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ORIGINAL ARTICLE /*Research and new developments*

Preclinical evaluation of the atraumatic nature of a spring loaded blunt tip coaxial needle in a swine model

P.P. Rao[a,b,c,*], **E. Breton**[a], **J. Garnon**[a,b], **R.L. Cazzato**[a,b], **G. Koch**[b], **J. Caudrelier**[b], **G. Tsoumakidou**[b], **A. Gangi**[a,b]

[a] *ICube UMR7357, CNRS, université de Strasbourg, 67091 Strasbourg, France*
[b] *Department of Interventional Radiology, hôpitaux universitaires de Strasbourg, 1, place de l'Hôpital, 67091 Strasbourg, France*
[c] *Department of Radiology, hôpitaux civils de Colmar, 68000 Colmar, France*

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Coaxial needle;
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Percutaneous procedure;
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Abstract
Purpose: To test in vivo in an animal model the inherent atraumatic characteristics of the spring loaded blunt tip of a coaxial needle (Gangi-SoftGuard®, Apriomed, Sweden) against a conventional sharp stylet coaxial needle.
Material and Methods: The study was conducted on a 40 kg male swine that was its own control for a vascular trauma model. The procedure consisted of voluntary attempts to transfix and traverse the artery/aorta under continuous real-time angiogram. Test and control needles were positioned in the region of the intercostal, superior mesenteric and femoral/deep femoral arteries, and in the aorta. Computed tomography (CT) angiogram was performed post trauma to check for bleeding in the form of extravasation of contrast material. One attempt was performed per site and needle, except for the intercostal artery where a second attempt was done with the test needle, resulting in a total of 4 and 5 tests for the control and test needles, respectively.
Results: With the spring loaded blunt tip, no vascular trauma or bleeding was noted in the intercostal, superior mesenteric and femoral arteries, nor in the aorta. Vascular spasm that recovered with time was noted during the second attempt to transfix the same intercostal artery. There were consistent vascular traumas and bleedings with the control needle in all three tested arteries and the aorta, confirmed on angiogram as well as CT angiogram.
Conclusion: The atraumatic feature offered by the spring loaded blunt tip prevented vascular trauma during the 5 attempts made to transfix the artery/aorta in a swine.

* Corresponding author at: ICube UMR7357, CNRS, université de Strasbourg, 67091 Strasbourg, France.
E-mail address: pramodrao@mac.com (P.P. Rao).

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Percutaneous biopsies are frequently performed in oncology as a means of diagnostic prior to therapy. Percutaneous image-guided biopsies have become the standard of care in day-to-day practice [1,2]. Similarly, image-guided drainage procedures have become common practices to drain abscesses, and are fast replacing surgical open drainages as the standard of care. Both percutaneous biopsies and drainage procedures are associated with relatively low complication rates [3] However biopsies and drainages in complex locations close to blood vessels, nerves and bowels, increase the risk of iatrogenic trauma to these sensitive structures [4,5]. Such procedures require higher technical competence such as hydro-dissection or CO_2 dissection in order to protect these structures [6,7]. Bleeding due to trauma from access needle after biopsy or drainage procedures leads to considerable morbidity, sometimes needing further intervention, and exceptionally mortality [8,9]. Iatrogenic trauma increases morbidity, and causes lengthened hospitalizations, thereby spiraling healthcare costs.

Blunt tip needles have been clinically used to reduce the risk of iatrogenic trauma [5,10,11]. Recently, a coaxial needle with a spring loaded blunt stylet has been proposed to provide further protection (Gangi-SoftGuard®, Apriomed). The first clinical evaluation of this new coaxial needle found it to be safe and effective in a limited number of patients [4].

The purpose of this study was to test in vivo in an animal model the inherent atraumatic characteristic of the spring loaded blunt tip of a coaxial needle (Gangi-SoftGuard®, Apriomed) against a conventional sharp stylet coaxial needle.

Material and methods

Animal

The study was approved by the institutional animal care committee (APAFIS#2832-2015112316135869vl). The study was conducted in a single swine (weight 40 kg), which served the dual purpose of test and control, following the European guidelines for optimization of number of animals involved in preclinical studies. The animal was placed under general anesthesia, intubated, ventilated and monitored. Isoflurane and 97% oxygen were used as anesthetic. Ketamine was used for pain management, and when required, along with curare for muscle relaxation.

The procedure consisted of voluntary attempts to transfix and traverse the artery/aorta under continuous real-time angiogram. Computed tomography (CT) angiogram was systematically performed post trauma to check for bleeding in the form of extravasation of contrast material. The procedure was led using both test and control needles in the region of the intercostal, superior mesenteric (SMA), femoral/deep femoral arteries, and in the aorta.

Needles

The tested 17-G coaxial needle was a new spring loaded blunt tip coaxial needle (Gangi-SoftGuard®, Apriomed). The coaxial needle set consisted of a regular beveled tip cannula (Fig. 1) and sharp tip trocar stylet, to which was added a spring loaded lockable blunt tip stylet. When placed within the coaxial needle, the blunt tip extended beyond the beveled tip of the cannula at resting state. A pin mounted on the spring mechanism provided visual and tactile feedback of the blunt tip retraction, as this pin springs back simultaneously with the blunt tip. The spring loaded mechanism allowed using the blunt tip stylet in two ways: (*i*), the pin was maintained down with a finger; the blunt tip was locked (i.e., similar to a regular blunt tip coaxial needle) this allowed advancing the needle through soft tissue in an atraumatic manner in order to protect sensitive structure; (*ii*), the pin was let free; the spring loading enabled the blunt tip to progressively retract within the cannula, exposing the sharp tip of the cannula to help penetrate through facia or non-osseous other rigid structures. This gave the operator the flexibility of having a blunt non-traumatic tip to advance through tissue at the same time as access to sharp tip without interchanging the stylet (Video 1).

In this study, the pin was let released on the spring loaded blunt tip needle. Hence, it was the unique protective characteristics against iatrogenic trauma of the spring loading that was tested against regular sharp tip stylet. The control needle was a conventional 17-G coaxial needle with a diamond tip stylet that is most frequently used in our clinical practice (Bard TruGuide®, Bard Medical). This study relied on the hypothesis that results with the control needle were independent of the specific needle manufacturer.

Imaging systems

Pre- and post-procedure control imaging were obtained with CT examinations (Somatom® Definition AS, Siemens Healthineers) to check for bleeding in the form of extravasation of contrast and compare with baseline scans. Coaxial needles were positioned under ultrasound (ACUSON® S3000, Siemens Healthineers) and C-arm guidance (ARCADIS® Orbic, Siemens Healthineers).

Procedure

The animal was positioned in supine position. After prepping and draping using aseptic precautions, the common femoral artery was accessed under ultrasound guidance. A 4-Fr sheath (Avanti+®, Cordis, Cardinal Health) was placed into the artery. A 4-Fr catheter (Uni-select®, Cordis, Cardinal Health) was used along with a hydrophilic coated guidewire (Glidewire®, Terumo Medical Corp.) to selectively catheterize the intercostal artery. Intercostal arteriogram was performed to demonstrate the course and caliber of the artery.

The procedure was performed in a similar manner for all targeted arteries and both stylets. A small nick was first cut into the skin at the entry point, using a surgical blade (number 11). Then, the coaxial needle was advanced up to the artery, under ultrasound and angio-fluoroscopy guidance. Finally, an attempt was made to transfix and traverse the artery under real-time angiogram using non-ionic iodinated contrast material (Visipaque® 320 mg/mL, GE Healthcare). The real-time angiogram helped optimize the attempt to transfix the artery, and reveal in real-time the constraints exerted by the needle on the artery. After each needle withdrawal, CT angiogram examination was performed while injecting non-ionic iodinated contrast material through the

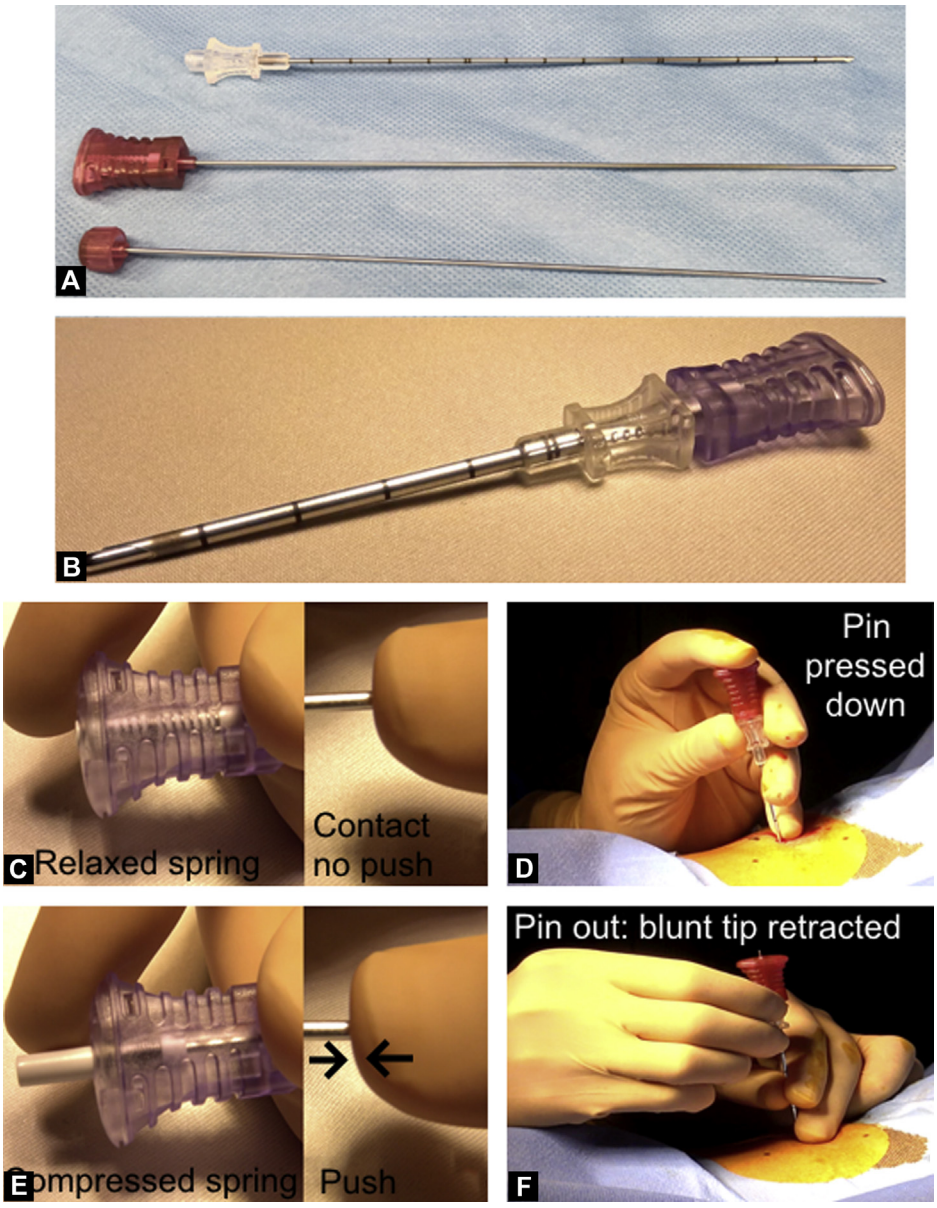

Figure 1. Figure show the commercially available coaxial needle biopsy used in this study at various stages of the procedure. (A). Commercially available coaxial needle set including the coaxial needle (top) along with the spring loaded blunt tip stylet (center) and the regular sharp diamond tip stylet (bottom). (B). The spring loaded blunt tip stylet is placed within the needle. The blunt tip extends beyond the beveled tip at resting state. (C). Spring loaded mechanism shown released. The blunt tip is in contact with a thumb, but no pressure is exerted (right), hence the spring mechanism is relaxed and the pin remains in (left). (D). The pin can be pressed with a finger in order to use the spring loaded blunt tip stylet as a regular blunt tip stylet (spring mechanism disabled). (E). Detailed view of the spring loaded blunt tip pressed against a thumb (right). Note the white pin extending at the top of the grip (left), indicating recoil of the spring loaded blunt tip. (F). When the pin is let free, its extension indicates the blunt tip retraction within the cannula, exposing its sharp tip.

catheter in order to evaluate the integrity of the artery, and reveal eventual bleed and hematoma. CT acquisition parameters were as follows: tube current, 172 mAs; tube voltage, 140 kVp; slice thickness, 1 mm; pitch, 0.6; reconstructed in plane resolution, 0.86 mm $\times$ 0.86 mm.

This procedure was first performed using the spring loaded blunt tip coaxial needle, then repeated with the conventional coaxial needle, at a different anatomical level. Needle order was not randomized in order to minimize the risk of hemorrhage induced animal demise before both needles were effectively tested.

This protocol was applied at two levels in the right intercostal space to access the arteries (one attempt with test needle at both levels, and one attempt with control needle at the first level), following which similar tests were performed on the SMA (main branch with test needle and first branch for control), the right femoral artery (test) and deep femoral artery (control), and aorta (one attempt per needle, two different levels). Each test was led at a different anatomical site, except for the attempt made with the control needle in the right intercostal space that was performed at the same site as the previous attempt led with the control

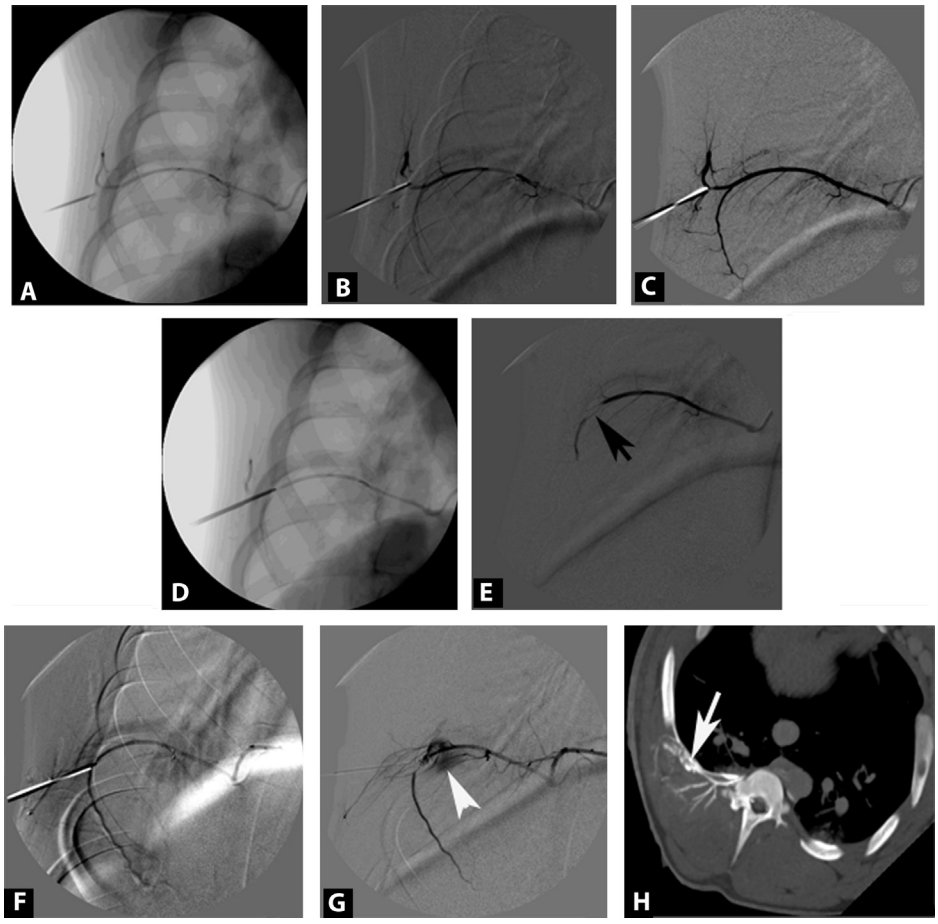

Figure 2. Attempts to transfix and traverse intercostal arteries. (A). Test needle adjacent to the intercostal artery on the angiogram. (B). Compression of the intercostal artery by the spring loaded blunt tip. (C). Post multiple attempts to transfix, the artery appears normal is course and caliber. (D). Second region targeted with the test needle. (E). Spasm seen in the intercostal artery (black arrow) post all efforts to transfix with test needle. (F). Control needle in contact with the intercostal artery. (G). Extravasation of contrast (arrowhead) secondary to trauma to the intercostal artery by conventional needle (real-time angiogram). (H). The bleed confirmed on CT angiogram with contrast spread in extravascular soft tissues (arrow).

needle, due to time constraints. Hence a total of nine real-time angiograms and nine CT angiograms were acquired, so that contrast leakage or absence thereof was specific of a given attempt.

Results

Intercostal arteries

With the spring loaded blunt tip stylet, there was atraumatic compression of the intercostal artery with no extravasation of contrast on angiography nor on CT angiogram (Video 2) for both attempts (Fig. 2). With the control needle the artery was transfixed and there was immediate extravasation of contrast on real-time angiogram (Video 3) and on CT angiogram thereafter, with contrast extravasation in the adjacent soft tissue. During the second attempt with the blunt tip test needle (one intercostal level above the previous tests), there was transient spasm of the artery noted after all efforts to transfix the artery (Video 4), however no rupture was seen neither during real-time angiogram nor CT angiogram directly following the test.

Superior mesenteric artery

With the test needle, the SMA was compressed to near occlusion, however it was not transfixed and no extravasation of contrast was noted nor during real-time angiogram (Video 5) nor on CT angiogram directly performed after the test. On post imaging, the artery was well preserved in course and caliber on CT angiogram as well as on the angiogram. With the conventional sharp tip needle, the SMA was transfixed with sudden extravasation of contrast on withdrawal of the needle on angiogram (Video 6). On CT angiogram, contrast was noted around the artery in the mesentery, suggestive of bleeding (Fig. 3).

Femoral artery

Using the spring loaded blunt tip needle, compression as well as mild displacement of the femoral artery was noted

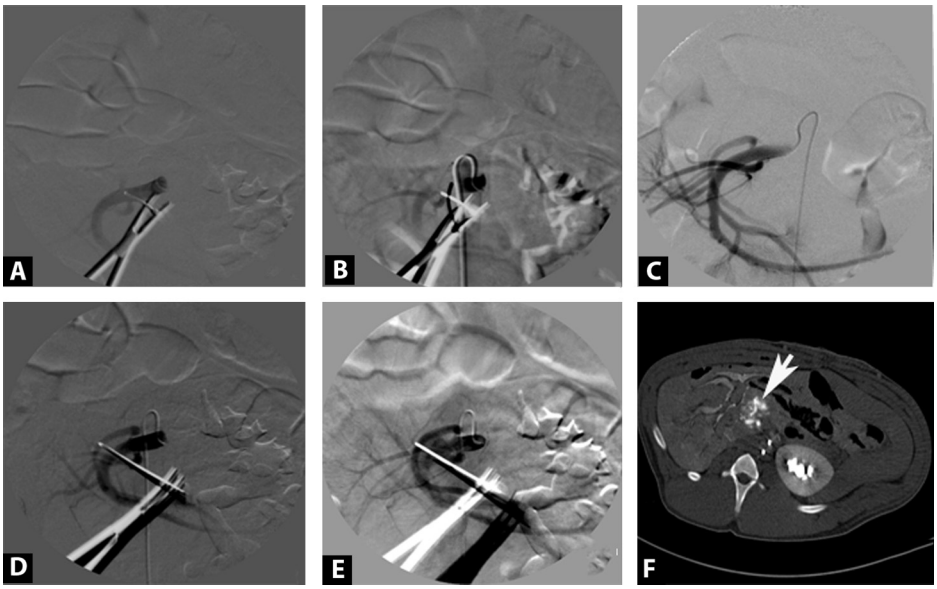

Figure 3. Attempts to transfix and traverse arteries in the region of the superior mesenteric artery (SMA). (A) Test needle adjacent to the SMA on the angiogram. (B). Test needle compressing the SMA, however the artery is not transfixed. (C). Artery appears normal on angiogram after the attempt with the test needle. (D) Control needle in contact with the artery on angiogram. (E). Extravasation of contrast secondary to trauma to the branch of SMA that was transfixed by the control needle. (F). CT angiogram confirms the bleed with contrast in the mesentery around the artery (arrow).

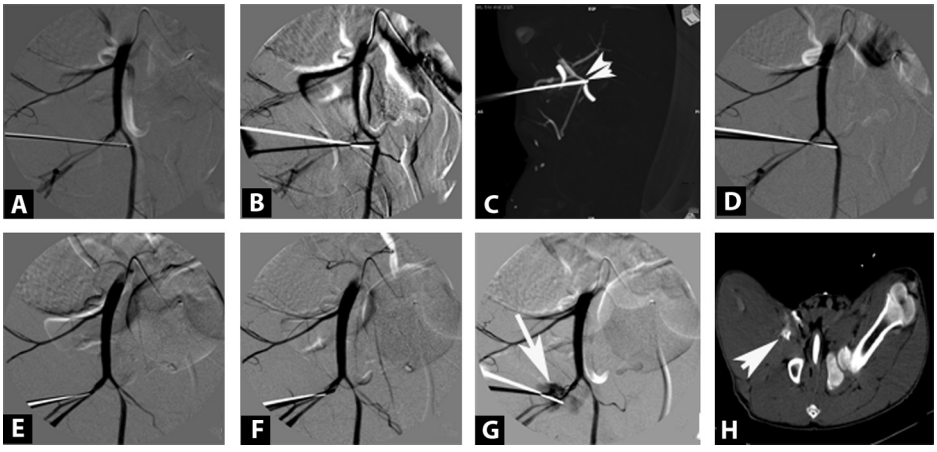

Figure 4. Attempts to transfix and traverse the femoral arteries. (A). Test needle adjacent to the femoral artery on the angiogram. (B). The test needle displaces and compresses the artery, however does not perforate it. (C). 3D reconstruction showing the atraumatic displacement and compression of the artery (double arrowhead). (D). Post attempt angiogram where the artery is intact. (E). Control needle in contact with the deep femoral artery on angiogram. (F). Control needle transfixing the deep femoral artery. (G). Extravasation of contrast (arrow) representing a bleed from the deep femoral artery after it was transfixed by the control needle. (H). CT angiogram confirming the bleed with contrast extravasation in the adjacent muscle (arrowhead).

(Video 7), however post imaging revealed the artery normal in its course and caliber, with no evidence of trauma on CT angiogram (Fig. 4). The conventional needle, as in the case of the arteries above, transfixed the deep femoral artery with bleeding in the real-time angiogram (Video 8) and extravasation of contrast noted into adjacent muscles on CT angiogram.

Aorta

With the test needle, near total compression of the aorta was observed, along slowdown of distal flow of contrast, and reflux of contrast in the proximal smaller arteries (Video 9, real-time angiogram). The conventional needle, as in the case of the above arteries, punctured into the aorta with

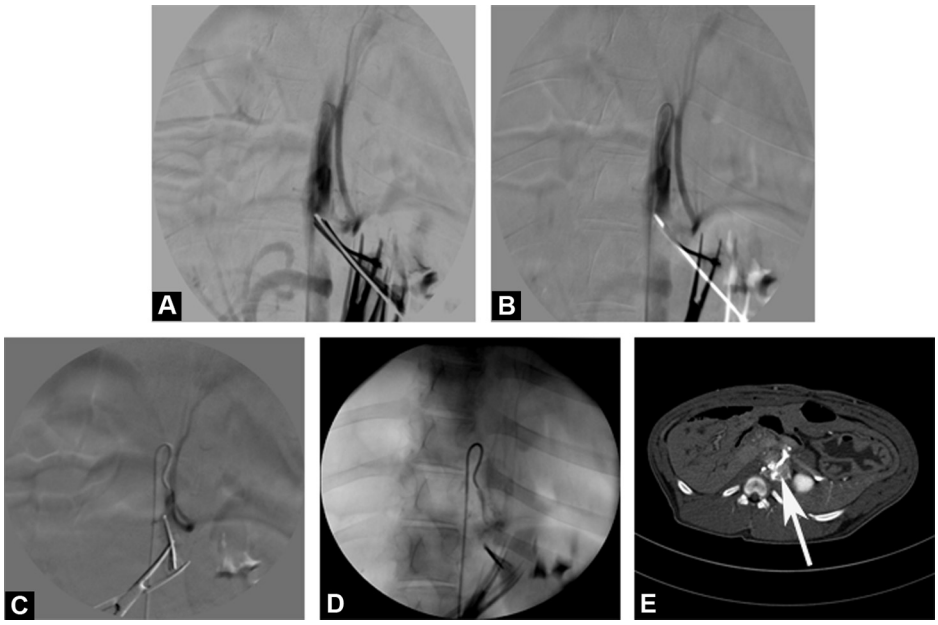

Figure 5. Attempts to transfix and traverse the aorta. (A). Test needle in contact with the abdominal aorta. (B). The test needle compresses the aorta with reflux of contrast into proximal branches. (C). Control needle transfixing the abdominal aorta. (D). Blush of contrast around the aorta after the withdrawal of the needle representing bleeding. (E). CT angiogram revealing contrast leak around the aorta (arrow) with evidence of trauma to aorta.

extravasation of contrast confirmed on real-time angiogram (Video 10) as well as CT angiogram (Fig. 5).

Discussion

With the ever-increasing number of percutaneous procedures, attempts have been continuously ongoing to reduce risk of procedure related complications. Akins et al. were the earliest to use blunt tip needles to reduce risk of iatrogenic trauma [10,11] in preclinical and clinical studies. In a retrospective study, de Bazelaire et al. found that the use of blunt tip needles reduces the risk of iatrogenic injuries to adjacent vascular structures or bowels, during complex biopsies under CT-guidance [5].

Recently, a prospective clinical study tested a new spring loaded blunt tip coaxial needle in procedures with complex access to the spine, abdomen and thorax. The use of the spring loaded blunt tip needle was found to be safe and effective, when targeting ''hard-to-reach'' lesions and abscesses (planned needle trajectory and/or target located less than 10 mm away from sensitive structures, such as vessels, nerves, bowel and parenchyma organs) [4]. However, further studies are required in order to confirm those results obtained in a limited number of patients. In this work, the same commercial spring loaded blunt tip coaxial needle was tested in an animal model. We have reproduced conditions typically leading to iatrogenic trauma in arteries located in three different anatomic compartments, and the aorta, with this spring loaded blunt tip needle and conventional diamond tip stylet. The inherent protective characteristic of the spring loaded blunt tip was tested, as the blunt tip was never manually locked.

Melloni et al. published a case report of an intercostal artery bleed post percutaneous lung fine needle aspiration biopsy [12]. Similarly, Vajtai et al. reported an iatrogenic intercostal artery pseudo-aneurysm presenting 6 days post liver biopsy [9]. In our swine model, with direct application of the spring loaded blunt tip needle on the intercostal artery, the only adverse event we could provoke was transient spasm of the vessel after multiple pushes, while with the control needle we actually caused an active bleed.

Several authors have reported trauma to inferior epigastric artery after percutaneous procedures [8,13,14]. In this animal study, we attempted to simulate trauma to an intraabdominal vessel, the SMA, and the aorta. Attempts with the spring loaded blunt stylet led to complete compression of the artery with no residual adverse effects; however with the conventional sharp stylet coaxial needle there was bleeding seen, as in the above cited case reports. Similarly, near total compression of the abdominal aorta was obtained with the test needle, with no trauma or residual effect noted.

To simulate vascular trauma in other regions of the body, we tested the femoral artery and the deep femoral artery, with the test and conventional needle, respectively. In this instance too, the spring loaded blunt stylet compressed and displaced the artery without causing any bleed, while there was bleeding and extravasation of contrast with the conventional sharp tip stylet.

Our study concurs with the past studies on the use of blunt tip needles being safe and leading to reduced risk of arterial bleeding [5,10,11]. The difference between the blunt tip needle tested in this work and those used in the above mentioned studies is that of the spring loading which makes it easier to use. The needle becomes versatile in the sense that one can choose to lock or not the spring loaded blunt tip, simply by pressing on the pin at the back of the stylet [4]. Hence, one can benefit from using the blunt tip isolated or in combination with the sharp bevel,

thanks to the spring loaded mechanism, to facilitate advancing through different anatomic planes (i. e., fascia, muscle, or fat).

Although not objectively measured, the operator (author PPR) noted that the spring loaded blunt tip needle was equally easy to use and advance through tissues as well as the conventional sharp stylet. It advanced through the subcutaneous space, fascia and the muscles with equal ease and feedback sensation. However a blinded comparison was not performed. Differences in terms of the insertion force required to penetrate tissues with a regular sharp diamond tip stylet compared to a regular blunt tip and the spring loaded blunt tip stylets may be quantitatively evaluated in the future [15].

The first limitation of this study is that it was performed on a single animal that was its own control, with limited comparative punctures. Although no iatrogenic trauma was found with the test needle (five attempts) while systematic bleeding was obtained with the control needle (four attempts), the number of attempts led in a single animal is not sufficient to perform any statistical analysis. Secondly, this was an intentional vascular trauma simulation model, which is obviously different from everyday clinical practice: the operator voluntarily tried to transfix and traverse the artery. Lastly, the operator could not be blinded to the used needle. Real-time angiograms of the attempts (Videos 2 to 10) are provided to prove that attempts were equally made for both needles, at different anatomical levels (no trauma can be attributed to previous test).

In conclusion, the atraumatic feature offered by the spring loaded blunt tip stylet appears effective in preventing vascular trauma: no bleeding was observed after each of the 5 voluntary attempts to transfix 3 arteries and the aorta with the spring loaded blunt stylet, while systemic bleed was obtained with regular sharp tip stylet. Clinical trial in a larger group of patients is required to confirm the actual clinical benefits of this type of coaxial needle.

Human and animal rights

The authors declare that the work described has been carried out in accordance with the EU Directive 2010/63/EU for animal experiments.

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Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

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Disclosure of interest

The cost of this preclinical study was supported by Apriomed (Uppsala, Sweden). The study was designed and executed by the authors, who had complete control of the data and information submitted for publication. One of the co-author (A. G.) holds a joint patent for designing the test needle; he was not involved in the experimental procedure.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.diii.2019.07.003.

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