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A novel technique for C1-C2 posterior screw insertion using patient-specific guides created by CT-based 3D printing

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ABSTRACT

C1-C2 fixation has been developed for the rigid fusion of atlantoaxial instability. C1 lateral mass screw (C1 LMS)-C2 pedicle screw fixation is used more frequently due to its rigid fixation and high bone fusion rate. However, C1 screw placement is relatively unsafe even with recently developed image-based navigation systems. Patient-specific screw guide templates (PSGT) were developed to improve the accuracy and safety of C1 screw placement. Herein, we investigated the outcomes of the C1-C2 posterior fixation technique using PSGT. This was a retrospective study of six patients who underwent posterior cervical spinal fusion using the PSGT between January 2022 and April 2023. Operative time, estimated blood loss, intraoperative radiation dose, surgical cost, and screw placement accuracy were evaluated and compared with those achieved with preoperative CT-based navigation (navigation group, n = 15). Screw accuracy was assessed using Neo's classification. PSGT showed good results, although the differences were not statistically significant (operation time: 104.3 ± 9.7 min vs 116.4 ± 20.8 min; estimated blood loss: 56.7 ± 72.4 mL vs 123.2 ± 162.3 mL; and radiation dose: 1.8 ± 1.2 mSv vs 2.6 ± 0.8 mSv, respectively). PSGT was particularly better in terms of the accuracy of C1 LMS (PSGT: 100%, navigation: 83.3%). The deviation at the entry point was minimal, and the difference between the sagittal and transversal angles from the preoperative plan was small. We investigated the clinical efficacy of using the PSGT for C1-C2 posterior fixation. PSGT improved the accuracy of C1 LMS insertion.

Keywords: C1-C2 fixation, patient-specific screw guide templates, navigation, C1 lateral mass screw, screw accuracy

Abbreviations:
PSGT: patient-specific screw guide templates
LMS: lateral mass screw
CT: computed tomography

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INTRODUCTION

C1-C2 fixation is performed for rigid fusion of atlantoaxial instability. In recent years, C1 lateral mass screw (C1 LMS)-C2 pedicle screw fixation has been used more frequently as it achieves rigid fixation with a high bone fusion rate.[1] C1 LMSs were first reported by Goel and Laheri,[2] and later by Harms and Melcher[3] in 2001. To avoid venous sinus injury around the C1–C2 complex, Resnick and Benzel[4] and Tan et al[5] described a revised technique for C1 screw insertion in 2002 and 2003, respectively. While this method reduces the risk of venous sinus injury, the structure of the posterior arch is extremely thin for screw insertion, which presents a challenge to the surgeon. Furthermore, there is still a risk of injury to the vertebral artery on the cephalic side of the posterior arch of the C1. Therefore, C1 LMS insertion is still a technically advanced procedure that requires both high accuracy and safety.

The development of C-arm or O-arm navigation-assisted spine surgery has helped improve the accuracy of screw insertion. However, screw misplacement may occur despite the use of these navigation systems.[6-8] In particular, the unique anatomy of the C1 often makes it difficult to place references, which is essential for navigation systems.[9,10] Thus, the accuracy of C1 screw placement is relatively low even with the use of navigation systems.[7] C1 LMS is applied for diseases with C1-C2 instability, but the navigation is prone to misalignment because C2 is set as the reference. Patient-specific screw guide templates (PSGT) are an innovative method that was developed to overcome this challenge. In addition to greater accuracy and safety, PSGT was shown to reduce operation time and radiation exposure.[1,2,11,12] In contrast to navigation, PSGT has a template in C1 itself, which we believe might be useful.

Recent years have witnessed further development of PSGT and these are now commercially available and are increasingly used. Fujita et al have reported a new patient-specific template guide for cervical pedicle screw (C3-7), which was designed based on information gathered from three-dimensional computed tomography (3DCT) scans and shaped to fit the lamina and lateral mass.[13] In their study, 98.7% screws were completely inside the pedicle (C3-7).[13] However, the considerations for C1 LMS insertion with PSGT are distinctly different from those at other cervical levels due to the unique anatomical morphology of C1. First, because of the lack of spinous process and apparent anatomic landmarks for C1, it is questionable whether PSGT can fit to C1 securely enough to ensure the same degree of accuracy as other cervical vertebrae. Second, due to the looping of the vertebral artery in close proximity to C1, it has a 3D relation with C1. This may affect the PSGT application or increase the risk of vertebral artery injury. Thus, determining the accuracy of PSGT for C1 screw placement is a key imperative. In this study, we investigated the efficacy of the C1-C2 posterior fixation technique using PSGT.

MATERIALS AND METHODS

Patients

Six patients (four men and two women; age range, 8–80 years) who underwent posterior cervical spinal fusion surgery using the PSGT performed by two spine surgeons between January 2022 and April 2023 were included in the present study. After approval by our Ethics Committee, written informed consent was obtained from each patient after detailed oral explanations regarding the present study. Three patients were diagnosed with atlantoaxial dislocation, two patients had pseudotumor, and one patient had atlantoaxial rotatory fixation (Table 1). To compare some of the outcomes achieved with the conventional methods, patients who underwent posterior cervical spinal fusion using the preoperative CT-based navigation system (Stealth station S8, Medtronic

Table 1 Patient background and surgical parameters of the 6 cases

	Age (years)	Sex	Diagnosis	BMI (kg/m^2)	Op time (min)	EBL (mL)	Radiation dose (mSv)	Surgical cost (yen)
Case 1	74	M	AAS	22.8	99	25	1.4	1,128,010
Case 2	8	F	AARF	16.5	93	2	2.0	962,460
Case 3*	71	F	AAS	24.6	119	155	1.0	3,039,910
Case 4*	80	M	Pseudotumor	23.7	105	144	1.6	3,149,790
Case 5	60	M	AAS	22.6	98	8	0.9	1,309,420
Case 6	81	M	Pseudotumor	24.0	112	6	4.1	1,249,240

AAS: atlantoaxial subluxation
AARF: atlantoaxial rotatory fixation
BMI: body mass index
M: male
F: female
EBL: estimated blood loss
* Cases in which procedures other than C1-2 fixation were performed simultaneously.

Sofamor Danek, Memphis, TN, USA) between June 2015 and June 2022 were also included. Since this was a retrospective study, obtaining renewed consent for this study from these surgical cases was exempted.

Imaging and guide construction for PSGT

The preparation of the system is described elsewhere.[13] A 3D model of each vertebra was reconstructed based on the preoperative CT images with a slice thickness of 1.0 mm using MySpine (MySpine web planner, Medacta International, Switzerland).

Then, a surgical plan for screw placement, including screw diameter, length, and direction in transverse and sagittal angles, was determined by the surgeon using the MySpine web planner (Figure 1). After the surgeon had agreed on the surgical plan, bone data were transferred to 3D modeling software. The patient-specific guide and 3D bone models were made with polyamide for medical use by a 3D printing system (Figure 2).

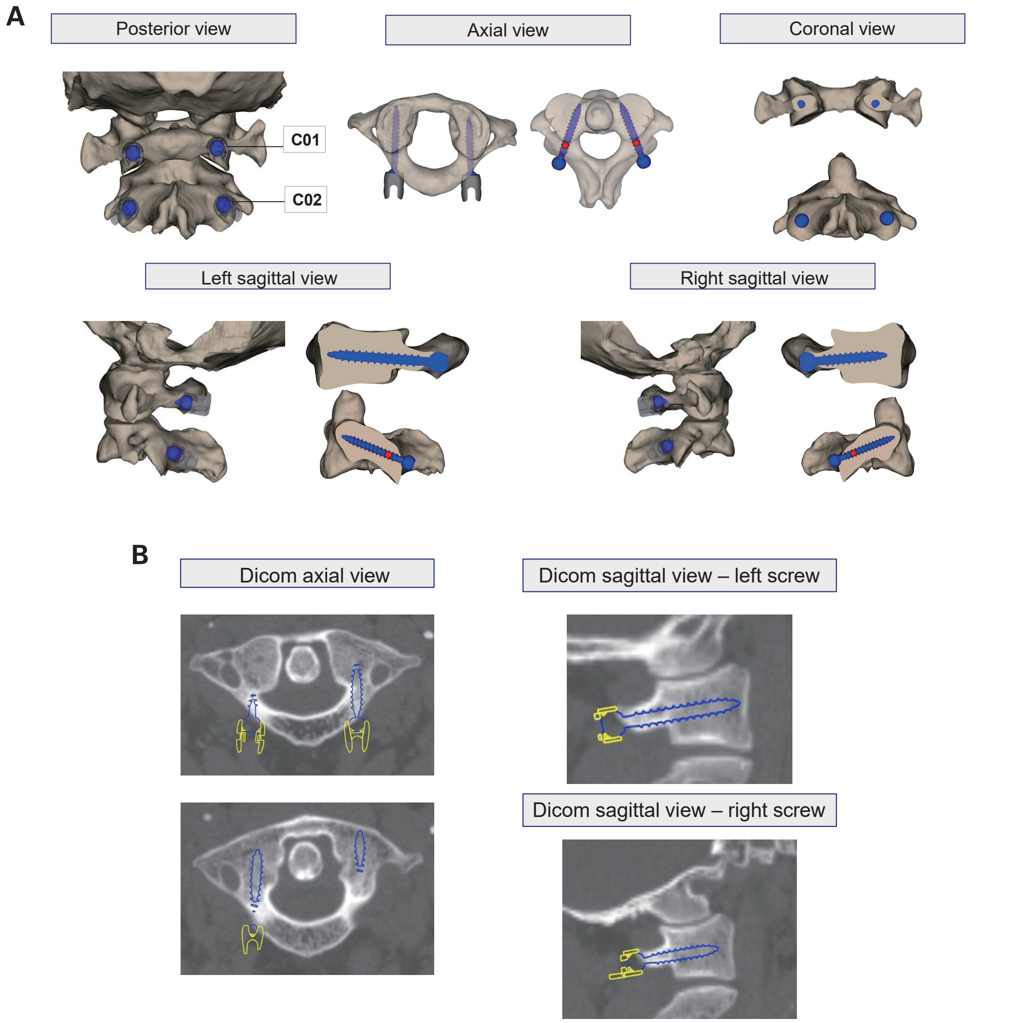

Fig. 1 Preoperative planning for pedicle screw placement using the MySpine Cervical system at C1, C2
Fig. 1A: Three-dimensional image view.
Fig. 1B: Dicom preoperative planning.

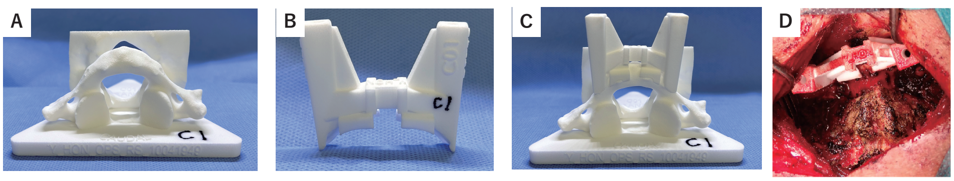

Fig. 2 Patient-specific template guide and three-dimensional (3D) model of the C1 vertebrae
Fig. 2A: 3D model of the cervical vertebra.
Fig. 2B: Patient-specific guide template.
Fig. 2C: Confirmation of fitting between patient-specific screw guide templates and 3D bone model.
Fig. 2D: Intraoperative photograph.

Surgical technique for PSGT

The patient was placed in the prone position with a Mayfield frame under general anesthesia. A midline incision was performed to expose the posterior arch of C1 and the lamina of C2 from the spinous process to near the facet of C2-3. The soft tissue attached to the bone was removed as much as possible to increase the accuracy of the guide. The surgeon pushed the guide firmly to the posterior bony surface to secure stable positioning. Screw insertion was carried out with a step-wise procedure: shaving the cortical surface with a steel bar to avoid skiving by a drill, drilling the hole down to 12 mm depth through PSGT, probing the screw holes to the planned screw length through PSGT, guiding rod placement, tapping and screw insertion through guide rod while checking the lateral image with C-arm fluoroscopy.

Outcome measures

Operative time, estimated blood loss (EBL), intraoperative radiation dose, surgical cost, and screw placement accuracy were evaluated. Because two of the PSGT cases simultaneously underwent laminoplasty using a plate system at other levels, the operative time and surgical cost were evaluated after excluding the two cases. The accuracy of placement of the C2 pedicle screw was assessed using Neo's classification[14]: grade 0, no deviation, the screw is contained in the pedicle; grade 1, deviation < 2 mm (ie, less than half of the screw diameter); grade 2, deviation > 2 mm and < 4 mm; grade 3, deviation > 4 mm (ie, complete deviation). Additionally, C1 LMS deviations were evaluated using modified Neo's classification in the narrow region transitioning from the rear bow to the lateral mass (Figure 3). In addition, 3D images workstation software (Solidworks Software, Dassault Systemes Company, Velizy-Villacoublay) was used to investigate the deviation between the planned screw position and the actual screw angle based on the preoperative and postoperative vertebral reconstruction images. The deviation of the screw positions was evaluated at the narrowest point of the pedicle (pedicle isthmus) and on the entry point on axial and sagittal views, respectively (Table 2, Figure 4).

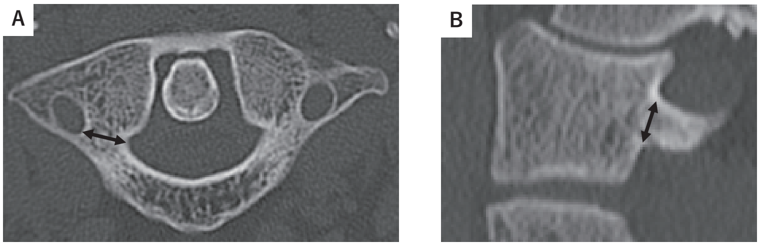

Fig. 3 Narrowest C1 portion for modified Neo classification
Fig. 3A: Axial image.
Fig. 3B: Sagittal image.

Table 2 Mean deviation between planned and actual screw positions

	Total mean
ΔVertical deviation at entry point, mm	0.61 ± 0.10
ΔHorizontal deviation at entry point, mm	0.69 ± 0.26
ΔSagittal angle, °	3.32 ± 1.79
ΔTransversal angle, °	3.44 ± 0.94

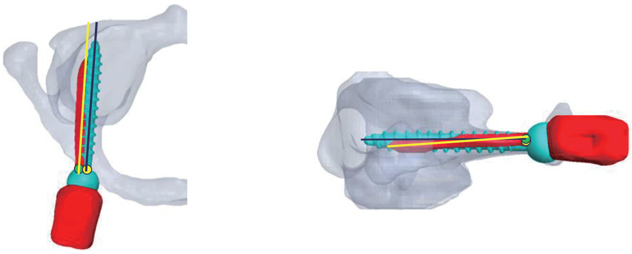

Fig. 4 Evaluation of screw position
Blue screw: intended screw insertion site; red screw: actual screw insertion site.
Screw positions were entry points of the pedicle (green and yellow).
The distance and angle from both points were defined as deviation.

Statistical analyses

Categorical variables are presented as frequency (percentage) while continuous variables are presented as mean ± standard deviation. Fisher's exact test was used to analyze categorical variables and Mann–Whitney *U* test was used for continuous variables. All statistical tests were conducted using EZR software version 1.40 (Jichi Medical School, Tochigi, Japan[15]); *P* values < 0.05 were considered indicative of statistical significance.

RESULTS

The mean operation time was 100.5 ± 8.1 min, the mean EBL was 56.7 ± 72.4 mL, and the mean radiation dose was 1.8 ± 1.2 mSv (Table 1). On comparing the results of PSGT with those of preoperative CT-based navigation, PSGT showed better results overall, especially in the accuracy of C1LMS, although the differences were not statistically significant (Table 3). All C1 LMS were

Table 3 Comparison between patients in the PSGT and preoperative CT-based navigation groups

	PSGT N = 6	Navigation N = 15	*P* value
Age, years	62.3 ± 27.7	67.5 ± 18.7	0.63
BMI, kg/m^2	22.4 ± 3.0	22.6 ± 2.3	0.88
Operation time, min*	100.5 ± 8.1	116.4 ± 20.8	0.16
EBL, mL	56.7 ± 72.4	123.2 ± 162.3	0.35
Radiation dose, mSv	1.8 ± 1.2	2.6 ± 0.8	0.12
Surgical cost, yen*	1,162,282 ± 153,095	1,062,351 ± 427,922	0.66
Screw placement accuracy			
C1	100%	83.3%	0.30
C2	91.7%	93.1%	1.0

BMI: body mass index
CT: computed tomography
EBL: estimated blood loss
PSGT: patient-specific screw guide template
* Cases in the PSGT group in which procedures other than C1-2 fixation were performed simultaneously (cases 3 and 4 in Table 1) were excluded.

Table 4 Screw placement accuracy using PSGT

Level	Grade 0	Grade 1	Grade 2	Grade 3	Accuracy
C1	12	0	0	0	12/12 (100%)
C2	11	1	0	0	11/12 (91.7%)
Total	23	1	0	0	23/24 (95.8%)

PSGT: patient-specific screw guide template

inserted without deviation. One C2 pedicle screw showed grade 1 lateral deviation (Table 4). The deviation at the entry point was minimal, and the difference between the sagittal and transversal angles from the preoperative plan was small (Table 2). None of the patients experienced any neurovascular complications associated with the screws and showed symptomatic improvement after surgery.

Case presentation

A 74-year-old man presented with loss of hand dexterity and gait disturbance. X-ray and magnetic resonance imaging (MRI) showed spinal cord compression due to atlantoaxial dislocation (Figure 5). The patient was diagnosed as having myelopathy at the C1-2 level. Posterior fixation (C1-C2) was performed using PSGT (Figure 2). The operative time was 99 minutes, and the EBL was 25 mL. Postoperative CT demonstrated correct screw positions and the patient was discharged on postoperative day 13 without any complications (Figure 6).

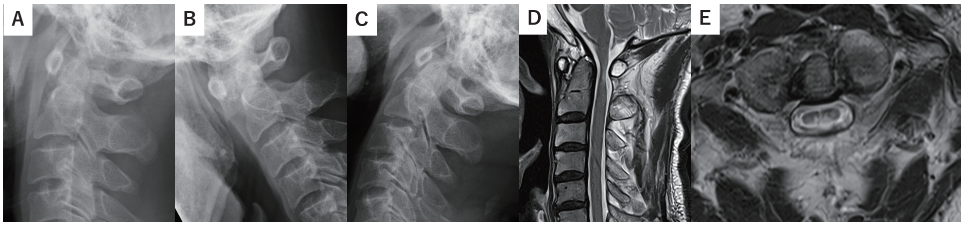

Fig. 5 Preoperative X-ray and magnetic resonance imaging (MRI) of a 74-year-old man with atlantoaxial dislocation

Fig. 5A: Intermediate position.
Fig. 5B: Anteflexion.
Fig. 5C: Retroflection.
Fig. 5D: MRI T2 sagittal image.
Fig. 5E: MRI T2 axial image.

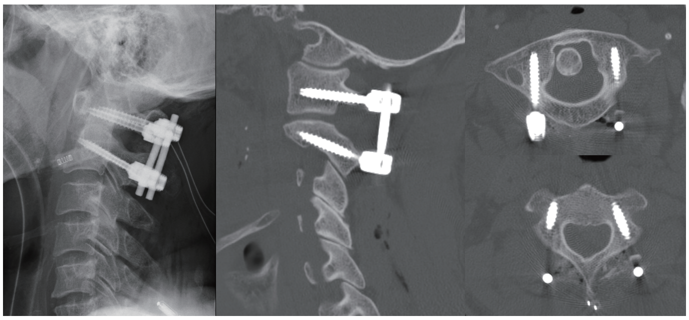

Fig. 6 Postoperative X-ray and computed tomography

DISCUSSION

In this study, we observed high accuracy of C1-2 fixation with PSGT, especially in C1. The vertical and horizontal deviation at the entry point between the preoperative planning and the actual surgery was very small. Surgical parameters were also favorable, and none of the patients developed any complications. The strength of PSGT is its ability to achieve high accuracy without additional equipment such as navigation systems. PSGT can be used at any facility once training is received, whereas the conventional approach requires a specialized setting.

C1-LMS and C2-pedicle screws can provide rigid fixation and reconstruct segmental instability; however, cervical screw placement can cause catastrophic surgical complications such as vertebral artery injury. There are several published reports of neurovascular injuries due to pedicle screw insertion; the reported incidence of vertebral artery injury during screw placement under C-arm fluoroscopic guidance is 0.3%.[16-18] Since vertebral artery injury can lead to delayed cerebral infarction, it is critical to improve the accuracy of screw placement. Deviations have also been reported with the use of preoperative or intraoperative CT-based navigation (Iso-C and O-arm).[7,19] This is because these navigation systems require a reference, but the unique anatomical configuration of the C1 vertebra makes it difficult to place a reference.[9,10,20,21] In addition, patients requiring fusion surgery usually have C1-C2 instability, making it very challenging to accurately navigate the C1 screw even when C2 is set as the reference. As for other methods, Berry et al first described the concept of personalized image-based 3D templates, and several navigation template systems have been reported in recent years.[22] In the present study, there was no deviation of the C1 LMS with PSGT, which is a notable result of this study. Once the PSGT fixes to a target bone, it is linked to that bone and serves as a reference in the navigation system. Therefore, PSGTs allow screw placement in C1 as accurately as in other vertebrae. PSGT adheres closely to the bone surface profile and is accurately placed even when the posterior arch is narrow. Therefore, it is not necessary to select PSGT depending on the case. In our series, there was no complication related to the C2 pedicle screw; however, deviation occurred in only one case. Since this particular patient was a child with a very small pedicle diameter, it was necessary to adjust the angle in preoperative planning and create a larger surgical field. Thus, PSGT is a useful approach for C1 LMS placement.

Operative time was relatively short in the PSGT group. The reported mean operative time with O-arm is 161.7 minutes,[23] and with C-arm fluoroscopy is 109 minutes.[24] In the study by Harel et al,[25] the mean operative time was 27 minutes longer in the image-assisted O-arm navigation group compared to the fluoroscopy guidance group ($p = 0.03$). Zhou X et al[7] reported comparable operative times for both (O-arm: 172 minutes; C-arm: 170 minutes, $p = 0.70$). PSGT does not require navigation settings and the guide is easily matched to the vertebral arch, which may help reduce the operative time. There is no objective measure for the range of incision and dissection, but we realize that it is probably comparable to navigation.

For spine surgeons, minimizing the intraoperative radiation exposure is a key concern. In a study, the average dose of surgical radiation received by patients during C1-2 fixation with O-arm was 1.83 mSv.[23] In this study, the PSGT group had a relatively low radiation dose. (PSGT: 1.8 ± 1.2 mSv; navigation: 2.6 ± 0.8 mSv). Moreover, there was little deviation at the entry point from the preoperative screwing plan in this study. Therefore, it was sufficient to check mainly the lateral view of the C-arm fluoroscopy during surgery, which may have led to a lower radiation dose.

Furthermore, the mean surgical cost in the PSGT group was not significantly different from that in the navigation group, although it was slightly higher in the PSGT group. PSGT has a disadvantage in terms of running costs because of the cost of transportation in every case.

However, it should be noted that the initial installation cost of an expensive intraoperative imaging navigation system is extremely large. From this perspective, PSGT seems to be more cost-effective as the transportation costs are comparatively low, and its running cost is not large.

Some limitations of this study should be acknowledged. The follow-up period in this study was relatively short. Therefore, long-term postoperative complications and successful fusion were not investigated. Additionally, because our facility does not have an intraoperative navigation system, it was not possible to compare PSGT with an intraoperative navigation system. Furthermore, since the two surgeons are experienced in the procedure, it is assumed that there will be no major changes in the results of this study. However, even in PSGT, the results may change depending on the learning curve. In addition, the creation of a PSGT currently takes approximately two weeks. Therefore, this approach is not suitable for use in traumatic injuries such as odontoid fractures. Finally, this was a preliminary study involving a relatively small sample size. However, the PSGT is an innovative surgical assist device with new clinical potential that is well worth reporting preliminary results.

CONCLUSION

In this study, we investigated the clinical efficacy of using the PSGT for C1-C2 posterior fixation. This method had high insertion accuracy for the C1 LMS. This study demonstrated the feasibility of applying PSGT to C1 LMS-C2 pedicle screw.

DISCLOSURE STATEMENT

Conflicts of interest

The authors declare that there are no relevant conflicts of interest.

Ethical approval

The study was approved by the Institutional Review Board of Anjo Kosei Hospital (IRB approval No.R22-009).

Informed consent

Informed consent specific to the current study was waived because all clinical and radiological interventions are routine assessments and also because of the retrospective study design.

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