MRI based navigated cryosurgery of extra-abdominal desmoid tumors: A proof of concept study

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Research Article

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Abstract

Background: Computer-guided MRI navigation for soft tissue tumors remains a challenge due to lack of a fixed landmark for registration. Extra-abdominal Desmoid Tumors (EDTs) are soft tissue tumors for which image-guided percutaneous cryosurgery (CRA) has emerged as a valid treatment modality. Successful CRA relies on precise intraoperative image guidance. This study, present a novel approach of using skin fiducial markers to overcome this challenge and navigate insertion of MRI-based CRA needles as a treatment for symptomatic or progressive EDTs.

Methods: In this retrospective study, conducted between 2018-2020, eleven patients at a single center with symptomatic or progressive EDTs were treated with CRA using intraoperative MRI navigation. 15 cryoablation procedures were performed, each adhering to a personalized pre-operative plan. We compared the total tumor size, necrotic and viable portions pre- and post-operation, and the SF-36 questionnaire evaluating subjective health.

Results: All CRAs demonstrated 100% adherence to the pre-determined plan. Overall, tumor size decreased significantly (p-value=0.02). Four patients required additional CRAs. Only one patient's tumor did not reduce in size. There was a significant reduction in viable tissue, (p-value=0.03), but not in necrotic tissue (p-value=0.66). According to the SIR adverse event classification guidelines, one participant experienced muscle necrosis, a mild complication. Both the physical and mental scores improved significantly (p-value (physical)=0.002; p-value (mental)<0.000).

Conclusion: These findings demonstrate the feasibility and efficacy of performing percutaneous cryosurgery using skin fiducial marker registration and MRI-computed navigation to safely treat EDTs. This navigation approach may be implemented in other soft tissue procedures requiring precision navigated surgery.

Trial Registration: Retrospectively registered.

Background

Desmoid tumors (DTs), also known as aggressive fibromatosis, are rare aggressive benign tumors that arise from clonal proliferation of spindle cells. With an incidence rate of roughly 2-4 cases per million in the general population, DTs account for 00.3%-0.1% of all solid tumors[1]. DTs occur in both sporadic and hereditary forms. Sporadic DTs account for 85%-95% of cases and give rise to extra-abdominal desmoid tumors, while the rare familial DTs account for 5-15% of cases, and are associated with familial adenomatosis polyposis syndrome (FAP)[2].

Although extra abdominal DTs have been shown not to metastasize, they often behave aggressively in their local environments and are thus associated with high morbidity[3],[4]. The gold standard of treatment previously included either en-block resection, radiotherapy, or systemic chemotherapy. However, these methods are associated with a high frequency of local recurrence and complications[5],[6].

Consequently, the treatment paradigm has shifted towards a "wait and see" policy of "active surveillance[7],[8],[9]." Yet, this approach cannot be applied in all cases, as 36% of tumors grow and progress, often causing debilitating symptoms with the potential to disable patients or jeopardize the function of adjacent critical organs[10]. In order to improve available treatment options, new modalities have emerged and are currently being implemented for treatment of EDT. One such treatment is percutaneous cryosurgery (CRA), which has proven effective in reducing tumor burden and improving symptoms while maintaining a low incidence of morbidity, with many authors advocating to establish CRA as a valid treatment option. However, successful CRA outcomes correlate directly with the use of precise intraoperative image guidance[11],[12],[13]. To date, most CRA procedures use CT-based guidance; however, this method is limited by its ability to distinguish between tumor and healthy tissue and does not allow tumor segmentation of viable and necrotic tissue in a precise manner like MRI scan.

Computerized navigation is currently used to guide precision surgeries in various fields of orthopedic surgery. It allows for optimal intraoperative execution of preoperative planning and reduces the risk of damaging untargeted structures during surgery[14–16]. MRI-computed navigation depends on a critical procedure called registration[17]. During registration, the surgeon identifies a predetermined landmark on the patient and matches it to preoperative images, thus enabling projection of these images onto the navigation system. Historically, this process relied on fixed bony landmarks as a reference point, since elastic soft tissue was unreliable. Consequently, MRI computer navigation could not be used for soft tissue tumors lacking exposed bony landmarks. [17]

Adhesive skin fiducial markers are one method to address this challenge, as they are easy to apply and identify on advanced imaging like MRI. This method is commonly used in practice   fields such as diagnostic radiology, interventional radiology and neurosurgery[18],[19],[20]. We propose the use of skin fiducial markers for registration as a tool to guide MRI-based navigation as an effective method to localize and treat soft tissue tumors such as EDT. The purpose of this study is to evaluate the feasibility and effectiveness of fiducial-based MRI navigated cryosurgery as a treatment for symptomatic or progressive EDT.

Materials And Methods

Patient selection

This retrospective study occurred between 2018-2020 in a single center and received Institutional Review Board approval. Inclusion criteria was determined as patients 18 years or older presenting with either a progressively growing tumor, demonstrated by two sequential MRI scans taken 3 months apart, or with a highly symptomatic tumor that was unresponsive to conventional analgesic treatment. All the patients in this study were reviewed by the institutional multi-disciplinary tumor board, comprised of an oncologist, radiologist, pathologist, and orthopedic oncologist. All treatment options were considered prior to transitioning from a hands-off, wait-and-see policy to cryosurgery.

Preoperative planning protocol

3D modules reconstruction

An MRI scan was used to generate a computerized three-dimensional module. The module was generated using Mimics® software (v23, Materialise, N.V. Leuven, Belgium). A customized preoperative plan was constructed for each individual patient (Figure 1). The module also considered potential at-risk structures such as major vessels, nerves, and vital organs, to ensure that any potential plan would not jeopardize them. To achieve optimal tumor coverage, the number of needles, trajectory, and placement were planned based on the generated modules. An ice ball with a radius of 4 cm was generated at the end of each cryo-needle to use a reference for the ablation zone of each needle. The total ablation zone was determined to equal the sum of all the individual ice balls.

Pre-operative MRI and fiducials markers placement

One day prior to ablation, skin fiducial markers (pinpoint, beekly medical LTD) were scattered in a random pattern around the tumor and a preoperative MRI scan was performed. The markers were kept in place for surgery the following day to ensure that the intraoperative registration included the precise location of the markers displayed in the navigation system. In addition, the MRI scans were used to re-evaluate the tumor size, location, and composition in order to assess for any deviations from the preoperative plan (Figure 3).

Intraoperative protocol

Preparation and image registration

All the interventions were performed by a fellowship-trained orthopedic surgeon specializing in orthopedic oncology. Surgeries were performed in an operating room and the patients were placed under general anesthesia. Stealth-station navigation system (StealthStation®, Medtronic Sofamor, Danek) was set to cranial model in order to allow optimal soft tissue demonstration. Then, the MRI scans taken the previous day were uploaded to the stealth station as DICOM files. Registration was performed for each individual skin fiducial marker using pointer (medtronics). At the end of the registration and calibration process, the skin fiducial markers were removed. Each individual cryo-needle was calibrated to the generated image using the sure-tract system (Danek and Sure-Track system by Medtronic). Using MRI based navigation, the cryo needles (Galil medical-ice rod) were placed inside the tumor mass according to the preoperative plan. The location and position of each needle were confirmed using an ultrasound (US) performed by I.D, a fellowship trained radiologist. After placing all the cryo needles, a Cone beam CT scan was performed as a cautionary measure to ensure that the chosen needle location was identical to the preoperative model (O-arm scanner Medtronic Sofamor; Dannek). Subsequently, the ablation protocol began.

Ablation protocol

The treatment protocol included ten minutes of freezing followed by five minutes of thawing and another ten minutes of freezing. Neuromonitoring was used as a precautionary in procedures that were performed close to major nerves. Skin temperature was closely monitored to avoid any thermal damage. To protect the underlying skin, a barrier was created by injecting continuous warm normal saline into the subcutaneous layer to hydrodissect the skin from underlying tissue. Patients were permitted to return home one day after the procedure

Implementation

Postsurgical surgical image analysis

Patients underwent MRI scanning at 3, 6 and 12 months post ablation. Following surgery, the IntelliSpace Discovery software platform (Philips Healthcare) employed a novel Gaussian mixture model (GMM) algorithm developed specifically for post-surgical imaging analysis This method employed a semi-automatic 3D segmentation tool to successfully identify variations in complex tissues at the macroscopic volumetric segmentation of the desmoid tumor tissue of each patient (Figure 3). Images were evaluated before and after ablation. Total Tumor Volume (TTV) was evaluated and compared to the preoperative protocol. Tumors were then further categorized into viable (high intensity/ bright) and non-viable tumors (low intensity/ dark) and were evaluated semi-automatically using Phillips software according to their density. Tumor dimension and composition were assessed using a series of consecutive postoperative MRI scans (3,6, and 12 months). Minimum follow-up time was 12 months.

Data collection and follow up

Medical records were reviewed for demographic and clinical data, tumor volume, tumor location, and symptoms prior to the intervention. Additionally, prior treatments were reviewed and documented. Intra-operative CT scans were used to compare each element of the procedure with the pre-operative 3D model, including the number of needles used and potential involvement of untargeted structures. Any discrepancy between the pre-operative plan and the execution was documented. Patient follow-up was conducted in the outpatient clinic at three, six, and twelve months. Pre-operative and post-operative symptoms were compared. An SF-36 was administered pre- and 12 months post-operation to evaluate individual patient health status and compare disease burden.

Statistical analysis

All continuous data was presented as mean ± SD and compared between pre- and post-operation using a paired t-test. Significance threshold was set at p-value<0.05. Comparisons were conducted using IBM SPSS software (V25).

Results

Between 2018-2020, eleven patients (average age ± SD = 39.9 ± 15.6, 6 females) with symptomatic DTs were treated with cryoablation using MRI navigation. Tumors were located in the shoulder (n=3), thigh (n=2), scapula (n=1), lower back (n=1), sacrum (n=1), foot (n=1), axilla (n=1) and posterior chest wall (n=1) (Table 1). Prior to the procedure, two patients were treated with chemotherapy (18%), one with surgical resection (9%), and one with chemotherapy, biological treatment, and surgical resection (9%). Each of the total 15 cryoablation procedures followed a personalized pre-operative plan. Each procedure included 2-12 needles, and all needles demonstrated 100% fit to the pre-determined plan. According to SIR adverse event classification guidelines, only one participant had a mild complication of muscle necrosis (grade 1). Four patients demonstrated continuous tumor growth and required additional cryosurgeries.

Post-operative analysis

Overall, tumor size decreased significantly from pre- to post-operation (p-value=0.02). Average tumor sizes pre- and post-operation were 185.8 mL ± 189.1 and 121.0 mL ± 143.9, respectively, yielding a reduction of 53.7% ± 33.8%. Only one patient’s tumor did not reduce in size. Before the operation, the tumors consisted of 37% ± 18% necrotic tissue and 62.9% ± 18.7% viable tissue, compared with 69% ± 16.1% necrotic tissue and 31% ± 16.1% viable tissue following surgery. No significant change was observed in the percentage of necrotic tissue from the whole tumor (p-value=0.66), while a significant reduction of 31% ± 16.1% was observed in percentage of viable tissue (p-value=0.03).

Subjective health questioner

To evaluate subjective health, we used the SF-36 questionnaire pre- and post-operation. Pre-operation, the average physical and mental scores were 38.9 ± 7.4 and 27.3 ± 13.0, respectively. Post-operation, the average physical and mental scores were 49.7 ± 11.2 and 40.3 ± 11.9, respectively. Both the physical and mental scores differed significantly from pre- to post-operation (p-value (physical)=0.002; p-value (mental)<0.000).

Discussion

This study of MRI-computed navigation cryosurgery for treating EDTs demonstrates a perfect correlation between preoperative modeling and intraoperative execution of needle placement and number.

Significant reductions in both Total Tumor Volume (TTV) and Viable Tumor Volume (VTV) were achieved while maintaining a low post-operative complication rate. SF36 scores demonstrated corresponding significant improvements in both mental and physical health scores.

The success rate of percutaneous cryosurgery directly correlates with the accuracy and precision of the ablation process[21],[12]. The feasibility of navigated cryosurgery for EDT ablation was demonstrated by Efrima *et al*. who used preoperative 3D computerized modeling and intraoperative CBCT to reduce tumor burden and improve symptoms[11].

MRI is the imaging modality of choice for optimal visualization of EDTs at preoperative planning and post-operative follow up[22]. Therefore, MRI computed navigation should simplify and improve cryosurgery once accurate image registration is achieved. Several findings from this study clearly demonstrate the feasibility of using skin fiducial markers for registration in MRI-navigated cryosurgery.

First, the perfect correlation between needle placement and number during the surgery compared with the preoperative 3D model indicates that the preoperative plan can be feasibly implemented using this navigation protocol. However, this procedure requires preoperative MRI scanning one day before cryosurgery, after fiducial marker placement, to allow for the surgeon to assess for any deviation from the preoperative plan.

The second indication of feasibility is the significant reduction observed in the TTV and VTV in all but one patient. This cohort demonstrated a reduction of 53.7% ± 33.8% and 31% ± 16.1% for TVT and VTV, respectively. This study reinforces findings from previous studies that similarly demonstrated significant reductions in both total and viable tumor volume after percutaneous cryosurgery[23][21][11][4]. Notably, one patient showed a reduction in VTV but not TTV. This patient was offered a revision cryosurgery but sought alternative treatment options instead. Four patients experienced local recurrence and subsequently underwent revision percutaneous cryosurgeries, importantly, this study demonstrated that CRA could be performed repeatedly with low comorbidities if necessary.

A total of 15 cryosurgeries were performed in 11 patients using the current navigation protocol. Only one participant (9%) experienced a post-operative complication, skin necrosis, classified as a mild complication (grade 1) according to SIR adverse event guidelines. This cohort had a low rate of complications compared with a similar study by Gangi *et al*[21], which reported a complication rate 36.6%, consisting mostly of mild complications. Furthermore, Tremlay *et al*[12] reported complication rates of 6.7% and 13.3% for major and minor complications, respectively. In this study, the preoperative plan and intraoperative execution protocol successfully achieved a low rate of postoperative complications while ensuring that no untargeted organs were damaged during the procedure. Both these outcomes further validate the effectiveness of the current navigation protocol.

We used the SF-36 questionnaire to evaluate the patients' health statuses at 12 months follow-up and compare them to their pre-operative health statuses. We found significant increases in both average physical and mental status. Overall, eight participants showed improved physical and mental status, while one participant had an increased mental status but decreased physical status, and two participants had increased physical but decreased mental status. These findings reinforce the promising results we obtained from MRI-navigated cryoablation.

The value of this study extends beyond merely establishing a new CRA technique. Although MRI navigation has proven to be a valuable tool for precision surgery, its application to soft tissue tumors in the trunk and extremities has been limited by difficulties in the registration process. In a previous study, Eccles *et al*[17] successfully achieved margin-free resection with remarkable accuracy while using skin fiducial marker-based MRI navigation to resect soft tissue tumors from cadavers. However, to the best of our knowledge, the current study represents the first attempt to apply this navigation technique *in vivo*. The success of this study indicates the potential to use this technique both for future cryosurgery and other indications. Introducing a new surgical technique should follow a specific, stepwise process including (1) concept/theory formation, (2) procedure development and exploration, (3) procedure assessment, and (4) long-term, ideally evidence-based studies[24]. We believe this study contributes significantly to the second stage.

Conclusion

These findings demonstrate the feasibility and efficacy of performing percutaneous cryosurgery using skin fiducial marker registration and MRI-computed navigation to safely treat extra-abdominal DTs. This navigation protocol may be implemented in future soft tissue procedures requiring precision navigated surgery.

Limitations

This was a retrospective study based on a small study population. The rare incidence of this tumor makes it difficult to aggregate a large volume of patients. We recognize the need to expand this study and test this procedure on a larger sample size. A long-term follow-up is necessary to validate this procedure.

Abbreviations

CRA= cryosurgery, EDTs = Extra-abdominal desmoid tumors, FAP- Familial Ademonatosis, Polyposis Syndrome, GMM- Gaussian Mixture Model, TTV= Total Tumor Volume, VTV= Viable Tumor Volum**e**

Declarations

Conflict of Interest Statement:

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Competing Interests:

The authors have no relevant financial or non-financial interests to disclose.

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Author Contributions:

All authors contributed to the study conception and design. Material preparation and data collection were done by [Ortal Segal, Amit Benady, Eliana Pickholz, Ehud Rath, Ben Efrima], analyses were performed by [Ido Drukman, Solomon Dadia, Assaf Albagli, Ehud Rath]. Operations and surgical planning and navigations were conducted by [Ortal Segal, Ido Drukman and Solomon Dadia]. The first draft of the manuscript was written by [Ortal Segal, Amit Benady, Eliana Pickholz, Assaf Albagli, Ben Efrima] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics Approval:

This study was performed in line with the principles of the Declaration of Helsinnki. Approval was granted by the Institutional Review Board of Tel Aviv Sourasky Medical Center.

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N/A

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Tables

Table 1

Imaging results of tumors taken pre- and post-operatively indicate tumor location and visibility before and after cryosurgery.

Patient	Location	Total volume pre	Dark pre	Bright pre	Total volume post	Dark post	Bright post
1	back	392.7	225.2	167.5	162.6	84.4	78.2
2	back	615.2	132.1	483.1	471.4	376.8	94.6
3	thigh	158.5	32.6	125.9	201.5	153.9	47.6
4	foot	38.4	15.4	23	10.7	6.5	4.2
5	shoulder	331.7	146.2	185.5	246.8	147.1	99.7
6	shoulder	196.3	84.9	111.4	44.8	39.5	5.3
7	back	115	72.4	42.6	77.9	77.6	0.3
8	shoulder	15.1	6.6	8.5	6.5	3.7	2.8
9	thigh	168.7	86.1	82.6	99.2	54.2	45
10	back	32.9	7.9	25	10.4	6.5	3.9
11	arm	2.3	0	2.3	0	0	0

Table 2

Demographic patient data, tumor locations, and procedure results for all patients in the study.

Patient	Age	Gender	Location	Previous Tx	Number of Cryoablations	Complications	Number of needles
1	46	M	Posterior chest wall	N/A	2	N/A	11
2	33	M	Scapula	Chemotherapy	2	Muscle necrosis	12
3	46	F	Thigh	N/A	3	N/A	12
4	18	F	Foot	Chemotherapy + Biologic Tx + Resection	1	N/A	11
5	65	M	Shoulder	N/A	1	N/A	12
6	22	M	Shoulder	N/A	1	N/A	12
7	42	F	Sacrum	N/A	1	N/A	6
8	55	F	Shoulder	Resection	1	N/A	2
9	57	M	Thigh	N/A	1	N/A	8
10	28	F	Lower back	N/A	1	N/A	5
11	27	F	Axilla	Chemotherapy	1	N/A	

Figures

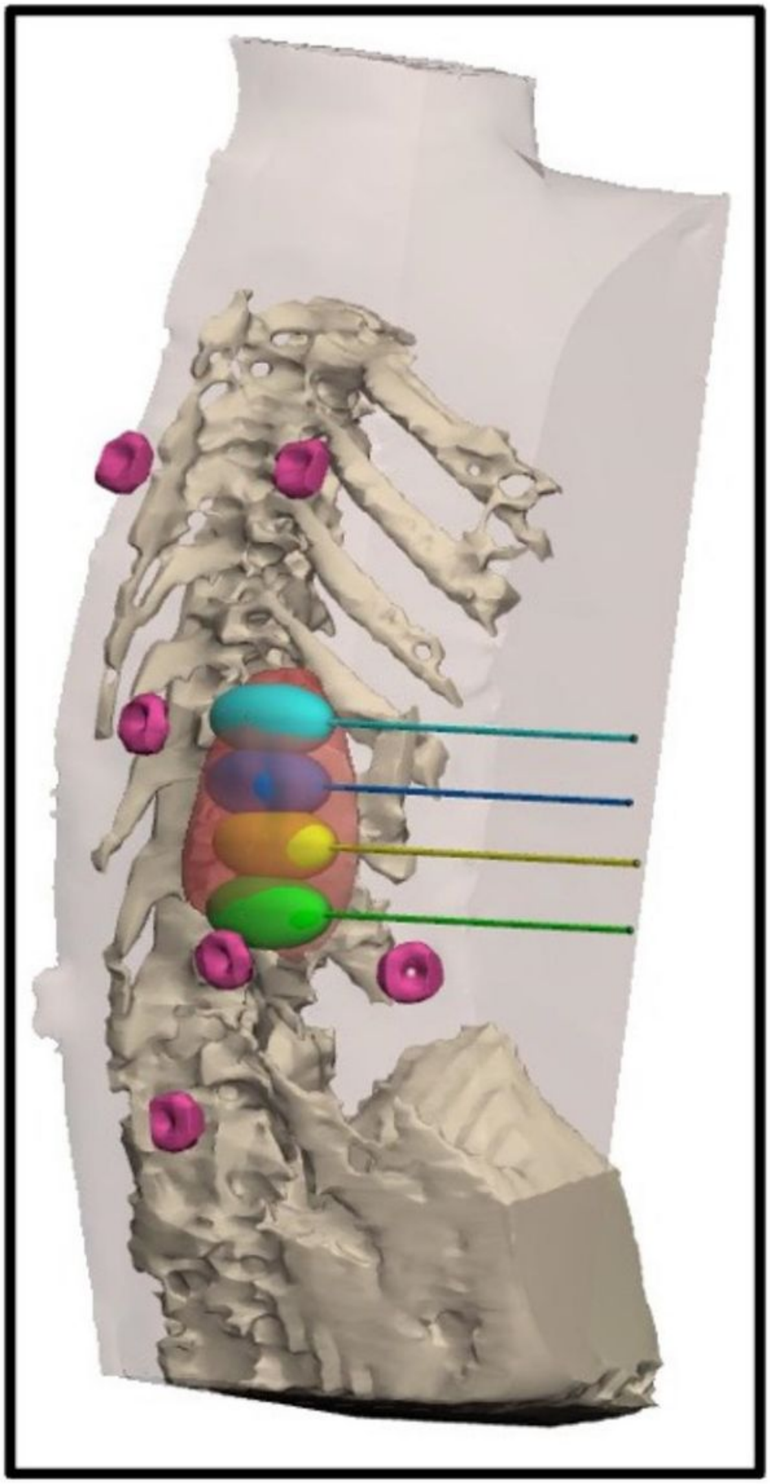

Figure 1

3D digital planning of the CRA procedure.

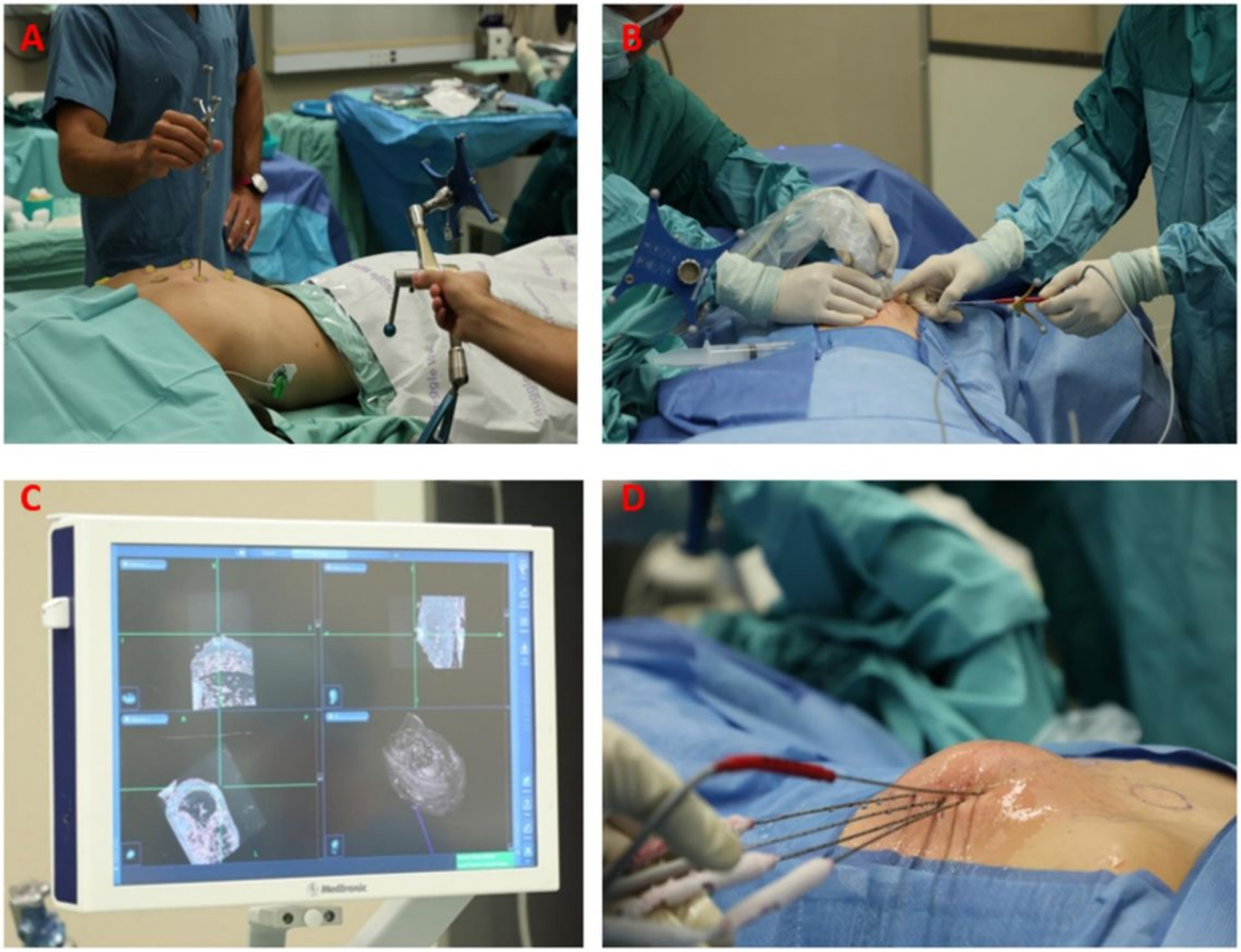

Figure 2

(A) A pointer registration of each fiducial marker. **(B)** The sure track system is attached to the ice rod cryo needle and calibrated. The needle can be inserted into the tumor using navigation according to pre-operative 3D planning. Ultrasonography was also used to verify position. **(C)** Stealth station MRI screen navigation shows bright and dark areas, indicating desmoid tumor visibility. **(D)** Cryo needles were inserted according to the preoperative plan, using warm saline to protect the skin. In addition, a thermometer guide needle was used to monitor and maintain core tumor temperature below -40 degrees Celsius.

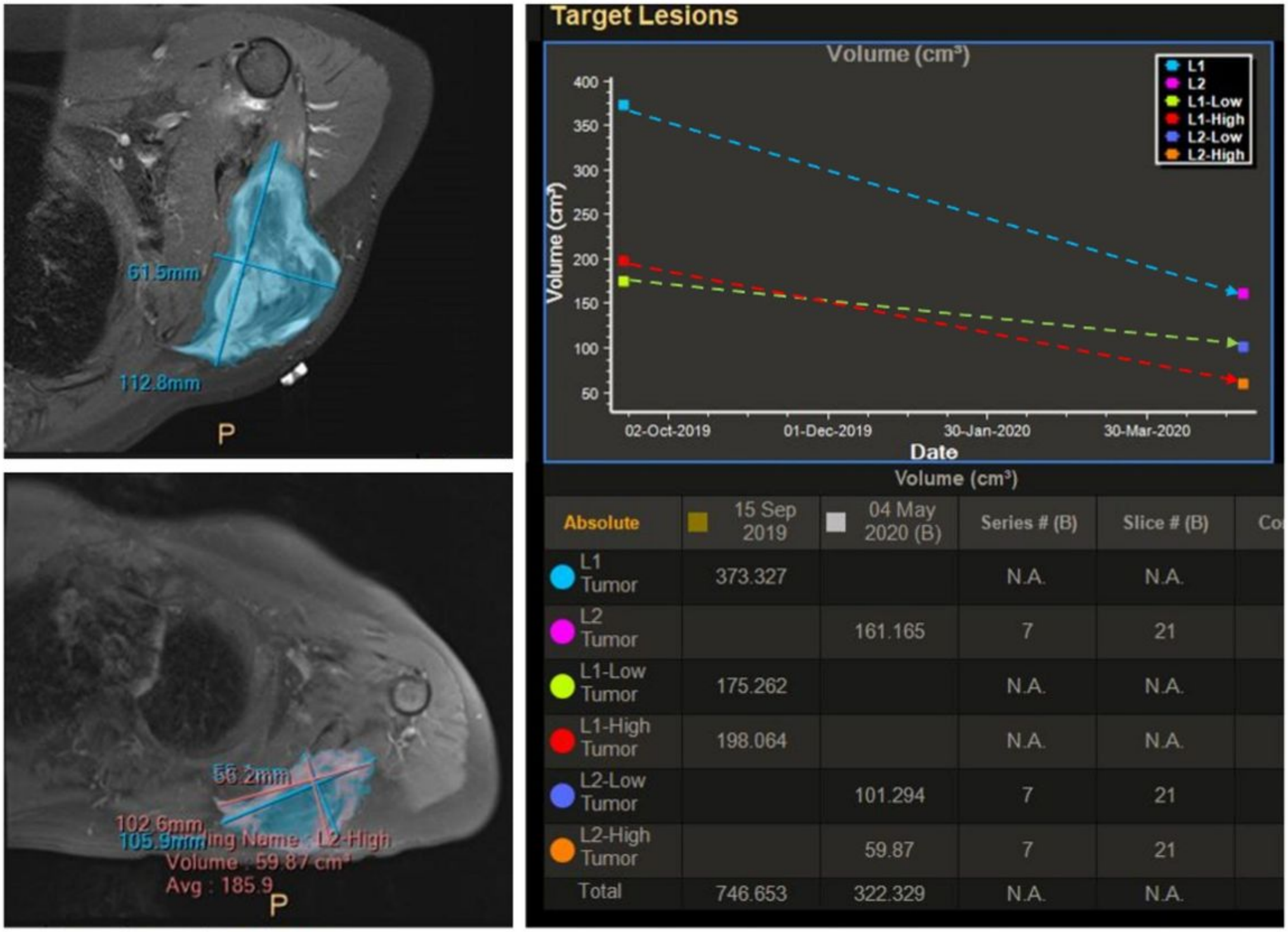

Figure 3

Gaussian Mixture Model (GMM) segmentation of a desmoid tumor. (**A**) tumor before CRA. (**B**) Tumor after CRA. Both in A and B note the difference between the high and low intensity (sub-segmentation), which represent the viable and necrotic tissue, respectively. (**C**) Light blue- total tumor size before ablation. Pink- Total tumor size after ablation. Red- high intensity (i.e., viable tissue) before ablation. Orange- high intensity after ablation. Green- low intensity (i.e., necrotic tissue) before ablation. Purple- low intensity after ablation. Light blue, red and green dashed lines shows the reduction in total size, viable and necrotic tissue, respectively.