



All-in-one intraoperative 3D imaging and navigation on percutaneous vertebroplasty. Preliminary results on the first 51 patients.

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Abstract

Vertebroplasty (VP) is the gold standard for vertebral compression fracture (VCF) treatment. VP could be improved by using intra operative cone beam computed tomography (CBCT) although duration is largely increased. We report first series of 51 patients whom underwent VP integrating intraoperative navigation to CBCT, in order to cut down time consumption. During a 8 month period, 51 patients were prospectively enrolled. The mean age was 71 years old (36-94). There were 17 male and 35 female. We stored 65 VP (14 thoracic and 51 lumbar). After percutaneous pins fixation to the spinous process of the “Butterfly” acquisition reference frame, 180° rotation of the C-arm CBCT (Surgivisio®, eCential, Grenoble France) generated a 3D volume. Optically localized, sterile self-calibrated trocar was navigated in order to reach the vertebral body center by an unilateral pedicular approach. Cement (Vertaplex HV®, Stryker) was injected under fluoroscopic lateral view by the same machine, using standard 2D X-ray modes. Considering the 38 patients who underwent 1 level VP, mean time procedure was 00:30:09 [00:21:00 to 00:54:00; SD 00:10:23]. The mean DAP was 5,41318 Gy.cm² and mean exposure duration 3,68 seconds. The mean efficient dose (E) was 1,32 mSv. In all cases cement placement was classified as excellent or mild, without any leakage. This new C-arm CBCT with integrated navigation is efficient to dramatically decrease operating time in comparison to literature (00:46:00 to 00:52:08). The reduction of radiation dose is already demonstrated in literature for navigated VP

1 Introduction

Vertebroplasty (VP) monitoring by intra operative fluoroscopy is nowadays the gold standard for vertebral compression fracture (VCF) treatment [1]. Procedure is safe, efficient and cost-effectiveness

[2]. Intra operative 3D imaging coupled to navigation becomes popular in spine surgery [3]. VP could be improved by using intra operative cone beam computed tomography (CBCT) although duration is largely increased 64.8 minutes [36–110] [4].

We report first series of 51 patients whom underwent VP integrating intraoperative navigation to CBCT, in order to cut down time consumption.

2 Methods

This is a prospective study of trauma patients with VCF at thoracic and lumbar levels. Patients were included at a single trauma center (Grenoble, France) during a 8 month period (from January to August 2018). The procedure featured general anesthesia on supine position. After percutaneous pins fixation to the spinous process of the “Butterfly” acquisition reference frame, 180° rotation of the C-arm CBCT flat panel (Surgivisio®, eCential, Grenoble France), produced 90 or 180 images and generate 3D volume of the spinal area of interest. The acquisition reference frame was then switched to the optical working reference frame. Optically localized, sterile self-calibrated trocar (figure 1) was used as the tool to navigate the trajectory in order to reach the vertebral body center by an unilateral pedicular approach. After check of the calibrating point, automatic axial and sagittal reconstruction views, display on large screen, allow safe, strictly intra osseous, convergent trajectory to the vertebral body (figure 2). Then the cement (Vertaplex HV®, Stryker) was injected, at 8' polymerization, under radiographical lateral view by the same machine, using standard 2D X-ray modes (figure 3). Then, a CBCT control of cement filling was done (figure 4).

We stored age, gender, spine level injection on each patient. Time, from pins insertion to the end of the cement injection, was stored in minutes (00:00:00 format). Characteristics of the irradiation were retrieved from the radiology information system providing the total dose area product (DAP) in Gy.cm². We noted also number of 90-images very low dose CBCT mode and the numbers of 180-images low dose CBCT mode. Duration of the full X-ray exposition was stored. The efficient dose (E) in mSv was calculated from the DAP by application of the conversion k coefficient of 0,26 for abdominal area and 0,19 for the thoracic area (Source: European commission, RADIATION PROTECTION N° 154, European Guidance on Estimating Population Doses from Medical X-Ray Procedures, http://ddmed.eu/_media/background_of_ddm1:rp154.pdf) Quality of the vertebral full filling was noted by poor, mild, excellent. We noted leakage existence (0-1), quality of the displayed images by sufficient or insufficient.



Figure 1 : Optically localized working reference frame and sterile self-calibrated trocar

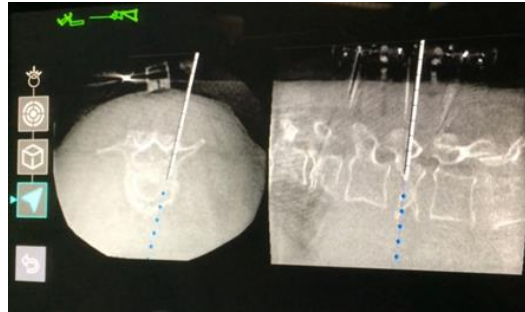


Figure 2 : Navigation of the trajectory on screen display in order to reach the vertebral body center by unilateral pedicular approach

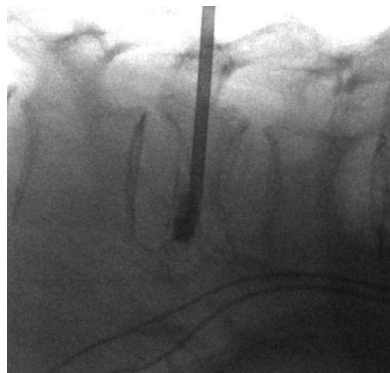


Figure 3 : Radiographical lateral view using standard 2D X-ray mode by the same C-arm machine

3 Results

During the so-called period, 51 patients were prospectively enrolled in the study. The mean age was 71 years old (36-94). There were 17 male and 34 female. We stored 65 VP (14 thoracic and 51 lumbar). We noted 38 patients with a single level VP, 12 patients with 2 levels VP and 1 patient with 3 levels VP.

Considering the 38 patients who underwent 1 level VP, mean time for full procedure was 00:30:09 [00:21:00 to 00:54:00; SD 00:10:23]. The mean DAP was 5,41318 Gy.cm² with mean exposure duration at 3,68 seconds. The CBCT volume was built 24 times with 90 images and 19 times with 180 images. Five patients had double CBCT (2 patients with 90 images, 2 with 180 images and 1 patient with one with 90 images and one with 180 images). The mean efficient dose (E) was 1,32 mSv for 1 level VP. In all cases cement was classified excellent in 25 cases and mild in 13 cases, located at the center of the body, without any leakage in the intervertebral space, foramina or the vertebral canal. Quality of the image was noticed sufficient to perform a secure trocar placement in all cases.

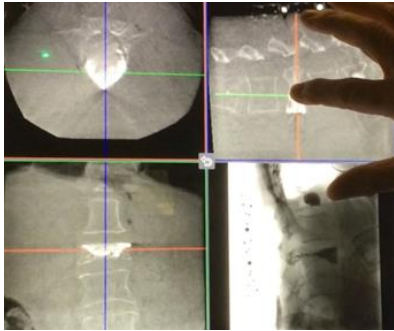


Figure 4 : intraoperative cone beam computed tomography (CBCT) control of cement filling

4 Discussion

In our experience this new C-arm CBCT with integrated navigation is efficient to dramatically decrease operating time. Tam et al. using Axiom Artis dTA VB31 (Siemens) found mean operating time 00:64:48 64 [range 36–110] [4]. Ruatti et al. using 3D intraoperative Arcadis Orbic system (Siemens) found a mean operative time by level 00:46:00 (± 25.13) [5]. Shin and Jeong using SIREMOBIL isoC3D (Siemens) found a mean operating time 00:52:08 [6]. Our 30 minutes time was consistent for all categories of surgeons in our academic hospital (resident, assistant and senior). It indicates that the step-by-step process, included in the system, helps to standardize the surgical technique.

The reduction of radiation dose is already demonstrated in literature for navigated vertebroplasty [7, 8]. Comparing the results is difficult without having full details on the series. However, our experience tends to show that improvement is still possible by using recent technologies.

We also noticed at the beginning of each procedure a high degree of confidence and predictability from the staff in the time. This brings calm and relax atmosphere in the OR.

The pin fixation of the reference frame is percutaneous. Stability is enhanced by fixation on 2 or 3 adjacent vertebrae spinous process. Using a conventional clamp for reference fixation would not be appropriate for vertebroplasty. In addition, using this special butterfly device, it is not necessary to stop patient breathing during 3D image acquisition, which is also an important element of the simplified process with this novel device.

5 Conclusion

Contrary to our previous experience with 3D imaging using CBCT and coupled with conventional navigation, this paper reports very positive feedback about using a novel CBCT imaging device, integrating navigation. For the studied vertebroplasty indication, an average surgical time of about 30 minutes was reported, which in our case, is less than our average time using conventional fluoroscopy.

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