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Management of unresectable and recurrent intra-abdominal desmoid tumors treated with ultrasound-guided high-intensity focused ultrasound

A retrospective single-center study

Yongming Yang[a,*], Jian Zhang[a], Ying Pan[a]

Abstract

To assess the efficacy and safety of ultrasound (US)-guided high-intensity focused ultrasound (HIFU) ablation for treatment of unresectable and recurrent intra-abdominal desmoid tumors. From June 2014 to March 2020, 15 patients with consecutive unresectable and recurrent diseases that pathologically proven to be intra-abdominal desmoid tumors had undergone the treatment of US-guided HIFU ablation. All patients underwent contrast-enhanced magnetic resonance imaging before and after HIFU treatment. Nonperfused volume ratio was used to evaluate the effect of HIFU therapy. Intraprocedural and postprocedural adverse effects and complications are recorded to assess the safety of the therapy. Outcome of HIFU ablation has been investigated through serial contrast-enhanced imaging examinations during follow up. Out of 15 patients 14 of them have successfully completed the whole therapy, 1 patient is ineffective and gives up further treatment. The mean nonperfused volume ratio is 71.1% (95% confidence interval, 3% to 88.2%). During a mean follow up of 29 months (range from 8 to 61 months), the mean tumor volume was reduced by 59% (95% confidence interval, +49% to −100%). No tumor spreads along the treated area in all patients except one. Complications have occurred in 5 patients (33.3%), including bowel rupture (1 case), intra-abdominal abscess (1 case), slight injury to the femoral nerve (1 case), and bone injury (2 cases), the bowel rupture patient underwent surgery; the others have been cured during the follow up. US-guided HIFU ablation is an effective treatment modality for patients suffered from unresectable and recurrent intra-abdominal desmoid tumors.

Abbreviations: HIFU = high-intensity focused ultrasound, MRI = magnetic resonance imaging, NPV = nonperfused volume, NPVR = nonperfused volume ratio, US = ultrasound.

Keywords: ablation, complication, intra-abdominal desmoid tumor, ultrasound-guided high-intensity focused ultrasound

1. Introduction

Desmoid tumor is a rare kind of fibroblastic tumors which derives from deep fascia planes or muscuofascia structures; it is prone to locally aggressive behavior but having no metastatic potential.[1] The incidence of desmoid tumors is 2 to 4 per million per year and more often in young adults.[2,3] Because of rarity, these tumors pose a diagnostic and therapeutic challenge. So far, there is still no large multicenter studies or recognized treatment guidelines. Desmoid tumors are usually classified as abdominal wall desmoid tumors, intra- and extraabdominal wall tumors, while the intraabdominal wall tumors are reportedly the least common. Intraabdominal desmoid tumors often occur in the mesentery, pelvis, and retroperitoneum.[4] Most of intra-abdominal tumors remain asymptomatic or painless masses, and symptoms arise in the form of complications, such as obstruction, bowel rupture, and fistula. Whenever possible, surgical resection with negative margins should be the first-line treatment modality.[5] But many times it is impossible to resect the tumor radically because of the involvement of the base of mesentery and proximity to vital neurovascular structures. Furthermore, the desmoid tumor recurrence rate is high even after complete resection. Additionally, extensive resection is associated with a high risk of mortality.[6–8] Radiation therapy is effective but it is rarely used because of high risk of radiation enteritis.[9] Alternative therapies, such as hormonal therapy, nonsteroidal antiinflammatory drugs, molecularly targeted therapy, and

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[a] Department of General Surgery, The First People's Hospital of HangZhou Lin'an District, China.

**Correspondence: Yongming Yang, Department of General Surgery, The First People's Hospital of HangZhou Lin'an District, Linan, Zhejiang 311300, China (e-mail: yymla@163.com).*

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chemotherapy, have shown limited success in the treatment of desmoid tumors.[10–13]

The optimal treatment for intra-abdominal desmoid tumors for unresectable and recurrent patients has not been established and the corresponding medical treatments have not been standardized due to the lack of clinical data regarding the rare disease.

High-intensity focused ultrasound (HIFU) is a noninvasive thermo-ablative technique, which has been successfully utilized in the treatment of malignant solid tumors of liver, breast, pancreas and uterine fibroids, benign solid thyroid nodule, and extraabdominal desmoid tumors [14–20] To our knowledge, there are still no published special studies about HIFU ablation treatment for unresectable and recurrent intra-abdominal desmoid tumors. In the study, we analyzed the outcomes of 15 unresectable and recurrent patients with intra-abdominal desmoid tumors who had received the treatment of US-guided HIFU. We reviewed our experience to provide clues for selecting the optimal strategy for the rare disease.

2. Materials and Methods

2.1. Study population

This was a retrospective single-center study. From June 2014 to March 2020, 15 consecutive unresectable and recurrent symptomatic intra-abdominal desmoid tumors patients (5 men, 10 women; mean age, 35.2 years) who had been pathologically proven were treated with US-guided HIFU ablation at The first people's hospital of HangZhou Lin'an district, Zhejiang province, China. The Ethics Committee of the First People's Hospital of Lin'an District, Hangzhou City approved this study (2022No.17). For all the cases, treatment options were discussed with the patients and informed consent was reached. Out of 15 patients 13 (13/15, 86.7%) had recurrent tumors in the area of previous surgical resection. The other 2 patients (2/15, 13.3%) had surgical biopsies when the tumor was found to be unresectable during the surgery. One of them was due to the involvement of the base of mesentery and oppression the superior mesenteric vein (Fig. 1), the other was due to the massiveness of the tumor which mandated resection of the entire small gut. Five cases (5/15, 33.3%) were Gardner syndrome. Five patients (5/15, 33.3%) had intestinal obstruction before surgical operation. Three patients underwent emergency surgery because of intestinal rupture and peritonitis caused by desmoid tumors. The characteristics of patients are presented in Table 1. Before HIFU ablation, all patients received color Doppler US and contrast-enhanced magnetic resonance imaging (MRI) or contrast-enhanced comp examination so as to evaluate the extents and volume of the tumors. The mean size of the largest tumor (the maximum diameter in 3 orthogonal directions) was 12.1 cm (range, 4.2–31.0 cm). The tumors were seen as hypoechoic nodules on US, while showing substantial enhancement on contrast-enhanced MRI or computed tomography.

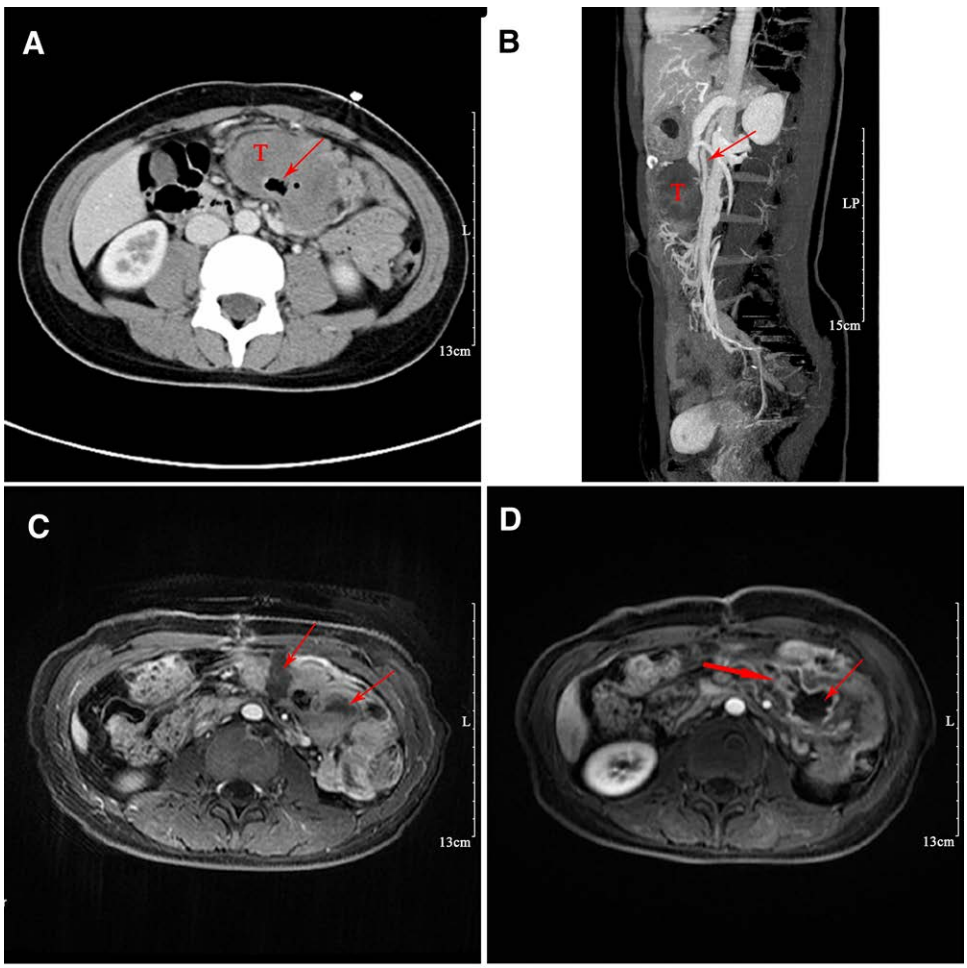

Figure 1. Spiral CT-enhanced scanning of portal phase from patient 5 with mesenteric desmoid tumor. (A) The small intestine(arrow) was wrapped in tumor(T). (B) CT angiography: the tumor (T) oppressed the superior mesenteric vein(arrow). (C) transverse view of contrast-enhanced MR images showed ablation treatment from multiple directions(arrow). (D) the NPVR reached 80.2% when treatment was end (arrow) while small intestine was not injured (bold arrow). CT = computed tomography, MR = magnetic resonance, NPVR = nonperfused volume ratio.

Table 1

Characteristics of patients.

Patient number	Age/ sex	Gardner syndrome	Intestinal obstruction or rupture before HIFU ablation	Location	Previous treatments	Number of radical resection	Recurrence interval time (mo)	Maximum tumor size (cm)
1	28/M	No	Rupture	Mesentery	Surgery	1	5	6.7
2	26/M	No	Obstruction	Pelvis	Surgery	1	17	7.3
3	34/M	No	Obstruction	Retroperitoneum	Surgery	2	24, 30	4.2
4	28/F	No	Obstruction	Mesentery	Surgical biopsies, cryotherapy	0	–	6.5
5	27/F	Yes	No	Pelvis	Surgery, chemotherapy, radiation	2	18, 6	26.1
6	30/F	No	Obstruction	Pelvis	Surgical biopsies	0	–	13.9
7	38/M	No	No	Pelvis	Surgery	1	6	10.8
8	47/M	No	Rupture	Mesentery	Surgery	2	21, 10	7.6
9	19/F	No	No	Mesentery	Surgery	1	12	31.0
10	32/F	No	No	Pelvis	Surgery	2	19, 5	9.2
11	37/F	Yes	No	Retroperitoneum	Surgery	1	8	10.0
12	39/F	No	No	Mesentery	Surgery	3	12, 8, 10	9.2
13	42/F	Yes	Rupture	Mesentery	Surgery	2	15, 8	15.0
14	53/M	Yes	Obstruction	Mesentery	Surgery, chemotherapy	2	36, 12	14
15	48/F	Yes	No	Pelvis	Surgery, chemotherapy, cryotherapy	1	12	10.7

F = female, HIFU = high-intensity focused ultrasound, M = male.

2.2. HIFU ablation procedures

The HIFU system (model FEPBY02) was manufactured by Yuande Biomedical Engineering Co. Ltd, Beijing, China. The authors had complete authority of the data and information submitted for publication. In order to arrange better observation and treatment for possible complications of HIFU ablation, all patients were treated as inpatients in the department. In order to relieve pain and keep the body position stable during the treatment, general anesthesia was administered during the HIFU treatment. The patients were carefully placed in prone or supine position according to the tumor location. Bowel cleansing was performed the day before the treatment. The procedures were performed according to ultrasound guidance. A vertical scanning mode was chosen with a slice thickness of 2 mm. The ultrasonic transmitter worked at a frequency of 1 MHz. Real-time ultrasound was used to monitor tumor response. Echogenic change and cavitation could be seen on monitor ultrasound during therapy. The output power 150 W of the HIFU was set at the beginning, and then was adjusted between 150 and 300 W according to the extent of ablation. The other therapeutic parameters were unchanged during the treatment: T1/T2 990 ms/10 ms; 40 transmissions per therapeutic point with 2 mm between adjacent therapeutic points; treatment of each unit (5 therapeutic points) for 200 s with an interval of 2 minutes between each unit; and a spacing of 5 mm between adjacent treatment slices. The treatment was performed automatically after setting of the parameters. The parameters of the treatment plan, particularly the energy, size, and angle of each sonication, were manually modified before and during the treatment, so as to minimize the heat on the skin and adjacent structures, such as nerves, bones, and vessels. The treatment took about 1 to 2 hour, depending on the size and location of the tumor. Large tumors near important organs or structures would require a longer treatment time. Contrast-enhanced ultrasonography was employed to evaluate the extent of HIFU ablation. Absence of enhanced signals in the tumor area under ultrasonography was considered to be attaining complete ablation. All HIFU treatments were performed by the experienced physician.

2.3. Posttreatment observation and follow-up

The decision to stage a patient's treatment into multiple sessions was made when the tumor was considered to be best treated with multiple directions, for example, medial and lateral. The interval time between 2 HIFU ablations was usually 3 weeks. After HIFU ablation, patients were carefully observed and recorded for possible complications such as intestinal obstruction, peritonitis, and side effects including pain and fever. If there was severe pain after HIFU ablation, oral nonsteroidal analgesic or morphine injection was administered depending on the pain degree. The treated area was reexamined by contrast-enhanced MRI 1 day after HIFU ablation. Areas which were not enhanced (nonperfused) after contrast administration on MRI were considered to be necrotic tissue. Enhanced areas were assumed to be viable tumor.[15] The postprocedural MRI was used to evaluate the nonperfused volume (NPV). The volume of tumors and NPV were measured by the following equation[21] for the prolate ellipsoid: volume = 0.5233*a*b*c (a, b, c were respectively the longitudinal dimension, anterior–posterior dimension and transverse dimension). The nonperfused volume ratio (NPVR) was defined as the NPV which divided according to the tumor volume when the treatment was end. In this study, once the NPVR exceeds 70% the treatment would finish. If the tumor was adjacent to a particular organ such as small intestine, nerve, and superior mesenteric artery, the ablated area was planned as much as possible at safe condition. During the follow-up period, the treatment area was reexamined by contrast-enhanced MRI every 3 months in the first year to assess the therapeutic response or tumor progression. Thereafter, follow up was carried out every half a year. Volume reduction percentage was calculated as: $([Vol_{basal} - Vol_{final}] 100\%)/Vol_{basal}$. If residual tumor enlarged significantly and caused symptoms or recurrent tumor was detected, another HIFU ablation session shall be planned.

3. Results

After US-guided HIFU ablation treatment, 14 in 15 patients (93.3%) successfully completed the procedure, 1 patient (6.7%) was ineffective (NPVR was 3% after 3 times of HIFU ablation) and gave up further treatment. The mean NPVR was 71.1% (95% confidence interval, 3% to 88.2%). During a mean follow up of 29 months (range from 8 to 61 months), the mean tumor volume was reduced by 59% (95% confidence interval, +49% to −100%). No tumor spreading along the treatment area was observed in all patients except 1 (Table 2). No patient received additional systemic or local treatment, such as chemotherapy or radiation. Treatment-related complications occurred in 5 patients (33.3%). One patient had a bowel rupture during the

Table 2

Treatment results.

Patient number	Initial tumor volume (cm^3)	Times of HIFU ablation	Tumor volume when the treatment end (cm^3)	NPV when the treatment was end (cm^3)	NPVR when treatment was end (%)	Tumor volume at most recent follow-up (cm^3)	Follow up (mo)	Volume reduction percentage (%)	Complication	Tumor progress
1	66.6	2	55.3	39.6	71.6	45.1	16	−32.4	No	No
2	107.0	5	76.5	62.0	81.0	24.2	36	−77.4	Sacrum injury	No
3	20.2	3	18.6	13.5	72.5	9.1	19	−45.0	No	No
4	68.5	4	11.6	9.3	80.2	0.0	31	−100.0	No	No
5	1471.3	3	1471.3	43.7	3.0	2193.6	8	+49.1	No	No
6	423.5	8	214.0	165.2	77.2	144.8	20	−65.8	No	No
7	384.5	3	124.1	107.4	86.6	96.7	20	−75	No	No
8	102.8	2	72.7	70.4	76.9	54.2	19	−38.5	No	No
9	5071.9	6	2265.7	974.7	32.0	818.5	32	−83.9	Bowel rupture	No
10	269.6	6	111.1	83.8	75.4	37.8	61	−86.0	Sacrum injury	No
11	218.5	3	216.6	181.5	83.8	98.6	58	−54.9	Nerve palsy	No
12	127.9	4	105.0	83.4	79.4	57.3	48	−55.2	No	No
13	418.2	4	394.6	348.2	88.2	128.4	31	−69.3	Intraabdominal abscess	No
14	305.9	5	171.4	141.7	82.7	103.0	23	−66.3	No	No
15	436.2	6	331.4	252.6	76.2	67.5	16	−84.5	No	No

HIFU = high-intensity focused ultrasound, NPV = nonperfused volume, NPVR = nonperfused volume ratio.

first treatment, and then underwent emergency intestinal anastomosis. After operation, the patient was subjected to 5 courses HIFU ablation, follow-up management, and survived up to now. Another patient had an intra-abdominal abscess at the core of the treatment area after the last treatment, and cured after drainage. One patient suffered a slight injury to the femoral nerve with right lower limb claudication and self-healing without any treatment after 3 months. Two patients had sacrum injury (Fig. 2), but were asymptomatic. All patients with treatment-related complications were cured during follow up.

4. Discussion

Although desmoid tumors are histologically benign, they show malignant behavior with a tendency to invade local tissue and recur after resection.[22,23] There is little universal agreement about the optimal management of this potentially locally aggressive neoplasm; however, the main goal of treatment is durable local control.[24] The mainstay of treatment of recurrent desmoid tumor is surgery with a goal of an R0 resection often combined with radiation therapy.[24–27] But, local control is a very difficult goal to achieve because recurrence rate ranges from 25% to 60% at 5 years in retrospective studies, despite radical treatment.[28] The high recurrence rate may relate to the incontrollable tumor fibrous tissue proliferation after surgery. However, that situation can be effectively avoided during HIFU treatment for it is a noninvasive technique. In this study, all the patients are suffering from symptomatic recurrent or metastatic desmoid tumors who having had surgery, chemotherapy, or radiotherapy before. Tumor progress of 14 patients (93.3%) was durably controlled during the short-to-long follow-up period. There were 3 patients who were followed up more than 4 years (48–61 months) without tumor progress. While before the HIFU ablation regimen, they had undergone 1 to 3 successfully radical resections of recurrent tumors in 3 years. Furthermore, tumor progress or recurrence was not observed in the patients who had undergone HIFU treatment (12 cases) after a mean follow up of 32 months (range 16–61 months) while their mean tumor recurrence time (19 times) was 14 months (range 5–36 months) before HIFU ablation. Since HIFU ablation requires no incision or resection, and the integrity of the fascial compartment is preserved, the risk of tumor spread is low.[18]

NPVR was used to evaluate the sensitivity of the tumor to HIFU ablation therapy. The higher the NPVR is, the more sensitive the tumor is to the therapy. If the tumor is adjacent to a vital structure, it would be ablated from multiple directions to ensure the safety (Fig. 1). Volume reduction percentage reflects the local control of the tumor during the follow-up period. If the tumor continues to shrink, the tumor is well controlled. In our study, the mean NPVR is 71.1%, the mean tumor volume is reduced by 59% during a mean follow up of 29 months (range 8–61 months). If the treatment is ineffective, the NPVR of the tumor would be small, and the tumor volume would enlarge, like Patient 5. In general, the smaller the tumor is, the easier it is to control. However, the therapeutic effect is ultimately determined by the characteristics of the tumor itself. Patient 5 is not sensitive to HIFU and the tumor is too large as well, and another important reason is that it is a cystic solid tumor, which makes the thermal energy accumulation impossible. In fact, effectiveness can be immediately determined after the first treatment. So another advantage of HIFU ablation is that even if it is ineffective it does not delay other therapeutic measures.

Another important issue is that when the HIFU ablation treatment should end? According to our experience, when NPVR reaches 70%, the tumor can be well locally controlled. In this study, once the NPVR exceeds 70% the ablation treatment would finish. If the tumor is adjacent to a particular organ, the ablated area should be as much as possible at safe condition.

In our study, complications include bowel rupture, intra-abdominal abscess, nerve palsy, and coccyx injury. All these damages are mild and relieved quickly except bowel rupture. We acknowledge that HIFU is a relatively new technology and there is undoubtedly a learning curve. Avedian et al[29] suggested that one shall not treat air-containing organs such as bowel because air interface results in dangerous temperature spikes. Li[30] reported that there would be intestinal obstruction and/or rupture in the process of desmoid tumor rapid regression during the treatment period. Patient 9 with maximum tumor size 310 mm could not be judged from all imaging examinations for her small intestine was wrapping in tumor. She had a bowel rupture after the first HIFU ablation, and underwent emergency intestinal anastomosis. After the operation, she completed 5 courses of HIFU ablation with tumor shrunken and survived up to now. Patient 13 got an abdominal abscess after the HIFU therapy, and recovered after receiving antiinfective therapy. There are a few cases in the literature with invasion of desmoid tumor into the bowel wall, which will result in fistula formation and translocation of intestinal bacteria for the tumor. Rarely, they

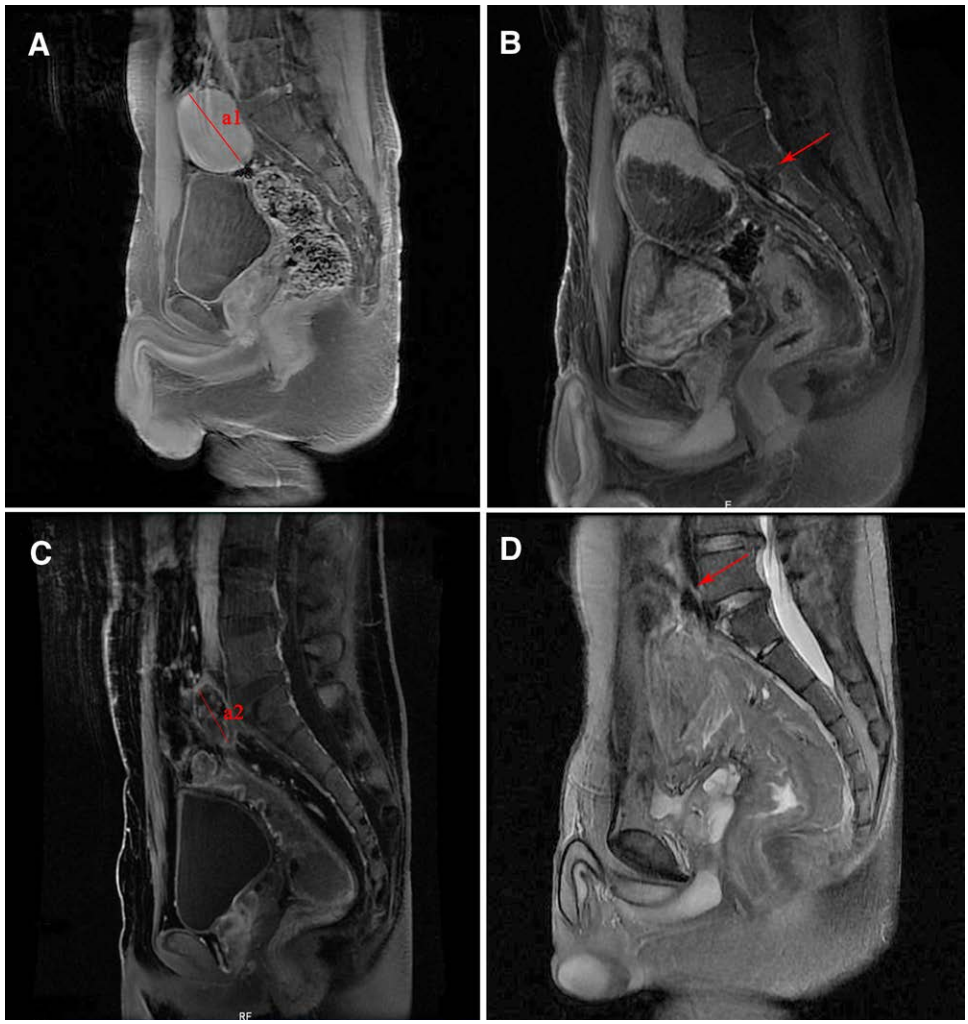

Figure 2. MRI from patient 2 with a recurrent pelvis desmoid tumor. (A) Sagittal T1-weighted images, the maximum tumor size was 7.3 cm (a1) before ablation. (B) sacrum injury (arrow) after the first ablation. (C) sagittal T1-weighted contrast-enhanced images showed the maximum tumor size was 4.5 cm (a2) when the treatment was ended. (D) sagittal T2-weighted image at 36 months follow up demonstrating complete tumor regression (arrow). MRI = magnetic resonance imaging.

can be complicated with intratumor abscess formation, which may be secondary, spontaneous, as a result of intestinal wall ischemia from tumor enlargement.[22] One patient suffered slight injury in femoral nerve with right lower limb claudication and self-healing without any treatment 3 months later. Notably bone absorbs ultrasound to a much higher degree than soft tissue.[18] Another 2 patients with pelvic desmoid tumor close to the sacrums developed a bone injury asymptomatically, but the boundary of the tumor was not destroyed (Fig. 2). There are many adjacent organs around the intra-abdominal tumor and anatomy is complex, so HIFU ablation treatment may easily damage surrounding organs. In our study, the average times of HIFU ablation was 4.3 times (range 2–8 times), the tumors were large and encircled the intestinal canal in several cases. However, bowel rupture occurred in only 1 case with extremely large tumor. While in the other cases, the damage to the organs around the tumor was mild. We sum up our experience that a fractional ablation, multiple directions, and low power treatment strategy would together reduce the injury to peripheral organs. As interventionists gain more experience on performing HIFU, their selectivity at ablating tumor tissue while preserving unaffected tissue would surely be improved.[25] This, together with higher accuracy due to technological advancements and improved beam distortion correction,[31] may eventually allow the use of HIFU for curative intent.

Another advantage of HIFU therapy is that it can be repeated over and over again due to its minimal damage to human body. At present view,[5] desmoid tumors that are asymptomatic, not enlarging, and located in areas that are remote from vital structures may be carefully observed. To our consideration, observation is also suitable for postablation intra-abdominal desmoid tumors. We developed a close follow-up plan, the treated area was examined by contrast-enhanced MRI every 3 months in the first year and then follow up was carried out every half a year. During the follow-up period, tumor stabilization or regression should be continuously observed, once the tumor progress is found another HIFU ablation session would be planned.

The results of this study indicate that the treatment of US-guided HIFU leading to local control in 14 of 15 patients (93.3%) with unresectable and recurrent intra-abdominal desmoid tumors. We have used it as an initial treatment to treat with <5 cm extraabdominal desmoid tumors and achieve good effect. However, we have not used it as initial treatment to treat with intra-abdominal desmoid tumors yet. It is difficult to collect large samples in a single center because it is such a rare disease. We hope our experience can provide evidence that US-guided HIFU can be used as a novel treatment for desmoids tumors and is worth further investigation. Hope a larger, multi-center, prospective study can be carried out to further confirm those results.

5. Conclusion

US-guided HIFU is an effective treatment for patients with unresectable and recurrent intra-abdominal desmoid tumors. When the tumor is adjacent to an air-containing organ or nerve, the ablation may lead to rupture of hollow viscus or nerve palsy. A fractional ablation, multiple directions, and low power treatment strategy may reduce the injury of peripheral organs. We recommend experienced physicians for this challenging work.

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Author contributions

YY conceived, designed and wrote this article. JZ and YP were involved in the collection and collation of references. All authors approved the final manuscript.
Formal analysis: Yongming Yang
Funding acquisition: Yongming Yang
Investigation: Yongming Yang
Methodology: Yongming Yang
Data curation: Jian Zhang, Ying Pan
Writing – original draft: Yongming Yang
Writing – review & editing: Yongming Yang.

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