

Interest of Intra-operative 3D Imaging In Spine Surgery. A Prospective Randomized Study.

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INTRODUCTION

In recent year internal fixation of the spine by using posterior approach with ORIF or percutaneous technique was increasingly used in trauma. Recent meta-analysis reported 10 to 31% of misplaced pedicle screws by using conventional surgical procedures [1, 2, 3]. We hypothesized that the ORIF and percutaneous procedures by using 3D intra-operative imaging for vertebral fractures allow short operative time with correct screw positioning and does not increase radiation exposure. We report a single-center, prospective and randomized study for pedicle screw insertion, by using a Computer Assisted Surgery (CAS) technique with three dimension (3D) intra-operative image intensifier versus conventional surgical procedure.

MATERIALS AND METHODS

143 patients (68 women and 75 men) were included in this study (March 2011 to July 2012). Randomization was done by using an independent website. 72 patients (42 men and 30 women; 56 y.o. on the average), underwent conventional surgery (C = conventional). 71 patients (40 men and 31 women; 63 y.o. on the average), were operated on with the help of a 3D intra-operative imaging system (N = navigated: 3D Orbic Arcadis - Siemens®, Saint-Denis, France and a navigation workstation Praxim® - La Tronche, France). 382 screws were implanted in group C and 174 in group N. Level repartition was comparable in both groups (Table 1). We measured the pedicle screw running-time, and surgeon's radiation exposure. All pedicle runs were assessed according to Heary's classification [4] by two independent radiologists on a post-operative CT-scan. Every judgment criterias were analysed with an univariate analysis, allowing to compare the two studied groups. Student t test was used to compare quantitative variables. In case of unchecked conditions, non parametric tests (Mann and Whitney) were used. According to conventions, the alpha risk was fixed to 5%, strength to 85%. For each patient, the study was closed at the seventh post-operative day.

143 PATIENTS	PATIENTS	ORIF	PERCUTANEOUS	SCREWS
C = CONVENT.	72	35	37	382
N = 3D FLUORO	71	25	34	174
Total	143			556

Table 1: 143 patients were included in this study, with two surgical techniques (ORIF and/or Percutaneous).

RESULTS

With conventional technique (C group), the misplaced pedicle screws rate reached 13%, in relation to the average range of literature. However in the N Group, 14% of insertions were extra-pedicle ones. 3D Fluoronavigation appeared less accurate with percutaneous procedures (24% of misplaced pedicle screws versus 5% in Group C) ($p=0,007$), but more accurate in opened surgeries (5% of misplaced pedicle screws versus 17% in Group C) ($p=0,025$). For one vertebra, the average surgical running time reached 8 minutes in group C versus 21 minutes in group N for percutaneous surgeries ($p = 3,42.10^{-9}$), 7,33 minutes in Group C versus 16,33 minutes in Group N ($p=2,88.10^{-7}$) for opened surgeries. The 3D navigation device delivered less radiation in percutaneous procedures (0.6 mSv versus 1,62 mSv in group C [$p = 2,45.10^{-9}$]). For opened surgeries, it was twice higher in group N with 0.21 mSv versus 0,1 mSv in group C ($p = 0.022$).

DISCUSSION/CONCLUSION

In this study, 3D-fluoroscopy navigation appears to be extremely accurate in opened procedures compared to conventional techniques but increase the instrumentation time, with a strongly higher radiation rate. With percutaneous procedures, the 3D-fluoroscopy navigation device appears less accurate, and increases instrumentation time. However, the radiation rate is significantly lower with 3D Fluoronavigation system. On a clinical point of view the advantages of the 3D fluoronavigation system are twofold: up-to date image data of patient anatomy and immediate availability to assess the anatomical position of the implanted screws [5, 6]. The advantages of dorsal percutaneous pedicle screw insertion for the patient are the chances of early mobilization and reduction of postoperative pain. With the development of new percutaneous instrument systems, short mono- segmental or bi-segmental instrumentations can be performed in addition to long percutaneous instrumentations. Therefore, our work hypotheses are partially confirmed according to the type of analyzed criteria.

REFERENCES

1. Kosmopoulos V, Schizas C. (2007) Pedicle screw placement accuracy: a meta-analysis. *Spine (Phila Pa 1976)* Feb 1;32(3):E111-20.
2. Tian NF, Xu HZ. (2009) Image-guided pedicle screw insertion accuracy: a meta-analysis. *Int Orthop.* Aug;33(4):895-903.
3. Mason A1, Paulsen R, Babuska JM, Rajpal S, Burneikiene S, Nelson EL, Villavicencio AT. (2014) The accuracy of pedicle screw placement using intraoperative image guidance systems. *J Neurosurg Spine.* Feb;20(2):196-203. doi: 10.3171/2013.11.SPINE13413. Epub 2013 Dec 20.
4. Heary RF, Bono CM, Black M. (2004) Thoracic pedicle screws: postoperative computerized tomography scanning assessment. *J Neurosurg.* Apr;100(4 Suppl Spine):325-31.
5. Tian NF, Huang QS, Zhou P, Zhou Y, Wu RK, Lou Y, Xu HZ. (2011) Pedicle screw insertion accuracy with different assisted methods: a systematic review and meta-analysis of comparative studies. *Eur Spine J.* Jun;20(6):846-59.
6. Gelalis ID, Paschos NK, Pakos EE, Politis AN, Arnaoutoglou CM, Karageorgos AC, Ploumis A, Xenakis TA (2012) Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques. *Eur Spine J.* Feb;21(2):247-55.

DISCLOSURE

The authors do not have any commercial, industrial or financial interest in spine surgery with or without navigation.