Turk Neurosurg 32(2):286-291, 2022

Original Investigation

DOI: 10.5137/1019-5149.JTN.35332-21.2

Received: 29.05.2021
Accepted: 02.07.2021

Published Online: 17.12.2021

A Retrospective Analysis of Intrathecal Catheter Tip Position in Plain Radiography: How Much Do We Agree?

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ABSTRACT

AIM: To assess interrater and intrarater reliability of postoperative plain radiographs, which are routinely performed to confirm the correct placement of the catheter tip after intrathecal drug delivery systems (IDDS) implantation.

MATERIAL and METHODS: This was a retrospective analysis of plain radiographs obtained from patients implanted with intrathecal catheters and morphine pumps. Each plain radiograph was assessed independently by three raters with varying expertise, at three different time points, to confirm the position of the intrathecal catheter tip. Krippendorff's alpha coefficient was used to calculate both the interrater and intrarater reliability.

RESULTS: There was a high level of agreement among the three raters and the three reviews of each rater separately when assessing the location of intrathecal catheter tips in plain radiographs from 126 patients. This was evidenced by the Krippendorff's alpha value being >0.99 in all cases, which was greater than the cutoff threshold value of 0.8.

CONCLUSION: The interrater and intrarater reliability of plain radiographs for determination of catheter tip position after IDDS implantation was high. The experience and expertise of the raters did not significantly affect the assessments.

KEYWORDS: Intrathecal, Reliability, Neuromodulation, Catheters, Chronic pain

INTRODUCTION

Intrathecal drug delivery systems (IDDS) are an effective treatment for patients with malignant and non-malignant chronic pain. Intrathecal analgesia is indicated for cancer pain, failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), peripheral neuropathies, rheumatoid arthritis, chronic pancreatitis, compression fractures, and spondylosis (4,11). Only three medications are currently approved by the US Food and Drug Administration (FDA) for intrathecal analgesia – morphine, ziconotide, and baclofen (5,6). The latter is rarely effective as monotherapy in pain management, but it can be used in combination with other drugs to treat pain associated with spasticity (6). Additional drugs used for pain management in clinical practice include clonidine, bupivacaine, hydromorphone, fentanyl, and sufentanil, but none of these is FDA approved (5,6).

Intrathecal analgesia is mostly used as a potential therapeutic option for patients who have not responded adequately to, or did not tolerate, pharmacological treatment (opioid or non-opioid), physiotherapy, psychotherapy, or transcutaneous electrical stimulation for pain relief (1). In the case of opioids, intrathecal delivery enables increased efficacy and avoidance of adverse effects that are seen with systemic administration, e.g., sedation, constipation, nausea, vomiting, and respiratory depression (10,12).

IDDS implantation is performed in two steps. In step 1, the catheter is inserted into the thoracolumbar intrathecal space, using fluoroscopy to ensure its proper placement. In step 2, after a successful trial of drug efficacy, the pump is typically implanted in either the lower quadrant of the abdomen or the gluteal region (2). Postoperative plain radiographs are then routinely performed to confirm the correct placement of all parts of the intrathecal delivery system. Evaluation of

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the catheter tip position is particularly important, as it can affect drug distribution into the target spinal cord segments and, subsequently, the level of pain control (9). However, this assessment is susceptible to interrater variability, with differences in experience, expertise, education/training, and competence all potentially influencing decisions.

The aim of this study was to evaluate the interrater and intrarater reliability of postoperative plain radiographs in determining intrathecal catheter tip location after IDDS implantation.

MATERIAL and METHODS

Patients

A retrospective analysis of plain radiographs from patients implanted with intrathecal catheters and morphine pumps was performed. The procedures were carried out between January 1, 2015, and December 31, 2019, at the Department of Stereotactic and Functional Neurosurgery, University Hospital of Cologne, Germany. Placement of the catheter in the intrathecal space of the spinal cord and of the pump in the abdomen was carried out in two stages. After implantation of the catheters, the patients underwent a drug trial in hospital, and as soon as they achieved pain relief with no, or minimal, side effects, they were implanted with morphine pumps.

Assessment of Radiographs

Each plain radiograph was assessed independently by three raters: the author (G.M.), a junior resident, and a senior radiologist. At the time of the evaluation, G.M. (neurosurgeon) had 6 years' experience in the field, and the junior resident (neurosurgeon) and the senior radiologist had 1 year and 10 years of experience, respectively. All three raters reviewed each radiograph at three different time points (interval between each review was 2 weeks) and determined the position of the catheter tip using the vertebral bodies as an anatomical landmark. After simultaneous review of the radiographs, G.M. and the radiologist came to an agreement about the locations of the catheter tips.

Statistical Analysis

The results of the three reviews from each rater were analyzed and the Krippendorff's alpha coefficient with the corresponding 95% confidence intervals was computed, to measure both the interrater and intrarater reliability (3,14). For the statistical analysis, Microsoft Excel version 2010 and IBM SPSS Statistics for Windows, version 25.0 (IBM Corp.; Armonk, NY, USA) were used.

RESULTS

In total, 142 patients (78 males, 64 females; mean age 62.13 ± 1.19 years) underwent morphine pump implantation because of FBSS (n=102; 71.8%), cancer pain (n=26; 18.3%), CRPS (n=5; 3.5%), or diabetic neuropathy (n=9; 6.4%). Patient characteristics and the technical characteristics of the pumps are shown in Table I. Plain radiographs were only available for 126 patients and these were all included for analysis.

The most frequent position of the catheter tip was T11 (27/126; 21.4%). Overall, the catheter tip was placed at the level of T9–T12 in 57.2 % (n=72), at T5–T8 in 31.7% (n=40), at L1–L3 in 7.1% (n=9), and at T1–T4 in 4% (n=5) of patients.

Table I: Patient Characteristics and Technical Characteristics of the Morphine Pumps

Characteristic	Value
Patients	
Mean age, years ± SD	62.13 ± 1.19
Sex, males; females	78/142 (54.9%); 64/142 (45.1%)
Medical condition	
Failed back surgery syndrome	102/142 (71.8%)
Cancer pain	26/142 (18.3%)
Complex regional pain syndrome	5/142 (3.5%)
Diabetic neuropathy	9/142 (6.4%)
Pumps	
Constant rate	68/142 (47.9%)
Archimedes	37/142 (26.1%)
Infusaid	1/142 (0.7%)
IP 1000V	2/142 (1.4%)
IP 2000V	22/142 (15.5%)
IsoMed	3/142 (2.1%)
Therex	3/142 (2.1%)
Programmable	74/142 (52.1%)
MedStream	12/142 (8.5%)
Synchromed II	62/142 (43.7%)
Volume (ml)	
15	1/142 (0.7%)
20	14/142 (9.9%)
30	3/142 (2.1%)
35	4/142 (2.8%)
40	78/142 (54.9%)
50	39/142 (27.5%)
60	3/142 (2.1%)
Intrathecal catheter tip location	
T1–T4	5/126 (4%)
T5–T8	40/126 (31.7%)
T9–T12	72/126 (57.2%)
T12–L3	9/126 (7.1%)

SD: *Standard deviation.*

Table II: Results of the Rater Reviews

Catheter tip location	Verified cases*	First review			Second review			Third review		
		R1	R2	R3	R1	R2	R3	R1	R2	R3
T1	1	1	0	2	1	1	1	1	1	1
T2	2	2	3	1	2	1	1	2	2	1
T3	0	0	0	0	0	1	1	0	0	1
T4	2	2	2	2	2	2	2	2	2	2
T5	7	7	7	7	7	7	7	7	7	7
T6	9	9	9	9	10	9	9	9	9	9
T7	10	10	10	10	8	10	10	10	10	10
T8	14	14	14	13	15	14	13	14	13	12
T9	21	21	21	23	20	20	22	21	22	23
T10	16	15	16	15	17	18	15	16	16	15
T11	27	28	27	27	26	25	28	27	27	27
T12	8	8	8	9	8	9	8	8	8	10
L1	3	3	3	3	4	3	5	4	2	4
L2	4	4	3	4	4	5	3	3	5	2
L3	2	2	3	1	2	1	1	2	2	2
Total					**126**					

R: *Rater. * Location of the catheter tip as determined by a senior radiologist and the author (R1) during simultaneous review.*

Table III: Intrarater Reliability

	Krippendorff's alpha (95% CI)
All three reviews	
Rater 1	0.9972 (0.9952–0.9989)
Rater 2	0.9947 (0.9919–0.9972)
Rater 3	0.9969 (0.9949–0.9989)
Rater 1	
Review 1 – Review 2	0.9959 (0.9918–0.9992)
Review 1 – Review 3	0.9986 (0.9957–1.0000)
Review 2 – Review 3	0.9972 (0.9937–0.9997)
Rater 2	
Review 1 – Review 2	0.9963 (0.9924–0.9996)
Review 1 – Review 3	0.9943 (0.9891–0.9990)
Review 2 – Review 3	0.9936 (0.9882–0.9980)
Rater 3	
Review 1 – Review 2	0.9974 (0.9934–1.0000)
Review 1 – Review 3	0.9955 (0.9908–0.9990)
Review 2 – Review 3	0.9979 (0.9949–1.0000)

CI: *Confidence interval.*

The review results from the three raters are summarized in Table II. In all cases, the Krippendorff's alpha value was >0.99, which was greater than the cutoff threshold value of 0.8 (3) (Tables III and IV). This indicates there was high interrater and intrarater reliability, and therefore strong agreement among the three raters and the three reviews of each rater separately when determining the position of catheter tips in plain radiographs. These excellent results for interrater and intrarater reliability are depicted graphically as bubble plots in Figure 1A–C and Figure 2A–C.

DISCUSSION

The study findings suggest that differences in experience and expertise do not significantly affect the determination of catheter tip position in plain radiographs. At the time of the evaluation, G.M. had 6 years of experience as a neurosurgery consultant, the junior neurosurgeon had only 1 year's experience, and the senior radiologist had 10 years' experience. The intrarater reliability was high and there was an apparent consistency in evaluation across the three reviews. To our knowledge, this is the first report to address the interrater and intrarater reliability of postoperative assessment of catheter location in the field of intrathecal drug delivery.

Correct catheter tip placement near the level of the targeted spinal cord segments is of paramount importance for effective drug delivery. Intrathecal drug spread is not homogeneous

Table IV: Interrater Reliability

	Krippendorff's alpha (95% CI)
Review 1	
Rater 1 – Rater 2	0.9986 (0.9957–1.0000)
Rater 1 – Rater 3	0.9964 (0.9921–0.9998)
Rater 2 – Rater 3	0.9950 (0.9898–0.9989)
All raters	**0.9967 (0.9940–0.9985)**
Review 2	
Rater 1 – Rater 2	0.9938 (0.9889–0.9977)
Rater 1 – Rater 3	0.9948 (0.9902–0.9987)
Rater 2 – Rater 3	0.9939 (0.9881–0.9985)
All raters	**0.9941 (0.9913–0.9966)**
Review 3	
Rater 1 – Rater 2	0.9971 (0.9943–0.9999)
Rater 1 – Rater 3	0.9956 (0.9908–0.9990)
Rater 2 – Rater 3	0.9927 (0.9869–0.9976)
All raters	**0.9951 (0.9927–0.9976)**

CI: *Confidence interval.*

and is limited to the area around the injection site (8); because of this, positioning the catheter at a higher or lower level in the subarachnoid space may lead to insufficient drug concentrations at the desired site of action and, consequently, a failure to provide pain treatment. It is not necessary to administer pain medication exactly at the target site but it must be injected close to it; however, what counts as an acceptable distance has not yet been defined (7). In addition, the cerebrospinal fluid flow dynamics vary at different levels of the spinal canal, and this may influence the extent of dilution and the velocity at which the drug penetrates the spinal cord tissue to exert its effect (13).

It is clear that accurate catheter tip placement plays a pivotal role in the long-term prognosis of the patient; therefore, thorough assessment of it after the implantation procedure is warranted. The identification of a placement at a higher or lower spinal level directly after surgery could lead to an immediate correction, thus improving the chances for successful pain management. Consequently, the radiograph examiner has a key role in this process.

The current study demonstrated that the experience and expertise of the rater do not seem to affect the proper assessment of catheter tip placement. Future studies with substantially larger numbers of raters and radiographs are needed to confirm and complement these preliminary findings. However, it should be pointed out that the high-

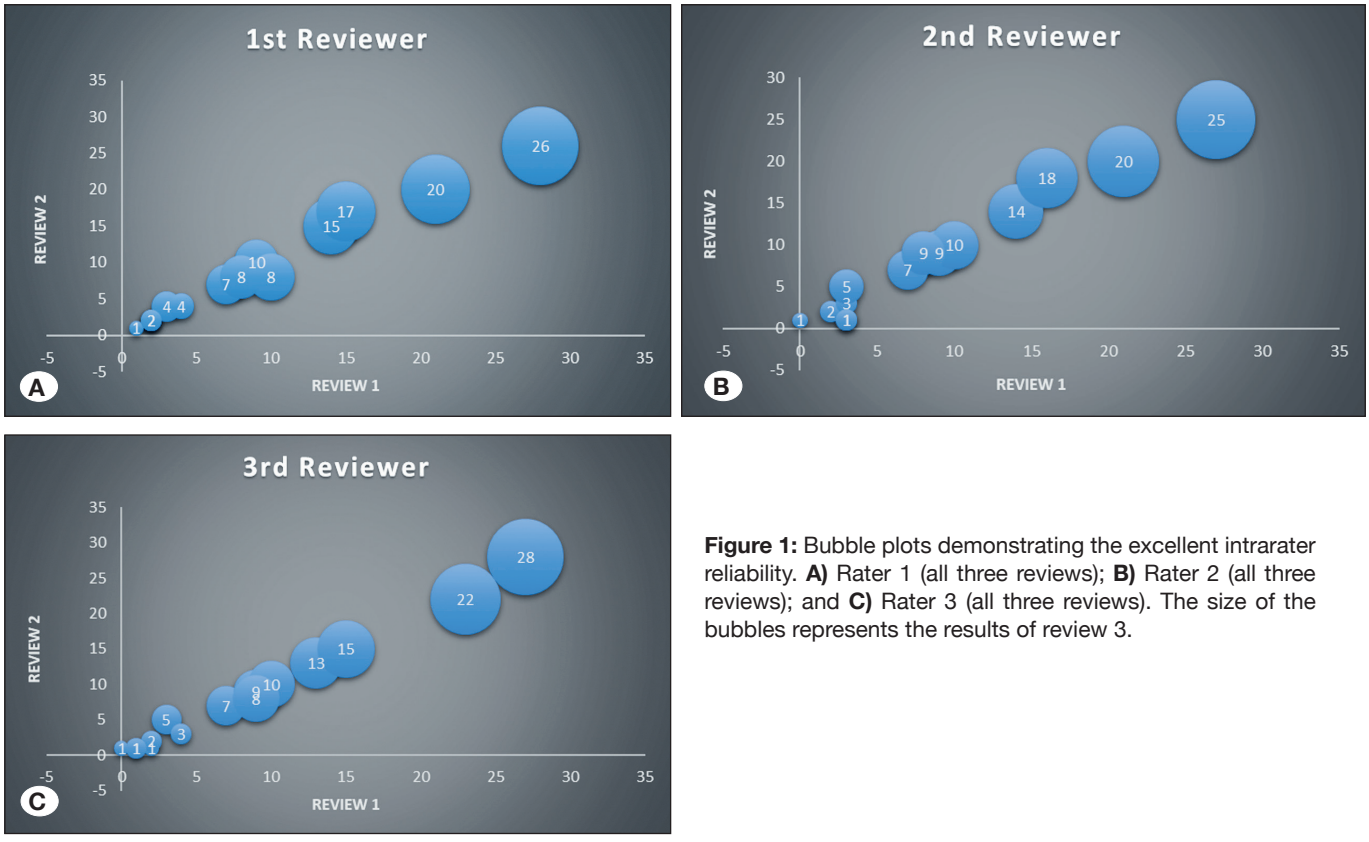

Figure 1: Bubble plots demonstrating the excellent intrarater reliability. **A)** Rater 1 (all three reviews); **B)** Rater 2 (all three reviews); and **C)** Rater 3 (all three reviews). The size of the bubbles represents the results of review 3.

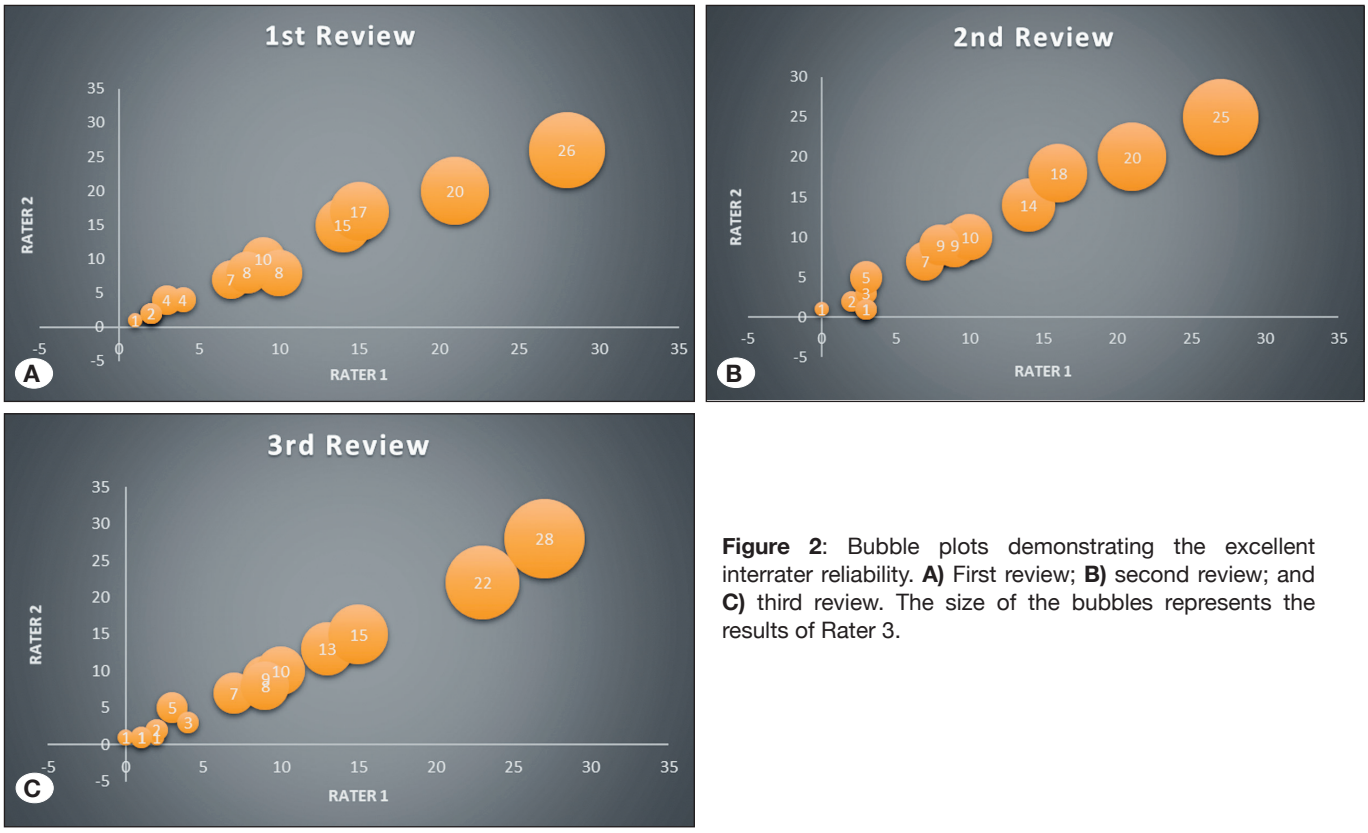

Figure 2: Bubble plots demonstrating the excellent interrater reliability. **A)** First review; **B)** second review; and **C)** third review. The size of the bubbles represents the results of Rater 3.

quality education in the reference center might have played a role in the observed high interrater agreement. Future studies should address this by developing a standardized protocol and scales for appraisal of each rater's background in terms of expertise, education/training, and competence. This could lead to the optimization of rater selection, which would ultimately benefit the patient. If future research reveals low interrater or intrarater agreement, contrary to the findings of the current study, the development of diagnostic algorithms or tools should be encouraged, to assist physicians and enable a more uniform approach in the evaluation of radiographs.

This study has some limitations. First, it included only three raters and 126 radiographs; larger numbers of raters and radiographs could lead to different findings. Furthermore, the blinding of surgeons cannot be fully guaranteed. In the current study, however, the operations were performed over 5 years and many of the radiographs were assessed ≥3 years after the implantations; therefore, the possibility that the neurosurgeons remembered any of the intraoperative catheter tip positions is deemed to be very low.

CONCLUSION

This study demonstrated that the interrater and intrarater reliability of plain radiographs for determination of catheter tip position after IDDS implantation was high. The experience (in years) and expertise (neurosurgery vs. radiology) of the three raters did not seem to affect the level of agreement among them. The correct positioning of the intrathecal catheter is important for effective drug delivery and achievement of pain relief; the careful assessment of catheter tip placement is therefore critical. Further studies are needed to investigate the level of agreement among more raters and the role of individual factors such as personal skills and educational background.

ACKNOWLEDGMENT

Medical writing assistance was provided by Maxine Skipp, independent medical writer.

AUTHORSHIP CONTRIBUTION

Study conception and design: GM

Data collection: GM

Analysis and interpretation of results: GM

Draft manuscript preparation: GM

All authors (GM) reviewed the results and approved the final version of the manuscript.

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