

Fluoroscopic-Guided Paramedian Approach for Lumbar Catheter Placement in Cerebrospinal Fluid Shunting: Assessment of Safety and Accuracy

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An oral presentation of the results of this study was presented at Hydrocephalus 2017, the Ninth Annual Meeting of the International Society for Hydrocephalus and Cerebrospinal Fluid Disorders, on September 24, 2017, in Kobe, Japan.

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Received, January 12, 2018.

Accepted, June 21, 2018.

Published Online, July 13, 2018.

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BACKGROUND: Spinal catheter insertion in lumboperitoneal (LP) shunt surgery for idiopathic normal pressure hydrocephalus (iNPH) is frequently associated with technical difficulties especially in patients with obesity and elderly patients with vertebral deformities.

OBJECTIVE: To elucidate the accuracy and safety of image-guided spinal catheter placement using a paramedian approach (PMA).

METHODS: We retrospectively analyzed 39 consecutive iNPH patients treated by LP shunting with spinal catheter insertion via the PMA. The success rate of catheter placement and the number of changes in puncture location were evaluated. Accuracy of catheter insertion was assessed by measuring both vertical and horizontal deviations in the point of catheter dural penetration from the center of the interlaminar space.

RESULTS: The success rate of catheter placement was 100% (39/39). The difficulty rate for catheter insertion, measured by the number of changes in puncture location, was 2.6% (1/39). No bloody punctures or surgical infections were observed. Accuracy of catheter insertion, measured as the degree of deviation, was 0.5 ± 1.9 mm horizontally and 0.0 ± 2.4 mm vertically. The rates of minor complications, including caudal catheter insertion, transient low-pressure headache, and root pain, were 5.1% (2/39), 10.4% (4/39), and 0% (0/43), respectively. Subdural hematoma requiring surgical intervention occurred in 1 case (2.6%). During the mean follow-up period of 36 mo, spinal catheter rupture at the level of the spinous processes was not observed.

CONCLUSION: Fluoroscopic-guided spinal catheter placement via the PMA was safe, accurate, and reliable, even for use in geriatric and obese patients.

KEY WORDS Idiopathic normal pressure hydrocephalus, Lumboperitoneal shunt, Spinal catheter, Image-guided surgery, CSF shunting, Lumbar spondylosis

Operative Neurosurgery 16:471–477, 2019

DOI: 10.1093/ons/opy176

Results from recent prospective studies (SINPHONI-2) have indicated equivalent effectiveness of lumboperitoneal (LP) shunting compared to ventriculoperitoneal (VP) shunting for the treatment of idiopathic normal pressure hydrocephalus (iNPH).^{1,2} Based on these results, and after careful informed

consent regarding the risks and benefits of LP and VP shunting, typically almost all patients and accompanying family members in Japan tend to prefer LP shunting over VP shunting because of the lesser degree of direct procedural-related brain damage. Furthermore, theoretically, LP shunting may be better suited for elderly iNPH patients who frequently are poor candidates for intracranial procedures. However, in practice, LP shunt surgery is associated with unique problems, such as difficulties in lumbar catheter insertion and delayed catheter rupture or severing at the level of spinous processes, especially in patients with excess subcutaneous fat and those with an aging vertebra.¹

ABBREVIATIONS: AP, anterior-posterior; BMI, body mass index; CSF, cerebrospinal fluid; CT, computed tomography; iNPH, idiopathic normal pressure hydrocephalus; LP, lumboperitoneal; MRI, magnetic resonance imaging; PA, posterior-anterior; PMA, paramedian approach; QRT, quick reference table; VP, ventriculoperitoneal

Epidemiologically, the majority of iNPH patients are 70 to 80 yrs of age.^{1,3,4} Coincidentally, this age group tends to exhibit a high incidence of asymptomatic degenerative lumbar spondylosis, especially at the L4 to L5 levels. In addition, hypertrophy of the spinous processes and arches, with associated narrowing of the interspinous spaces and interlaminar spaces, are common age-related deformities.⁵⁻⁸ Therefore, various combinations of these age-dependent lumbar deformities can be responsible for difficulties in insertion of spinal catheters as well as delayed catheter damage. Delayed catheter rupture is potentially due to a pinching mechanism where the catheter passes between the spinous processes or from luminal narrowing because of surrounding degenerated hypertrophic tissue. Moreover, accurate catheter placement is difficult in obese patients, where excessive subcutaneous fat can mask the deep bony anatomical landmarks and can also extend the distance from the skin to the cerebrospinal fluid (CSF) space.

One solution to avoid catheter needle puncture misplacement and accompanying complications, such as multiple punctures and neurovascular injury typically encountered with the standard midline puncture method, is the paramedian approach (PMA). The PMA has many advantages over the midline approach. In particular, the PMA offers a relatively wider access route than the interspinous route which is typically narrower especially in the elderly.^{9,10} Furthermore, most previous reports on LP shunting have employed a blind maneuver for catheter insertion via either the paramedian and or the median approach.¹ However recently, Qureshi et al¹⁰ reported the effectiveness of the image-guided PMA for insertion of spinal catheters for various CSF drainage indications. The image-guided PMA has also been recommended for implantation of spinal catheters in intrathecal baclofen therapy.¹¹⁻¹³ From a safety standpoint, procedures using image-guided visualization, especially access to the spinal canal, are now considered the standard of clinical care and training,¹⁴ compared to blind maneuvers which are associated with a greater risk of complications. However, to date there have been no reports describing the safety and accuracy of image-guided PMA in shunting for iNPH.

In this paper, we introduce the fluoroscopic image-guided PMA for spinal catheter insertion, and retrospectively investigate the safety and accuracy of this technique in 39 consecutive iNPH cases treated with LP shunting.

METHODS

Patients

Thirty-nine consecutive patients (22 men and 17 women, mean age: 77 ± 6.3 yrs) underwent LP shunt operations using the fluoroscope-guided PMA between December 2013 and November 2015 at the authors' institution. All patients met the diagnostic criteria of the guidelines for management of idiopathic normal pressure hydrocephalus. Exclusion criteria for LP shunt surgery included the presence of severe spinal subarachnoid space blockade, detected using whole spine magnetic resonance imaging (MRI), or severe lumbar deformity extending from L1

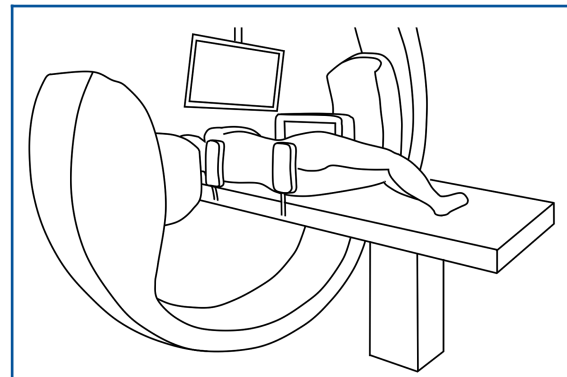


FIGURE 1. Schematic operative setup of the C-arm of the fluoroscope with the patient in the left lateral decubitus position. There is minimal hip and knee flexion and the monitor screen of the fluoroscope makes it possible to view the location of needle penetration in real-time.

to L3 levels, detected by 3-dimensional (3D) lumbar computed tomography (CT) prior to CSF shunting. During the screening period, a total of 8 iNPH patients were excluded because of spinal canal stenosis and all 8 underwent VP shunt surgery. Patients were followed-up on an annual outpatient basis at the authors' institution using CT scanning and data were collected by means of a retrospective chart review. A retrospective analysis was performed on the 39 LP shunted cases in accordance with the STROBE checklist. Due to the retrospective nature of the study, institutional review board/ethics committee approval and patient consent were not performed.

Lumbar Catheter Insertion

After induction of general anesthesia, the patient was placed in the left lateral decubitus position (Figure 1). In order to perform an objective repeatable unbiased procedure, the following methodology was employed. The fluoroscope was set for posterior-anterior (PA) lumbar vertebra monitoring. Initial dermal marking was made on the patient's back at the projection point of the lower margin of the second lumbar spinous process as confirmed on the PA view of the fluoroscope. This point was used as the target for dural penetration in the interlaminar space (Figure 2). A second dermal marking was made at the projection point 2 cm lateral to the midline of the spinous process on the lower border of the L3 vertebral body the upper border of the L4 vertebral body for demarcating the skin insertion point of the Tuohy needle. This procedure was a modification of the Nagaro method.¹⁵

After disinfection and sterile draping, the Tuohy needle was inserted at the second dermal mark, and advanced toward the dural target penetration point under fluoroscopic guidance. Superior angulation ranged from approximately 45° to 60° . The Tuohy needle typically penetrated the dura and reached the CSF space at an average depth of 7 cm from skin insertion, at which point CSF egress was confirmed. If no CSF egress was detected, further insertion of the needle at 5 mm intervals was performed until CSF outflow was observed. Subsequently, the spinal catheter was advanced via the Tuohy needle. A programmable valve (Codman Hakim Programmable Valve (Integra Lifesciences, Plainsboro, New Jersey) used in 35 cases and Strata Adjustable Valve (Medtronic Neurologic Technologies, Medtronic Inc, Dublin, Ireland; used in

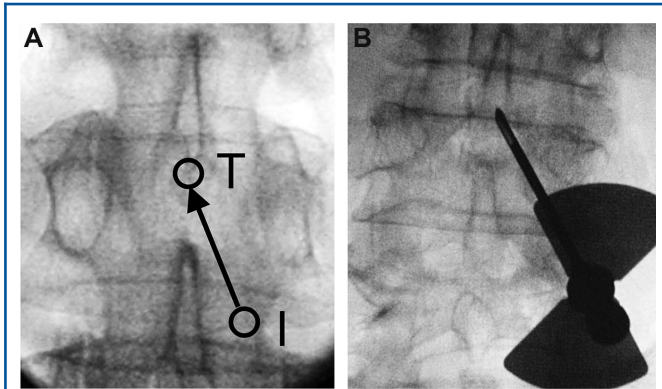


FIGURE 2. Tuohy needle insertion at the L2/3 level using fluoroscopic guidance. **A**, Schematic overlay drawing showing target (T) for penetrating the dura mater is at the center of the L2/3 intervertebral space. The Tuohy needle punctures the skin at the schematic insertion point (I) approximately 2 cm lateral from the midline, and at the level of the lower end of the L3 vertebral body or the upper end of the L4 vertebral body. **B**, The elevation angle of the needle should be between 45° and 60°. The actual needle is oriented in the target direction using real-time fluoroscopic imaging, and then advanced. T: target point, I: insertion point.

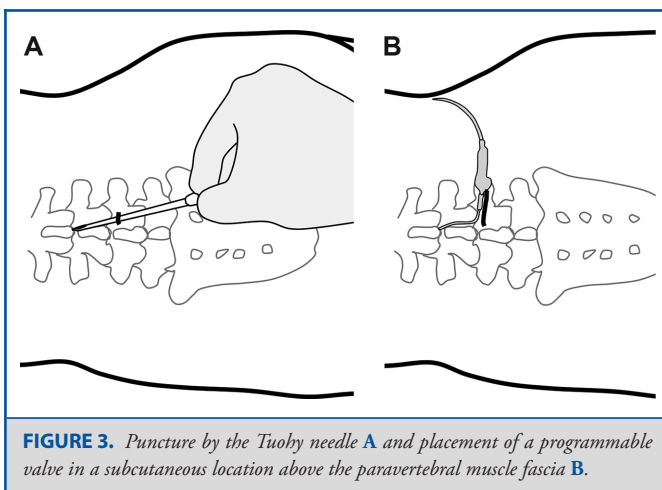


FIGURE 3. Puncture by the Tuohy needle **A** and placement of a programmable valve in a subcutaneous location above the paravertebral muscle fascia **B**.

6 cases) was connected to the spinal catheter and implanted from the right in the subcutaneous tissue above the paravertebral muscle fascia of the patient's back (Figure 3). Next, the peritoneal catheter was connected to the valve and advanced 30 cm into the intra-abdominal cavity, after opening the peritoneal cavity from the ventral side in the conventional manner. Initial pressure settings were calculated using Miyake's quick reference table (QRT) based on the patient's height and weight in the upright position, as validated in the SINPHONI study.¹⁶ In patients with greater stature and reduced weight, the risk of overdrainage can be expected to be high as calculated in reference to the QRT, and consequently in such cases the Codman Siphon Control Device (Integra Lifesciences) was employed.

Outcomes

To evaluate difficulty of fluoroscope-guided spinal catheter insertion, we measured the success rate of catheter insertion and the number of different Tuohy needle puncture locations. For evaluation of catheter insertion accuracy, both vertical and horizontal deviations of the catheter dural penetration point from the center of the interlaminar space were measured on postoperative lumbar CT scans. The incidence rates of postoperative spinal root pain and positional headache, reportedly due to postoperative transient overdrainage from leakage around the side of the tube,¹⁷ were measured.

Subarachnoid Space Evaluation

Evaluation of lumbar subarachnoid space size in elderly patients was performed by measuring the difference between anterior-posterior (AP) depths at the L2/3 lumbar spinal CSF cavity level and bilateral deviation from midline (at 0, 3, 6, and 9 mm intervals) using T2-weighted MRI (Figure 4). Because of the retrospective nature of the study with a lack of prior established protocol, lumbar MRI measurements were found to be performed in 23 patients.

Statistical Analysis

All statistical analyses were performed using JMP software (SAS Institute Inc, Cary, North Carolina).

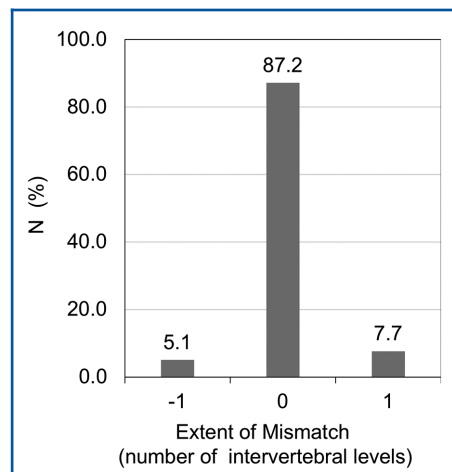
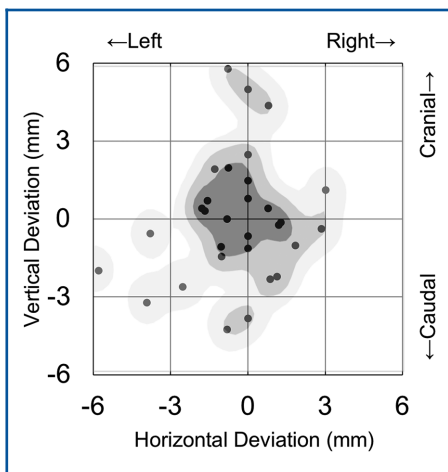
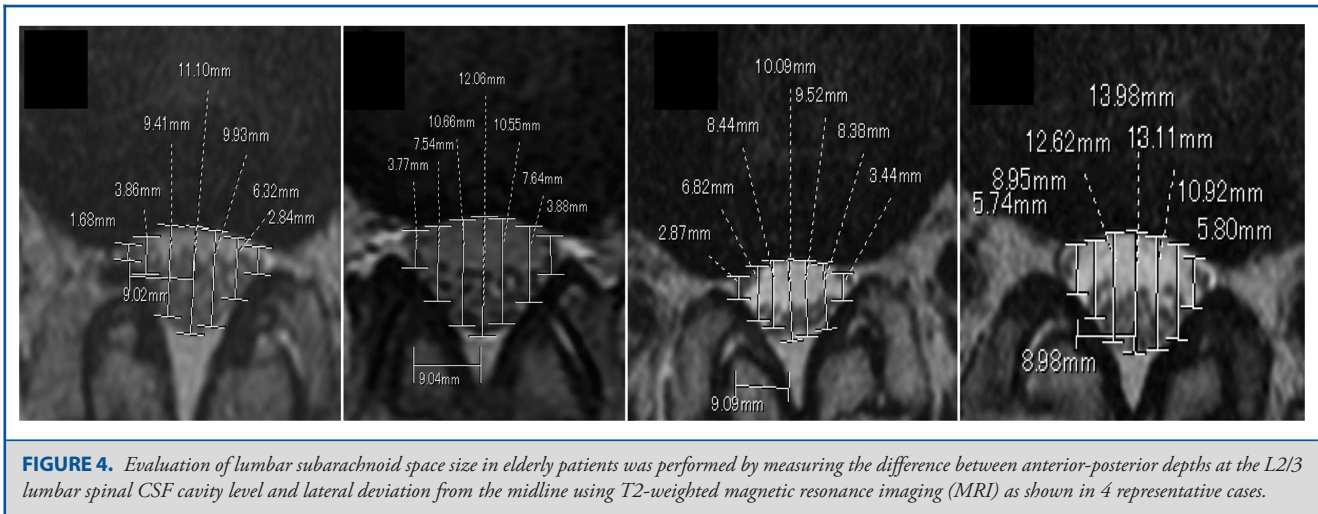
RESULTS

Success Rate and Accuracy of Fluoroscope-Guided Spinal Catheter Placement

The success rate for penetrating the CSF space with the Tuohy needle was 100% (39/39). In 1 patient, with severe scoliosis and canal stenosis, puncture with the Tuohy needle achieved CSF egress; however, a change in the puncture site was necessary because of difficulties with spinal catheter insertion via the Touhy needle. In this case, after changing the puncture site, the spinal catheter was smoothly inserted. As demonstrated by this case, scoliosis was not an absolute contraindication, and with mild cases of scoliosis, catheter placement could be performed safely using image guidance. Based on these data, the difficulty rate for catheter insertion, where insertion difficulty was defined as requiring a change in puncture location, was only 2.6% (1/39). In the other 38 cases, spinal catheters were smoothly inserted without the need for any location changes. The total success rate for catheter insertion was 100% (39/39). Accuracy of catheter insertion, as measured by deviation from the center of the interlaminar space, was 0.5 ± 1.9 mm horizontally and 0.0 ± 2.4 mm vertically (Figure 5).

Minor Complications Related to Spinal Catheter Insertion

Unintended caudal insertion of the spinal catheter was observed in 2 cases (5.1%). However, in these cases, caudal insertion was not associated with shunt dysfunction or root pain. Postoperative positional headache was observed in 4 cases (10.4%). However, headache symptoms in all 4 patients almost fully resolved within 1 wk without the need for any additional

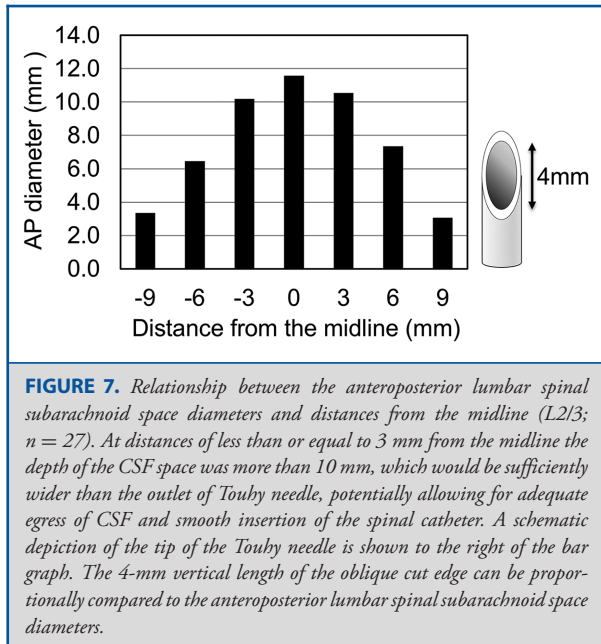


treatment. In 5 cases (12.8%), the intervertebral space level of catheter insertion did not match the intended insertion level (Figure 6).

Spinal Catheter Rupture, Infection, and Overdrainage

In theory, using the PMA the spinal catheter is not passed through the interspinous space, thus avoiding complications due to mechanical catheter compression. In Japan, there is a consensus especially for treatment in the elderly population for use of the midline approach, and rupture from compression at the spinous processes tends to be more common than

disconnection between the catheter parts. During a mean follow-up period of 36 mo, there was no evidence of catheter rupture or tube severing from compression at the upper and lower spinous processes in any of the cases. However, 2 catheters ruptured at the transition site between the lumbar muscular fascia and the subcutaneous fatty tissue, possibly because of manual lumbar massage or traumatic impact due to falling. There was no evidence of shunt infection in any case during the observation period. Postoperative chronic subdural hematoma requiring operation occurred in one case. Aside from this case, there was no evidence of shunt malfunction in any other case during the follow-up period. In all patients, postoperative head CT was performed



at 1 wk and 1 mo. With detection of very mild subdural fluid collection at these checkpoints, valve adjustment was performed at these times to prevent the occurrence of chronic subdural hematoma. In the one case complicated by a chronic subdural hematoma there was no concurrent administration of anticoagulation medication. However, in this case there was a delay in performing the postoperative head CT, and findings at the time of the CT showed a significant subdural fluid collection. Despite valve adjustments, burr-hole drainage treatment was performed. Following the burr-hole drainage procedure, the chronic subdural hematoma completely resolved, with subsequent successful iNPH therapy.

Anteroposterior Diameter of the Subarachnoid Space at the L2/3 Level

A maximum AP diameter of 11.6 ± 2.5 mm was measured in the center of the lumbar subarachnoid space at the L2/3 level. AP diameters of the lumbar subarachnoid space at a distance of 3, 6, and 9 mm from midline were 10.4 ± 2.1 , 6.9 ± 2.0 , and 1.9 ± 1.9 mm, respectively. The relationships between the AP diameters of the lumbar spinal subarachnoid space and the distances from the midline as well as a proportional comparison of the 4-mm vertical length of the oblique cut edge of the Touhy needle are shown in Figure 7.

DISCUSSION

Reliability of Fluoroscopic-Guided Spinal Catheter Placement

Despite the presence of the following three pathophysiological conditions which have traditionally lead to technical

complications in lumbar catheter placement, use of the fluoroscopic-guided PMA in our study achieved an insertion success rate of 100%. The first unfavorable condition is spinal deformity which is a common comorbidity in the elderly. The second obstacle occurs in obese patients with excessive subcutaneous fatty tissue. The third technical hurdle is frequently related to inherent complications associated with blind placement of the catheter, especially with less experienced surgeons.

In recent years, standard safety precautions and guidelines for most major procedures have incorporated the use of direct visual monitoring devices to reduce periprocedural complications. In particular, devices capable of direct or real-time visualization of surrounding anatomy, such as ultrasound-assisted central venous line placement and image-guided access to the spinal canal for invasive procedures, have replaced many so-called blind procedures.^{14,18} In this sense, use of the fluoroscopic-guided technique in our study was intended to add procedural safety as well as to offer improved effectiveness and reliability in spinal catheter placement, especially with regard to the above three technically difficult conditions.

Safety of Fluoroscopic-Guided Spinal Catheter Placement

Initial results from our study indicated that use of the fluoroscopic-guided PMA, enabled precise localization of the center of the interlaminar space, accompanied by a high frequency of first pass placement of the lumbar catheter. Furthermore, accurate insertion of the Touhy needle in the midline of the interlaminar space may allow the beveled outlet edge of the Touhy needle to be positioned in a wider CSF cavity, which may decrease the possibility of complications due to nerve impingement or damage to other neurovascular structures in and around the subdural space of the spinal cord. Thus, our results indicate that use of fluoroscopic-guidance combined with the PMA has the potential for more accurate lumbar catheter placement as well as a reduced number of dural punctures and a higher probability of first-pass puncture. More accurate catheter placement and a reduced number of dural punctures could ultimately translate into less adverse events, such as bloody punctures, root pain, positional headaches due to CSF overdrainage, and catheter rupture. The objective nature of this method may be useful for less experienced physicians and the technique itself can be mastered relatively quickly.

In our study, anatomical CT measurements of the lumbar region showed that the depth of the CSF space was more than 10 mm at distances of less than or equal to 3 mm from the midline. Therefore, taking into consideration the 4-mm vertical length of the oblique cut edge of the Touhy needle, a CSF depth space of more than 10 mm would be sufficiently wider than the outlet of Touhy needle, thereby potentially allowing for adequate egress of CSF and smooth insertion of the spinal catheter (Figure 7). Furthermore, results showed that the spinal catheter penetrated the spinal dura matter within 3 mm of the

midline in most of the cases (Figure 5). These data suggest that the Tuohy needles could be placed in a more optimal location at a depth where the CSF space is widest. This could potentially lead to a decreased likelihood of damage to nearby neurovascular structures as well as possibly ensure a freer path of catheter insertion with less chance of obstruction. Ultimately, we believe that this method ensures the likelihood of a more successful first-pass catheter placement, with a lower chance of associated complications.

Moreover, bloody punctures are typically related to “overshooting” of the needle with damage to the internal vertebral venous plexus on the dorsal side of the vertebral body.¹⁹ Thus, according to the literature, the cause of bloody punctures is typically attributed to injury to the venous plexus located on the vertebral posterior surface; therefore, avoidance of deep puncture could avert this complication. Despite the limitations of our study, our results show that bloody punctures may be prevented to a large extent by using fluoroscopic guidance combined with the PMA. Another possible explanation for our positive outcomes may be that the Tuohy needle was precisely placed in the widest CSF cavity, at a safer distance from the venous plexus.

Obesity and Spinal Catheter Insertion

Although international criteria for obesity may vary, based on our experience with elderly patients in Japan, a body mass index (BMI) of greater than 25 kg/m² in the elderly Japanese patient population is quite uncommon and as such obesity was considered as a BMI of greater than 25 kg/m². Based on these considerations, approximately 30% of the patients in our study were obese, with a BMI of greater than 25 kg/m². The presence of excess subcutaneous fatty tissue in the lumbar region can make spinous process palpation difficult, consequently reducing accurate identification of the underlying anatomy. This obstacle contributes to the blind nature of the traditional puncture procedure and may increase the possibility of complications. In addition, increased subcutaneous fatty tissue leads to a deeper distance for dural puncture which may decrease the accuracy of catheter placement. Our results indicated that many of these disadvantages could potentially be overcome, especially with the use of fluoroscopic guidance.

Age-Related Lumbar Deformities and the PMA

Deformity of the lumbar spine is a fairly inevitable pathophysiological process inherent with aging. The spinous processes also undergo hypertrophy with age, with linear increases in dimensions of both height and width over time.⁵ As a result, the spinal interspinous spaces in elderly individuals are almost universally narrowed.⁸ Rabinowitz et al⁹ reported that many of the technical difficulties encountered when inserting spinal catheters in elderly patients using the median approach were significantly improved after changing to the PMA. Therefore, in addition to the advantages of fluoroscopic guidance, use of the PMA was another potential reason for the high success rate of spinal catheter placement observed in our study.

Another presumed advantage of the PMA is potential prevention of spinal tube rupture by avoiding midline structures which can damage catheter tubing from mechanical contact forces. In the midline approach, the spinal catheter passes through the narrow interspinous space, where the upper and lower spinous processes may cause a pinching effect. Over time, and especially in elderly patients and patients with bony hypertrophy, excessive mechanical compression of the fragile tubing material may lead to catheter rupture or severing. In contrast, the PMA avoids catheter passage through the interspinous space. Therefore, our results seem to support the use of the PMA as a physiologically appropriate method for reducing spinal catheter damage.

Limitations

The study was limited by the inherent features of a retrospective examination of a small number of cases at a single institution, which may have introduced selection and treatment biases and consequently, the results may not be generalizable. A prospective, randomized, double-blinded design could provide more reliable conclusions.

CONCLUSION

This study showed that the fluoroscopic-guided PMA can be a safe and reliable method for spinal catheter placement in LP shunt surgery, especially in obese and or elderly iNPH patients with lumbar spine deformity. This method theoretically enhances accurate penetration of the midline dura at the widest subarachnoid lumbar space, allowing for smoother spinal catheter insertion. Further prospective studies, demonstrating improved patient outcomes and increased safety, are required to evaluate the validity of the techniques described in this paper. Future guidelines and educational simulation training programs may benefit from use of this methodology.

Disclosure

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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