Significant reduction of fluoroscopy repetition with lumbar localization system in minimally invasive spine surgery

A prospective study

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Abstract

The conventional location methods for minimally invasive spinal surgery (MISS) were mainly based on repeated fluoroscopy in a trial-and-error manner preoperatively and intraoperatively. Localization system mainly consisted of preoperative applied radiopaque frame and intraoperative guiding device, which has the potential to minimize fluoroscopy repetition in MISS. The study aimed to evaluate the efficacy of a novel lumbar localization system in reducing radiation exposure to patients.

Included patients underwent minimally invasive transforaminal lumbar interbody fusion (MISTLIF) or percutaneous transforaminal endoscopic discectomy (PTED). Patients treated with novel localization system were regarded as Group A, and patients treated without novel localization system were regarded as Group B.

For PTED, the estimated effective dose was 0.41 ± 0.13 mSv in Group A and 0.57 ± 0.14 mSv in Group B (P < .001); the fluoroscopy exposure time of PTED was 22.18 ± 7.30 seconds in Group A and 30.53 ± 7.56 seconds in Group B (P < .001). The estimated cancer risk of radiation exposure was 22.68 ± 7.38 (10⁻⁶) in Group A and 31.20 ± 7.96 (10⁻⁶) in Group B (P < .001). For MISTLIF, the estimated effective dose was 0.46 ± 0.09 mSv in Group A and 0.58 ± 0.09 mSv in Group B (P < .001); The fluoroscopy exposure time was 25.41 ± 5.52 seconds in Group A and 32.82 ± 5.03 seconds in Group B (P < .001). The estimated cancer risk was 24.90 ± 5.15 (10⁻⁶) in Group A and 31.96 ± 5.04 (10⁻⁶) in Group B (P < .001). There were also significant differences in localization time and operation time between the 2 groups either for MISTLIF or PTED.

The lumbar localization system could be a potential protection strategy for minimizing radiation hazards.

Abbreviations: AP = anteroposterior, DAP = dose-area product, E = effective dose, ET = fluoroscopy exposure time, FTAP = anteroposterior fluoroscopy times, FL = lateral fluoroscopy times, ICRP = International Commission on Radiological Protection, L = lateral, MISS = minimally invasive spinal surgery, MISTLIF = minimally invasive transforaminal lumbar interbody fusion, MRI = magnetic resonance imaging, PTED = percutaneous transforaminal endoscopic discectomy, RC = radiation-induced cancers, RH = hereditary disorders, SD = standard deviation.

Keywords: minimally invasive spinal surgery, novel lumbar localization methods, percutaneous transforaminal endoscopic discectomy, radiation exposure, transforaminal lumbar interbody fusion

1. Introduction

Degenerative lumbar disease is a common spinal disease. Although a selected group of patients with degenerative lumbar disease can be managed with conservative treatment, many patients require surgical intervention to relieve pain, restore function, and improve quality of life. The efficacy of surgical treatment for degenerative lumbar disease has been confirmed by prospective randomized controlled trials. Recently, minimally invasive spine surgery (MISS) has been rapidly spread all over the world, among which minimally invasive transforaminal lumbar interbody fusion (MISTLIF) and percutaneous transforaminal endoscopic discectomy (PTED) are 2 of the most popular and representative techniques for degenerative lumbar disease.

MISTLIF has been confirmed by robust data with noninferior efficacy to open TLIF as well as merits of less intraoperative blood loss, lower infection rates, cost saving, and shorter hospital stay. Similarly, PTED was well validated by numerous studies with minimal tissue injury, local anesthesia, no neuromuscular retraction, rapid recovery, and short operation time.

However, MISS technique requires radiographic fluoroscopy to compensate the lack of open visualization, which is associated with great radiation concerns among medical staff and...
patients.\textsuperscript{[8]} It is well validated that MISS induced more radiation exposure than open procedures.\textsuperscript{[9]} Therefore, it is essential to minimize the iatrogenic radiation exposure to surgeons and patients during MISS. The implication of fluoroscopy for MISS is to induce an accurate preoperative localization of the spine and guiding the instruments and therapy. The conventional localization methods for MISS were mainly based on repeated fluoroscopy in a trial-and-error manner preoperatively and intraoperatively.\textsuperscript{[10]} The fluoroscopy repetition increases the radiation exposure to patients and operators with a higher risk of radiation-related hazards, even at low radiation doses.\textsuperscript{[11]} Therefore, a lumbar localization system consisted of practical preoperative radiopaque frame and intraoperative guiding devices were developed for MISS to modify the fluoroscopy methods and minimize fluoroscopy repetition.\textsuperscript{[3]} The primary goal of the study was to investigate the efficacy of the lumbar localization system in reducing radiation exposure and risks of radiation-induced disease in MISTLIF and PTED.

2. Methods

2.1. Participants

This prospective observational study was approved by the Ethical Committee of Shanghai Tenth People’s Hospital, and informed consent was obtained from all subjects. We confirmed that all methods were carried out in accordance with relevant guidelines and regulations. We identified patients who have persistent or recurrent low back pain or leg pain and a significant reduction of quality of life, despite conservative therapy, including physical therapy and pain management. The eligible patients were degenerative lumbar disease confirmed by imaging assessment [e.g., magnetic resonance imaging (MRI), computed tomography, X-ray radiography] with corresponding symptoms and signs. The inclusion criteria for PTED was symptomatic lumbar disc herniation with/without calcification or foraminal stenosis or lateral recess stenosis, and the inclusion criteria for MISTLIF was symptomatic lumbar stenosis or degenerative disc disease combined with segmental instability. The exclusion criteria of the current study were severe mental illness; severe obesity or osteoporosis; active infection, vertebral fractures, lumbar sacralization at L5/S1 level; combination of coronal and/or sagittal deformities that needed a surgical correction; and age less than 18 years. Patients receiving novel localization methods were regarded as Group A, and those with a conventional localization method were regarded as Group B. There were 3 spine surgeons involved in the study, and all of them conducted MISS in both groups.

2.2. Localization system

Localization system mainly consisted of preoperative applied radiopaque frame and intraoperative guiding device. The radiopaque frame is portable and can be used repeatedly without sterilization. It is made up of radiopaque material with a size of $9 \times 18$cm, which consists of 4 longitudinal crossbars and 19 horizontal crossbars with 1cm interval (Fig. 1A). For rapid recognition of surrounding anatomic features, sequential numbers of different patterns (circle, triangles, rectangular, etc) are made on horizontal crossbars. For PTED, preoperative applied radiopaque frame was used to plan the puncture trajectory on the skin. For MISTLIF, preoperative applied radiopaque frame can be used to identify the related vertebral arch of the surgical level.

For MISTLIF, the intraoperative guiding device is a plastic bullet-shaped screw-assisted tool with 7 tubes 12cm in length and 1.5cm in diameter (Fig. 1B). The tubes of the screw-assisted device are used for the insertion of K-wires, among which we can identify the most ideal one for percutaneous pedicle screw placement under fluoroscopy. The screw-assisted device reused several times after plasma sterilization. For PTED, the intraoperative guiding device is a puncture-guided instrument that is mainly based on isocentric theory keeping the puncture trajectory in tract (Fig. 1C). The arc can be rotated freely along the vertical axis and is equipped with a slider. There are 2 beam generators in the terminal vertex of the arc for localization. The rotation of the arch creates a sphere that can keep the puncture target always remain at the center of a virtual sphere.

2.3. Localization methods

2.3.1. Conventional localization methods. Patients in Group B underwent the conventional localization methods. For preoperative localization, we used surgical instruments (e.g., K wire or nucleus pulposus clamp) with repeated fluoroscopy to identify the surgical target in a trial-and-error manner (Fig. 2A). In PTED, the intraoperative fluoroscopy was repeated on the basis of a trial-and-error manner to conduct an ideal puncture and obtain an optimal placement of working channel (Fig. 2B). In MISTLIF, the intraoperative fluoroscopy was also repeated on the basis of a trial-and-error manner to achieve accurate placement of percutaneous pedicle screws (Fig. 2C). The abovementioned methods have been well documented in previous studies.\textsuperscript{[2,12–14]}

2.3.2. Novel localization methods. In Group A, the novel lumbar localization method for MISS was modified by adding localization. For preoperative localization, the radiopaque frame
was attached to the skin by adhesive tape (Fig. 3A). Generally, we might just need 1 fluoroscopy to identify all the anatomic features with the surrounding markers on the radiopaque frame (Fig. 3B). Then, we marked the anatomic details on the skin with the surrounding relationship of the radiopaque frame (Fig. 3C). Usually, we marked the upper and the inferior vertebral arches of the surgical level, as well as the midline and the edge of inferior vertebrae (Fig. 3D). A trajectory was planned for PTED (yellow arrow) and incisions lateral to the vertebral arches were made for MISTLIF (short blue line). The intraoperative modified fluoroscopy methods are demonstrated as follows.

For PTED, we conducted the anteroposterior (AP) fluoroscopy and lateral fluoroscopy with radiopaque frames attached to the back and the lateral skin (Fig. 4A). Then, we planned the ideal...
trajectory on the skin with the references of anatomic features (Fig. 4B). The entry point (green point) for puncture was the intersection of the posterior projection line and the lateral projection line of the planned trajectory to the puncture target (Fig. 4C). Thereafter, the puncture-guided instrument was positioned with the vertical beam onto the posterior projection of the puncture target and the lateral beam onto the lateral projection of the puncture target (Fig. 4D). At the moment, the puncture target remained at the center of a virtual circle. When the arch was rotated along the vertical axis, the puncture target still remained at the center of a virtual sphere (Fig. 4E). The puncture-guided instrument could also be applied for PTED in lateral position (Fig. 4F).

For MISTLIF, we inserted the screw-assisted tool with several Kirschner wires (Fig. 5A). Under fluoroscopy, we identified the most ideal Kirschner wire and selected it for percutaneous pedicle screw placement (Fig. 5B). Several Kirschner wires were placed; ideally, we selected a suboptimal one and used it for rotation (Fig. 5C). Then, we inserted several Kirschner wires again for fluoroscopy (Fig. 5D). The most appropriately placed Kirschner wire was identified and the others were removed (Fig. 5E). Then, we inserted the guide wire to replace the Kirschner wire and removed the screw-assisted tool (Fig. 5F). The following procedure of MISTLIF was as usual.

2.3.3. Observational outcomes. Basic information of the patients in the 2 groups including age, gender, surgical segment, and surgical technique were collected. The primary outcome was estimated effective dose (E) and radiation-induced risks, and the secondary outcomes were fluoroscopy exposure time (ET), fluoroscopy times, preoperative localization time, and operation time. Other clinical outcomes such as estimated blood loss, hospital stay, perioperative complications, and postoperative satisfaction (MacNab criteria: excellent, good, fair, poor) were also recorded.

In order to estimate effective dose and ionizing radiation induced risks, we adopted a well-validated estimation method primarily referenced in a systematic review.[15] In our study, the surgical site was L4/5 level and L5/S1 level, and the focus to image intensifier distance of the C-arm fluoroscope was 90 to 100cm. Thus, we could generally suppose the mean values for tube voltage, tube current, and source to skin dose to be the same.[15] Because the dose-area product (DAP) in the AP and lateral (L) position were not measured in the study, we might not directly calculate the skin entry dose and effective dose. However, we could use the fluoroscopy ET in minutes to estimate the corresponding DAP summarized in a previous regression study.[16] The DAP values (cGy × cm²) could be calculated using the following formula.

$$DAP_{AP} = 4.77 \times ET_{AP}$$
$$DAP_{L} = 6.19 \times ET_{L}$$

We might not directly obtain the ET_{AP} or ET_{L} from the C-arm fluoroscopy machine, but we recorded the AP fluoroscopy times (FT_{AP}) and lateral fluoroscopy times (FT_{L}). As we assumed linear relationship between fluoroscopy times and fluoroscopy ET, ET_{AP} and ET_{L} could be calculated with the following formula.

$$ET_{AP} = ET_{TOTAL} \times FT_{AP} / FT_{TOTAL}$$
$$ET_{L} = ET_{TOTAL} \times FT_{L} / FT_{TOTAL}$$
Thereafter, we calculated $E$ by weighting the radiation concentration stored in organs with constants that reflect the radiation type and the potential for radiation hazards to organs in a reference subject\cite{17,18}:

$$E_{\text{TOTAL}} = E_{\text{AP}} + E_{L} = \left( e_{\text{AP}} \times D_{\text{AP}} \right) + \left( e_{L} \times D_{\text{L}} \right)$$

As demonstrated in a prior validated study\cite{19}, the dose conversion coefficients ($e_{\text{AP}}$ and $e_{L}$) in the lumbar spine (L5) were 3.47 and 0.93, respectively.

According to the International Commission on Radiological Protection (ICRP) publication 103\cite{20}, the risk for radiation-induced cancers ($R_{C}$) and detrimental hereditary disorders ($R_{H}$) could be calculated by the following formulae:

$$R_{C} = 0.055 \times E \ (\text{Sv})$$

$$R_{H} = 0.002 \times E \ (\text{Sv})$$

2.3.4. Statistical analysis. Statistic software SPSS17.0 (SPSS, Inc., Chicago, IL) was used to conduct the statistical analysis of the study. Measurement data were demonstrated as mean ± standard deviation (SD). Mann–Whitney $U$ test was used to compare the difference of continuous variables between the 2 groups. Chi-square test was used to compare the difference of enumeration data of the 2 groups. Statistical differences were regarded as significant when the probability value was less than 0.05.

3. Results

A total of 249 eligible patients were included from July 2015 to May 2016 in our center (Table 1). There were no significant differences in gender, age, surgical levels, surgical technique, and surgeons ($P > .05$). All included patients successfully completed PTED (Fig. 6) or MISTLIF (Fig. 7) without transfer to open surgeries.

As demonstrated in Table 2, the fluoroscopy ET of PTED was $22.18 \pm 7.30$ seconds in Group A and $30.53 \pm 7.56$ seconds in Group B ($P < .001$). The estimated effective dose was $0.41 \pm 0.13$ mSv in Group A and $0.57 \pm 0.14$ mSv in Group B ($P < .001$). The estimated cancer risk was $22.68 \pm 7.38 \times 10^{-6}$ in Group A and $31.20 \pm 7.96 \times 10^{-6}$ in Group B ($P < .001$). The estimated risk for detrimental hereditary disorders was $0.82 \pm 0.27 \times 10^{-6}$ in Group A and $1.13 \pm 0.29 \times 10^{-6}$ in Group B ($P < .001$). However, there were no significant differences in hospital stay, patients’ satisfaction of MacNab criteria, and perioperative complications ($P > .05$).

As demonstrated in Table 3, the fluoroscopy ET of MISTLIF was $25.41 \pm 5.52$ seconds in Group A and $32.82 \pm 5.03$ seconds in Group B ($P < .001$). The estimated effective dose was $0.45 \pm 0.09$ mSv in Group A and $0.57 \pm 0.11$ mSv in Group B ($P < .001$). The estimated cancer risk was $22.68 \pm 7.38 \times 10^{-6}$ in Group A and $31.20 \pm 7.96 \times 10^{-6}$ in Group B ($P < .001$). The estimated risk for detrimental hereditary disorders was $0.82 \pm 0.27 \times 10^{-6}$ in Group A and $1.13 \pm 0.29 \times 10^{-6}$ in Group B ($P < .001$).
mSv in Group A and 0.58 ± 0.09 mSv in Group B (P < .001). The estimated cancer risk was 24.90 ± 5.15 (10^-6) in Group A and 31.96 ± 5.04 (10^-6) in Group B (P < .001). The estimated risk for detrimental hereditary disorders was 0.91 ± 0.19 (10^-6) in Group A and 1.16 ± 0.18 (10^-6) in Group B (P < .001). However, there were no significant differences in hospital stay, estimated blood loss, patients’ satisfaction of MacNab criteria, and perioperative complications (P > .05).

4. Discussions
Repeated fluoroscopic scanning is essential for MISS such as PTED and MISTLIF, which increased the radiation exposure to patients. Therefore, the tactics of minimizing radiation exposure is reducing the necessity of repeating fluoroscopic scanning. The novel lumbar localization was developed to reduce the necessity of repeated fluoroscopic scanning. Applying this technique, we achieved a significant reduction of fluoroscopy ET, and radiation dose, lower radiation-induce disease risks, shorter localization time, and operation time in PTED and MISTLIF. The novel localization system could be a potential protection strategy for minimizing ionizing radiation hazards.

Radiation exposure is a great concern, as it is associated with an increased risk of cancer and other disorders in fluoroscopically guided procedures. High-dose ionizing radiation could directly induce cancer, hereditary disease, cataract, cardiovascular disease, and so on, and even low-dose radiation is associated with them. Although MISS offers numerous advantages over open spine surgery in reducing blood loss, hospital stay, and perioperative complication rates, it is associated with a prolonged operation time and an increased ionizing radiation exposure. A recent systematic review found that patients who underwent MISTLIF were exposed to 2.4-fold more radiation than those who underwent open TLIF. Similarly, Bindal et al found that annual dose limits recommended by ICRP for surgeons would be potentially exceeded if a large volume of MISTLIF was conducted. They also quantified patient’s skin dose with 59.5 mGy in AP fluoroscopy and 78.8 mGy in lateral fluoroscopy. As for PTED, the data quantifying the radiation exposure dose to patients was scarce. Only 1 study found that the average radiation exposure dose to patients was 1.5 mSv at L4/5 level and 2.1 mSv at L5/S1 level. The only other study concerning radiation exposure for PTED focused on measuring the radiation dose to surgeons, and they found that only 291 PTED cases could be conducted annually to stay occupational dose limits without any protection. However, there were no studies to demonstrate the risk of radiation-induced cancer or hereditary disease in PTED. To the best of our knowledge, the present study is the first to estimate \( R_c (22.68 \pm 31.20 \times 10^{-6}) \) and \( R_h (0.82 \sim 1.13 \times 10^{-6}) \) of patients in PTED. We also estimated \( R_c (24.90 \sim 31.96 \times 10^{-6}) \) and \( R_h (0.91 \sim 1.16 \times 10^{-6}) \) of patients in MISTLIF, which were similar with a previous report. The estimated radiation-induced disease risks might be tolerable, but the stochastic effects of radiation exposure in MISS should not be disregarded.
However, people were endeavored to take all kinds of protection strategies for minimizing the radiation exposure. In brief, all kinds of radiation protection methods could be summarized into several strategies, including extending the distance, enhancing the shielding, and controlling the source of radiation. Extending the distance and enhancing the shielding are conventional strategies that surgeons adopted routinely in practice.[28] For patients, however, we have to focus on the strategy of source control, including improvement of the imaging guidance system and their frequency of use. More and more novel instruments such as O-arm fluoroscopy and MRI guidance systems were developed to obtain more accurate 3-dimensional reconstruction for navigation in MISS.[29,30] However, while O-arm fluoroscopy provided more facilities and less scatter radiation to surgeons, it also increased more iatrogenic radiation exposure to patients than conventional fluoroscopy.[31] MRI-guided technique did not gain widespread adoption because of the high cost of the technology.[32] A feasibility also introduced the ultrasound-tracked techniques for navigation, but this technique was still under development and further studies are required to improve and validate this technology.[33] On the contrary, robotic guidance systems were also found to facilitate reduction of radiation exposure of surgeons.[34] However, the robotic guidance system is very costly and space consuming, and it theoretically requires absolute immobilization. Moreover, the registration has inherent localization errors, and conventional surgical table will disturb the referencing process.[35] Instead, the novel and practical localization system is characterized by high

Table 2

| Variables                          | Group A (n = 89) | Group B (n = 88) | P      |
|------------------------------------|-----------------|-----------------|--------|
| Exposure time, s                   | 22.18 ± 7.30    | 30.53 ± 7.56    | <.001  |
| Fluoroscopy times                  | 24.98 ± 7.87    | 33.85 ± 8.04    | <.001  |
| Fluoroscopy times (AP)             | 12.49 ± 3.91    | 16.91 ± 4.16    | <.001  |
| Fluoroscopy times, L               | 12.48 ± 3.88    | 16.04 ± 4.17    | <.001  |
| Estimated DAP<sub>AP</sub>, cGy·cm<sup>2</sup> | 88.19 ± 28.87  | 121.25 ± 31.00  | <.001  |
| Estimated DAP<sub>L</sub>, cGy·cm<sup>2</sup> | 114.32 ± 37.06  | 157.66 ± 40.35  | <.001  |
| Estimated effective dose, mGy<sub>s</sub> | 0.41 ± 0.13  | 0.57 ± 0.14    | <.001  |
| Estimated cancer risk, 10<sup>–6</sup> | 22.68 ± 7.38  | 31.20 ± 7.96    | <.001  |
| Estimated risk for detrimental hereditary disorders, 10<sup>–6</sup> | 0.82 ± 0.27 | 1.13 ± 0.29 | <.001  |
| Location time, min                | 4.64 ± 1.04     | 5.95 ± 1.21     | <.001  |
| Operation time, min               | 69.40 ± 12.59   | 77.42 ± 14.00   | .001   |
| Hospital stay, d                  | 3.31 ± 1.18     | 3.24 ± 1.16     | .764   |
| MacNab criteria                   |                 |                 |        |
| Excellent                         | 48              | 51              |        |
| Good                              | 36              | 33              |        |
| Fair                              | 4               | 3               | .382   |
| Poor                              | 1               | 1               |        |
| Perioperative complications        |                 |                 | .155   |
| Superficial surgical site infection | 1             | 0               |        |
| Postoperative dysesthesia          | 1               | 2               |        |
| Asymptomatic residual disc         | 2               | 3               |        |

Figure 7. Typical case of minimally invasive transforaminal lumbar interbody fusion with localization methods. (A) Insertion of screw-assisted tools with several Kirschner wires; (B) We obtained 1 fluoroscopic image to identify the most appropriate Kirschner wire; (C) The screw-assisted tool was removed and the puncture needle was inserted; (D) Guide wires were inserted; (E) Final anteroposterior fluoroscopic scan of minimally invasive transforaminal lumbar interbody fusion; (F) Final lateral fluoroscopic scan of minimally invasive transforaminal lumbar interbody fusion.
compatibility with conventional fluoroscopy methods. The core tactic was to reduce the fluoroscopy repetition, resulting in lower radiation exposure in both patients and surgeons. Nearly 30% reductions were observed in fluoroscopy ET, estimated effective dose to patients, RC and RH for PTED in the study. Similarly, over 20% reductions were observed in fluoroscopy ET, estimated effective dose, RC and RH for MISTLIF with novel localization system. In addition, the localization time and operation time with the novel localization system were also significantly lower than those with the conventional fluoroscopy, either for PTED or MISTLIF.

Several limitations should be noted when interpreting our data. First of all, several assumptions were made to estimate the effective dose and disease risk of radiation exposure. We admit that there are many other affecting factors such as fluoroscopy setting and body habitus, but estimation calculations of effective dose have been widely used in many other robust studies including one published in New England Journal of Medicine.\[15,16,17,31,36–38\] Regardless, clinical trials are still needed to quantify the actual radiation dose to patients. In addition, we could not apply double-blinded procedures in our study. Last but not least, we did not estimate the effective dose or potential risks to medical staff because of complex situations. This was another major concern. However, we are currently conducting a study to measure the radiation dose to sensitive organs of surgeons.

5. Conclusions
The whole tactics of the novel localization system reduced the necessity of repeated fluoroscopic scanning. We achieved a 20% to 30% reduction in ET to ionizing radiation, estimated effective dose to patients, and RC and RH for MIST. The radiation protection tactic of reducing fluoroscopy repetition was feasible and practical. This novel localization method could be a potential protection strategy for minimizing the radiation hazards.

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