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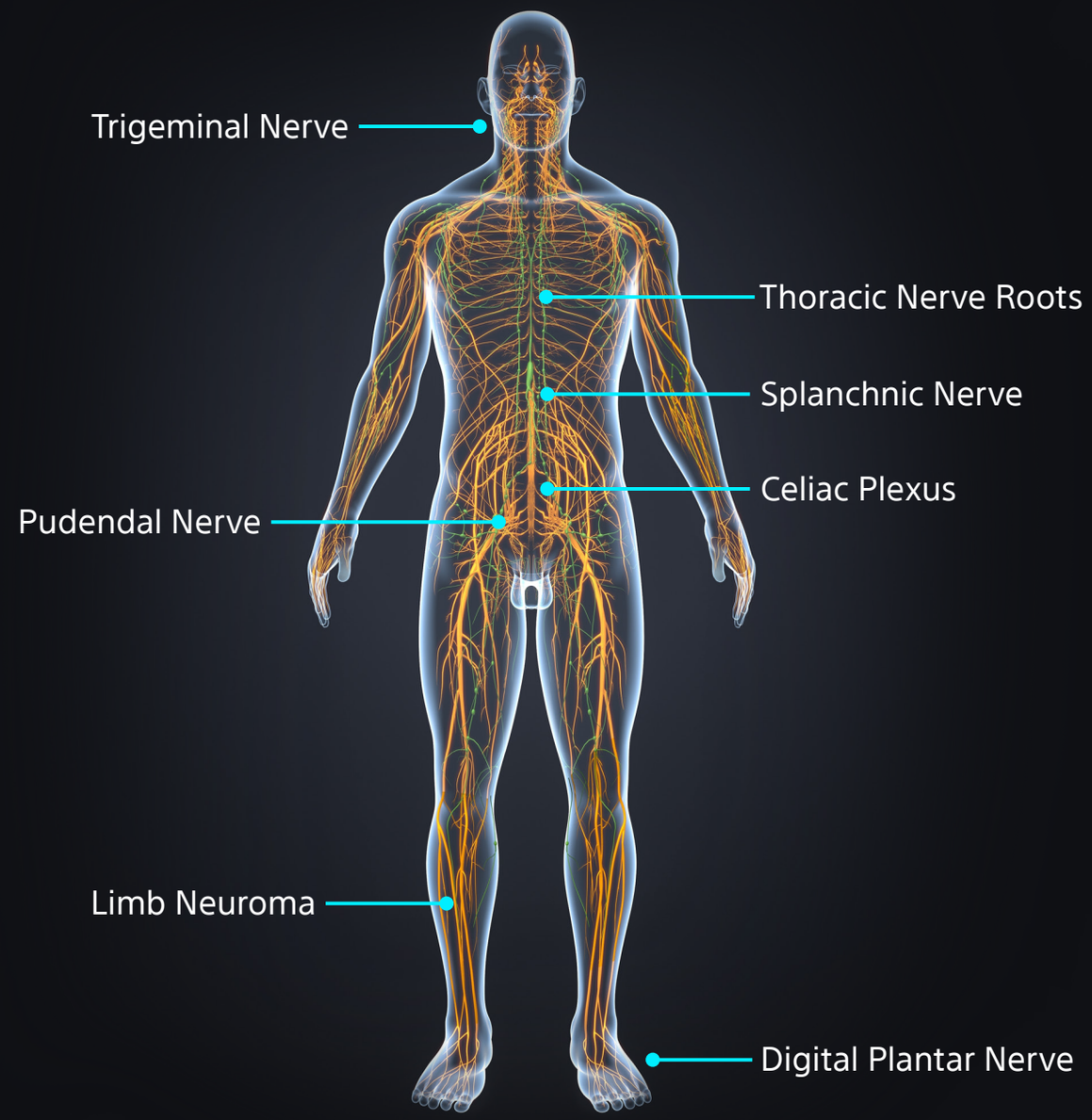
CRYONEUROLYSIS | CLINICAL REVIEW

Due to the opioid crisis, there is a growing need for alternate pain palliation methods for hard-to-treat neuropathies. Because of this, Interventional Radiologists are playing an increasing role in the pain management space. The IR's ability to percutaneously access otherwise unreachable nervous system structures, visualize and monitor ablation zones, and induce predictable neuroregeneration in clinical settings has unlocked a myriad of opportunities.



THERAPY OVERVIEW

IRs must be aware of key nerve targets, have an in-depth understanding of which patients are candidates for image-guided percutaneous cryoneurolysis, and the differentiators between cryoablation and heat or alcohol-based neurolysis.

Global approach to the patient with pain in IR

This article breaks down pain into four categories: spine pain related to cancer, non-spine pain related to cancer, spine pain unrelated to cancer, and non-spine pain unrelated to cancer, and offers best practices for each scenario. (Bittman et al., 2020).

Interventional Cryoneurolysis – An Illustrative Approach

This article provides case illustrations for oncologic and non-oncologic scenarios, as well as treatment algorithms for when to ablate or not ablate the nerve. (Prologo et al., 2020).

Natural History of Mixed and Motor Nerve Cryoablation in Humans—A Cohort Analysis

Retrospective review of 5 patients who underwent percutaneous cryoablation of mixed and/or motor nerves. Illustrates the rate at which nerves regenerate compared to distance from ablation site. Outcomes measured include distances from the ablation sites to origins of distal musculature, times to initial clinical recovery and muscle activation, and rate of nerve regeneration based on distance to the origin of the assessed musculature and time to muscle activation. (Prologo et al., 2019).

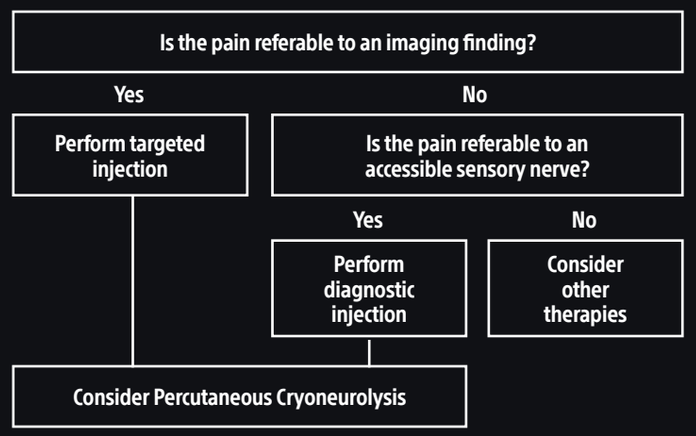
Percutaneous Image Guided Cryoneurolysis

This article provides an overview of key nerve targets for cryoneurolysis, as well as a data summary of both prospective and retrospective studies done in this space. (Prologo et al., 2017).

Global approach to the patient with pain

	Spinal	Non-spinal
Neoplastic	Radiofrequency Ablation Vertebral Augmentation Cryoablation	Ablative Techniques Catheter-Directed Therapy Cryoneurolysis
Non-Neoplastic	Vertebral Augmentation Facet Block/Ablation Scroilliac Block/Ablation Intradiscal Therapy Nerve Root Block Epidural Injection	Joint Injection Bursa Injection Peripheral Nerve Block Sympathetic block Sympathetic Ablation Cryoneurolysis

Percutaneous Cryoneurolysis



SUPPORTING FIGURES

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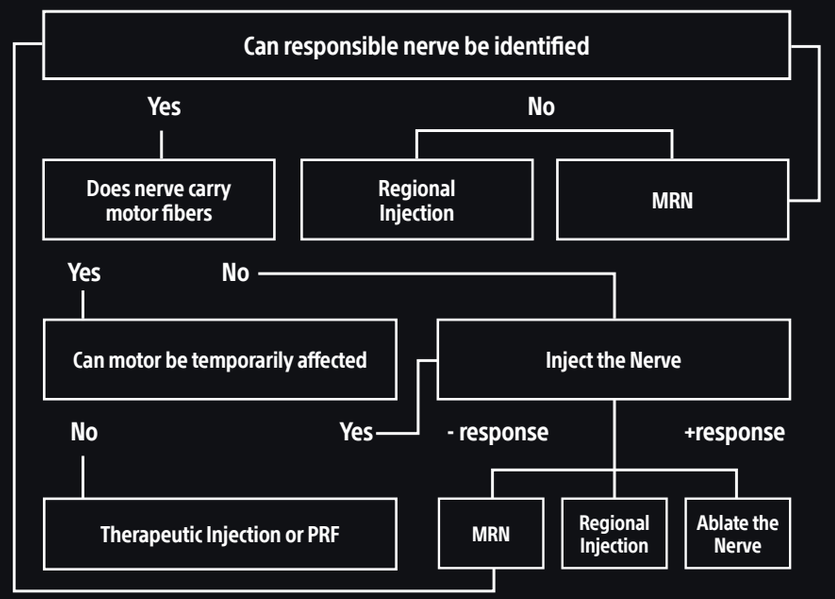
Approach to the patient with non-cancer related pain



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Descriptive Statistics for Measured Nerve Distance, Time to Muscle Activation, and Calculated Rate of Regeneration

	Minimum	Maximum	Mean	SD
Distance (mm)	40	840	314.3	242.3
Time (d)	89	540	226.3	128.8
Rate (mm/d)	0.3	4.1	1.5	1.2

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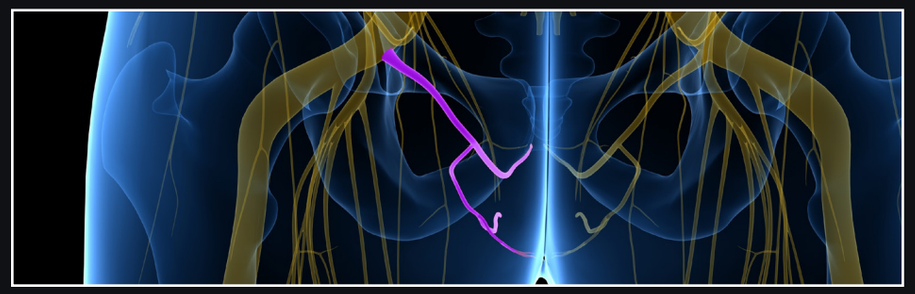
Other noteworthy therapy overview articles

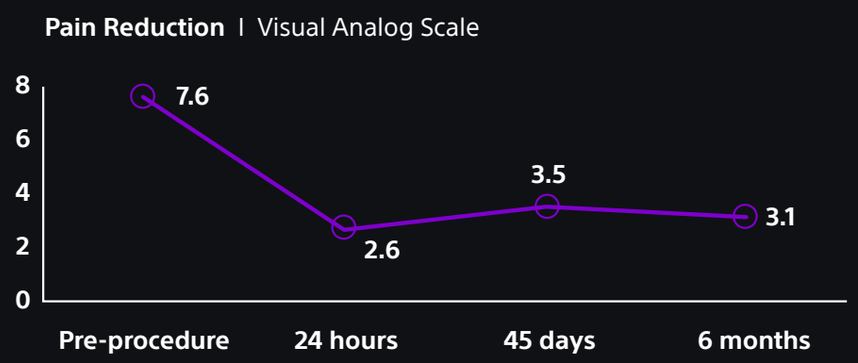
Interventional Cryoneurolysis: What Is the Same, What Is Different, What Is New? (Bittman et al., 2019)

Percutaneous cryoanalgesia for pain palliation: Current status and future trends (Filippiadis et al., 2021)

SUPPORTING FIGURES

PUDENDAL NERVE





Title	Percutaneous CT-guided cryoablation for the treatment of refractory pudendal neuralgia Prologo et al., 2014
Type of Study	Single center retrospective
Number of Patients	11
Indication	**Childbirth** **Gynecological surgery** **Rectocele repair** **Trauma** **TURP/radical prostatectomy** **Pelvic surgery**
Approach & Protocol	Single 17-gauge cryoablation probe advanced to distal portion of pudendal canal via transgluteal approach **8 min freeze** **5 min thaw** **8 min freeze** **5 min thaw**
Pain Reduction Outcomes	Pain reduction from 7.6 (VAS) pre-procedure to 2.6 (VAS) at 24 hours, 3.5 (VAS) at 45 days, and 3.1 (VAS) at 6 months
Other Outcomes	Safety – no procedure-related complications
Device Used	Needle: IceSphere™

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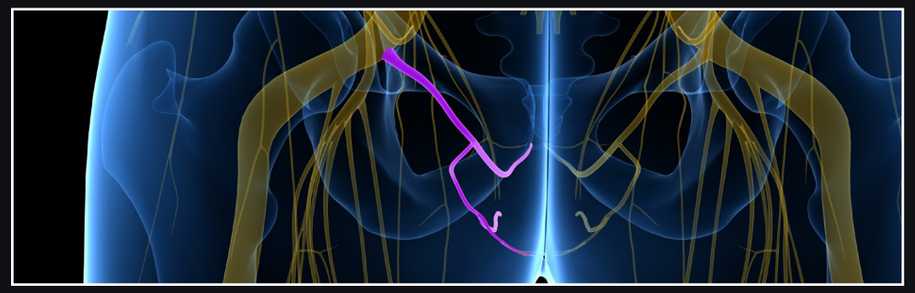
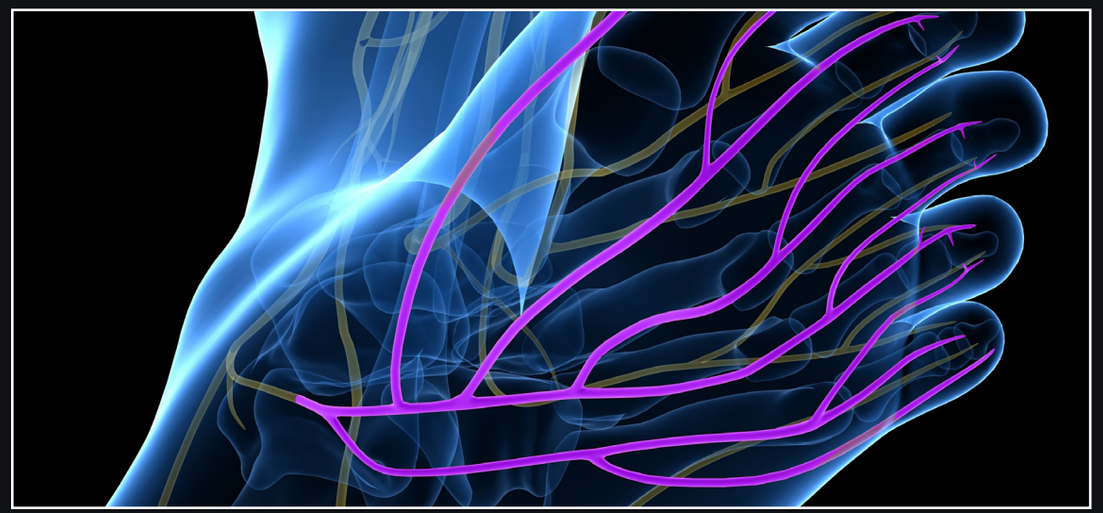
PUDENDAL NERVE

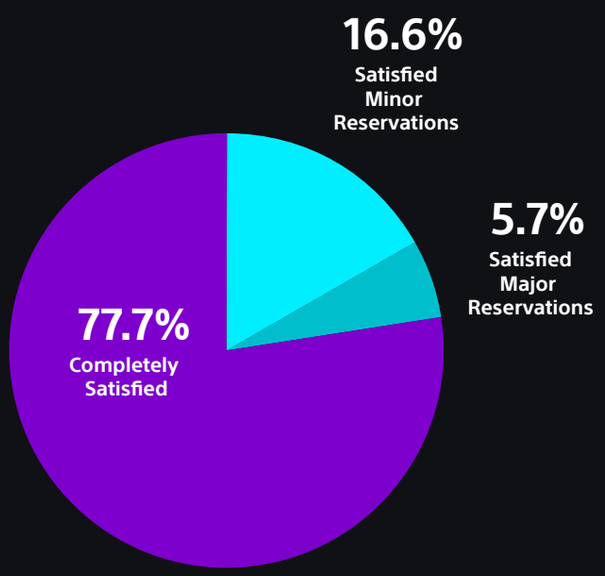


Title	**Percutaneous CT-guided cryoablation of the bilateral pudendal nerves for palliation of intractable pain related to pelvic neoplasms** Prologo et al., 2020.
Type of Study	Retrospective cohort analysis
Number of Patients	10
Indication	Rectal mass, primary rectal small cell neuroendocrine tumor Rectal mass, HIV lymphoma, rectovaginal fistula Rectosigmoid mass, primary colon cancer Anal cancer, squamous cell primary Vaginal carcinoma, squamous cell primary Bladder cancer, undifferentiated urothelial cell origin Bladder cancer, urothelial carcinoma primary Colorectal cancer Cervical cancer Recta CA
Approach & Protocol	Singe 17-gauge probe guided to position parallel and medial to pudendal nerve is it courses proximally in pudendal canal Goal of including pudendal nerve in -20 °C to 40 °C **8 min freeze** **4 min passive thaw** **8 min freeze** **4 min passive thaw**
Pain Reduction Outcomes	Mean pain reduction of 5.2 (VAS) pre- and post-procedure
Other Outcomes	Time to discharge: 2.3 days
Device Used	Needle: IceSphere™

MORTON’S NEUROMA

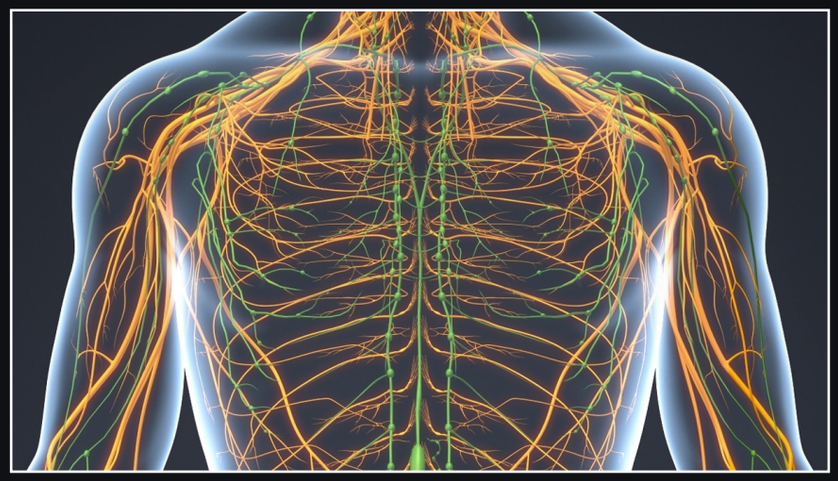


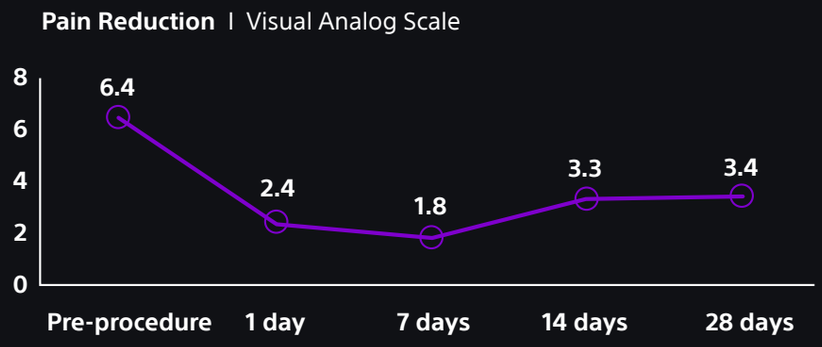
Title	**Percutaneous MR-guided cryoablation of Morton’s Neuroma: Rationale and technical details after the first 20 patients** Cazzato et al., 2016
Nerve Treated	Digital plantar nerve
Type of Study	Single center retrospective
Number of Patients	24
Indication	**Morton’s Neuroma**
Approach & Protocol	2 cm active tip cryoprobe inserted free hand via inter-metatarsal approach 0 °C **freezing cycle** for 150s. Additional 90s freezing cycles if lesion not completely covered by initial iceball Followed by short **thawing cycle** before removing needles
Pain Reduction Outcomes	Patient satisfaction score. 77.7% completely satisfied, 16.6% satisfied with minor reservations, 5.7% satisfied with major reservations
Other Outcomes	Safety – no procedure-related complications
Device Used	Needle: IceSeed™



DORSAL NEUROPATHIES

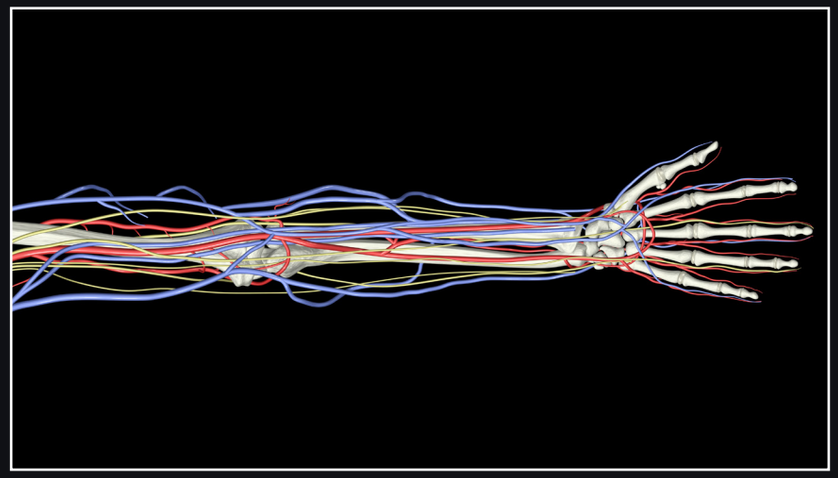
Title	**Cryoneurolysis in patients with dorsal neuropathic pain secondary to tumor invasion** Daubie et al., 2020
Nerve Treated	Thoracic nerve roots
Type of Study	Single center retrospective
Number of Patients	26
Indication (Tumor type)	Pulmonary 5 Soft-tissue sarcoma 4 ENT carcinoma 3 Colorectal cancer 3 Endometria carcinoma 2 Papillary thyroid carcinoma 2 Giant cell 1 Pleural mesothelioma 1 Prostate carcinoma 1 Kidney carcinoma 1 Breast carcinoma 1 Esophageal carcinoma 1 Gastric carcinoma 1 Epithelioid Hemangloendothelioma 1
Approach & Protocol	Probe inserted near the intervertebral foramina 10 min freeze 8 min thaw 10 min freeze Active thaw to remove
Pain Reduction Outcomes	Pain reduction from 6.4 (VAS) scale pre-procedure to 2.4 (VAS) at day 1, 1.8 (VAS) at day 7, 3.3 (VAS) at day 14, and 3.4 (VAS) at day 28. Median duration of pain relief was 45 days
Other Outcomes	Technical success rate 96.7% (One minor complication - high dorsal pain during needle positioning, which prevented full procedure).
Device Used	Needle: IceRod™ and IceSphere™



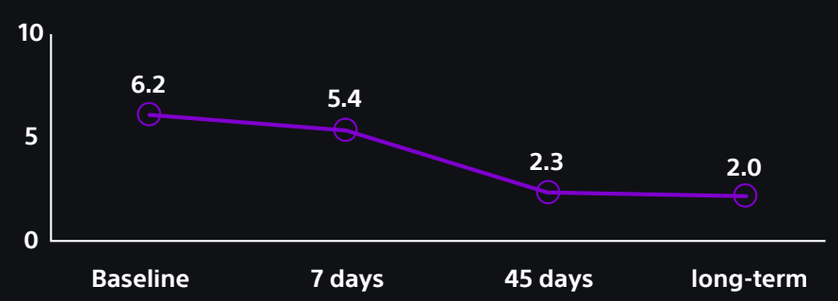


LIMB NEUROMA: PHANTOM LIMB

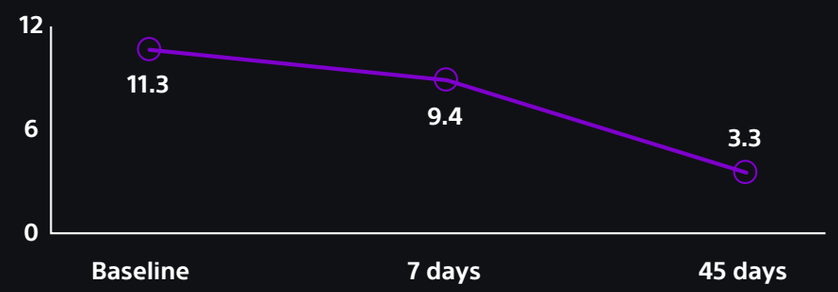
Title	**Percutaneous image-guided cryoablation for the treament of phantom limb pain in amputees: A pilot study** Prologo et al., 2016
Nerve Treated	Various
Type of Study	Single-arm, prospective pilot cohort
Number of Patients	21
Indication	Phantom limb pain post amputation
Approach & Protocol	Neuromas in limb identified by CT and Ultrasound. Suspected neuromas injected with 4 mL 0.25% bupivacaine and 6 mL betamethasone. If symptoms decreased, the neuroma was targeted. At -40 °C: 10 min freeze 5 min passive thaw 10 min freeze 5 min passive thaw
Pain Reduction Outcomes	Pain reduction from 6.2 (VAS) at baseline to 5.4 (VAS) at 7 days, 2.3 (VAS) at 45 days, and 2.0 (VAS) long-term.
Other Outcomes	Safety and feasibility. 1 unrelated death and 29% minor complications. 100% technical success, with all neuromas fully ablated. Improvement in functional status (RMDQ scale) of 11.3 at baseline, 9.4 at 7 days, and 3.3 at 45 days
Device Used	System: Visual ICE™ Needle: IceSphere™



Pain Reduction | Visual Analog Scale



Improvement in Functional Status | RMDQ scale



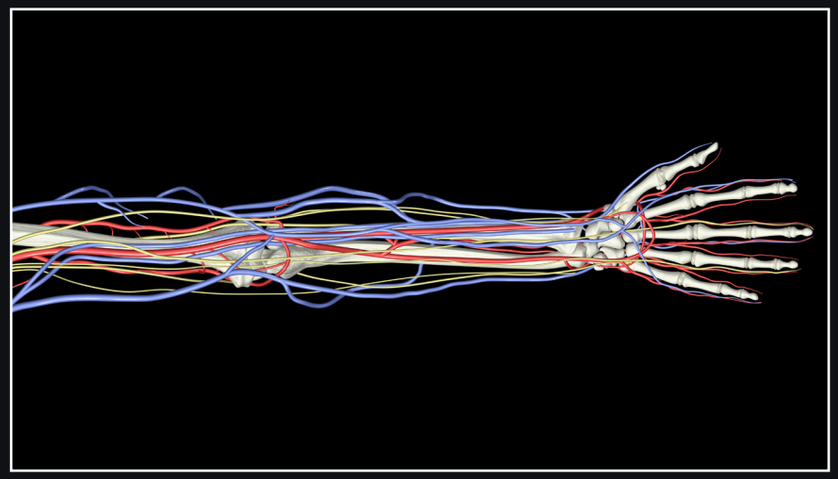
Other Limb Neuroma Studies

Treatment of phantom limb pain by Cryoneurolysis of the amputated nerve
(Moesker et al., 2014). Cryoablation of peripheral nerves in 5 patients with phantom limb pain, followed for 2.5 years.

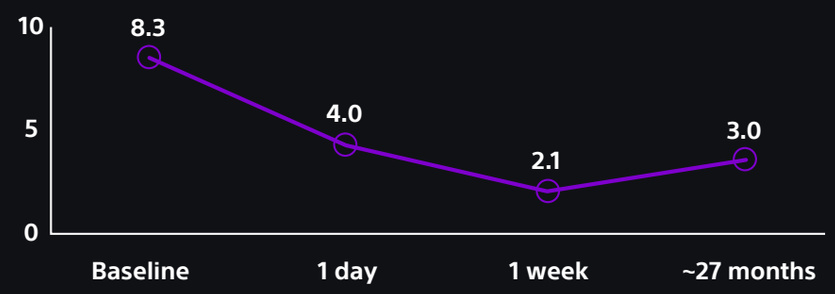
Cryoprobe treatment: an alternative to phenol injections for painful neuromas after amputation
(Neumann et al., 2008). Cryoablation of stump neuromas in 10 patients with phantom limb pain, followed for 3 years.

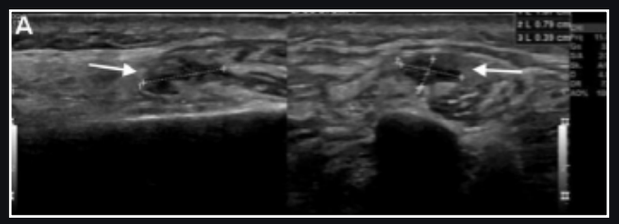
LIMB NUEROMA: POST-AMPUTATION PAIN

Title	**Icing the Pain-Ultrasound-Guided Cryoablation of Symptomatic Post-Amputation Stump Neuroma** Falck et al., 2022
Nerve Treated	Painful stump neuroma
Type of Study	Observational
Number of Patients	7 patients (8 neuromas)
Indication	Sonographically identifiable, painful stump neuroma and decrease of pain after probatory perineural infiltration.
Approach & Protocol	Sonographic evaluation of the stump to identify neuroma, followed by image-guided perineural infiltration with 5 ml prilocaine and 5 ml ropivacaine using 20 G needle. If patient reported pain reduction, cryoablation performed: **6 min freeze** **4 min thaw** **6 min freeze** **4 min thaw**
Pain Reduction Outcomes	Pain reduction (VAS) from 8.3/10 at baseline to 4/10 (VAS) at 1 day, 2.1/10 (VAS) at 1 week, and 3/10 (VAS) at last follow up – mean 27 months
Other Outcomes	• 100% technical success. • Patient satisfaction 70/100 • 6/7 patients reported willingness to undergo re-ablation • 1 patient experienced skin redness one day post ablation, which resolved on its own • 1 patient received repeat ablation for same neuroma during follow up due to aggravating pain after initial pain palliation
Device Used	System: Visual ICE™ Needle: IceSphere™ or IceSeed™

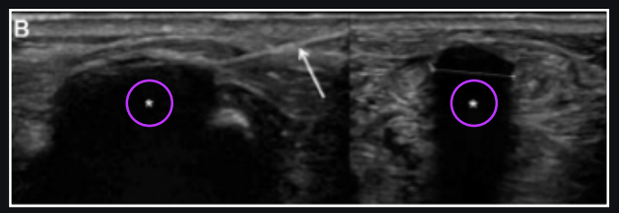


Pain Reduction | Visual Analog Scale





A: Depiction of a typical neuroma (11 x 8x4 mm) causing pain, which could be triggered by pressure.



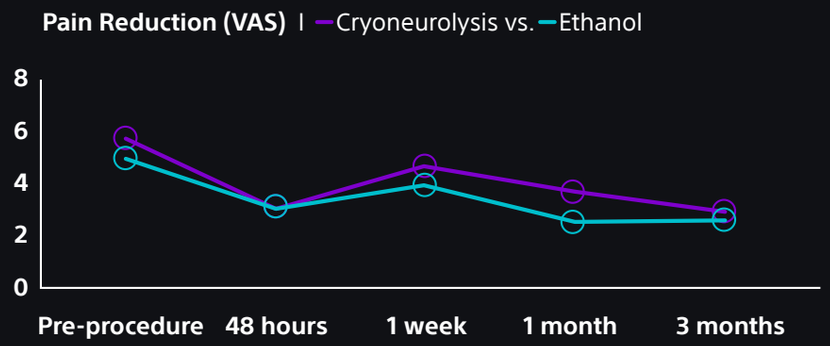
B: Ultrasound-guided placement of the cryoprobe (open arrow) and monitoring of the evolving iceball (*) that covers the neuroma completely

CELIAC PLEXUS

Title	**Percutaneous CT-guided cryoablation of the Celiac Plexus: A retrospective cohort comparison with ethanol** Chary et al., 2020
Type of Study	Retrospective cohort comparison
Number of Patients	83
Indication (cryoablation vs. ethanol)	

	Cryoablation	Ethanol
Pancreatic cancer	26	30
Colon cancer	3	4
Pancreatitis	4	2
Gastric adenocarcinoma	2	1
Esophogeal cancer	1	1
Cholangiocarcinoma	1	1
Ovarian cancer		2
Median arcuate ligament syndrome	2	
Hepatocellular carcinoma		1
Persistent gastric ulceration		1
Bladder cancer		1

Approach & Protocol	**Cryoablation** Two 17-gauge cryoablation probes advanced to celiac plexus bilaterally **8-10 min freeze** **3-5 min passive thaw** **8-10 min freeze** **3-5 min passive thaw**	**Ethanol** For each alcohol case, two 22-gauge needles were advanced to the celiac plexus (one on each side) and injected with contrast to confirm extravascular location of the needle tips. A total of 40 mL of absolute alcohol was split between sides and injected. Needles were flushed before removal.
Pain Reduction Outcomes	**Cryoablation** 5.8 (VAS) pre-procedure, reduced pain to 3.1 (VAS) at 48 hr, 4.7 (VAS) at 1 week, 3.7 (VAS) at 1 month, and 2.9 (VAS) at 3 months	**Ethanol** 5.0 (VAS) pre-procedure, dropped to 3.7 (VAS) at 48 hr, 3.9 (VAS) at 1 week, 2.5 (VAS) at 1 month, and 2.6 (VAS) at 3 months
Other Outcomes	**Cryoablation** Patients had a 5.1% incidence of diarrhea post-procedure	**Ethanol** Patients had a 20.5% incidence of diarrhea post-procedure
Device Used	Needle: IceRod™ and IceSphere™	



Other studies

Percutaneous computed tomography guided cryoablation of the celiac plexus as an alternative treatment for intractable pain caused by pancreatic cancer

(Yarmohammadi et al., 2011). Case study of 43-year-old male with pancreatic cancer using 17 gauge IceSphere cryoablation probe.

CT-guided celiac plexus neurolysis: a review of anatomy, indications, technique, and tips for successful treatment

(Kambadakone et al., 2011). Overview of current protocol for celiac plexus block with alcohol. Includes key anatomy, most common indications, and CT imaging strategies.

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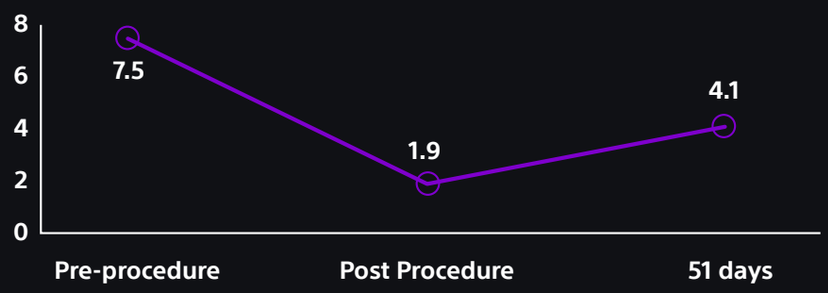
TRIGEMINAL NERVE

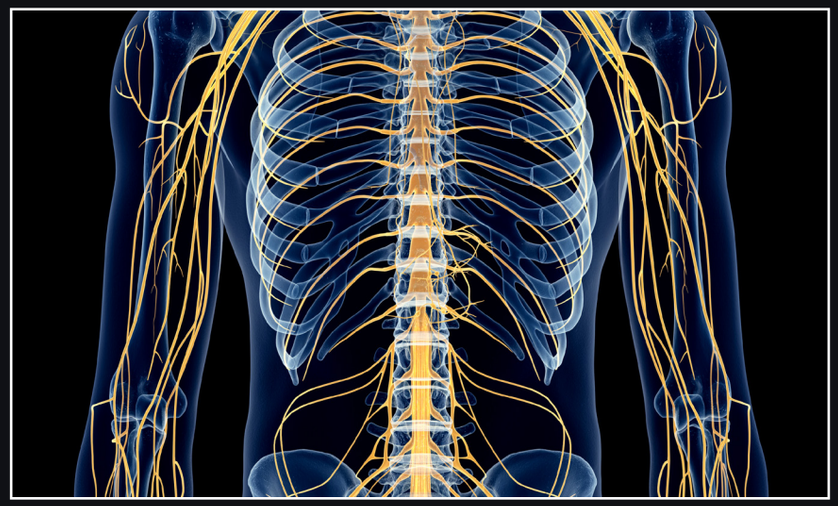
Title	**CT-guided cryoablation for palliation of secondary trigeminal neuralgia from head and neck malignancy** Prologo et al., 2012
Type of Study	Single center retrospective
Number of Patients	3
Indication	Squamous cell carcinoma Recurrent mucoepidermoid carcinoma.
Approach & Protocol	1-2 probes placed in tumor and 2-4 freeze-thaw cycles performed **10 min freeze** **6-8 min thaw**
Pain Reduction Outcomes	Pain reduction from 7.5 (VAS) pre-procedure to 1.9 (VAS) immediately after procedure and 4.1 (VAS) after 51 days
Other Outcomes	No post-procedure outcomes
Device Used	Percryo 15, Siemens

Pain Reduction I Visual Analog Scale

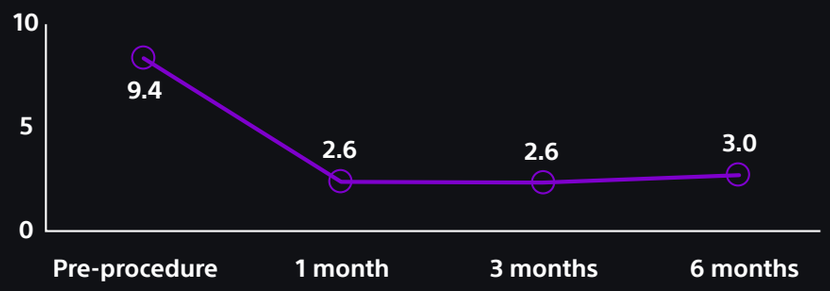


SPLANCHNIC NERVE

Title	**A technical report on the performance of percutaneous cryoneurolysis of splanchnic nerves for the treatment of refractory abdominal pain in the patients with pancreatic cancer: Initial experience** Flilippiadis et al., 2021
Type of Study	Retrospective review of prospectively collected data
Number of Patients	5
Indication	Pancreatic Cancer
Approach & Protocol	Target for splanchnic nerves neurolysis lies retrocruraly at the anterolateral border of the T12 vertebral body. At this point located posterior to the diaphragmatic crus splanchnic nerves can be destroyed before they penetrate the crus Local anesthesia with Lidocaine Hydrochloride 2% and intra-venous analgesia with paracetamol was used to treat intra-procedural pain Percutaneous posterior paravertebral approach in all cases with cryoprobes placed anterolaterally to the vertebral body; in 4/5 patients cryoprobes were placed bilaterally at T12 level whilst in 1/5 patient cryoprobes were placed unilaterally on the left side at T12 and T11 levels **10 min freeze** **4 min passive thaw** **1 min active thaw**
Pain Reduction Outcomes	Pain reduction from 9.4 (VAS) pre-procedure to 2.6 (VAS) at 1 month, 2.6 (VAS) at 3 months, and 3 (VAS) at 6 months.
Other Outcomes	No complications All patients reported decrease in analgesic use, with 3/5 patients moving from transdermal opioid patches to oral anti-inflammatory analgesics
Device Used	Needle: IceSphere™ 1.5 CX



Pain Reduction I Visual Analog Scale



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DATA COMPARISON

Title	Percutaneous CT-guided cryoablation for the treatment of refractory pudendal neuralgia Prologo et al., 2015	Percutaneous CT-Guided Cryoablation of the Bilateral Pudendal Nerves for Palliation of Intractable Pain Related to Pelvic Neoplasms Prologo et al., 2020	Percutaneous MR-Guided Cryoablation of Morton's Neuroma: Rationale and Technical Details After the First 20 Patients Cazzato et al., 2016	Cryoneurolysis in Patients with Dorsal Neuropathic Pain Secondary to Tumor Invasion Daubie, et al., 2020	Percutaneous Image-Guided Cryoablation for the Treatment of Phantom Limb Pain in Amputees: A Pilot Study Prologo, et al., 2016	Icing the Pain-Ultrasound-Guided Cryoablation of Symptomatic Post-Amputation Stump Neuroma Falck et al., 2022	Percutaneous CT-Guided Cryoablation of the Celiac Plexus: A Retrospective Cohort Comparison with Ethanol Behbahani, Chary et al., 2020	CT-guided cryoablation for palliation of secondary trigeminal neuralgia from head and neck malignancy Dar, Prologo, et al., 2012	A Technical Report on the Performance of Percutaneous Cryoneurolysis of Splanchnic Nerves for the Treatment of Refractory Abdominal Pain in Patients with Pancreatic Cancer: Initial Experience Filippiadis et al., 2021
Nerve Treated	Pudendal nerve	Pudendal nerve	Digital plantar nerve	Thoracic nerve roots	Various	Painful stump neuroma	Celiac Plexus	Trigeminal nerve	Splanchnic nerve
Pain Reduction Outcomes	Pain reduction of 4.5 on visual analog scale (VAS)	Pain reduction of 5.2 on VAS	N/A	Pain reduction of 3.0 on VAS	Pain reduction of 4.2 on VAS	Pain reduction of 5.3 on VAS	Pain reduction of 2.9 on VAS with cryoablation, compared to pain reduction of 2.4 with ethanol	Patient reported pain reduction in all 3 cases	Pain reduction of 6.4 on VAS
Other Outcomes	No procedure related complications	N/A	94.3% patient satisfaction 100% technical success	96.7% technical success rate	29% minor complications. 100% technical success. 1 unrelated death.	100% technical success rate Patient Satisfaction 70/100	5.1 % incidence of diarrhea with cryoablation, compared to 20.5% with ethanol patients	N/A	No complications All patients reported decrease in analgesic use, with 3/5 patients moving from transdermal opioid patches to oral anti-inflammatory analgesics
Device Used	Needle: IceSphere™	Needle: IceSphere	Needle: IceSeed™	Needle: IceRod™ and IceSphere	System: Visual ICE™ Needle: IceSphere	System: Visual ICE™ Needle: IceSphere or IceSeed	Needle: IceRod and IceSphere	Needle: IceSeed and IceSphere	Needle: IceSphere 1.5 CX

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