

# CAS-One<sup>®</sup> IR

## CLINICAL EVIDENCE SUMMARY

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This is a selection of 5 critical scientific studies. To see a complete list of 30+ publication featuring CAS-One IR please [visit our publication website.](#)

# CAS-One<sup>®</sup> IR reduces procedure time and increases accuracy



## Published

Beyer LP, et al., Stereotactically-navigated percutaneous Irreversible Electroporation (IRE) compared to conventional IRE: a prospective trial. *PeerJ*. 2016 Aug 11

## Objectives

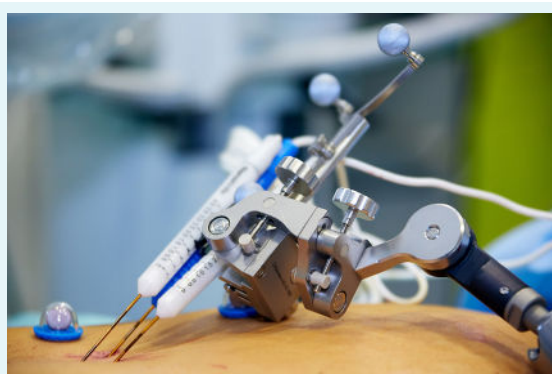
To compare CT-guided stereotactic IRE (SIRE) using CAS-One<sup>®</sup> IR to conventional IRE (CIRE) for percutaneous ablation of liver malignancies.

## Results

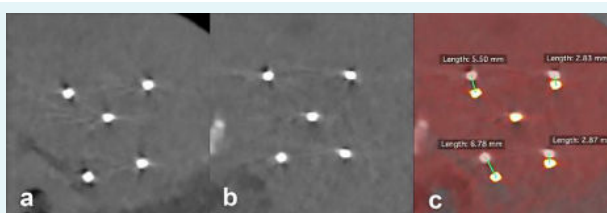
A total of 20 IREs of hepatic malignancies (16 HCC, four liver metastases) were performed, with ten procedures in each arm. The mean time for placement of IRE electrodes in the CAS-One IR group (SIRE) was significantly shorter at  $27 \pm 8$  min compared to  $87 \pm 30$  min for CIRE ( $p < 0.001$ ). The accuracy of instrument placement for SIRE was higher than CIRE (2.2 mm vs. 3.3 mm mean deviation,  $p < 0.001$ ). The total dose-length product (DLP) and the fluoroscopy DLP were significantly lower in SIRE than in CIRE. Technical success rate and complication rates were equal in both arms.

## Key insights

- The CAS-One IR group demonstrated a significant reduction in instrument placement time
  - 69% reduction in placement time (27 vs. 87 minutes)
  - 73% reduced variability (8 minutes versus 30 minutes)
- When adding planning, the total time (to ablation start) was 47% shorter (55 vs. 104 minutes)
- The CAS-One IR group also demonstrated a 50% higher accuracy (2.2mm vs. 3.3mm)
- DLP was significantly lower for SIRE



**Fig. 1** Positioning the needle guidance device for inserting the IRE electrodes.



**Fig. 2** Evaluation of the lateral deviation of the IRE electrodes.

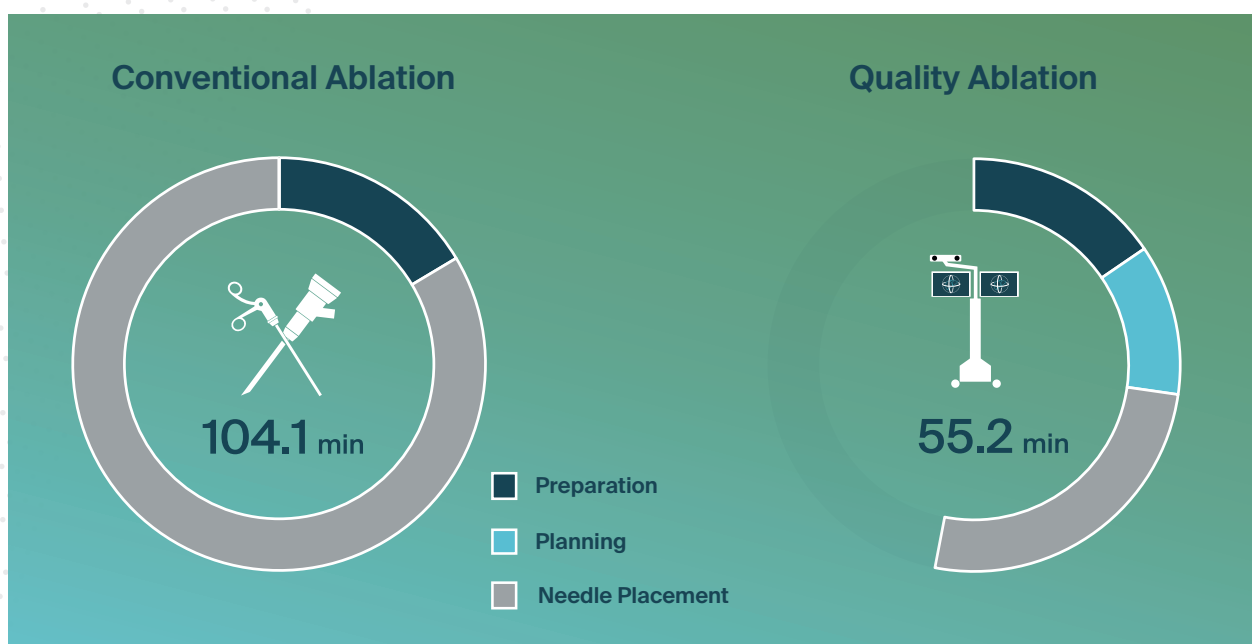
- (A) Orthogonal plane (thickness 0.7 mm) at the tip of the reference electrode.  
 (B) Orthogonal plane at a distance of 3 cm from the tip of the reference electrode.  
 (C) Fusion of (A) and (B) with determination of lateral probe deviations.

## CLINICAL EVIDENCE SUMMARY

CAS-One® IR reduces procedure time and increases accuracy

### Material and Methods

- Prospective, non-blinded, non-randomized, two-armed study carried out between July 2015 and February 2016.
- CAS-One IR was used to plan, execute, and confirm instrument placement in the SIRE group. In contrast, ablations in the CIRE group were performed using conventional CT fluoroscopy without navigational assistance.
- Instrument placement accuracy was measured as the degree of parallelism defined as the lateral deviation of each IRE electrode over the last 3cm (from the probe tip) with respect to the reference electrode defined as the probe in the most central position in the tumour.
- Median overall follow-up was 17.5 months after intervention and 24 months after initial diagnosis.



**Fig. 3** Detail of the procedure preparation, planning, and needle placement with regards to time.

Conventional or stereotactic	CIRE (N = 10)	SIRE (N = 10)	t-test
Total DLP–mG<sup>*</sup> cm	4886 ± 1775	3510 ± 887	t (13.2) = 2.2
Verification DLP–mG<sup>*</sup> cm	1351 ± 479	725 ± 326	t (15.8) = 3.4
Fluoroscopy DLP–mG<sup>*</sup> cm	1705 ± 1583	136 ± 206	t (9.3) = 3.1

**Table 1** Dose length product (DLP) of the entire intervention, CT fluoroscopy and all verification scans. Data are presented as means and standard deviations.

### Strengths

- Prospective
- 2-arm comparison
- All endpoints were statistically significant

### Limitations

- Single-center
- Not randomized
- Low sample size (10 subjects per arm)

# CAS-One<sup>®</sup> IR reduces local recurrence rate and radiation exposure compared to a freehand CT approach



## Published

Schaible, J. et. al., (2020). Primary efficacy of percutaneous microwave ablation of malignant liver tumors: comparison of stereotactic and conventional manual guidance. Scientific Reports, 10(1), 18835. <https://doi.org/10.1038/s41598-020-75925-6>

## Objectives

To compare primary efficacy and dose-length product of CAS-One IR-guided microwave ablation with conventional CT-guided microwave ablation for malignant liver disease.

## Results

A total of 221 patients (140, 17 and 64 with HCC, CCC and other liver metastases, respectively) with 423 liver lesions underwent microwave ablation (MWA). The CAS-One IR and conventional groups included 287 and 136 tumours, respectively. The primary efficacy rate was significantly higher in the CAS-One IR group (84.3%) than in the conventional group (75.0%,  $p = 0.03$ ). The dose length product was significantly lower for the CAS-One IR group ( $p < 0.01$ ).

## Key insights

- CAS-One IR significantly improves the primary efficacy rate (see materials and methods) compared to a freehand approach
- CAS-One IR significantly reduces radiation exposure compared to a freehand approach
- Both groups had similar characteristics in tumor size and location.

	Freehand	CAS-One IR	P-value
Lesions size			0.531
< 3 cm	119	243	
≥ 3 cm	17	44	
Liver segment			0.200
I	2	6	
II	15	38	
III	18	17	
IV	27	44	
V	16	37	
VI	21	38	
VII	15	42	
VIII	22	65	
Primary Efficacy			0.030
Complete	102/136 (75%)	242/287 (84.3%)	

**Table 1**

Characteristics of malignant liver tumors in patients who underwent ablation using conventional or CAS-One IR guidance.

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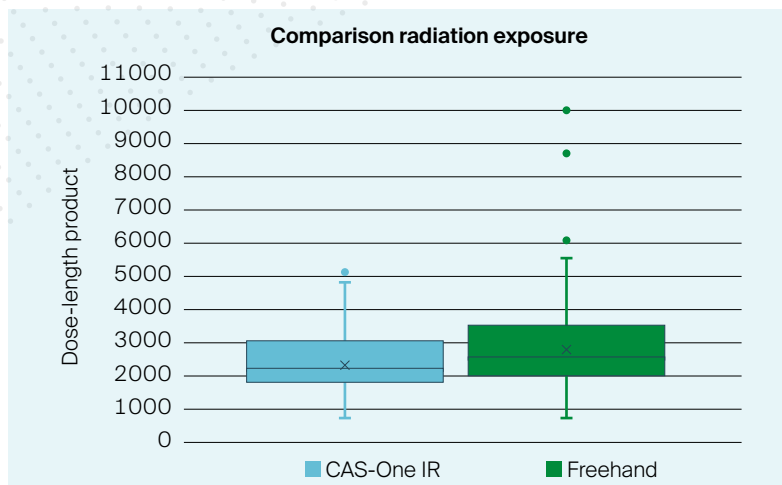
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## CLINICAL EVIDENCE SUMMARY

CAS-One® IR reduces local recurrence rate and radiation exposure compared to a freehand CT approach

**Figure 1**

Comparison of radiation exposure.



**Table 2**

Comparison of radiation exposure.

CAS-One IR		Freehand	
Mean	2461.4	Mean	2930.4
Standard Error	70.2	Standard Error	146.9
Median	2321	Median	2651
Std	936.7	Std	1439.3
Sample Variance	877488.1	Sample Variance	2071496.4
Minimum	679	Minimum	695
Maximum	5211	Maximum	9969

## Material and Methods

- Retrospective analysis of patients treated with conventional and CAS-One IR guided MWA
- All ablations were performed under general anaesthesia. During CT planning and instrument positioning, temporary apnoea was used to control respiratory motion in both groups
- Primary efficacy determined by the absence of residual tumour tissue on 6-week follow-up MRI scans with a liver-specific contrast agent; scans were evaluated by two experienced radiologists
- Dose-length product was calculated based on the dose report

## Strengths

- Large number of lesions in both groups
- Tumors were located in all segments of the liver
- High number of large tumors
- High level of experience of interventionists in both groups
- The only comparative study of Freehand CT vs CAS-One IR

## Limitations

- Single center
- Retrospective analysis
- Potential inter-user bias (three experienced interventionalists)
- Large amount of HCC (63%)

# CAS-One® IR enables successful treatment of ‘invisible’ lesions



## Published

Cathomas, et al. “Value of MRI/CT Image Fusion for Targeting “invisible” Lesions in Stereotactic Microwave Ablation (SMWA) of Malignant Liver Lesions: A Retrospective Analysis” *Cardiovascular and Interventional Radiology* 2020

## Objectives

To assess the technical feasibility of MRI/CT fusion and completeness of ablation treatment for liver tumors invisible on contrast-enhanced CT in patients treated with stereotactic microwave ablation (SMWA).

## Results

During the study period, 236 patients underwent 312 SMWAs for 496 lesions. 24 lesions in 15 patients (mean age, 62 years; range, 43–80 years) were ‘invisible’ and included. Following MRI/CT fusion with CAS-One® IR, all 24 lesions could be localized to perform SMWA. The first follow-up imaging showed complete ablation of 22 lesions (91.7%). Two initially incompletely ablated HCC lesions were successfully re-ablated.

Intrahepatic localization (liver segment)				Tumor type	
I	0	V	1 (4.2%)	Hepatocellular carcinoma (HCC)	11 (73.3%)
II	2 (8.3%)	VI	6 (25.0%)	Cholangiocellular carcinoma (CCC)	1 (6.7%)
III	1 (4.2%)	VII	4 (16.7%)	Metastasis of colorectal cancer (CRLM)	3 (20%)
IV	2 (8.3%)	VIII	8 (33.3%)		

MRI-CT fusion is accurate, safe, and enables effective treatment of liver lesions not visible during CT-guided percutaneous interventions even with multiple operators.

## Key insights

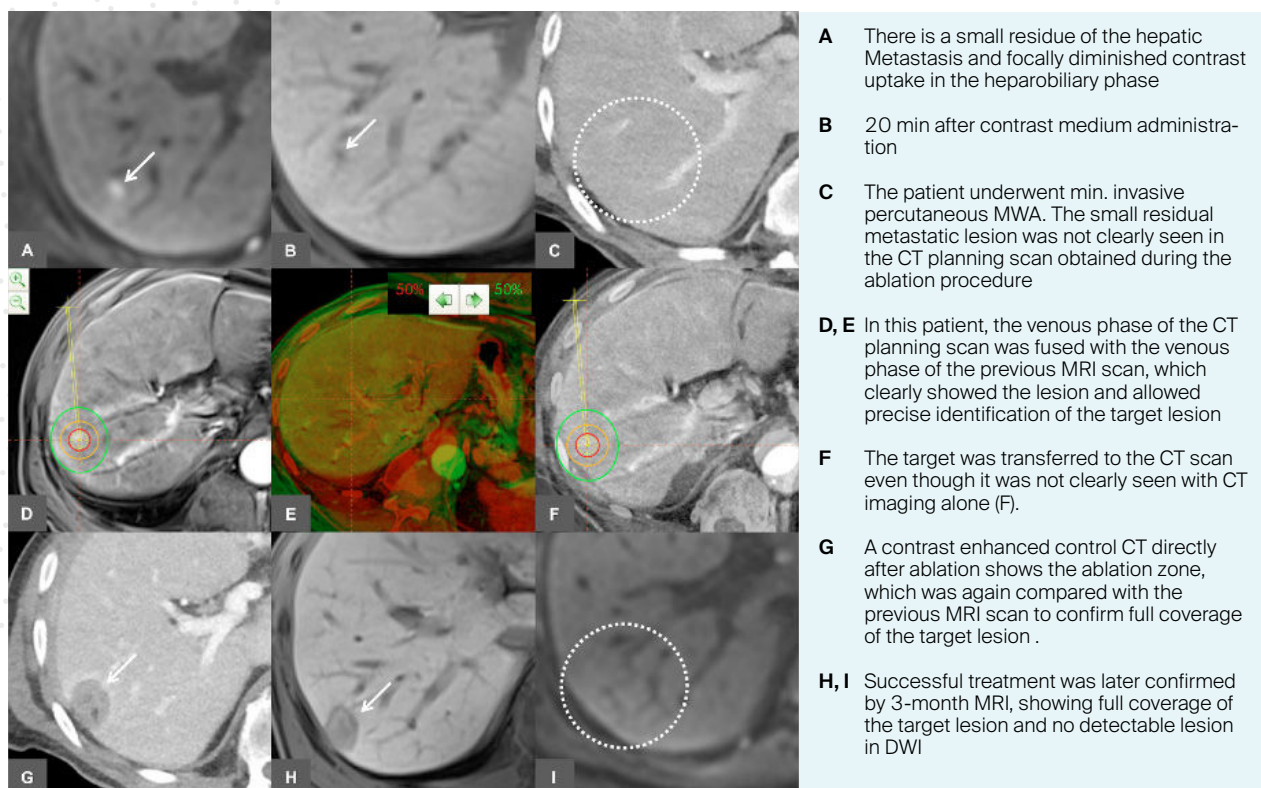
- 7.4% of 496 lesions in nearly 10% (22/236) patients were deemed invisible. This center has a self-reported a very high proportion of HCC, other centers may experience an ever higher invisibility ratio
- With CAS-One IR, technical success of SMWA of invisible lesions using MRI/CT fusion was 100% (24 of 24) – even with the extended definition of technical success that was used
- Median tumor size was 12mm (3-28)
- Patients with incomplete ablation (n = 2) were scheduled for re-ablation and did not show recurrence at 3-month follow-up MRI

## CLINICAL EVIDENCE SUMMARY

CAS-One® IR enables successful treatment of 'invisible' lesions

## Material and Methods

- Patients who underwent SMWA between Jan. 2015 and Dec. 2018 were retrospectively analysed
- All liver lesions for which MRI/CT fusion was performed due to invisibility on pre-interventional CT planning scans were included.
- Technical success (in %) of MRI/CT fusion was assumed when the venous phases of both the MRI and CT scans were brought in full coverage with less than 2 mm of deviation.
- Complete ablation (in %) directly after SMWA was defined as full coverage of the target lesion with a safety margin of 5 mm in all three dimensions.
- The extended definition of technical success was used – lesions considered to be completely ablated only if no viable tumor tissue was detectable in the ablation zone rim in the 3-month post-ablation MRI – in contrast to other studies who evaluated directly after, or one day after.



**Fig. 2** A 67-year-old patient with a history of rectal cancer and a single hepatic metastasis in the right liver lobe.

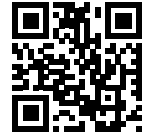
## Strengths

- Several types of liver tumors (HCC, CCC, CRLM), located in segments II-VIII of the liver were treated
- SMWA decision made according to EASL guidelines and tumor board recommendations
- Inclusion of time points after intervention and at standardized first follow-up MRI examination at 3 months

## Limitations

- Retrospective analysis
- Patient population from a single center with a large number of HCC that are typically well visible in the CT planning scan, so only a small number of lesions were invisible

# CAS-One<sup>®</sup> IR enables treatment in all segments of the liver



## Published

Lachenmayer A, et. Al. Stereotactic image-guided microwave ablation of hepatocellular carcinoma using a computer-assisted navigation system. *Liver Int.* 2019

## Objectives

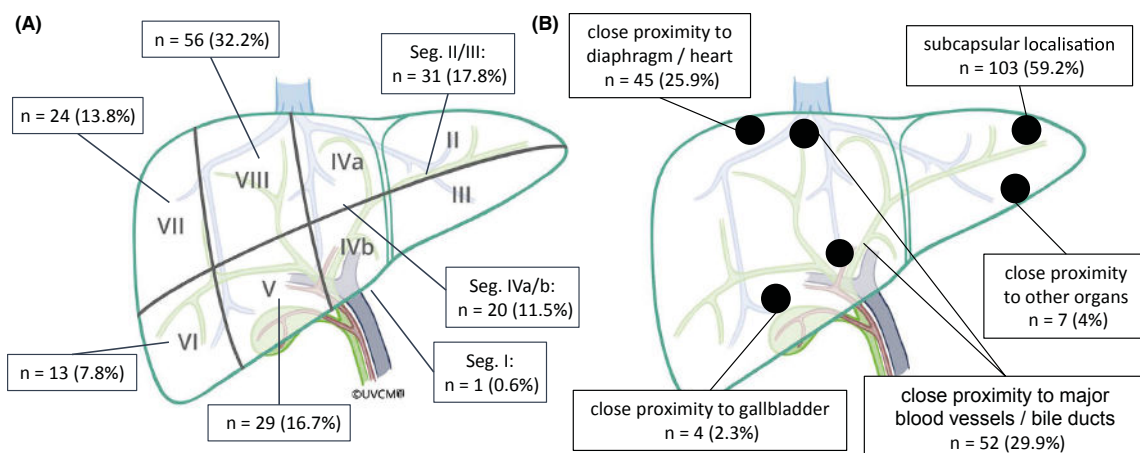
To analyse the safety, therapeutic, and procedural efficiency of CAS-One IR guided Microwave Ablation (stereotactic MWA) for HCC in all locations of the liver.

## Results

174 ablations were performed in 88 patients during 119 interventions. Median tumour size was 16 (4–45) mm. Median lateral and longitudinal error of needle placement were 3.2 (0.2–14.1) and 1.6 (0–15.8) mm. There was one Clavien-Dindo Grade IIIb (0.8%) complication, and six (4.8%) minor complications. After re-ablation of 12 lesions, a secondary efficacy rate of 96.3% was achieved. Local tumour progression was 6.3% (11/174).

## Key insights

- Stereotactic MWA is a safe and efficient treatment for HCC offering a curative treatment approach – even for lesions in difficult anatomical locations
- Tumors were ablated in all segments of the liver, many close to critical structures and adjacent organs
- Only proximity to major blood vessel was significantly correlated to local tumor progression (p-value of 0.044)
- 12% recurrence at 1–3 months. Following retreatment overall 6 month recurrence was 6%.



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## CLINICAL EVIDENCE SUMMARY

CAS-One® IR enables treatment in all segments of the liver

Factors	P-value	Odds ratio	95% confidence interval
Tumour >3 cm	.062	3.912	0.935-16.360
Child stage	.582	1.378	0.439-4.321
BCLC stage	.997	1.002	0.327-3.006
Previous HCC treatment	.634	0.787	0.294-2.110
Close proximity (within 5 mm) to major blood vessels (>3 mm)	.014	0.175	0.044-0.704
Tumour within 10 mm of capsule	.637	0.789	0.295-2.113
Distance to previous resection site/Clip <10 mm	.741	0.717	0.100-5.162
Number of tumours treated in 1 session	.115	1.271	0.545-2.962

**Table** Logistic regression analysis local recurrence

## Material and Methods

- Retrospective analysis of patients treated with stereotactic MWA between Jan 2015 and Dec 2017
- Interventions were performed using the CAS-One IR procedure to plan, execute and confirm ablation
- During instrument placement and image acquisition the patient was under general anaesthesia with jet-ventilation
- Median overall follow-up was 17.5 months after intervention and 24 months after initial diagnosis

## Strengths

- Large quantity of lesions
- All locations in the liver – different segments as well as proximity to critical structures

## Limitations

- Single-center
- Retrospective analysis
- No long term follow up

# Reduce Tumour Recurrence with CAS-One<sup>®</sup> IR



## Published

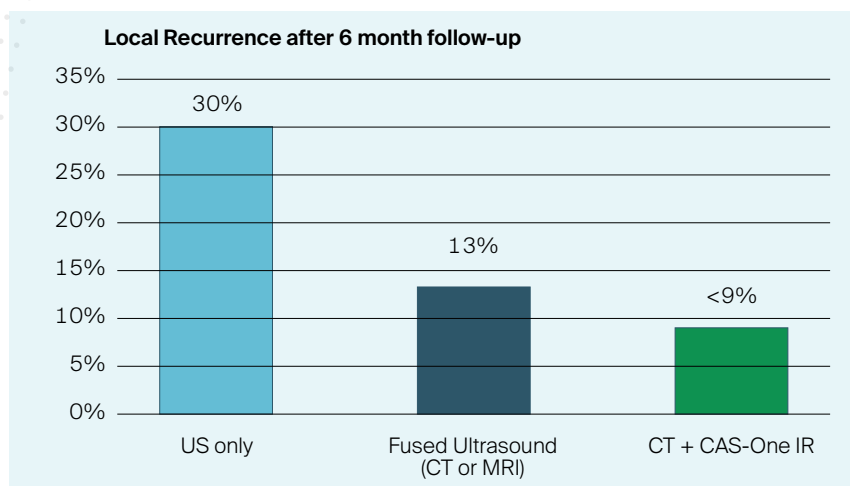
Beermann, Marie et al. "1000 consecutive ablation sessions in the era of computer assisted image guidance - Lessons learned." European Journal of Radiology Open vol. 6 1-8. 5 Dec. 2018.

## Objectives

The aim of the study was to share the positive experience of introducing image-guided therapy sessions (Fused Ultrasound and CAS-One) and ablation modalities such as MWA and IRE for the ablation of cancer related to abdominal organs from 2010 to 2017.

## Results

**1000 total ablation sessions** involving **787 tumors** were treated with CAS-One IR. The local 6 month recurrence rate decreased from an "unacceptably high" 30% (percutaneous ultrasound approach) to below 9% after adopting CAS-One IR. The CAS-One IR procedures were conducted by 10 interventionists (radiologists and surgeons) and did not show a difference in ablation site recurrence rate amongst the different operators. 96.4% of procedures had no complications of grade 3 or higher.



## Key insights

- This study indicates the adoption of image-guided therapy systems such as CAS-One IR may greatly benefit patients and hospitals to achieve lower recurrence rates compared to ultrasound or other methods
- The results were obtained across different indications including liver, lung and kidney cancer

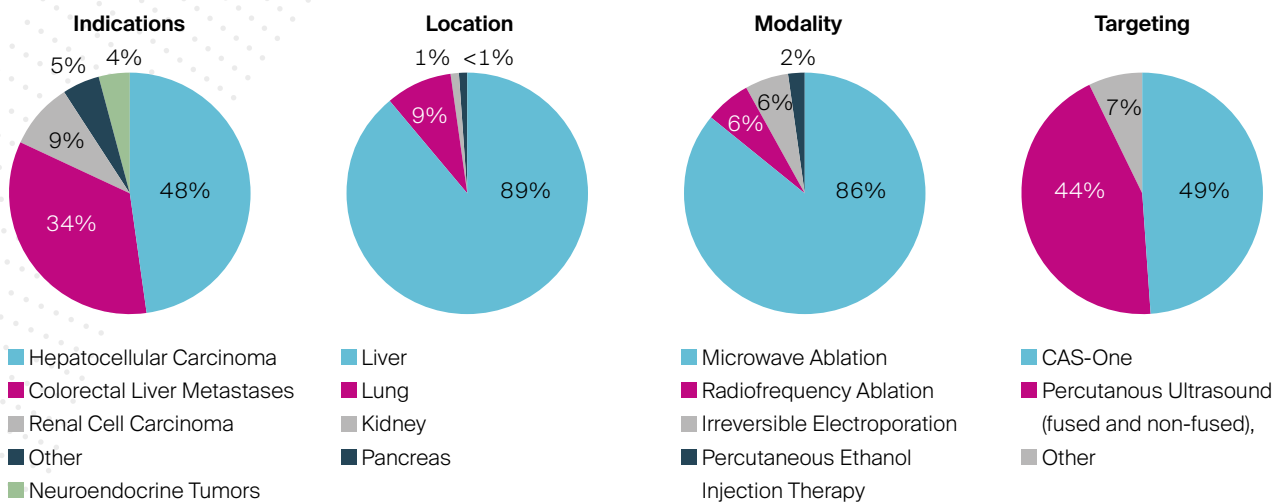
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## Material and Methods

- Retrospective analysis of prospectively collected data
- CAS-One® IR was installed in 2012. Previously mostly US-guided were performed. Fused ultrasound was made with Toshiba Aplio 500 and LOGIQ E9 Systems
- Multiple modalities were performed: MWA, IRE, RFA, PEIT
- Data was collected from 2010 to 2018 and involved a minimum 6 months follow up per patient
- Local recurrence defined as new tumour within 10mm of ablation volume within 6 months of treatment



## Strengths

- Large number (10) of physicians involved as operators
- 1000 treatments, 605 individual patients, 2495 tumours across 8 years

## Limitations

- Single Center
- Not Randomized
- Mixed reporting across all modalities, organs and ablation modalities used in the past years. No detailed reporting on CAS-One IR specific treatment results on all levels