFS and OS

Variable	OS HR and 95%CI	p	PFS HR and 95%CI	p
Grading				
poor differentiation	0.205 0.075-0.564	0.002	0.234 0.095-0.580	0.002
High or moderately differentiation	1		1	
Diameter				
≤50mm	0.873 0.386-1.971	0.743	0.822 0.362-1.863	0.638
>50 mm	1		1	
BED				
≥100Gy	0.628 0.284-1.392	0.252	0.597 0.269-1.327	0.206
<100Gy	1		1	
Number of concurrent metastases at the time of first SBRT				
<3	0.349 0.151-0.804	0.013	0.372 0.155-0.892	0.027
≥3	1		1	

Table 5 A Multi-Logistic Regression Analysis of PFS and OS

	PFS	OS
Grading	P=0.002	P=0.002
	HR 0.231(0.092-0.578)	HR 0.174(0.059-0.512)
Number of concurrent metastases at the time of first SBRT	P=0.019	P=0.008
	HR 0.303(0.112-0.819)	HR 0.261(0.097-0.700)

Table 6 Univariate Analysis and A Multi-Logistic Regression Analysis of LC

Local Control				
	A Multi-Logistic Regression Analysis	Univariate Analysis		
			HR and 95%CI	p
Grading	P=0.018 HR 0.225 0.066-0.770	poor differentiation	0.282 0.091-0.879	0.029
		High or moderately differentiation	1	
Diameter	P=0.040 HR 0.224 0.054-0.932	≤50mm	0.170 0.038-0.761	0.021
		>50 mm	1	
BED	P=0.056 HR 3.839 0.965-15.269	≥100Gy	1	0.107
		<100Gy	2.880 0.797-10.409	
Number of concurrent metastases at the time of first SBRT	P=0.013 HR 0.155 0.036-0.671	<3	0.538 0.166-1.740	0.301
		≥3	1	

Case presentation

The patient is a 71-year-old male with a mucinous liposarcoma of the medial thigh. The first surgical resection was performed on 2000-08-29, followed by in situ recurrence followed by tumor resection on 2008-12-10, 2011-02-14, 2016-06-20, 2017-08-13, and 2018-11-19, respectively. The postoperative pathology was all mucinous liposarcoma. In May 2019, the patient's repeat MRI suggested a recurrence of Stereotactic radiotherapy for recurrent lesions was performed on 2019-06-06 with a specific plan of 50Gy/5fx. As shown in Figure 4, review after 1 year of treatment suggests disease reduction.

Toxicity

There have been no cases of acute or late grade 4 toxicity or possible treatment-related death. The most common acute toxicity was grades 1–2 fatigue (8/37,21.6%). Acute grades 1–2 radiation pneumonitis occurred in one patients (2.7%), and acute grade 1-2 radiation enteritis was observed in two patients (2.7%). Late grade 3 radiation dermatitis was observed in one patient (2.7%) at 6 months after SBRT.

Discussion

Sarcomas are heterogenous malignancies of mesenchymal origin and are classified into more than 100 distinct subtypes. Due to the biology of the tumor, soft tissue sarcoma is prone to recurrence and metastasis. According to the guideline recommendations, the treatment of choice for this tumor is surgery, and in some patients, after multiple surgeries, it is difficult to undergo surgery again, in which case radiotherapy can be an alternative local treatment.

Soft tissue sarcomas are prone to recurrence and metastasis. Recurrent and metastatic soft tissue sarcomas are often difficult to treat surgically due to anatomical location limitations, At the same time, drug therapy for soft tissue sarcomas that cannot be surgically resected has limited efficacy, and stereotactic radiotherapy targeting primary and metastatic lesions of soft tissue sarcomas is available.

In recent years, SBRT has been increasingly used for patients with tumors that are not candidates for surgery. In lung cancer, for example, it is now the standard treatment option for early-stage inoperable non-small cell lung cancer due to its superior efficacy.^[9] Likewise, SBRT plays an important role in hepatopulmonary metastases from colon and breast cancers^[10-11]. For patients with recurrence and metastasis, several small, single-institution retrospective studies have shown that SBRT has a relatively high local control rate and low toxicity in the treatment of sarcoma PM^[19-21]. Numerous retrospective studies have shown that SBRT can provide durable local control of lung metastases from soft tissue sarcomas. In response to SBRT versus surgery, C. Tetta et al study showed that topically applied SBRT for STS lung metastases was associated with lower cumulative overall mortality and similar overall and disease-free survival compared to surgery^[22]. In contrast, SBRT was associated with higher disease survival compared to metastasectomy [MTS].

Current studies on the role of SBRT in soft tissue sarcoma including primary and metastatic lesions are shown in the table^[12-13]. Based on their experience. Previous studies addressing the role of SBRT in sarcoma have focused on metastases of the lung and spine, with Billingsley et al^[14]. reporting a median OS of 33 months after resection of lung metastases compared to 11 months for nonsurgical treatment. However, most SBRT studies reported median overall survival of less than 30 months.^[15-19] In our study, the OS was 24 months, probably due to the fact that the selected patients were recurrent and metastatic patients who had received multiple treatments and almost all of them had more than one metastatic lesion before undergoing SBRT. In the study, 70% received surgery prior to stereotactic radiotherapy, 49% received chemotherapy, and 32% received both surgery and chemotherapy.

Table 7. Summary of studies on stereotactic body radiotherapy for sarcoma

Study	Site	N Patients	N Metastases	Dose and fraction of radiation	LC	OS	DMFS	Median Follow-up
Mauro Loi 2018	Mixed	16	26	30-60Gy/1-6fx	4years:78%	Median:69 months	17months	36
Christina Linder Stragliotto 2012	Mixed	46	136	10-48Gy/1-5fx	-	Median:26 months	-	22
Our study	Mixed	37	58	20-75Gy/1-10fx	One year:75.3% Two years:55.2%	Median:24months	-	20

Based on common sense speculation, the relevant factors affecting the efficacy of SBRT may be tumor size, prescribed dose, and histology. The prognosis of soft tissue sarcoma is inferred by the interaction of multiple factors, including varying characteristics of the patient, varying characteristics of tumorigenesis and presentation and

specificity of the different modalities, sequences and combinations of combination therapy, so that even the conclusions obtained from a single-factor analysis or even a multifactor analysis, evaluated in a number of reports, reveal the impact of the bias of the selection criteria of the patient and the limitation of the sample size. In our study, patients' OS and PFS were not related to biologically equivalent dose (BED), but to tumor grade and number of tumors at the time of first treatment. In the regression analysis for LC, multivariate analysis was related to pathological grade, tumor size and number of tumors at first SBRT treatment, but not to BED. In the univariate analysis, it was only related to pathologic grade and tumor size. We can infer that the prognosis of soft tissue sarcoma is related to the characteristics of the tumor itself rather than the characteristics of the treatment.

The treatment response in this study was mild, mainly grade 1-2 fatigue and radiation pneumonia, with only one case of grade 3 skin reaction, the side effects of this treatment were mild, may be related to the relatively low impact of SBRT on normal tissues. The local response was comparable to surgical intervention, and the long-term survival rate ([36 months]) of 30% for metastatic sarcoma was significant, compared to an overall 5-year survival rate of approximately 70% for non-metastatic sarcoma [23]. This demonstrates the effectiveness of SBRT in metastatic sarcoma and the urgent need for further development and evaluation of this approach in future controlled clinical trials.

There are several limitations of our study. First, the number of cases in this study is small. And as a retrospective study of patients treated over a long period of time, selection bias cannot be excluded. Due to the rarity of the disease, a multicenter, clinically controlled study is necessary.

Conclusion

Stereotactic radiation therapy might offer a useful alternative to surgery in the treatment of metastatic and recurrent. Such therapy is well tolerated and provides a realistic opportunity for eradication, or at least stabilization, of metastatic lesions.

Abbreviations

STS Soft tissue sarcoma

SBRT Stereotactic Body Radiotherapy

LC Local control

OS Overall survival

PFS Progression free survival

CI Confidence interval

BED Biologically effective dose

PTV: Planned target volume

GTV: Gross tumor volume

LF: Local failure

BED: Biologically equivalent dose

CI: Conformity index

nCI: New conformity index

HI: Homogeneity index

MTS: Metastasectomy

Declarations

Ethics approval and consent to participate

The study protocol was in accordance with the ethical guidelines of the Declaration of Helsinki and was approved by the independent ethics committees at Jinling Hospital. In addition, all inclusion patients gave written informed consent.

Consent for publication:

Not applicable.

Availability of data and materials:

The datasets supporting the conclusions of this article are included within the article and its additional files. They are also available from the corresponding author on reasonable request.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions:

Xiaoyao Feng: Methodology, Software, Writing- Original draft preparation. Jing Li: Conceptualization, Methodology, Software. Zhen Wang: Visualization, Investigation, Writing - Review & Editing, Formal analysis. Aomei Li: Project administration. Han Zhou: Data curation, Investigation, Writing - Review & Editing. Xi-xu Zhu: Funding acquisition, Supervision, Validation.

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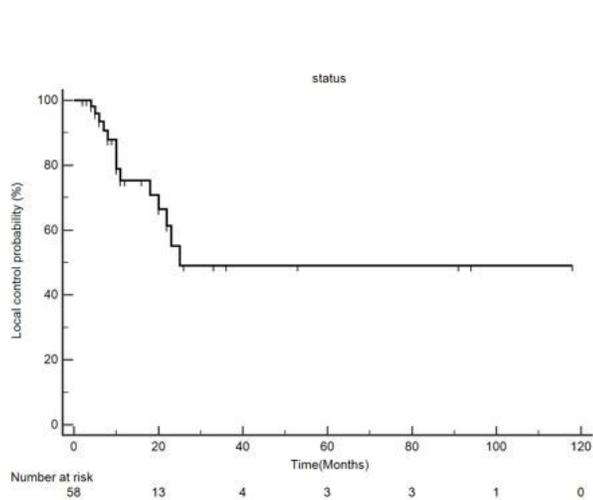
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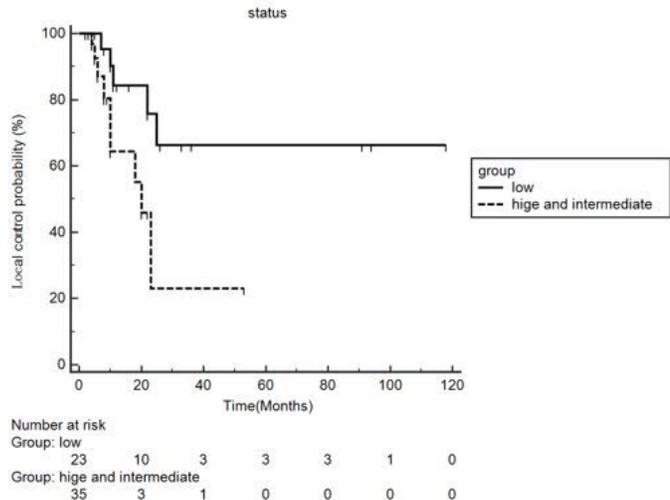
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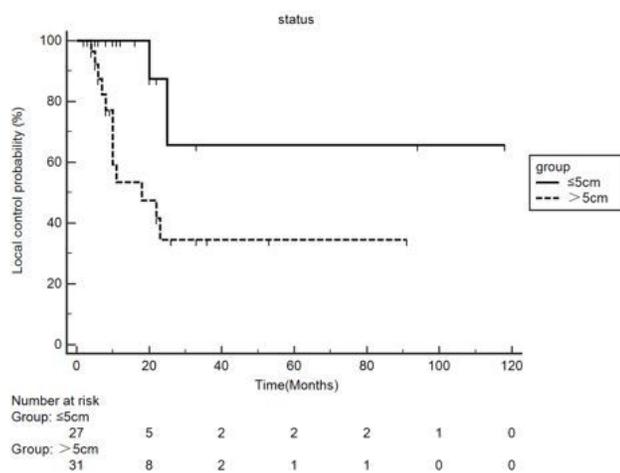
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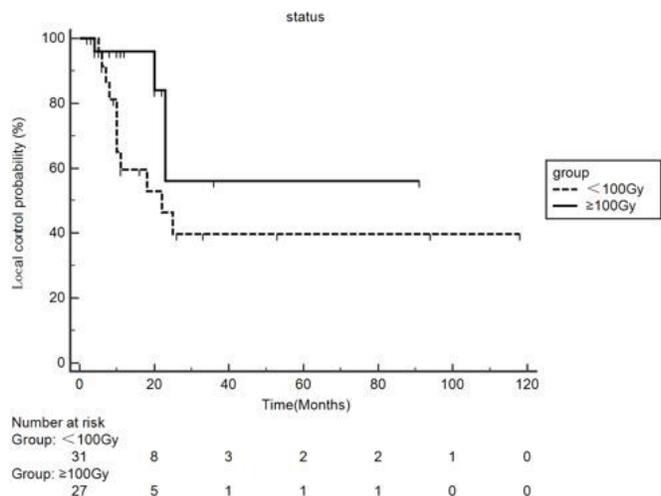
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Figure 1

Kaplan–Meier plots for: a local control following stereotactic body radiation therapy (SBRT). b Local control following SBRT stratified by low differentiation (dashed line) and high and intermediate (solid line).c Local control following SBRT stratified by tumor diameter less than or equal 5cm (dashed line) and more than 5cm (solid line). d Local control following SBRT stratified by BED<100Gy (dashed line) and BED≥100Gy (solid line).

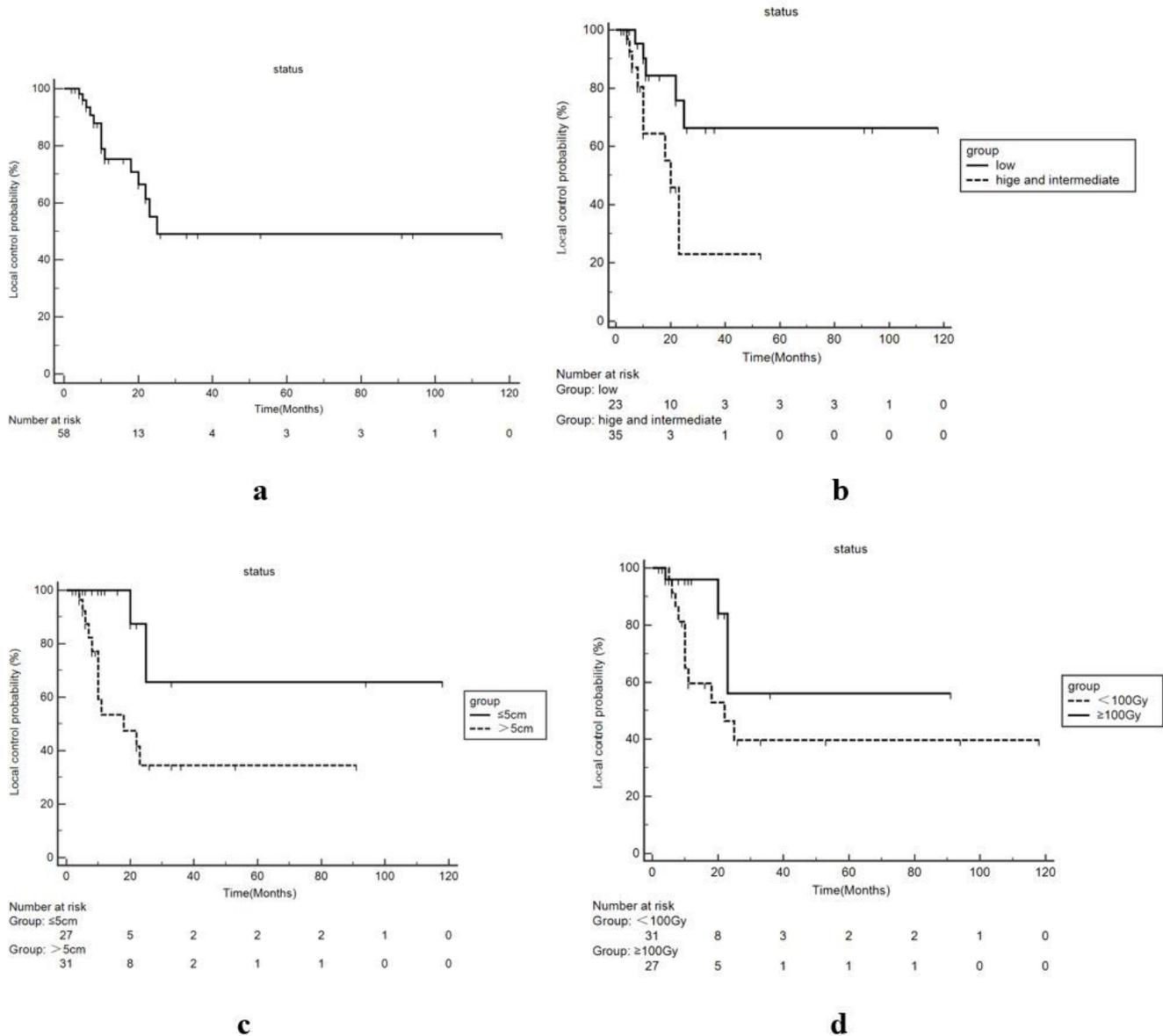


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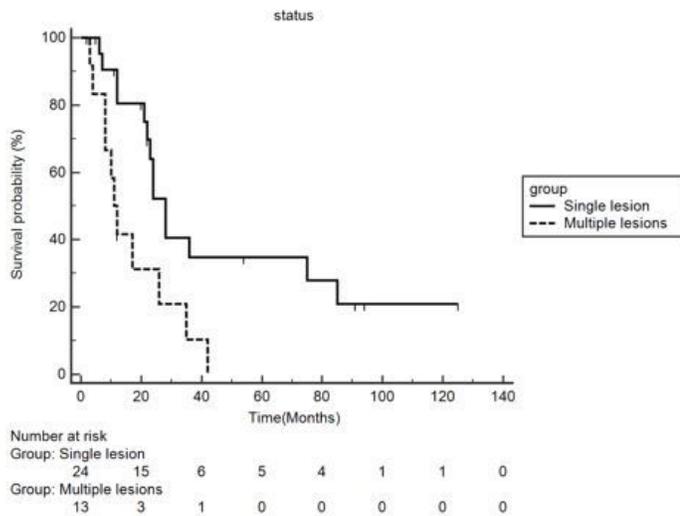
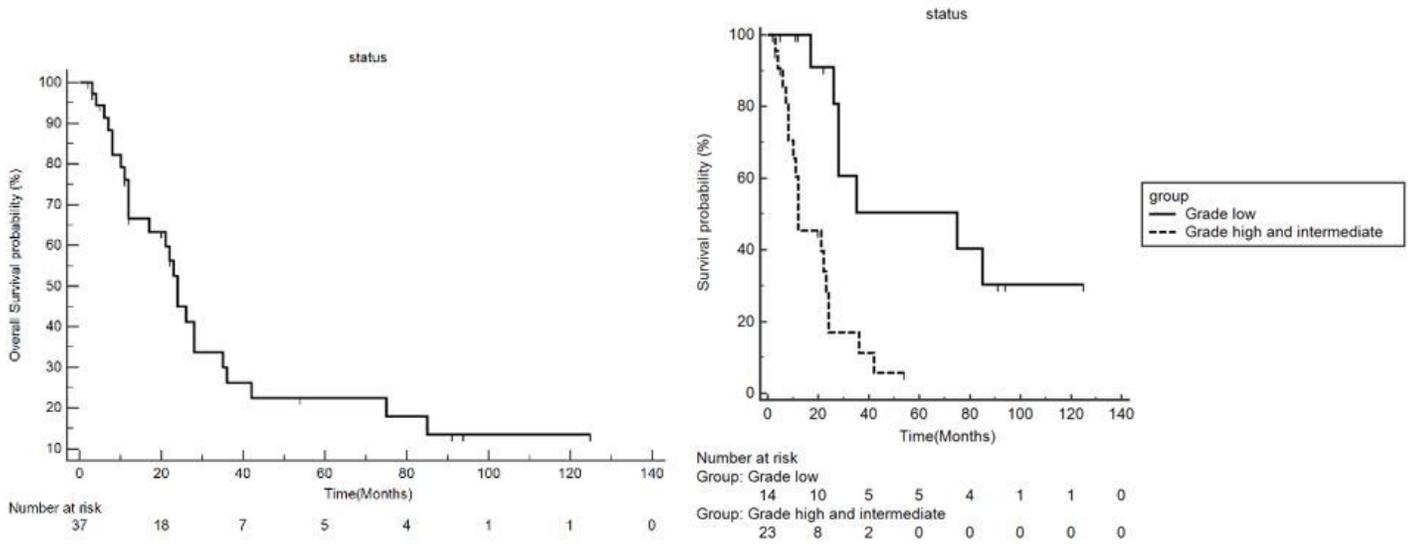


Figure 2

Kaplan–Meier plots for: a overall survival following stereotactic body radiation therapy (SBRT). b Overall survival following SBRT stratified by low differentiation (dashed line) and high and intermediate (solid line). c Overall survival following SBRT stratified by single lesion (dashed line) and multiple lesions (solid line)

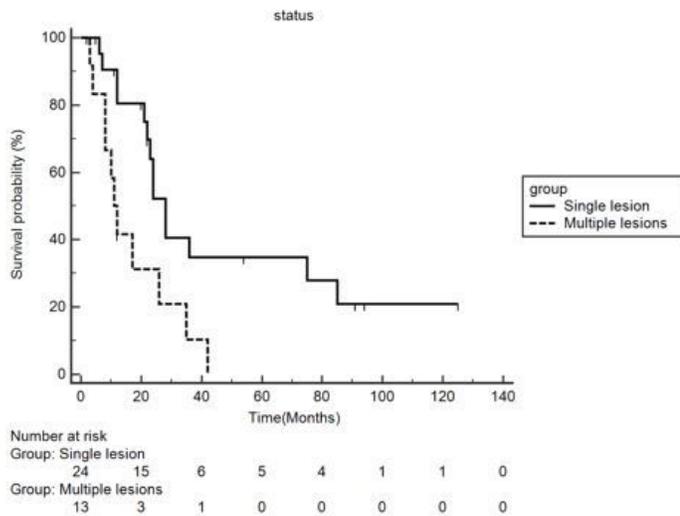
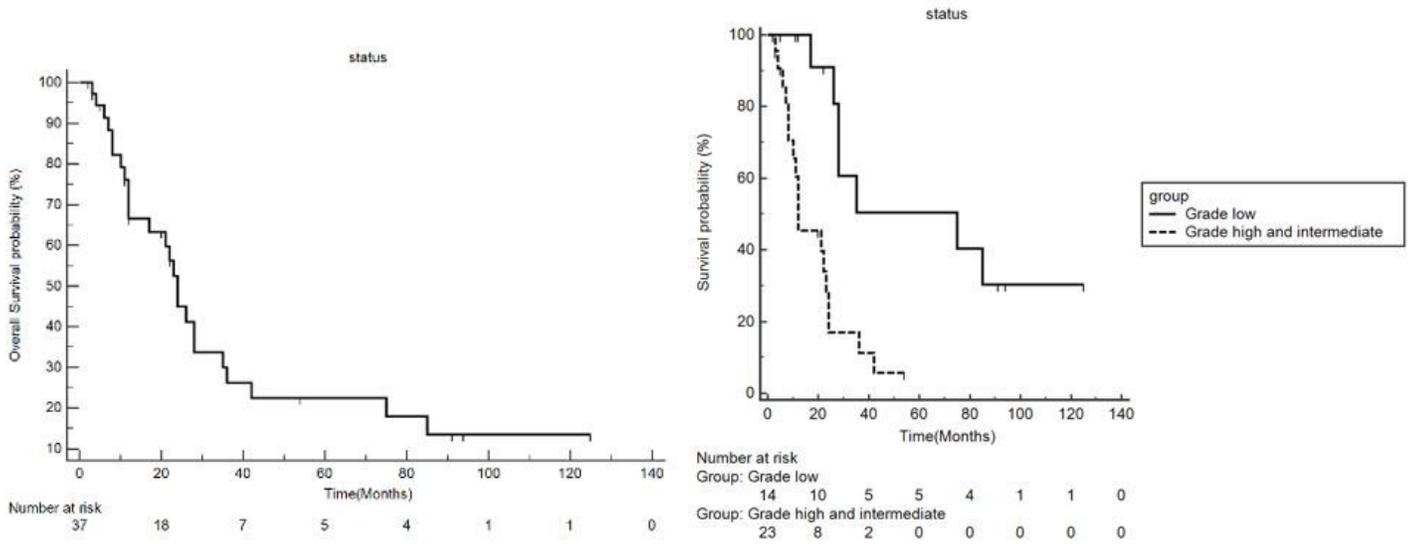
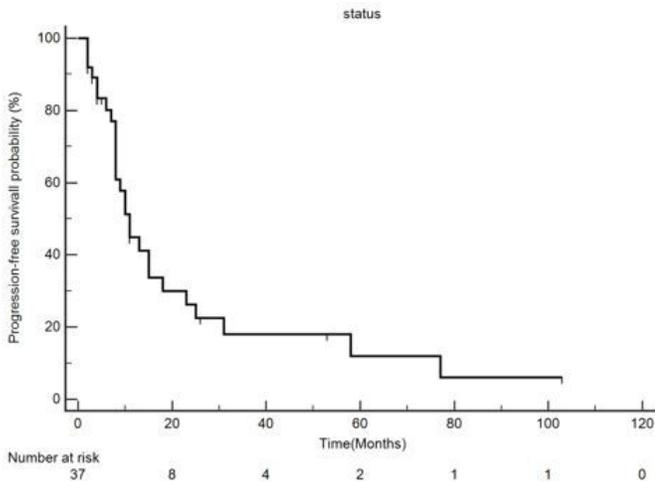
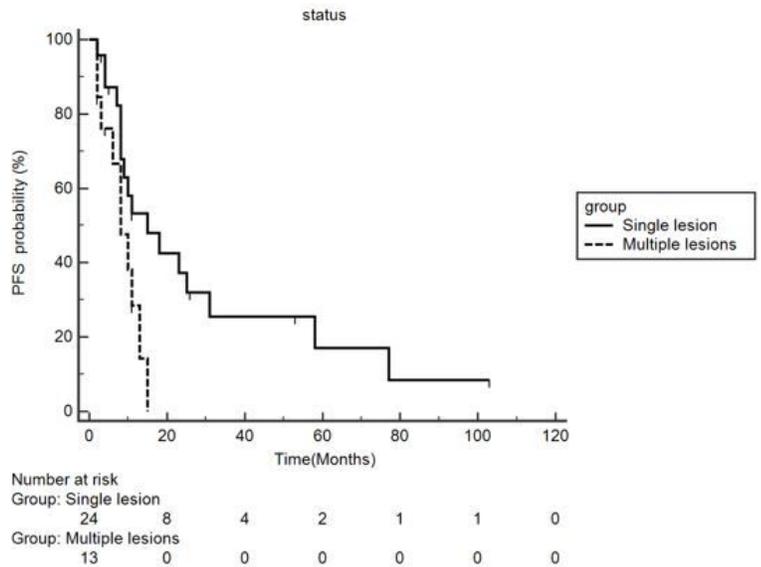


Figure 2

Kaplan–Meier plots for: a overall survival following stereotactic body radiation therapy (SBRT). b Overall survival following SBRT stratified by low differentiation (dashed line) and high and intermediate (solid line). c Overall survival following SBRT stratified by single lesion (dashed line) and multiple lesions (solid line)



a



b

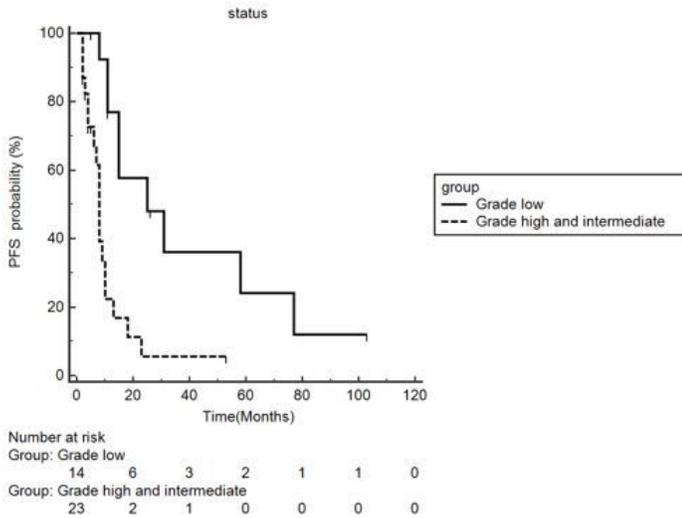
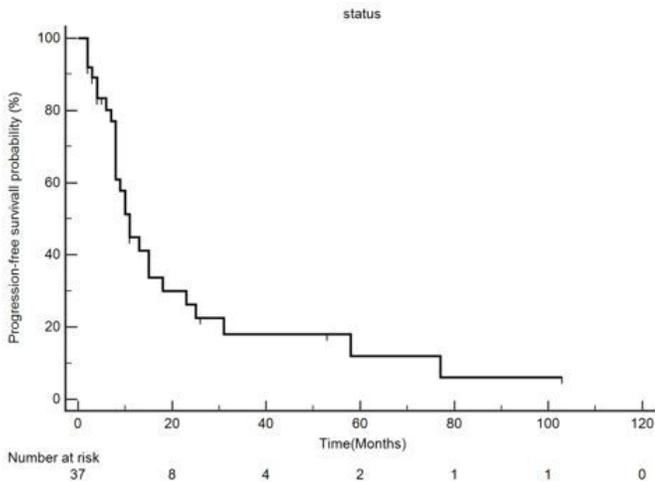
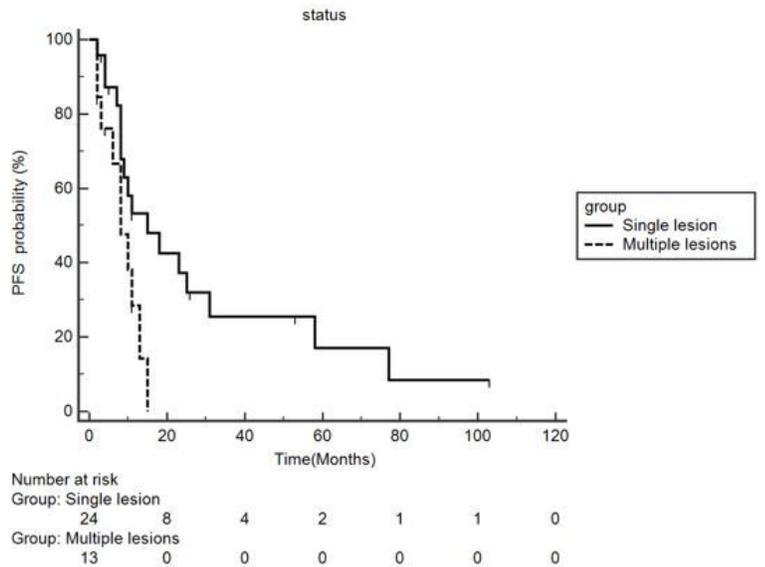


Figure 3

Kaplan–Meier plots for: a progression-free survival following stereotactic body radiation therapy (SBRT). b progression-free survival following stereotactic body radiation therapy (SBRT) stratified by single lesion (dashed line) and multiple lesions (solid line). c progression-free survival following stereotactic body radiation therapy (SBRT) stratified by low differentiation (dashed line) and high and intermediate (solid line).



a



b

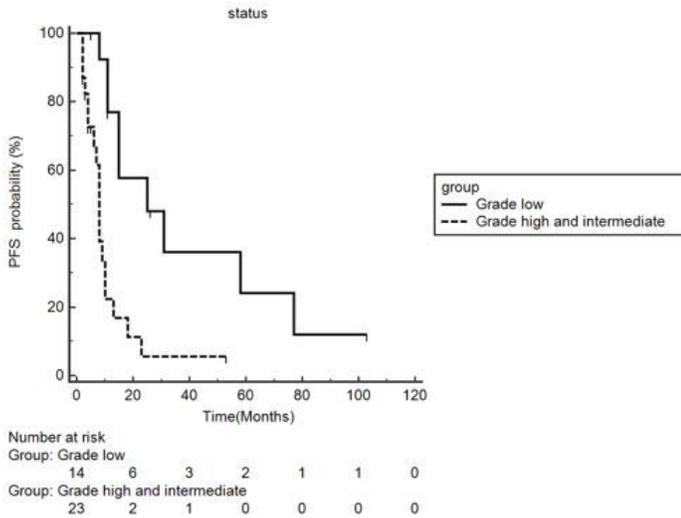


Figure 3

Kaplan–Meier plots for: a progression-free survival following stereotactic body radiation therapy (SBRT). b progression-free survival following stereotactic body radiation therapy (SBRT) stratified by single lesion (dashed line) and multiple lesions (solid line). c progression-free survival following stereotactic body radiation therapy (SBRT) stratified by low differentiation (dashed line) and high and intermediate (solid line).

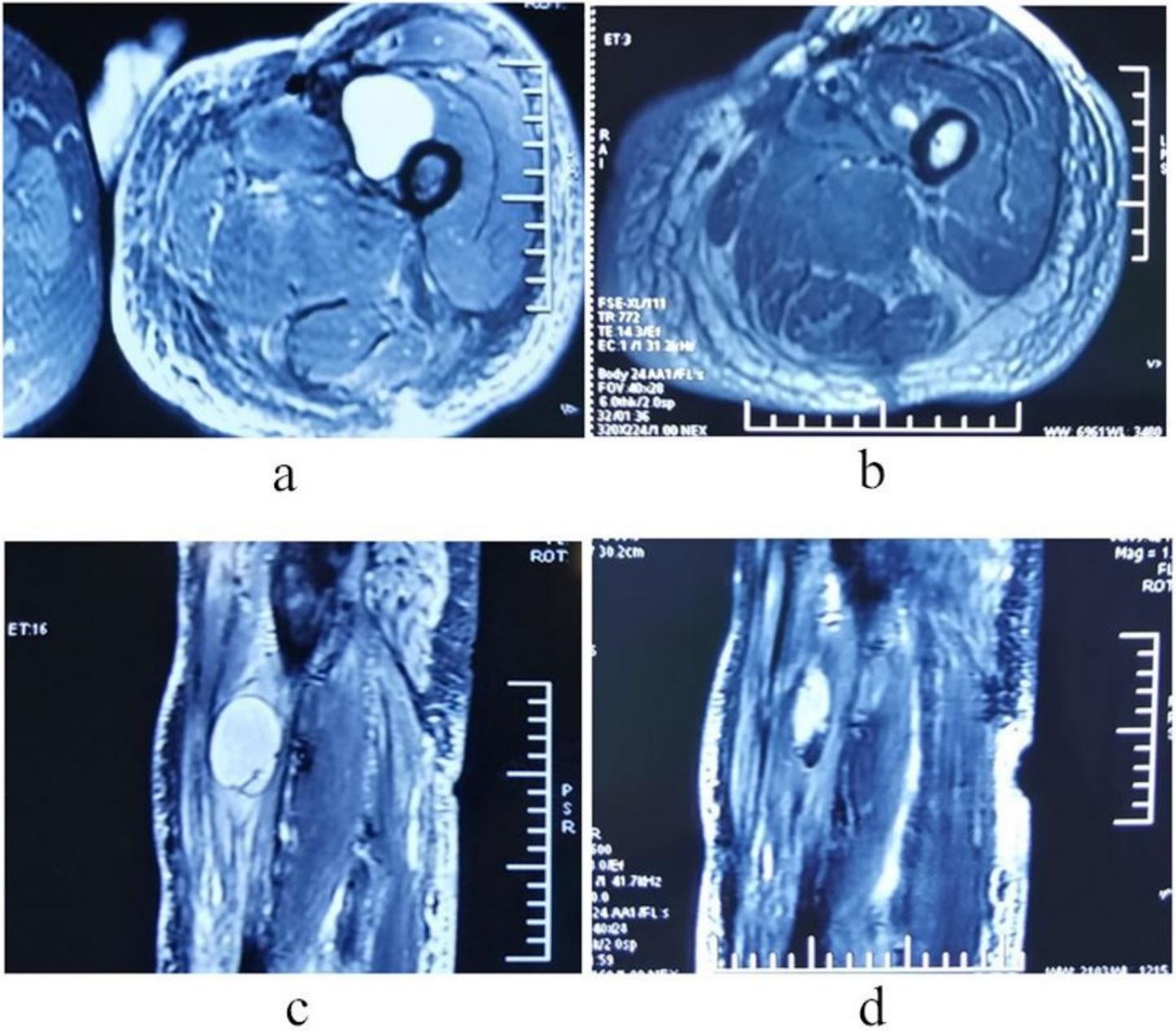


Figure 4

Recurrence of mucinous liposarcoma of the inner thighs in a 71-year-old male. Axial (a and c) and sagittal (b and d) T1-weighted images acquired with gadolinium before treatment (a and b) and after treatment (c and d).

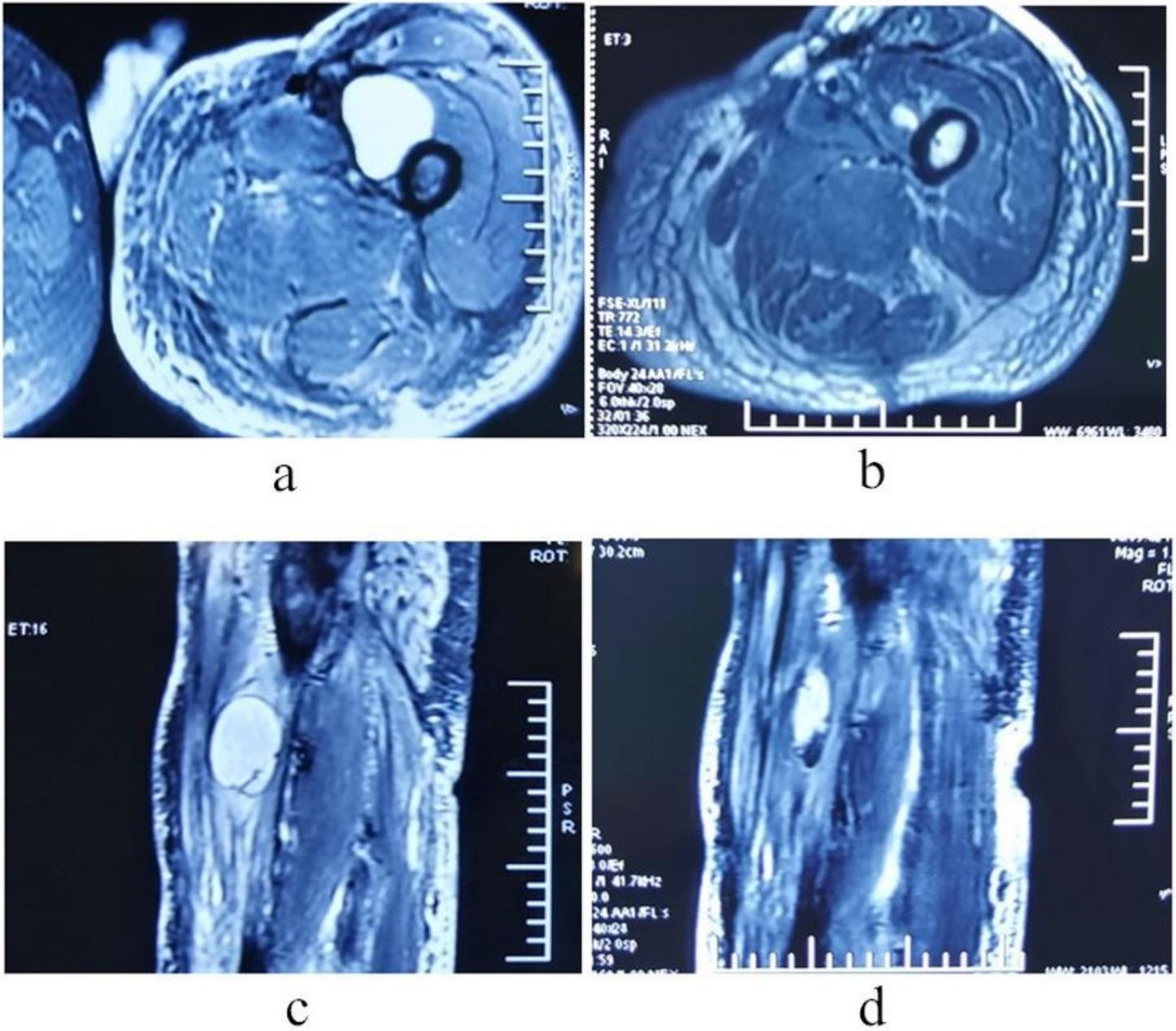


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