

# Safety and efficacy of cryoablation of soft-tissue tumours: a systematic review

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## Abstract

**Objectives:** To assess the safety and efficacy of percutaneous cryoablation (CA) of soft-tissue tumours [desmoid tumours (DTs), vascular malformations (VMs), and abdominal wall endometriosis (AWE)].

**Methods:** This systematic review of studies published before January 2024 encompassed a detailed analysis of CA techniques and technical aspects for the treatment of soft-tissue tumours. Data concerning CA efficacy, complication rates, and other relevant metrics were extracted and included for analysis.

**Results:** The analysis included 27 studies totalling 554 CA procedures. For DT (13 studies, 393 sessions), CA showed an average pain reduction of  $79 \pm 17\%$  (range: 57–100) and a lesion volume decrease of  $71.5 \pm 9.8\%$  (range: 44–97). VM (4 studies, 58 sessions) had a 100% technical success rate and an average pain reduction of  $72 \pm 25\%$  (range: 63–85). The average pain reduction for AWE (6 studies, 103 sessions) was  $82 \pm 13\%$  (range: 62–100). Overall, the complication rate for CA was low, with minor adverse events (AEs) in about 20% of patients and major events in less than 5% of patients.

**Conclusions:** Showing substantial efficacy in pain reduction and lesion volume decrease, as well as low incidence of severe AE, CA presents as a highly effective and safe alternative for the treatment of soft-tissue tumours.

**Advances in knowledge:** CA is effective and safe in treating soft-tissue tumours, particularly DT, VM, and AWE.

**Keywords:** cryoablation; desmoid tumour; vascular malformation; abdominal wall endometriosis; systematic review.

## Introduction

Percutaneous image-guided ablations are increasingly used as alternatives to surgery for various indications, particularly in patients for whom surgery is contraindicated or considered complex.<sup>1</sup> Percutaneous cryoablation (CA)—performed by inserting cryoprobes into tissue under imaging guidance<sup>2</sup>—has primarily concerned tumours of the liver, lung, prostate, breast, and kidney.<sup>3</sup> However, study of CA's application for the treatment of soft-tissue tumours has increased in recent years.<sup>1,2,4,5</sup>

CA works on the principle of freezing tissue to intracellularly induce ice crystals and, in turn, cell death. Application of CA in the soft tissue was developed because, unlike radiofrequency ablation (RFA), high-intensity focussed ultrasound, laser, or microwave ablation, CA does not compromise fibrillar structures like collagen. Collagen fibres consist of long, triple-helical protein strands that are less susceptible than cellular water content to the formation of ice crystals during freezing. Cold exposure can also slow nerve conduction, or the speed at which signals

travel along nerve fibres. Reducing nerve activity and dampening pain signals produces an anaesthetic effect, which improves patient tolerance to the procedure and makes CA performance possible under local anaesthesia.<sup>1,2,5</sup> This literature review aims to synthesize the use of CA technique for the treatment of soft-tissue tumours, and examine its safety and efficacy.

## Methods

A systematic review of soft-tissue tumour CA studies published before January 2024 was performed. Registered under the number CRD42024505263 (PROSPERO), this review following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 recommendations, which describes an evidence-based minimum set of items for systematic review reporting and diagnostic study meta-analyses.<sup>6</sup> This exploration was organized into 3 pivotal categories, which are summarized in Table 1. Figure 1 summarizes the study design, and Figure 2 shows the evolution of the number of publications per year.

Received: 10 February 2024; Revised: 26 March 2024; Accepted: 4 April 2024

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Table 1. Methodology used in the review.

| Aims                                                                                                                                                                                   | Search strategy                                                                                                                                                                                                                                                                                                                                                                                                        | Search terms                                                                                                                                                                                                | Identification of relevant published studies                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Data extraction                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Assessment of risk of bias                                                                                                                                                                                                                    | Data synthesis and analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Applications of CA in soft tissue medical fields were evaluated. This part evaluates the procedure's effectiveness and adaptability in treating soft-tissue tumours (DT, VM, and AWE). | On January 1, 2024, the PubMed (MEDLINE) database was queried to identify potentially relevant articles using the below search strategy. This study focuses on this database because of the many easily accessible and referenced, high-quality articles. Two reviewers (SB and CM) screened each article. The reference lists of included studies, relevant systematic reviews, and meta-analyses were also screened. | Cryoablation OR Cryotherapy AND Technique OR Cryobiology OR Soft tissue tumour OR Desmoid tumour OR Desmoid Fibromatosis OR Vascular Malformations OR Abdominal Wall Endometriosis NOT Laparoscopic/surgery | All studies assessing CA of soft tissue (featuring DT, VM, and AWE) were identified. Studies were eligible for inclusion if they: (1) were R or P; (2) assessed CA of soft tissue; and (3) reported efficacy. Studies meeting the following criteria were excluded: (1) only abstracts available; (2) studies not in the English language; (3) nonhuman studies; (4) editorial style reviews; (5) abstracts and posters; (6) conference papers; and (7) case reports. Two authors (SB and CM) examined each full-text article according to the prespecified eligibility criteria. | A predefined data collection form was prepared to extract the relevant information from the selected studies, including title, first author's name, study design (R or P; comparative or not, etc.), number of involved centres (single or multicentre), date of journal publication, sample size and patient age, the other technique compared with CA (such as surgery, RT, chemotherapy, active surveillance), efficacy, number of complications; other relevant information; reported measures of associations (eg, correlation analysis, HR, OR, ROC, and CI). Data extraction was independently conducted by 2 radiologists (SB and CM). To ensure quality and accuracy of extraction process, results were meticulously compared, and any discrepancies were resolved through a consensus decision involving the input of a third senior radiologist (FC). | The QUIPS tool was used, allowing for quality assessment in 6 domains: study participation, study attrition, prognostic factor measurement, outcome measurement, adjustment for other prognostic factors, and statistical analysis/reporting. | The outcome measures for this systematic review focussed on the efficacy of CA, such as technical success rate, clinical response, and adverse events. The included studies were carefully analysed and synthesized to assess CA's efficacy and impact. Collected data were subject to comprehensive statistical analysis to identify trends, patterns, and significant differences between CA and other treatments, including surgery. Statistical analyses were conducted using Jamovi (2.3.26). |

Abbreviations: AWE = abdominal wall endometriosis, CA = cryoablation, CI = confidence interval, DT = desmoid tumour, HR = hazard ratio, OR = odds ratio, P = prospective, QUIPS = quality in prognosis studies, R = retrospective, ROC = receiver operating characteristics, RT = radiotherapy, VM = vascular malformation.

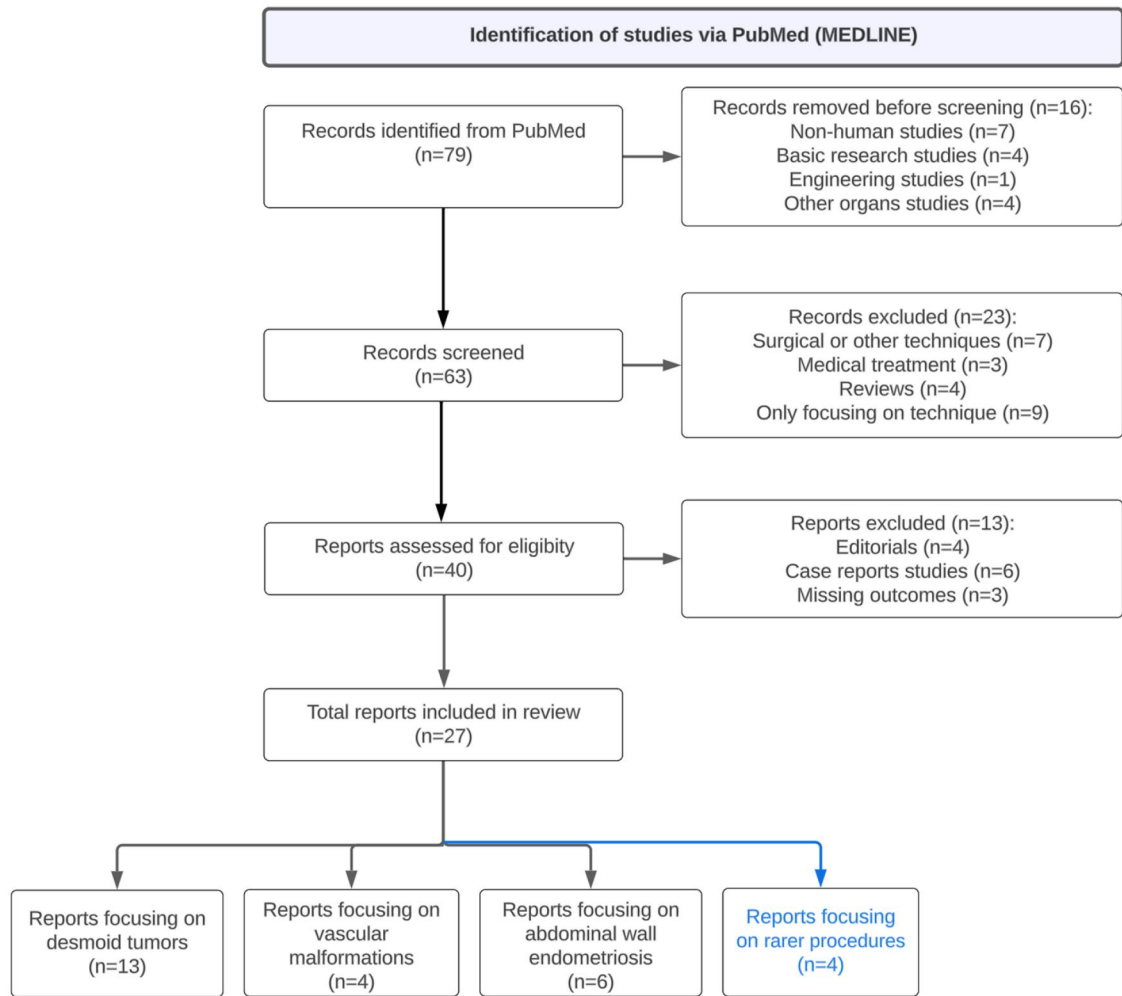


Figure 1. Study design.

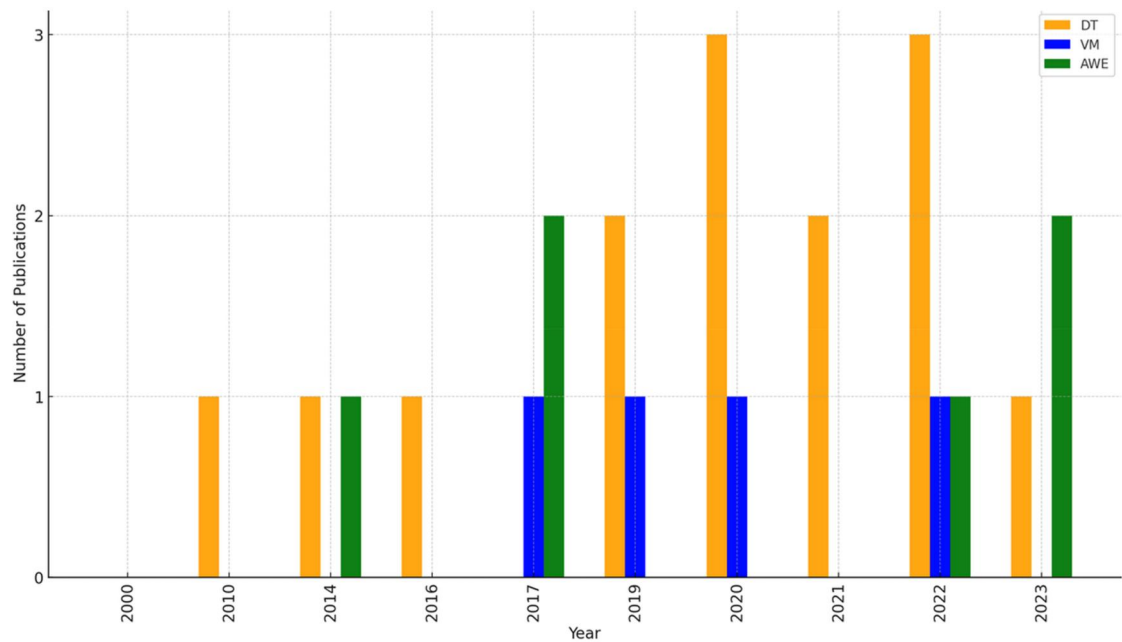


Figure 2. Evolution of the number of publications per year.

## Results

### Cryoablation of desmoid tumour

Thirteen studies specifically targeting CA for desmoid tumour (DT) were examined, encompassing a total of 393 CA sessions. Two of these studies were prospective, including 1 nonrandomized multicentric trial (Kurtz et al<sup>8</sup>). Three studies compared CA to other treatments, including surgery, radiotherapy, chemotherapy, and RFA (Mandel et al,<sup>9</sup> Colak et al,<sup>10</sup> de Bruyns et al<sup>11</sup>). The median number of patients treated by CA in each cohort was 20, ranging from 5 to 84 patients. The median age of patients was 39 years, with ages ranging from 9 to 80 years. The median follow-up period was 16.3 months, ranging from 3 months to 77 months.

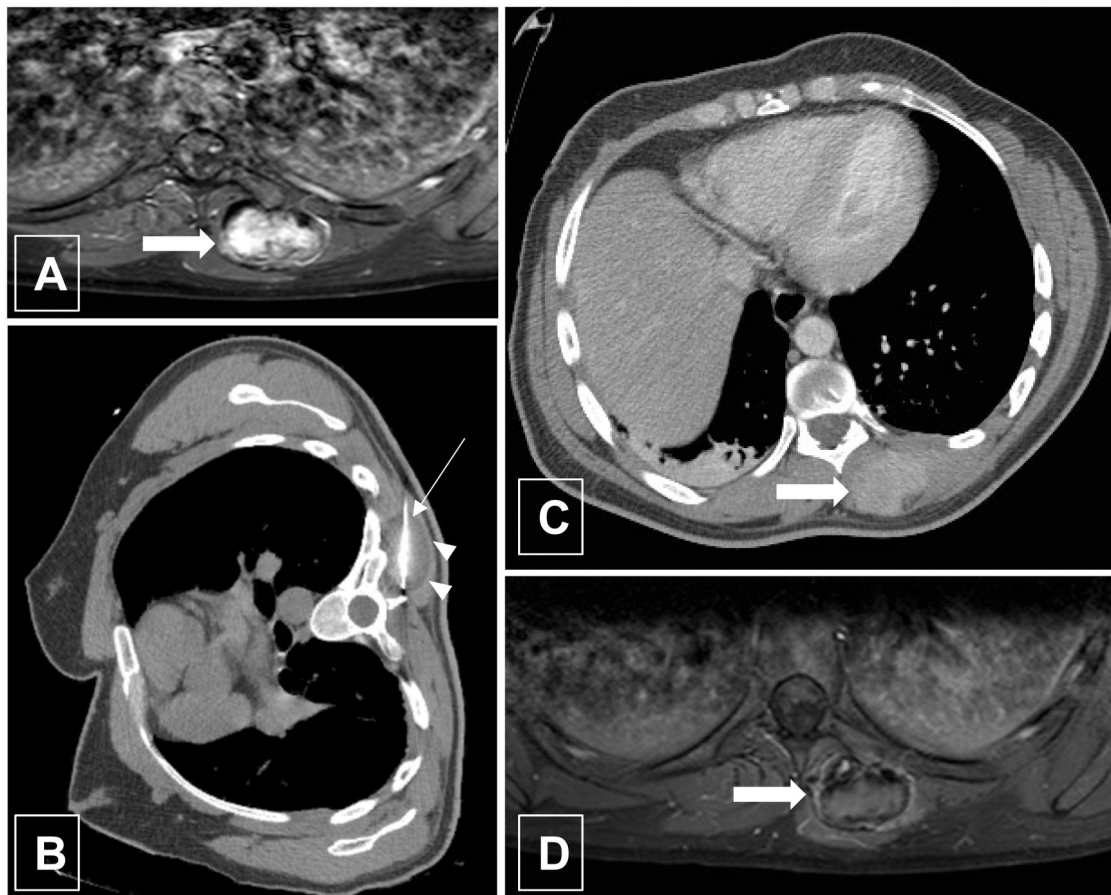
Pain reduction, assessed in 5 studies, showed a significant average decrease of  $79 \pm 17\%$  (ranging from 57% to 100%). The average lesion volume decrease was approximately  $71.5 \pm 9.8\%$  (ranging from 44% to 97%), while there was an average rate of complete response (CR) of approximately 26.33%, partial response (PR) of approximately 48.75%, stable disease (SD) of approximately 29.4%, and an average rate of disease progression of 7.7% (excluding salvage therapy). The overall objective response rate was 80%. Moreover, average rates of progression-free survival (PFS)/disease-free survival (DFS) were 85.6% at 12 months, 71.77% at 24 months, and 62.5% at 36 months. Colak et al<sup>10</sup> noted a lesion size reduction after 3 months common in surgery and CA versus after medical therapy, RT, and RFA.

Mandel et al<sup>9</sup> showed no difference in local recurrence-free survival (LRFS) or disease control between CA and surgery. Finally, de Bruyns et al<sup>11</sup> noted a response rate of 80% for CA versus 40% for surgery, and a disease control rate of 100% for CA versus 25% for surgery. The response rates and disease control rates for RT were 68% and 96%, respectively; 31% and 67% for tamoxifen; and 53% and 80% for chemotherapy.

Approximately 19.88% of patients experienced minor adverse event (AE), which included oedema, temporary increase in pain postprocedure, transient radial nerve palsy, and non-severe postoperative hematomas. On the other hand, approximately 4.85% of patients encountered major AEs, such as skin necrosis, infection, brachial plexopathy, and neuropraxia, along with cases of palsy of the common fibular nerve. Moreover, 2 studies compared CA and surgery (Colak et al,<sup>10</sup> Mandel et al<sup>9</sup>) and found a lower rate of AE in CA. Figure 3 shows an example of CA treatment of DT. Table 2 summarizes the results of studies addressing CA of DT.

### Cryoablation of vascular malformation

Four studies specifically targeting CA for vascular malformation (VM) were examined, encompassing a total of 58 CA sessions. One was a prospective nonrandomized trial.<sup>22</sup> The size of patient cohorts varied, with a median of 12 participants ranging from 5 to 14. The median age of patients was



**Figure 3.** Thirty-three-year-old man with DT treated by CA (6 needles). (A) MRI showing the DT before treatment (arrow); (B) CT during ablation showing the probe (thin arrow) and the ice ball (head arrows); (C) CT showing the DT at the end of the procedure (arrow); and (D) MRI showing the DT at 6-month follow-up (arrow).

Table 2. Studies addressing CA of DT.

| Authors [ref#]                            | Technique | Study type | No. of patients                 | Median age (year), (IQR, range or 95% CI) or (mean and SD) | Follow-up (month) (range) | Efficacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Adverse events                                                                      | Other relevant information                                                                                     |
|-------------------------------------------|-----------|------------|---------------------------------|------------------------------------------------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Kujak et al 2010 <sup>12</sup>            | CA        | R          | 5                               | 9-41                                                       |                           | <i>Clinical response:</i> Three local control, 2 complete absence of pain at 13 and 49 months with tumours completely resolved; 1 improved mild pain at 6 months with moderate decrease of tumour size. Two palliative therapy: initial partial pain relief 2 weeks post-CA. At 58 months: 1 tumour reduced in size, local pain returned to its former moderate level; 1 enlarged mass with pain returned to the pretreatment, moderate level. <i>Residual tumours:</i> 8 (47%) asymptomatic. <i>DFS rate</i> stable: 82.3% (95% CI, 0.55-0.94) at 6, 12, and 24 months. <i>Local tumour progression rate:</i> 0% at 6, 12, and 24 months. Two (12%) in situ recurrence. <i>Technical success:</i> 100% <i>Clinical response:</i> No residual viable tumour for 9/23 (39.1%), Volume reduction for 22/23 (95.7%). Progressive disease for 1/23 (4.3%). <i>VAS pain scores:</i> 5.7 and 2.4 at pretreatment and 6 months; mean reduction of 3.3 ( $P < .001$ ). <i>Tumour dimensions:</i> At 6 months all significantly lower. <i>DFS</i> at 3 years: 42.2% <i>Technical success:</i> 100% <i>Symptomatic improvement:</i> 89% <i>Clinical response:</i> At 12 months viable volume –80% (–100% to +10%); mRECIST: CR 36%, PR 36%, SD 28%. Four repeat CA for residual or recurrent disease. No rapid post-CA growth or track seeding | N/A                                                                                 |                                                                                                                |
| Havez et al 2014 <sup>13</sup>            | CA        | P          | 13 (17 lesions)                 | 39.3 (15-74)                                               | 11.3 (6-27)               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1 major (5.8%)                                                                      | Inoperable extra-abdominal desmoid tumours. Two patients with Gardner syndrome and 9 recurrences after surgery |
| Schmitz et al 2016 <sup>14</sup>          | CA        | R          | 18 (26 lesions, 31 CA sessions) | 39.9 ± 15.4 (9-77)                                         | 16.2 ± 20.0               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | No more severe than Clavien-Dindo grade I                                           | Cases with residual/progressive disease: recurrence at margin of treated tumour in all cases                   |
| Bouhamama et al 2019 <sup>15</sup>        | CA        | R          | 34 (41 lesions)                 | 38 (16-73)                                                 | At least 6                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 2 postoperative hematomas CIRSE 2 and 2 CIRSE 4 (palsy of the common fibular nerve) | 12 curative and 22 debulking treatments (risk of neighbouring structures)                                      |
| Redifer Tremblay et al 2019 <sup>16</sup> | CA        | R          | 23 (30 sessions)                | 16-77                                                      | 15.4 (3.5-43.4)           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 2 major (neuroparaxia)                                                              | First-line (61%), salvage (39%)                                                                                |

(continued)



Table 2. (continued)

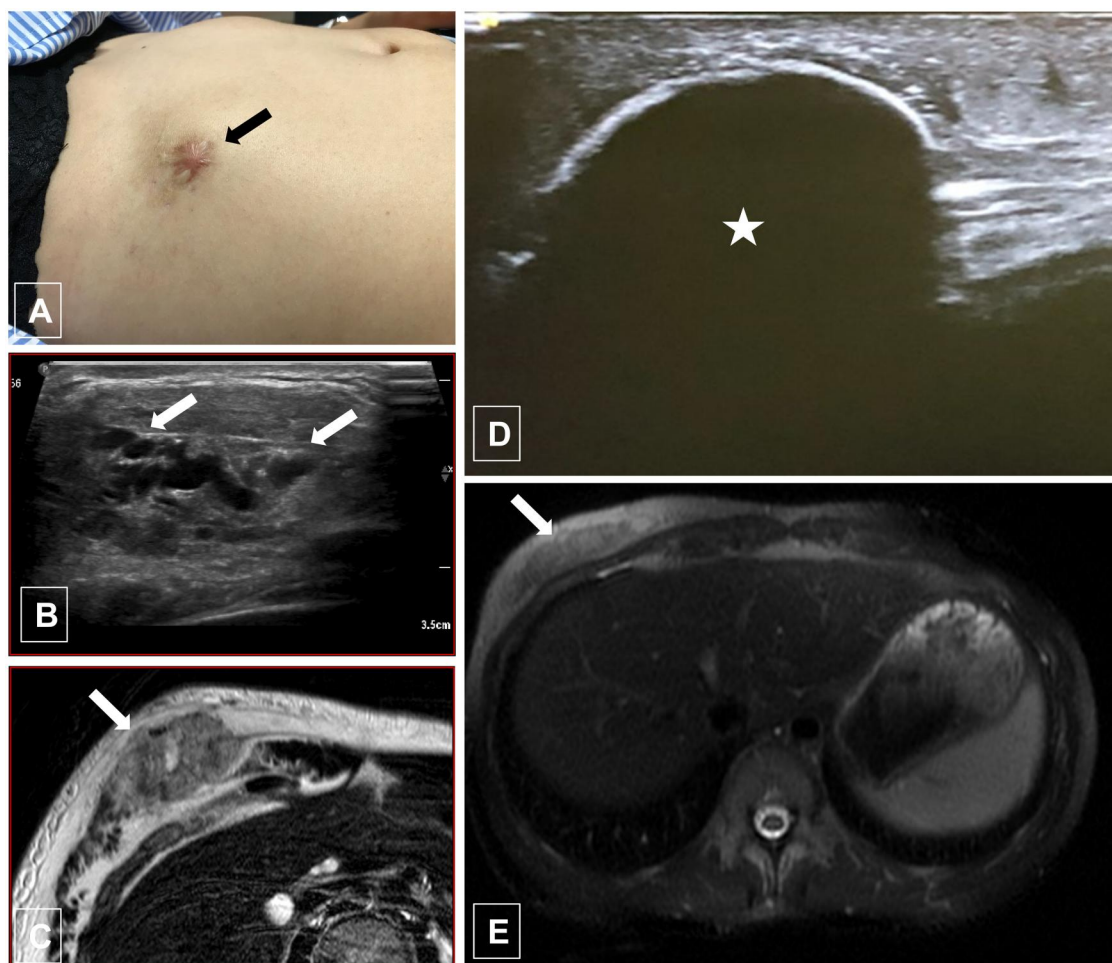
| Authors [ref#]                     | Technique                           | Study type                                      | No. of patients                                                      | Median age (year), (IQR, range or 95% CI) or (mean and SD) | Follow-up (month) (range)     | Efficacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Adverse events                                                                                                                                           | Other relevant information                                                                                                             |
|------------------------------------|-------------------------------------|-------------------------------------------------|----------------------------------------------------------------------|------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Satriel et al 2020 <sup>17</sup>   | CA                                  | R                                               | 14                                                                   | 33 ± 18                                                    | 53.7 (12-83)                  | <i>ETV change:</i> Curatively treated patients: -97 ± 7%, -44 ± 143%, and +103 ± 312% at 3, 6, and 12 months, respectively. Debulking patients: -98 ± 4%, +149 ± 364%, and +192 ± 353% at 3, 6, and 12 months, respectively. <i>Response rate:</i> 4/5 (80%) for CA, 40% for surgery. <i>Disease control rate:</i> 5/5 (100%) for CA, 25% for surgery. (Response rates and disease control rates: N/A and 76% for active surveillance; 68% and 96% for RT; 31% and 67% for tam.; 53% and 80% for chemotherapy)                                                                                                                                                                                  | 1 grade III and 1 grade IV                                                                                                                               | first-line ( <i>n</i> = 4) or salvage therapy ( <i>n</i> = 6) with curative intent ( <i>n</i> = 8) or tumour debulking ( <i>n</i> = 2) |
| de Bruyns et al 2020 <sup>11</sup> | Surgery, tam., RT, chemotherapy, CA | R                                               | 227 (79%), (13%), (5.0%), (1.8%), (1.2%)<br>Active surveillance: 26% | 40                                                         | 77                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                          | Multivariable analysis: young age associated with recurrence risk ( <i>P</i> = .010)                                                   |
| Kurtz et al 2020 <sup>8</sup>      | CA                                  | P, non-randomized, non-Comp., multicentre trial | 50                                                                   | 41 (19-73)                                                 | 31                            | <i>Clinical response:</i> CA significantly improved functional status and pain scores. Rate of nonprogressing disease at +12 months: 86% (95% CI, 73-94)<br><i>PFS:</i> 85.1% at 1 year, 77.3% at 3 years<br><i>Objective response:</i> 80% (CR: 43%)<br><i>Pain reduction:</i> 96.7% (95% CI, 90.3-100)<br><i>Change of TLV:</i> 66.6% (95% CI, 37.2-72.3; <i>P</i> = .002) at 1 year and 76.4% (95% CI, 59.1-89.8; <i>P</i> = .002) at 3 years<br><i>TLV and VTV:</i> at 7-12 months, -6.7% ( <i>P</i> = .809) and -43.7% ( <i>P</i> = .01). At 10-12 months, mRECIST: CR, 0%; PR, 61.5% (8/13); SD, 30.8% (4/13); PD, 7.7% (1/13). Symptomatic relief (partial or complete) in 96.9% (32/33) | Grade 1 and 2 toxicity in 32.8% and 44.5% of patients, grade 3-4 in 22%. No Grade 5 toxicity                                                             | No. of prior treatments: 2.00 [1-4] (NSAIDs, hormone therapy, chemotherapy, antiangiogenics)                                           |
| Auloge et al 2021 <sup>18</sup>    | CA                                  | R                                               | 30                                                                   | 39 (31-50)                                                 | 18.5 (range 6-93, IQR: 12-55) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | AER: 36.6% (oedema and temporary increase of pain in the days following CA). Four (13.3%) major: 2 skin necrosis, 1 infection, and 1 brachial plexopathy | All patients with prior systemic therapy; no. of medical treatments: 2 (1-4); 11 (36.7%) prior surgery; no patients had prior RT       |
| Yan et al 2021 <sup>19</sup>       | CA                                  | R                                               | 25 (26 lesions, 44 CA sessions)                                      | 12-80                                                      | 21.0                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 1 major (2.4%)                                                                                                                                           | 14 patients had previous medical therapy, RT, and/or surgery                                                                           |

(continued)

**Table 2.** (continued)

| Authors [ref#]                     | Technique                    | Study type | No. of patients              | Median age (year), (IQR, range or 95% CI) or (mean and SD) | Follow-up (month) (range)           | Efficacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Adverse events                                                                                                                                                                                                                       | Other relevant information                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------|------------------------------|------------|------------------------------|------------------------------------------------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Colak et al 2022 <sup>10</sup>     | Medical therapy, CA, RT, RFA | R, Comp.   | 31, 24, 7, 6, 4 respectively | 34 (18-79)                                                 | At least 3                          | <i>Lesion size reduction:</i> after 3 months most common in surgery and CA                                                                                                                                                                                                                                                                                                                                                                                                            | 10 minor, 3 major (infection and hematoma requiring incision/drainage or skin graft). Lowest in CA (0), highest in RFA (2 major, 1 minor)                                                                                            | Highest response treatment for lesions of the back and thorax                                                                                                                                                                                                                                                                                                                                                |
| Mandel et al 2022 <sup>9</sup>     | CA vs surgery                | R, Comp.   | 22 and 33, respectively      | > 25-≤65                                                   | 16.3 after CA vs 14.9 after surgery | <i>Two-year LRFs:</i> 59% after CA, 71% after surgery; <i>median LRFs:</i> 26.6 months after CA, not reached after surgery. <i>Two-year disease control</i> (all patients): 85%. No difference in LRFs or disease control between CA and surgery. No local recurrences after first CA in patients with 0 or 1 of the following risk factors: tumour size > 5 cm; age ≤ 25 years; locally recurrent disease. All patients with 2 or more risk factors recurred locally after first CA. | CA: 1 expected pneumothorax resolved following chest tube placement. No other postprocedure AE. Surgery: AER of up to 42% after abdominal wall reconstruction (wound infection, ventral herniation, bowel erosion, and evisceration) | Hydrodissection performed in 14 cases (64%) and used more for primary tumours than for locally recurrent tumours (83% vs 40%, $P = .035$ )                                                                                                                                                                                                                                                                   |
| Johnston et al 2022 <sup>20</sup>  | CA                           | R          | 10 (13 lesions)              | 51, IQR 42-69                                              | 11.6, IQR 2.83-26.15                | <i>Clinical response:</i> 8/10 symptomatic benefit 3 started systemic therapy                                                                                                                                                                                                                                                                                                                                                                                                         | 1 transient radial nerve palsy                                                                                                                                                                                                       | Prognostic factors of local recurrence: nonabdominal wall location ( $P = .042$ ), debulking strategy ( $P = .0105$ ), risk of visceral ( $P = .034$ ) or peripheral nerve injury ( $P = .033$ ), previous RT ( $P = .043$ ), treatment before 2016 ( $P = .008$ ). Multivariate analysis: abdominal wall tumours best outcome and neck and trunk high rate of recurrence (HR, 7.307 [95% CI, 1.396-38.261]) |
| Bouhamama et al 2023 <sup>21</sup> | CA                           | R          | 84                           | 35 ± 14.25                                                 | 36                                  | <i>Local relapse:</i> 19/84 (22.62%) <i>PFS rates</i> at 12, 24, and 36 months: 89% (95% CI, 79-94), 74% (95% CI, 60-83), and 68% (95% CI, 53-79), respectively                                                                                                                                                                                                                                                                                                                       | 9 (10.7%) grade 1, 7 (8.3%) grade 2, 2 (2.4%) grade 3 (1 palsy of the fibular nerve and 1 palsy of the tibial nerve)                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                              |

Abbreviations: 95% CI = 95% confidence interval, AE=adverse event, AER=adverse event rate, CA=cryoablation, Comp.=comparative, CR=complete response, DFS=disease-free survival, ETV=enhanced tumour volume, HR=hazard ratio, IQR=interquartile range, LRFs=local recurrence-free survival, mRECIST=Modified Response Evaluation Criteria in Solid Tumours, NSAIDs=nonsteroidal anti-inflammatory drugs, P=prospective, PFS=progression-free survival, PR=partial response, R=retrospective, RFA=radiofrequency ablation, RT=radiation therapy, SD=stable disease, Tam.=tamoxifen, TLV=total volume lesion, VAS=visual analogue scale, VTV=viable tumour volume.



**Figure 4.** Forty-five-year-old woman with VM treated by CA (2 needles). Images show (A) clinical aspects (black arrow); (B) US visualization; (C) MRI visualization of the VM (arrow); (D) US control during ablation showing the ice ball (star); and (E) MRI follow-up at 4 years (arrow).

33.6 years, ranging from 19 to 39.4 years. Follow-up periods varied from 6 months to 4 years.

All the studies reported a technical success rate of 100%. Pain reduction, assessed in 3 studies, showed a significant average decrease of approximately  $72 \pm 25\%$  (ranging from 63% to 85%). This pain reduction was measured using the Numerical Rating Scale, which dropped from 3-10 to 0-3 ( $P < .01$ ). Autrusseau et al<sup>23</sup> noted instances of persistent or recurrent pain linked to local residual or recurring disease, which were completely managed with a second CA session. The average lesion volume decrease was around 85% (ranging from 76% to 93%), with a CR rate over 90% at 6 months. In their prospective trial, Cornelis et al<sup>22</sup> found a clinical response in 12 out of 14 patients (85.7%) (95% CI, 57.2-98.2), and a mean visual analogue scale (VAS) at 7 days after treatment of  $28.7 \pm 22$  mm, decreased by  $-13.8 \pm 29$  mm compared to the preintervention rating. This was  $18 \pm 18$  mm at 2 months and  $12 \pm 18$  mm at 6 months ( $P = .002$ ). Moreover, the mean European Organization for Research and Treatment of Cancer Core Quality of Life questionnaire (EORTC QLQ-C30) for global health status was  $62.5 \pm 20.3$  (range 17-92) at 2 months after treatment and  $75.6 \pm 17.2$  (33-100) at 6 months post-CA, and physical functioning improved in 9 patients at 6 months (69.2%). The mean EORTC QLQ-C30 score for physical function was  $78.3 \pm 21.3$  (33-100) at 2 months after treatment and  $92.8 \pm 11.7$  (67-100) at

6 months posttreatment. These improvements were observed particularly for everyday tasks ( $56.4 \pm 32.3$  in mean before;  $56.9 \pm 40.5$  after 2 months; and  $76.9 \pm 21$  after 6 months). The treatment effect was particularly evident in the mean QLQ-C30 pain score (50 in mean before, 41.7 at 2 months, and 26.9 at 6 months). In terms of safety, the studies generally reported minimal AE. However, Cornelis et al<sup>22</sup> noted 2 severe AE (grade 3), amounting to 14.3% of their study population, which included immediate sciatic paralysis and delayed paraesthesia.

Figure 4 shows an example of VM treated by CA. Table 3 summarizes the results of studies addressing CA of VM.

### Cryoablation of abdominal wall endometriosis

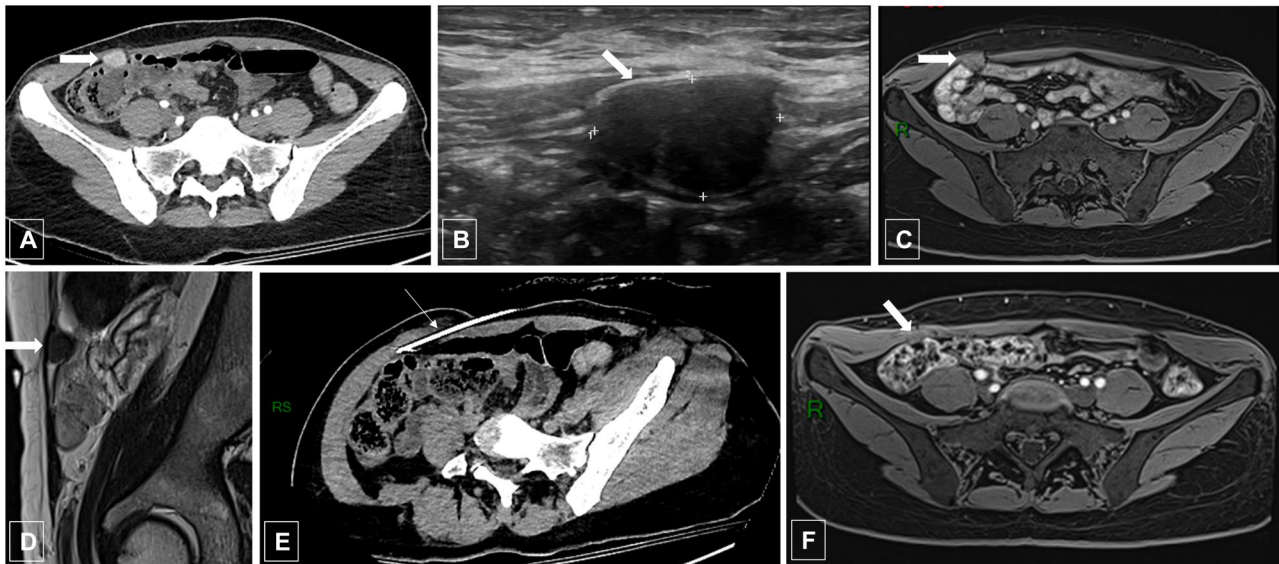
Six studies specifically targeting CA for abdominal wall endometriosis (AWE) were examined, encompassing a total of 103 CA sessions. One of these also featured a comparative surgery group. One prospective trial (CRYOENDOMET) was interrupted due to the COVID-19 pandemic and incorporated into the retrospective study of Najdawi et al.<sup>26</sup> The patient cohorts (treated by CA) varied in size, with a median of 12 participants, ranging from 3 (in a case series) to 42. The median age of patients was 36.9 years, consistent across all studies, ranging from 34.5 years to 40 years. The follow-up durations ranged from 6 months to nearly 2 years (22.5 months).



**Table 3.** Studies addressing CA of VM.

| Authors [ref#]                      | Technique | Study type              | No. of patients | Median age (y) (IQR or range or 95% CI) or (mean and SD) | Follow-up (month) (range) | Efficacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Adverse events                                                                                                                                                                                                                                                                                                                                                                                                                                               | Other relevant information                                                                                                                   |
|-------------------------------------|-----------|-------------------------|-----------------|----------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Cornelis et al 2017 <sup>22</sup>   | CA        | P, non-randomized trial | 14              | 31.3 ± 12.7                                              | 6                         | <p><i>Technical success:</i> 100%</p> <p><i>Clinical response:</i> 12/14 (85.7%) at 6 months. Pain decreased from 42.5 ± 14.2 mm to 11.8 ± 17.9 mm at 6 months (<math>P = .002</math>). Significant decrease in volume from 12.8 ± 14.3 to 3 ± 2.7 cm<sup>3</sup> at 6 months (<math>P = .002</math>)</p>                                                                                                                                                                                                                                                                                                                                                                              | <p>11 (78.6%) (13 grade 1-2 and 3 grade 3) [2 skin lesions, 2 neuropathic pain, 2 skin blisters, 1 transient numbness, 2 discomforts, 1 pain, 3 dysesthesia, 2 toe retraction, 3 oedema, 1 pyelonephritis, 1 renal infection, 1 lung infection]. Two severe (grade 3) (14.3%) (1 immediate sciatic paralysis and 1 delayed paraesthesia)</p> <p>Three minor (2 skin blisters and 1 transient numbness) resolved with conservative management</p> <p>None</p> |                                                                                                                                              |
| Ramaswamy et al 2019 <sup>24</sup>  | CA        | R                       | 11 (14 lesions) | 19 (10-50)                                               | 6.8 (3.94-29.11)          | <p><i>Technical success rate:</i> 100%</p> <p><i>Clinical response:</i> At 1-month, CR for 13/14 lesions (93%) and PR for 1 (7%). At 6-month CR for 12/13 (92%) and PR for 1 (8%)</p> <p><i>Technical success:</i> 9/9 (100%)</p> <p><i>Pain:</i> persistent/recurrent pain: 3/9 cases (33%) at 30, 133, and 639 days post-CA, and in all cases of MR-confirmed local residual/recurring disease. Second CA performed in these 3 cases with complete pain control at last follow-up (153, 25, and 91 days). In the whole population, pain dropped from 6.4 ± 2.1 (3-9/10) to 0.3 ± 0.9 (0-3/10) after (<math>P = .009</math>) at 161 days (range 25-413) after the last treatment.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                              |
| Autrusseau et al 2020 <sup>23</sup> | CA        | R                       | 5 (9 lesions)   | 39.4 ± 15.3 (15-68)                                      | 18.0 (0.99-58.34)         | <p><i>Technical success rate:</i> 100% (21/21)</p> <p>NRS: dropped from 7 [IQR 6-8] to 1 [IQR 0-2] (<math>P &lt; .001</math>). 50% full effectiveness on symptoms (11/21).</p> <p><i>Lesional volume:</i> decreased from 3.7 cm<sup>3</sup> [1-10.4] to 0.25 cm<sup>3</sup> [0-2.0] (<math>P &lt; .001</math>)</p>                                                                                                                                                                                                                                                                                                                                                                     | <p>No major, 4 minor (2 skin lesions, 2 neuropathic pain) (19%)</p>                                                                                                                                                                                                                                                                                                                                                                                          | <p>14 general anaesthesia (14/21, 67%), 6 local anaesthesia (6/21, 29%), 1 local anaesthesia combined with conscious sedation (1/21, 5%)</p> |
| Duteau et al 2022 <sup>25</sup>     | CA        | R                       | 21              | 36 (IQR 26-52)                                           | 48 (12-72)                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                              |

Abbreviations: 95% CI = 95% confidence interval, AE = adverse event, CA = cryoablation, Comp. = comparative, CR = complete response, IQR = interquartile range, NRS = numerical rating scale, P = prospective, PR = partial response, R = retrospective.



**Figure 5.** Thirty-two-year-old woman with AWE treated by CA (1 needle). Images show (A) CT scan; (B) US; (C and D) MRI before treatment of the AWE (arrow); (E) CT scan performed during the procedure showing the needle (thin arrow); and (F) MRI at 6-month follow-up.

All the studies showed a significant reduction in pain, with a decrease in VAS scores from 5-9 to 0-5. Average pain reduction was  $82 \pm 13\%$  (ranging from 62% to 100%). Additionally, Maillot et al<sup>27</sup> found no significant difference between CA and surgical treatment ( $P = .45$ ). Five studies assessed tumour response, demonstrating significant results ranging from 72.2% to 100%. In a retrospective study of 42 treated patients, Najdawi et al<sup>26</sup> found a median VAS score before the procedure of 8/10 (IQR, 7-9), which dropped to 0/10 (IQR, 0-1) at the last follow-up (Wilcoxon test  $P < .0001$ ). The median patient global impression of change score recorded at the last follow-up was 1/7. The primary efficacy rate of CA was 90.4% (38/42), and the secondary efficacy rate was 97.6% (41/42). According to the Kaplan-Meier method, the median pain-free survival rate was 93.8% (95% CI, 77.3-98.4) at 6 months, and 82.7% (58.8-93.5) at 12, 24, and 36 months.

Regarding safety, the studies generally reported minimal AE except for 1 study, which noted 2% severe AE. Contrastingly, Maillot et al<sup>27</sup> reported 23.1% severe AE with surgery and 69.2% concerning aesthetics ( $P = .05$ ). Figure 5 shows an example of AWE treated by CA. Table 4 summarizes the results of studies addressing CA of AWE.

### Other applications

Other soft-tissue tumours, including sarcomas, have become targets for percutaneous CA.<sup>32</sup> Indeed, some retrospective studies have reported the effectiveness and safety of CA in such cases.<sup>33</sup> Additionally, percutaneous CA has shown efficacy in addressing certain gynaecological diseases within the pelvic region. In a systematic review, Moynagh et al<sup>34</sup> observed that image-guided CA offers an alternative modality to achieve local tumour control without the risks associated with surgery or systemic treatment in appropriately selected patients with retroperitoneal nodal metastases, pelvic side wall disease, and vaginal or vulvar tumours. Protective manoeuvres, such as hydrodisplacement of the bowel, neuro-monitoring, and retrograde pyeloperfusion via ureteral stents, can enable safe ablation despite close proximity to vulnerable

nerves or organs. Further, Ahmed et al<sup>35</sup> reported an early experience with percutaneous US-guided CA to treat painful plantar fibromas, suggesting it to be a safe and effective treatment option with early and near-complete symptom improvement.

While interest in percutaneous CA for various other soft-tissue tumours has grown, the existing literature consists primarily of a few isolated publications. There is not a substantial volume of research to enable comprehensive literature review or meta-analysis. The available studies provide some valuable insights, but more extensive research is needed for a thorough assessment.

### Discussion

This review evaluates the clinical outcomes of CA in soft-tissue tumours, particularly VM, DT, and AWE, based on an analysis of 24 pertinent studies published before January 2024 and encompassing 554 CA sessions. Quantitative data assessment of CA's efficacy and AE in these tumour types were derived through meta-analysis. In terms of efficacy, CA treatment of DT exhibited significant benefits, including an average  $79 \pm 17\%$  pain reduction and a  $71.5 \pm 9.8\%$  decrease in lesion volume. This aligns with existing literature,<sup>36</sup> which reports a PFS rate of 84.5% at 1 year and 78.0% for 3 years. Comparatively, the local control rate of surgical resection fluctuates between 47% and 86%, with R0 resections achieving slightly higher rates of 68%-86%.<sup>37-39</sup> RT has a success rate ranging from 65% to 83%.<sup>40,41</sup> A 100% technical success rate was noted in VM treated with CA, alongside an average  $79 \pm 17\%$  reduction in pain and a decrease in lesion volume of approximately 85%. These outcomes are comparable to sclerotherapy, which is effective in 71%-100% of cases,<sup>42-44</sup> and RFA, which shows significant resolution of symptoms in 62%-100% of patients. However, this alternative percutaneous treatment for VM remains limited.<sup>22,45</sup> For AWE, CA showed a significant average pain reduction of  $82 \pm 13\%$ . Hormonal therapy and surgical interventions are typically the primary treatments for AWE,<sup>46</sup> but their effectiveness (especially hormonal treatment) is limited in advanced

**Table 4.** Studies addressing CA of AWE.

| Authors [ref#]                      | Technique     | Study type  | No. of patients | Median age (years) (IQR or range or 95% CI) Or (mean and SD) | Follow-up (month) (range)  | Efficacy                                                                                                                                                                                                                                                                  | Adverse events                                                               | Other relevant information                                                                                                                                           |
|-------------------------------------|---------------|-------------|-----------------|--------------------------------------------------------------|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cornelis et al 2014 <sup>28</sup>   | CA            | Case series | 4               | 34.5 (28-39)                                                 | 6                          | <i>Pain response</i><br>M6: VAS 1.7 (0-5) vs 6.5 (5-9)<br><i>Tumour volume response</i><br>M6: 72.2-100% ( $P = .028$ )                                                                                                                                                   | None > CTCAE 2                                                               |                                                                                                                                                                      |
| Maillot et al 2017 <sup>27</sup>    | CA vs Surgery | Comp., R    | 7<br>13         | 35.7 (28-39)<br>31.9 (24-41)                                 | 22.5 (6-42)<br>54 (14-149) | <i>Pain response</i><br>Cryoablation<br>M12 100%<br>M24 66.7%<br>Surgery<br>M12-M24 92% ( $P = .45$ )                                                                                                                                                                     | Cryoablation: none<br>Surgery: 23.1% severe<br>69.2% aesthetic ( $P = .05$ ) | Median procedure durations: 41.5 min (24-66) vs 73.5 min (35-160) ( $P = .01$ )<br>Median hospitalization durations: 0.8 days (0-1) vs 2.8 days (1-12) ( $P = .01$ ) |
| Dibble et al 2017 <sup>29</sup>     | CA            | Case series | 3               | 40 (37-43)                                                   | 6-12                       | <i>Pain response</i><br>100%<br>M6 VAS 0 to 2<br>M12 VAS 0<br>vs 5 to 9 before<br><i>Tumour volume response</i><br>100%                                                                                                                                                   | Minor<br>66% acetaminophen and ibuprofen taken orally                        |                                                                                                                                                                      |
| Smith et al 2022 <sup>30</sup>      | CA            | R           | 18              | 36.9 (30-46)                                                 | 7.1                        | <i>Tumour volume response</i><br>94%<br><i>Pain response</i><br>93%                                                                                                                                                                                                       | 11% self-limited inflammatory response                                       | Hydrodisplacement used in 13/18 cases (72%) to displace adjacent bowel, bladder, or neurovascular structures<br>Mean number of probes used per case: 3               |
| Najdawi et al 2023 <sup>26</sup>    | CA            | R           | 42              | 37 (33-39.5)                                                 | 13.5 (1.1-37.7)            | <i>Pain-free survival (VAS):</i><br>M6 93.8%<br>M12 82.5%<br><i>VSA pain decrease:</i><br>from a median of 8/10 (IQR, 7-9) to 0/10 (IQR, 0-1) at the last follow-up ( $P < .0001$ )<br><i>Pain decrease</i><br>M1 62.1%<br>M6 72.4%<br><i>Tumour response</i><br>M6 72.4% | 9.5% including 2% severe                                                     | Efficacy rate of CA to avoid secondary surgery: 92.8% (39/42) per patient and 93.6% (44/47) per nodule treated                                                       |
| Jouffrieau et al 2023 <sup>31</sup> | CA            | R           | 29              | N/A                                                          | 6                          |                                                                                                                                                                                                                                                                           | 3.5% minor complication                                                      |                                                                                                                                                                      |

Abbreviations: CA=cryoablation, Comp.=comparative, CTCAE=Common Terminology Criteria for Adverse Events, R=retrospective, VAS=visual analogue scale.

cases<sup>46</sup> and offers only temporary symptom relief.<sup>47</sup> Moreover, surgical treatment of AWE requires thorough removal of endometriotic lesions with clean margins, while not breaking the lesion or spreading microscopic pieces of endometrial tissue.<sup>48</sup> The widespread nature of AWE makes complete lesion removal difficult, particularly when they are numerous. Consequently, the postsurgery AWE recurrence rate is approximately 4.3%.<sup>49</sup> Recurrence risk factors include lesion size and reach, and the involvement of certain muscles or the peritoneum.<sup>49</sup>

Regarding AEs, CA-associated complications were generally minor, affecting approximately 20% of patients. Severe cases were noted in less than 5% of cases, which is consistent with the literature and comparable to other therapies. Bates et al<sup>50</sup> reported a 37% incidence of grade 3 or higher toxicity in patients whose DT was treated with RT. The major complication rate after open surgery was 6.2%, with a 60% chance of achieving an R0 margin.<sup>51</sup> Systemic therapies are often associated with bone marrow toxicity, neutropenia, and peripheral neuropathy.<sup>52</sup> A national phase II trial<sup>53</sup> revealed that imatinib treatment for unresectable or progressive symptomatic DT leads to major complications in 45% of cases. In VM, a meta-analysis of over 700 patients treated for sclerotherapy reported a 34% rate of undesirable effects, with 16% being severe AEs.<sup>54</sup> The ability of CA to ablate both venous malformations and surrounding tissues—which leads to immediate disruption of the tissue structure and cellular damage<sup>55</sup>—has made CA the first-line treatment when a tissular portion is predominant on preoperative imaging.<sup>25,56</sup> However, Cornelis et al<sup>22</sup> showed CA to demonstrate a higher overall rate of AE (78.6%) compared to sclerotherapy, albeit mostly low rate. These AE could be controlled with the use of short prescriptions of steroid drugs, protective dissection, or a minimal distance of CA 5 mm from the skin and 3 mm from the nerves.<sup>57</sup> Hormonal therapy of AWE entails various side effects, including irregular bleeding, breast soreness, nausea, bloating, weight gain, hair loss, headaches, depression, anxiety, decrease in bone density, and a higher risk of osteoporosis after prolonged use.<sup>47</sup> Besides the general surgical risks of bleeding, infection, and nerve damage, there are specific complications in abdominal wall surgery, such as reactions to foreign substances, mesh displacement, and the possibility of hernia development.<sup>49</sup> Wide resection, which includes the removal of 5 mm to 10 mm of healthy tissue surrounding the lesion, can have its own negative impacts.<sup>48</sup>

This literature review acknowledges limitations due to its reliance on small, single-institution cohort studies with varying follow-up periods. The scarcity of randomized controlled trials in this field is evident, with CRYODESMO-01<sup>8</sup> being the only prospective trial evaluating CA for DT, CRYOMAV<sup>22</sup> for VM, and CRYOENDOMET for AWE (stopped due to the COVID-19 pandemic and incorporated into Najdawi et al<sup>26</sup>). Additional prospective, randomized, controlled, well-powered trials with more extended follow-up are needed to assess optimal therapeutic management of soft-tissue tumours. These must include comparison of minimally invasive procedures against or in combination with current medical, surgical, and radiation therapeutic measures. Unfortunately, the rarity of soft-tissue tumours may impede trial establishment and recruitment, often resulting in institution-specific treatment protocols. Moreover, regarding VM, the heterogeneity and paucity of data regarding the sequence of therapy lines in their treatment restricted the ability to conclusively discuss the use of treatments as first,

second, or subsequent line therapies and should be considered when interpreting our findings. Finally, cost analysis was not included in this review, however Narvaez et al<sup>58</sup> observed that the total cost for percutaneous CA (€5774.78/patient a year) was lower than conventional surgery (€6780.98/patient a year), suggesting potential cost-effectiveness.

In summary, CA is an effective, minimally invasive option for treatment of soft-tissue tumours, including DT, VM, and AWE. CA shows notable efficacy in pain reduction and lesion size decrease with fewer severe AE compared to conventional therapies. Nonetheless, the limited scale and lack of randomized trials in existing CA research necessitate further in-depth studies to comprehensively evaluate the clinical benefits and safety of CA for soft-tissue tumour treatment.

## Acknowledgements

The authors thank the technologists and nursing staff of MSK and Cecile Berberat (grant writer/editor of MSK) for the grammatical editing service.

## Funding

MSK is funded through the NIH/NCI Cancer Center Support (P30 CA008748).

## Conflicts of interest

F.H.C. is a Boston Scientific, Varian, and IceCure consultant.

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