

# Performance of a New Blunt-Tip Coaxial Needle for Percutaneous Biopsy and Drainage of “Hard-To-Reach” Targets

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## Abstract

**Aim** To present a new blunt-tip coaxial needle (SoftGuard) applied to access “hard-to-reach” targets undergoing percutaneous image-guided biopsy or drainage.

**Materials and Methods** All consecutive patients presenting between August and December 2016 with “hard-to-reach” (<10 mm from a critical nearby structure such as vessels, nerves, bowel or adjacent parenchymal organs) solid lesions requiring biopsy (group A) or abscesses requiring drainage for sepsis (group B) were prospectively included.

The individual features of each patient and lesion as well as technical and clinical data were collected and analysed.

**Results** Twenty-six patients (18 males, 8 females, mean age  $59.81 \pm 17.53$  years) were enrolled in group A and nine (6 males, 3 females, mean age  $58.33 \pm 13.8$  years) in group B. Technical success was achieved in 92.3% of cases from group A and 100% of cases from group B. Five (19.2%) minor complications were noted in group A (four small self-limiting pneumothoraces and one small self-limiting peri-pancreatic haematoma). There were no complications in group B. Histological results in group A accounted for 95% sensitivity, 100% specificity and 95.2% diagnostic accuracy. In group B, mean post-operative C-reactive protein was  $41 \pm 48.3$  mg/L in comparison with  $155 \pm 117.5$  mg/L at baseline ( $P = 0.004$ ).

**Conclusions** The SoftGuard blunt-tip needle is a safe and effective tool when applied as a coaxial working cannula for percutaneous biopsy or drainage of “hard-to-reach” targets.

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## Introduction

Percutaneous image-guided biopsy and drainage are routinely performed for diagnostic and therapeutic reasons [1]. However, such procedures are not without risk since needles used to reach the target may unintentionally injure nearby critical structures. In most cases, the classical coaxial technique performed with sharp needles is adequate to allow safe, multiple tissue sampling without the need for additional passes through overlying tissues. As such, there

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is a demonstrable reduction in complication rate and less reported patient discomfort [2]. However, for “hard-to-reach” lesions (e.g. lesions in close proximity to critical nontarget structures) the coaxial technique may not be adequate to grant safe access to the target. In order to limit such a drawback, several different technical advances have been adopted including specific imaging guidance techniques [2–6], nontarget lesion hydro-displacement [7] and curved- [8, 9] or blunt-tip [10] needles. In particular, the latter are provided with a rounded nontraumatic tip that, in case of tissue resistance exerted by a critical structure (e.g. arterial vessel), slips over the structure, thus avoiding iatrogenic injuries. The aim of this study was to present the performance of a new coaxial blunt-tip needle (SoftGuard<sup>®</sup>, AprioMed AB, Uppsala, Sweden) applied to approach “hard-to-reach” targets undergoing image-guided biopsy or drainage.

## Materials and Methods

The institutional review board approved this prospective single-arm, single-centre, observational study. Informed consent was obtained from all enrolled patients to undergo biopsy or drainage and to be included in the study.

### Study Population

Enrolment was conducted between August and December 2016 at a tertiary University Hospital. The study population was made up of patients presenting with: thoraco-abdominal solid lesions suspected to be malignant, thus needing biopsy sampling for definitive histological diagnosis (*group A*), and abdomino-pelvic collections needing drainage due to sepsis (*group B*). In both groups, patients were enrolled if the target lesion or collection was defined as “hard-to-reach” due to close proximity (<10 mm) to a critical nearby structure (i.e. vessels, nerves, bowel and parenchymal organs) or if the planned needle trajectory on scout imaging crossed or passed nearby (<10 mm) the critical structure.

### Procedures

Procedures were performed by six experienced (5–20 years) interventional radiologists and by three 3rd–5th-year residents in radiology under the supervision of a senior radiologist. In all cases, strict sterile conditions were applied. Local anaesthesia was used with the exception of the uncooperative patients. In all cases, anticoagulants were stopped 5 days prior and blood clotting parameters were tested 24 h prior to the procedure, ensuring minimum prothrombin time of 50% and platelet count of 50,000/

mm<sup>3</sup>, according to the Society of Interventional Radiology (SIR) guidelines [11].

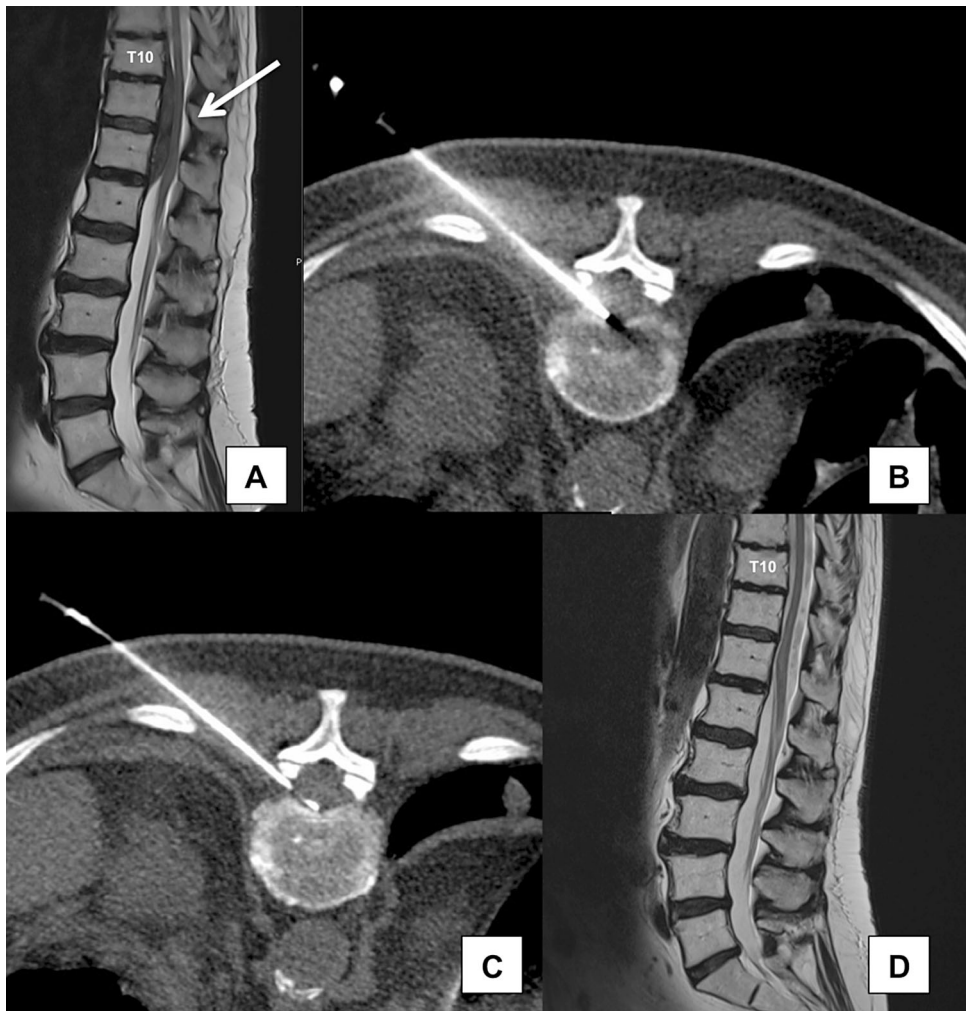
### Group A

All procedures were scheduled in the CT room, and patients were appropriately positioned (prone, supine or lateral) to provide the most convenient and shortest distance between the target lesion and the skin. CT guidance (Somatom Sensation 128, Siemens, Forchheim, Germany) was systematically used even though, according to operators’ choice, ultrasound guidance was also available and was used in combination with the CT scanning when required. Following CT scouting limited to the target area and needle pathway tracking, the needle entry point was marked on the skin using the CT gantry laser. After local anaesthesia, the SoftGuard needle was advanced along the planned trajectory under intermittent CT fluoroscopy. Needle advancement was always performed with the blunt stylet in place (Fig. 1). In particular, in case of tissue resistance, the blunt tip retracted into the needle and the sharp needle was exposed in order to pass through the resistance. At the same time, the pin at the stylet hub sprang back. If the resistance was exerted by a critical structure, the sharp needle was not advanced and the operator advanced the needle with the blunt tip in place by pressing the pin in the hub with the thumb (Fig. 2).

Once the target was reached, the stylet was removed and the SoftGuard served as a classical coaxial needle allowing biopsy needle passage. Following tissue sampling, the needle was retracted and a final CT scan was acquired to rule out complications. Patients were hospitalized overnight, and when required, specific instructions were followed according to the target lesion (e.g. patients undergoing lung biopsies received a chest X-ray 4–6 h following the procedure, and patients undergoing biopsy of a solid parenchymal organ had a blood test 3–6 h following the procedure to rule out haemorrhagic complications).

### Group B

Procedures were carried out in the CT room (Fig. 3) under combined CT and fluoroscopy guidance. In particular, CT guidance was used for SoftGuard pathway tracking and advancement towards the target as previously described for group A. Once the SoftGuard entered the target, the stylet was removed and a drainage tube was deployed over a stiff guide wire under fluoroscopic guidance. If needed, the drainage pathway was sequentially dilated before the final deployment. Fluid collection sampling was always obtained for laboratory tests. Following deployment, a final CT scan was obtained to verify the tube position and rule out complications. Patients from group B were always



**Fig. 1** Sagittal T2-weighted MRI (A) revealing a mass of the anterior epidural space (between T10 and T12, *white arrow*) in a 70-year-old male presenting with a history of completely remitted cutaneous lymphoma. The patient was proposed to undergo percutaneous CT-guided biopsy; however, concerns were raised due to the close proximity between the target lesion and the dural sac; and due to the trans-foraminal approach of the needle. Axial CT scan showing the SoftGuard needle reaching the target through a left trans-foraminal

approach (B); in particular, the blunt tip was kept in place while advancing the needle through the foramen in order to prevent iatrogenic injury to the nerve root and foraminal vessels. Once the SoftGuard was in contact with the target, the biopsy needle was deployed coaxially (C). The final pathological diagnosis concluded for “haematic material and absence of lymphomatous localization”. The benign nature of the lesion was confirmed by the 3-month MRI follow-up showing complete disappearance of the epidural mass (D)

hospitalized, and serial blood tests were obtained to follow-up the septic status. Targeted antibiotic therapy was always subsequently commenced based on the specific pathogen isolated from samplings obtained at the time of the procedure.

#### Data Collection and Analysis

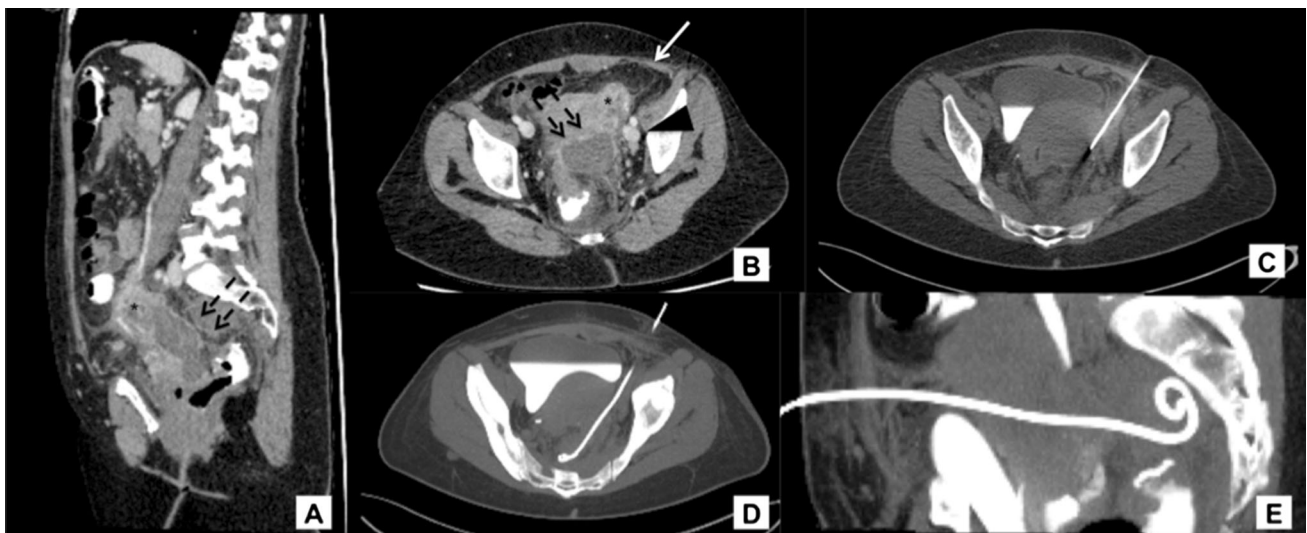
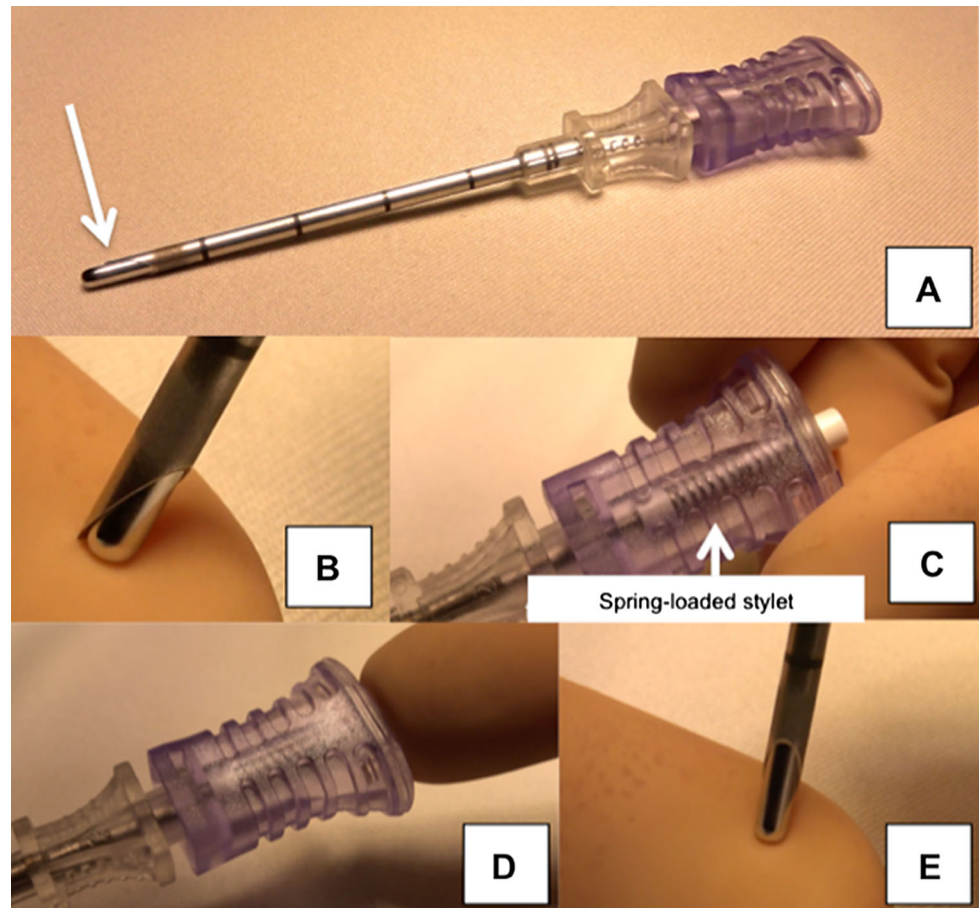
On an electronic database, the interventional radiologist performing the procedure reported the following data:

- Patient demographics (sex and age);
- Target lesion or collection size and location;

- Procedure-related variables (type of imaging guidance and anaesthesia; distance between skin entry point and target lesion; type of critical nontarget structures; minimal distance between SoftGuard and nearby critical structure; type of needles used; number of obtained biopsy samples; time needed to deploy the SoftGuard; total procedural time; technical success and complications);
- Data concerning clinical evolution: the final histological diagnosis for group A and C-reactive protein (CRP) trend in order to monitor septic evolution for group B.

Target size was evaluated by means of the maximum diameter displayed on CT multi-planar images. Lesion

**Fig. 2** Basic configuration of the SoftGuard needle: **A** This figure illustrates the coaxial needle with the blunt-tip stylet exposed; note that the blunt tip of the stylet protrudes beyond the sharp needle (*arrow*). **B** When the needle faces tissue resistance, the blunt tip retracts and the sharp tip is exposed in order to allow needle passage through the resistance. **C** The retraction of the blunt-tip stylet causes the white pin at the top of the hub to emerge due to the spring-loaded mechanism of the stylet (*arrow*). **D** If the resistance is exerted by a critical structure, the sharp-tip exposure can be prevented by pressing on the designated pin on the hub with the thumb. **E** This causes the nontraumatic blunt tip to protrude beyond the needle



**Fig. 3** Sagittal (A) and axial (B) contrast-enhanced CT scan revealing a post-surgical pelvic collection (*dotted arrows*) in a 46-year-old female affected by a deeply infiltrating endometriosis. Critical nearby structures were: left ovary (*black asterisk*), which was oedematous and enlarged due to contiguous spread of the inflammatory process, the left epigastric (*white arrow*) and external iliac vessels (*black*

*arrow head*). C A 17G- 12.1-cm SoftGuard needle was applied to reach the target with the blunt tip in place in order to avoid iatrogenic injuries. Maximum intensity projection axial (D) and sagittal (E) CT images demonstrating the drain appropriately positioned within the collection. No complications were noted at the end of this procedure

location was defined in relation to the target organ or anatomical site. Distances between the skin entry point and the target lesion and between the SoftGuard and the non-target nearby critical structure were measured on multi-planar CT images obtained during the procedure. Time needed to deploy the SoftGuard was recorded from the needle entering the skin to the needle reaching the target. Total procedural time was recorded from the preliminary CT scout performed to localize the target to the needle withdrawal.

The procedure was recorded as a technical success if:

- CT images obtained just before tissue sampling showed the needle tip within the target lesion (group A);
- CT images obtained at the end of the procedure showed the drain appropriately placed within the collection (group B).

Complications were classified according to the grading system of the Society of Interventional Radiology [11].

Regarding histology, a biopsy was defined as true positive (TP) when the histological examination revealed malignancy. A true negative (TN) was recorded when benignancy or no malignancy was found on histology, and there was no suspicion of malignancy at subsequent imaging follow-up or if the benignancy was proved on surgically acquired tissue sample. A false positive (FP) was recorded if histological examination revealed malignancy on percutaneous samples, but there was no evidence of malignancy after surgical removal. A false negative (FN) was recorded if histological examination concluded a benignancy, but there was evidence of malignancy on subsequent follow-up imaging or after surgical removal. Descriptive statistics were used to evaluate results. Sensitivity, specificity and accuracy were calculated for group A. Two-tailed *t* test was used to compare CRP levels before and after drainage in group B. Statistical analysis was performed using MATLAB<sup>®</sup>.

## Results

Twenty-six patients (18 males, 8 females, mean age  $59.81 \pm 17.53$  years, range 7–88) were enrolled in group A (Table 1) and nine (6 males, 3 females, mean age  $58.33 \pm 13.8$  years, range 35–75) in group B (Table 2).

Mean lesion size was  $35.62 \pm 18.58$  mm (range 9–80; 95% CI 28.11–43.12) in group A. Mean collection size was  $62.22 \pm 20.61$  mm (range 30–97; 95% CI 46.38–78.07) in group B.

Twenty-four biopsies (92.3%) were performed under sole CT guidance and two (7.7%) under combined CT and US guidance. All but two cases from group A were performed under local anaesthesia. The exceptions were one

paediatric patient and one lung biopsy performed during a lung ablation procedure under general anaesthesia. All cases from group B were performed under combined CT and fluoroscopy guidance and local anaesthesia.

Technical success was 92.3% in group A since two cases of technical failures unrelated to the SoftGuard needle were noted. In particular, in both these cases, the operator could not adequately deploy the biopsy needle inside the target lesion due to the small size ( $\leq 10$  mm) and the difficult anatomical location (i.e. adjacency between the target and a large pulmonary vessel in one case and lung posterior para-mediastinal lesion located in the highly moving costo-diaphragmatic recess in the other case) of the targets. Moreover, insufficient material was obtained in both cases. Technical success in group B was 100%. Technical data are summarized in Table 3.

Five (19.2%) minor complications were noted in group A, including four small self-limiting pneumothoraces and one small self-limiting peri-pancreatic haematoma. Patients from group B reported no complications.

A definitive histological outcome was available in 21/26 (80.7%) patients from group A. In 5/26 cases, no definitive histological outcome was obtained as two cases were technically unsuccessful and three cases with inconclusive histological diagnoses were lost to follow-up. In the whole, 19 TP, one TN and one FN results were obtained, accounting for 95% sensitivity, 100% specificity and 95.2% diagnostic accuracy. Mean post-operative CRP was  $41 \pm 48.3$  mg/L compared with  $155 \pm 117.5$  mg/L at baseline ( $P = 0.004$ , 95% CI 48.147–179.919). The mean time between pre- and post-CRP evaluation was 5.56 days (range 3–9).

## Discussion

Several different efforts have been done to increase the success rate of image-guided access to target lesions while performing percutaneous biopsy and drainage [2–10]. Most of these efforts regarded the technique of imaging guidance. Grasso et al. [4] reported about the utility of an optical CT-based navigation system to guide lung biopsies with a low-dose CT protocol. Abi-Jaoudeh et al. [12] compared cone-beam CT navigation to standard CT guidance while performing biopsies. They concluded that cone-beam CT navigation improved targeting accuracy and reduced the number of needle repositioning and the radiation dose, with comparable rates of histopathologic diagnosis. On the other hand, no many improvements have been reported regarding the type of needle applied to reach the target; in fact, the classical coaxial technique performed with sharp needles is still the most commonly performed approach. Although generally safe (e.g. complications such

**Table 1** Group A population

No. patients	Sex	Age	Target organ	Lesion maximum diameter	Critical nearby structures	Biopsy result	Follow-up
1	M	41	Pleura	26	V	Fib	Lost
2	M	72	Rib	40	V	Met	TP
3	M	41	Lung	44	V	Fib	Lost
4	M	57	Lung	10	V	Fib	No technical success
5	M	62	Mesentery	80	V PO B	Lym	TP
6	M	88	Lung	9	V	NC	No technical success
7	F	66	Pancreas	30	PO B	Ac	TP
8	F	62	Hip	25	N	PVNS	TP
9	M	64	Lung	12	V	Met	TP
10	F	75	Pancreas	27	V PO B	Ac	TP
11	M	72	Lung	29	V	Ac	TP
12	F	76	Pancreas	37	V B	Ac	TP
13	M	54	Pelvic LN	34	V B	Met	TP
14	M	52	Mediastinum	30	V	Car	TP
15	M	71	Liver	44	B	Met	TP
16	M	79	Mediastinum	65	V N	Car	TP
17	F	66	Lung	21	V	Fib	FN
18	F	65	Retro-peritoneal LN	25	V PO	Met	TP
19	M	70	Epidural space	18	V N	No malignancy	TP
20	F	67	Pancreas	44	V PO B	Car	TP
21	M	41	Mediastinum	55	V	No malignancy	TN
22	M	31	Lung	55	V	Lym	TP
23	M	40	Retro-peritoneal LN	47	B	Nec	Lost
24	M	70	Pancreas	73	V	Ac	TP
25	M	7	Costo-vertebral Space	26	V N	Neu	TP
26	F	66	Iliac mass	20	V N	Car	TP

*F* female, *M* male, *LN* lymph node, *V* vessels, *PO* parenchymal organs, *B* bowel, *N* nerves, *Fib* fibrosis, *Lym* lymphoma, *NC* noncontributive, *Met* metastasis, *Ac* adenocarcinoma, *PVNS* pigmented villonodular synovitis, *Car* carcinoma, *Nec* necrotic tissue, *Neu* neuroblastoma, *TP* true positive, *FN* false negative, *TN* true negative, *Lost* lost to follow-up

**Table 2** Group B population

Patient	Sex	Age	Collection location	Maximum diameter of collection	Critical nearby structures	Pre-procedure CRP	Post-procedure CRP	Number of days follow-up
1	F	54	Pelvis	70	V PO	69	17	4
2	M	35	Pelvis	50	V	176	25	6
3	M	55	Pleural	88	V	221	72	9
4	M	49	Pelvis	51	V	21	7	3
5	F	70	Morrison's pouch	97	V PO	36.9	17.1	7
6	M	75	Pelvis	50	V B	112.5	12	6
7	M	71	Mesentery	61	V B	342	159	3
8	M	70	Greater omentum	63	V B	99	21	7
9	F	46	Pelvis	30	V PO	318	39	5

*F* female, *M* male, *V* vessels, *PO* parenchymal organs, *B* bowel

as bleeding, bowel perforation or organ injury have been reported in up to 2% of cases undergoing abdominal biopsies and in up to 6% of cases undergoing drainage of

abdominal or pelvic fluid collections [1]), such method may be not suitable to approach "hard-to-reach" targets since substantial risks exist due to close proximity of a

**Table 3** Technical data from groups A and B

	Mean distance between skin entry point and target	Minimal distance between the SoftGuard and the nontarget critical structure	Mean time needed to deploy SoftGuard	Total procedural time	Applied devices	Number of tissue samplings	Technical success
Group A	75.88 ± 31.09 mm (Range 9–144) (95% CI 63.33–88.44)	4.27 ± 2.93 mm (Range 0–9) (95% CI 3.08–5.45)	11.04 ± 8.06 min (Range 3–40) (95% CI 7.78–14.29)	34.65 ± 9.88 min (Range 13–60) (95% CI 30.66–38.64)	SoftGuard: 15G–121.1 cm (2 cases) 17G–7.1 cm (7 cases) 17G–12.1 cm (14 cases) 17G–17.1 cm (3 cases) Biopsy needles: 18–20G 11–15–20 cm SoftGuard: 17G–7.1 cm (2 cases) 17G–12.1 cm (5 cases) 17G–17.1 cm (2 cases) Drainages: 7–16 Fr	2.35 ± 0.94 (Range 1–4) (95% CI 1.97–2.72)	92.3% (24/26)
Group B	65.5 ± 29 mm (Range 9–125) (95% CI 49.437–81.563)	4.89 ± 3.72 mm (Range 1–10) (95% CI 2.03–7.75)	6 ± 4.39 min (Range 1–15) (95% CI 2.63–9.37)	41.67 ± 16.39 min (Range 20–70) (95% CI 29.07–54.27)			100% (9/9)



**Fig. 4** Axial contrast-enhanced CT scan obtained at the arterial (A) and portal time (B) revealing a 25-mm tumour developing in a transplanted kidney in the right iliac fossa of a 62-year-old male. It was decided to treat this lesion with percutaneous CT-guided cryoablation. However, concerns were raised due to the close proximity of the target lesion to bowel loops (*white arrows*). Multi-

planar intra-procedural CT images show that the SoftGuard needle (C) was safely advanced in the fat plane between the kidney and bowel loops in order to inject 5% contrast-enhanced saline solution to obtain a safe margin between the hypo-dense ice ball and bowel loops (*double-headed arrows*, D and E)

critical nearby structure such as vessels, nerves, bowel and parenchymal organs.

The blunt-tip technique was firstly reported by Akins et al. [13] in order to overcome complications related to unintentional puncture of a nontarget organ. They published a series of 52 interventional procedures, including biopsy or drainage, in 46 consecutive patients with an overall 98% technical success rate and an acceptable complication rate (6/52, all minor). More recently, de Bazelaire et al. [10] applied the same technique to perform 30 difficult nodal biopsies due to inescapable interpositions of different structures including bowel loops and vessels. Their experience proved to be safe with only three reported minor self-limiting complications, including two pneumothoraces and

one haematoma. From a technical point of view, they applied a three-part needle set, including a 17G external cannula, an 18G sharp stylet and a second 18G stylet with a blunt tip. Procedures always started with the sharp-tip stylet in place in order to cross-thoracic, abdominal or pelvic wall, and then, following this step, the sharp-tip stylet was replaced by the blunt-tip stylet in order to safely advance the coaxial cannula towards the target. From this perspective, the SoftGuard needle seems more ergonomic as there is no need for the stylet exchange, and when the blunt tip is in place, the operator can easily select for sharp- or blunt-tip exchange by choosing whether or not to press the designated pin on the top of the hub (Fig. 2). Nevertheless, a separate sharp trocar stylet is also provided with the SoftGuard kit



mainly for skin entry. However, in the present series, the sharp trocar was never used since skin entry was always obtained through a small skin incision.

More recently, an interesting technique using curved needles has been reported. It is consistent with using a custom-made needle, which is curved by the operator in order to shape the distal tip so that it can reach the target lesions while avoiding the nearby critical structures [8]. Although promising, this technique remains challenging since advanced operator skills are required due to the “out-of-plane” advancement of the needle. Moreover, only limited cytological size samples can be obtained by this technique as according to the authors, only the smaller calibre needles (20–22G) can be shaped to a desirable curve. Therefore, when compared to the aforementioned technique, the coaxial SoftGuard technique seems more effective as there are no “out-of-plane” trajectories. Furthermore, with this technique, adequate tissue biopsy samples are obtainable by using the standard biopsy needles through the coaxial system rather than the smaller calibre needles. This will subsequently increase the likelihood of obtaining a definitive histological diagnosis as compared to limited cytological samples. This aspect has also been demonstrated by the high diagnostic rate reported in the current study (95% sensitivity, 100% specificity and 95.2% diagnostic accuracy).

In addition, since SoftGuard can function as a versatile coaxial cannula, it can be easily adopted for various interventional procedures such as drain insertions (Fig. 3) as well as other procedures such as hydro-displacement during percutaneous tumour ablation (Fig. 4).

Finally, compared to the hydro-displacement technique [7], the advantage of the SoftGuard is that no additional manoeuvres other than those strictly related to the classical coaxial technique are required to reach the target lesions. Moreover, hydro-displacement is somehow an unpredictable technique whose success mostly depends on the direction in which the saline or the CO<sub>2</sub> flows.

Limitations of the present study include the relatively small number of patients recruited as well as the lack of a comparative group undergoing the procedures using the conventional technique with sharp coaxial needles. However, due to the limited experience available with the blunt-tip technique and the absence of experience available with the SoftGuard coaxial needle, this study was more focused on the investigation of technical success as well as safety of this new device.

In conclusion, the blunt-tip SoftGuard coaxial needle is a safe and effective tool when applied as a coaxial working cannula for percutaneous biopsy or drainage of “hard-to-reach” targets. Further studies are needed to corroborate these promising results.

## Compliance with Ethical Standards

**Conflict of interest** Roberto Luigi Cazzato, Julien Garnon, Behnam Shaygi, Jean Caudrelier, Salem Bauones, Georgia Tsoumakidou, Guillaume Koch have no conflict of interest to disclose. Afshin Gangi is consultant for Apriomed AB (Uppsala, Sweden).

**Ethical Standards** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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