

Epione

Clinical Evidence

Epione[®] robotic-assisted percutaneous tumor ablation



April 2024



BONNET B., DE BAÈRE T., BEUNON P., et al.

Robotic-assisted CT-guided percutaneous thermal ablation of abdominal tumors: An analysis of 41 patients

Diagn Intern Imaging. 2024 Feb 16.



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GOALS & OBJECTIVES

Evaluate feasibility, safety, accuracy, clinical success of Epione® robotic solution and short-term local tumor control for percutaneous abdominal tumor ablation.

Organs: Abdomen (liver, kidney, adrenal gland, retroperitoneum)
 Ablation methods: Thermal ablation (MWA, cryo, RFA) and irreversible electroporation (IRE)
 Sample size: 41 patients (48 tumors)

RESULTS & CONCLUSIONS

Study characteristics: 35 patients (85%) were treated for 1 lesion, 4 patients (10%) for 2 lesions and 2 patients (5%) for 3 lesions. Mean lesion sizes were 20.3 mm ± 8.4 (long axis) and 16.2 mm ± 7.6 (short axis). MWA was performed in 54% patients, cryoablation in 39%, RFA in 5% and IRE in 2%. Treatment was administered for lesions located in the liver (58%), kidney (31%), adrenal glands (8%), and retroperitoneum (2%). **23/48 (39%) lesions were considered challenging, and 38/79 (48%) needles were not in the axial plane** (oblique insertions).

Procedure time: The median time from robot-assisted planning to needle insertion was 24:22 min:sec ± 16:06 (range: 06:45 min:sec–01:22 h:min). The mean duration of needle insertion was 47 ± 43 (SD) sec. **40/75 (53%) needles were inserted in 30 sec or less.**

Feasibility: Technical success rate was reported in 39/41 (95%) patients and 76/79 (96%) needle insertions.

Accuracy: **The lateral accuracy was 3.2 mm ± 4.5** after first robotic needle insertion. The mean 3D distance between the needle tip and its planned robotic trajectory was **1.6 mm ± 2.6** after 29 minor adjustments (37% of insertions) and 33 moderate adjustments (42%). The **lateral accuracy** before adjustments was **similar for the challenging and non-challenging needle insertions.**

Safety: A pleural hemorrhage was reported in one patient, sent home 48 hours after the procedure. An additional control CT exam 12 days after the intervention (chest pain) was performed, with no complication found.

Clinical success and oncologic outcome: **The clinical success rate was 100%.** All ablations were complete. **The ablation margin was 5.5 mm ± 3.1.** Local tumor control was reported in 38/41 patients (95%).

L'HUILLIER R., DUMORTIER J., MASTIER C., *et al.*

Robotic-assisted percutaneous irreversible electroporation for the treatment of hepatocellular carcinoma

Diagn Interv Imaging. 2023 Sep 9.



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GOALS & OBJECTIVES

Evaluate Epione® robotic solution for percutaneous tumor ablation treatment of HCC using irreversible electroporation.

Organ:	Liver
Ablation method:	Irreversible electroporation
Sample size:	5 patients

RESULTS & CONCLUSIONS

- Letter sharing experience using Epione® robotic platform in the percutaneous **irreversible electroporation ablation treatment of HCC** in 5 patients.
- Preliminary feedback shows promising results for **complex procedures (3 to 6 needles inserted)** in **challenging locations** close to at-risk structures (e.g., gallbladder, biliary ducts).
- **No adverse events** were reported.
- 2 of these procedures **were successfully performed by radiologists with only 1 and 2 years of experience** in percutaneous tumor ablation.

MILOT L., L'HUILLIER R., DUMORTIER J., et al.
**Robotic-assisted percutaneous microwave
 ablation of hepatocellular carcinoma**

Diagn Interv Imaging. 2023 Feb 13.



Click or scan to
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GOALS & OBJECTIVES

Evaluate Epione® robotic solution for percutaneous tumor ablation treatment of HCC using microwave.

Organ:	Liver
Ablation method:	Microwave
Sample size:	3 patients

RESULTS & CONCLUSIONS

- Letter sharing experience using Epione robotic platform in the percutaneous **microwave ablation treatment of HCC** in 3 patients.
- Preliminary feedback shows promising results in **challenging locations** (hepatic dome and subcapsular)
- **No adverse events** were reported.

DE BAÈRE T., ROUX C., DESCHAMPS F., *et al.*

Evaluation of a New CT-Guided Robotic System for Liver Tumors: A Prospective Pilot Study

Cardiovasc Intervent Radiol. 2022 Sep 20.



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GOALS & OBJECTIVES

Evaluate feasibility and safety of Epione® robotic solution for percutaneous liver tumor ablation using radiofrequency and microwave.

Organ:	Liver
Ablation method:	Thermal ablation (radiofrequency and microwave)
Sample size:	21 patients (24 tumors)

RESULTS & CONCLUSIONS

Study characteristics:	The mean largest diameter of the tumors was 15.6 ± 7.2 mm (range 5–32 mm). 11 (45.8%) targeted tumors were judged as challenging by the operators in regard with their location including 9 (81.8%) lesions located in the hepatic dome and 2 (18.2%) subcapsular lesions. 18 (75%) trajectories were not in the axial plane and 15 (62.5%) trajectories had a double angulation (i.e., craniocaudal and lateral). MWA was used in 23 (95.8%) tumors and RFA was used in 1 (4.2%) tumor.
Procedure time:	The mean overall procedure duration was 73.8 ± 29.2 min from first pre-interventional CT-scan to last post-ablation CT-scan.
Feasibility:	95.7% feasibility rate. Robotic needle placement was judged adequate to perform ablation for 22/23 lesions.
Accuracy:	The mean number of adjustments per lesion was 0.4 ± 0.7 : No needle placement adjustment was needed in 17 (70.8%) tumors, while 6 (25%) lesions required 1 adjustment and 1 (4.2%) lesion required 3 adjustments.
Safety:	No procedure-related complications were observed on post-procedural CT-scan, and no adverse events were detected. 20 patients were discharged from hospital the day after the procedure, 1 patient after 2 days.

DE BAÈRE T., ROUX C., NOEL G., *et al.*

Robotic assistance for percutaneous needle insertion in the kidney: preclinical proof on a swine animal model

Eur Radiol Exp. 2022 Mar 8.



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GOALS & OBJECTIVES

Evaluate accuracy, safety, and feasibility of Epione[®] robotic solution for needle placement in swine kidney model.

Organ:	Kidney
Needle type:	17G Coaxial Needle
Sample size:	2 swine (8 needles)

RESULTS & CONCLUSIONS

Study characteristics:	A total of 8 needle insertions with 8 different trajectories were planned and executed, with 7 (87.5%) of trajectories out of plane ($\geq 5^\circ$ in the z-axis).
Procedure time:	The median [min; max] time was 21 [13; 35] minutes from the beginning of the procedure (turning on the device) to the visual verification on the CT scan acquired after needle placement.
Feasibility:	100%. All needles were inserted on the first attempt, without readjustment.
Accuracy:	All 8 fiducials were accurately targeted on the first attempt according to the visual evaluation of the operator. Blinded evaluation showed an accuracy of 2.8 ± 1.3 mm , the means lateral deviation and depth deviation were 2.3 ± 1.2 mm and 0.7 ± 1.7 mm, respectively. Neither orbital angulation, craniocaudal angulation, nor trajectory length had an impact on the accuracy of needle placement.
Apnea repeatability:	100% (<2 mm between apneas) . All fiducials depicted on CT moved less than 2 mm between two consecutive apneas. The 3D deviation of the fiducials between CT-scans acquired during 2 consecutive apneas was significantly lower than 2 mm ($P = 0.019$) with a least-squares mean of 0.5 mm and a 95% upper limit of 1.1 mm.
Safety:	2 minor procedure-related complications (subcapsular hematomas in the same animal).

GUIU B., DE BAÈRE T., NOEL G., *et al.*

Feasibility, safety, and accuracy of a CT-guided robotic assistance for percutaneous needle placement in a swine liver model

Sci Rep. 2021 Mar 4.



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GOALS & OBJECTIVES

Evaluate accuracy, safety, and feasibility of Epione® robotic solution for needle placement in swine liver model.

Organ:	Liver
Needle type:	17G Coaxial Needle
Sample size:	10 swine (66 needles)

RESULTS & CONCLUSIONS

Study characteristics:	66 fiducials were surgically inserted into the liver of 10 swine.
Procedure time:	The median [min; max] time was 24.8 [15; 45] minutes from the beginning of the procedure (switch on the device) to last needle placement (needle in place).
Feasibility:	100%. All needle insertions (43/43) were successful.
Accuracy:	Blinded evaluation showed an accuracy of 3.5 ± 1.3 mm and did not differ between novice and experienced operators (3.7 ± 1.3 versus 3.4 ± 1.2 mm, P = 0.44).
Apnea repeatability:	100% (<2mm between apneas). All fiducials depicted on CT moved less than 2 mm between two consecutive apneas. The 3D deviation of the fiducials between CT-scans acquired during 2 consecutive apneas was significantly lower than 2 mm (P<0.0001) with a least-squares mean (and 95% upper limit) of 0.61 ± 0.77 mm.
Safety:	No procedure-related complications.



About Quantum Surgical

Quantum Surgical is a French medical robotics company, focused on developing breakthrough solutions to address complex medical issues. Its Epione[®] robotic percutaneous ablation platform offers a new approach to cancer treatment by standardizing ablation procedures for the curative and early treatment of cancers, allowing more patients to benefit from better targeted and less invasive treatments.

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Epione[®] device is CE marked and FDA cleared.

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