

A Comparison Study between Newly-Designed Pencil-Point and Cutting Needles in Spinal Anesthesia

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Objectives: The goal of this single blinded randomized study was to compare the use of routine cutting-tip spinal needle and newly-designed pencil-point Pajunk[®] in terms of success rate, complications and satisfactions in priests undergoing spinal anesthesia for orthopedic, general and urological surgery at Priest Hospital, Thailand.

Material and Method: After Institutional Review Board approval and patients' signed consent, from August 2006 to October 2007, 91 priests were randomly assigned to have 27-gauge Quincke (control group, C) or 25-gauge Pajunk[®] (study group, S) spinal needles used in their spinal anesthesia. The number of attempts to successful cerebrospinal fluid return and the success rate of the spinal blockade were documented. Postoperatively, an investigator blinded to the study interviewed patients daily.

Results: The first-time needling success rate for Quincke was 79% but for Pajunk[®] only 46%, lower than reported. The incidence of minor complications was small, even there were 2 postoperative dead cases not related to anesthesia. Over 80% of both groups still preferred the same technique and surgeon satisfaction was good to excellent.

Conclusions: The newly-designed, pencil-point spinal needle was another example on the development of more refined towards quality anesthesia. To be cost-effective, it should be selected for patients at risk of CSF leakage-related complications.

Keywords: Anesthesia, Postdural puncture headache, (PDPH), Postdural puncture backache, (PDPB)

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More than a century since 1885 that J Leonard Corning accidentally put cocaine into canine subarachnoid space and found its hind limbs to be paraplegic⁽¹⁾, spinal anesthesia (SA) has been widespread practiced as a regional technique for operations below the diaphragm. Popularity is stemmed from its high reliability to block all perceptual modalities, its simplicity in practice, low cost and short-term skill acquisition. SA, without exception from the rules, can be accompanied with complications that range from life-threatening to

ones related to cerebrospinal fluid (CSF) like postdural puncture headache (PDPH), postdural puncture backache (PDPB) and transient neurological syndrome (TNS). Over these long-evolving years, there have been numerous works on developing techniques and equipments to minimize all these complications. One issue is the design of the spinal needle tip which plays a major role on CSF leakage. Historically, in 1890, the spinal needle tip geometry was cutting or Quincke type, then pencil-point Whitacre was introduced in 1951 to have more benefits and later Sprotte was developed in 1979⁽²⁾. The routine cutting tip Quincke is believed to leave a gaping hole in the dura more than a pencil-point such as Whitacre, Atraucan and Sprotte. Recently the Sprotte needle tip and hub have been redesigned

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to facilitate rapid CSF flow and gain a magnifying view under the brand of Pajunk[®](²). Our objective was therefore to contribute more information on this newly designed 25-gauge spinal needle including comments from anesthesiologists, patients and surgeons.

Material and Method

The study was ethically approved and had all patient consents obtained. It was single blinded, prospective case analysis in that the postoperative interviewers did not know which patient belonged to which group. Ninety-one patients underwent spinal anesthesia for operations in the departments of orthopedics, general surgery and urology from August 2006 to October 2007. On the assumption that the chance of first-time success for 25-gauge pencil-point spinal needle was 62%(³) while that of routine 27-gauge cutting needle over 90%, the sample size was calculated to number approximately 36 cases per group on 95% confidence and 80% power(⁴). The patients were randomly allocated into 59 cases in control(C) and 32 in study(S) groups for which anesthesiologists did SA with 27-gauge Quincke (Becton-Dickinson, Rutherford, NJ, USA or Dr. Japan Co, Tokyo, Japan) and 25-gauge Pajunk[®] (Pajunk, GmbH Medizin Technik, West Germany), respectively. They could freely change to the other needle if one used had failed. Patient characteristics such as age, body weight, height, past history, anesthetic experience, vital signs, diagnoses, types of surgery, were recorded. SA procedure was conducted after good hydration in the lateral position with preferred side of surgery underneath. Hyperbaric 0.5% Bupivacaine 2.5-3.5 ml was injected through the needle after subarachnoid access and CSF gain on the rate of 0.1 ml/second. Intrathecal narcotics were considered per case as appropriately or requested by surgeons. Needling approaches were midline or paramedian up to the anesthesiologist discretion and times till success were counted or noted as failed. Anesthetic dermatomal level was cold temperature tested after 5-10 minutes. In case systolic blood pressure fell below 100 mm.Hg., the patient was given ephedrine 3-5 mg as frequently until he was stabilized. Intra-operatively, volumes of intravenous fluid and blood loss, tourniquet time, need for sedative supplements and surgeon impression were documented. On postoperative visit, nurse anesthetists asked about blurred vision, headache, difficulty in hearing, satisfaction, preferences of anesthesia and so on until they were discharged from the hospital. This study was carried out without any conflict of interest.

Parametric data were reported as mean \pm SD, while anesthetic levels as median. Student t-test and Chi-square were tested with or without Yate's correction as appropriate(⁵). Two-sided $p < 0.05$ at power 80% was counted as statistical significance.

Results

Patient demographic data, type of surgery, needling times, anesthetic level, sedative supplements, surgeon rating, patient comments and postoperative complications (mean \pm SD) were presented in Table 1.

In group C: missing data for type of surgery 1 case; first-, second-, third-, fourth- and fifth-time success in needling 46, 7, 1, 1 and 1 cases respectively and 2 cases performed more than 7 times. One case was switched from failure in S group. Two patients died within a day of surgery but not related to anesthesia (septic and hemorrhagic shock). A single case was continued with general anesthesia due to prolonged vascular surgery of the leg. One had nausea-vomiting and the other one headache but not PDPH, both were better after symptomatic care.

In group S: First-time success 15 cases, second-, third-, fifth- and tenth-time were 12, 2, 2 and 1. Backache occurred in 1 and a single patient complained of the technique during surgery.

Discussion

The tip of the newly designed Pajunk[®] appears as ogive, that is rounding and smooth enough to cause less soft tissue injury than the former cutting tip(²). More importantly, the dural tear does not remain gaping open due to fiber separation but not cutting through(^{1,6}). This limits the CSF leakage which is related to a complication like PDPH. Reina MA et al studied tissue reaction after various spinal needles and found that the pencil-point causes more fibrosis thus better sealing the dural tear(⁷⁻¹⁰). Closer to the tip end is the lateral opening which has a neat trimming rim and wider diameter than the original Sprotte; coupled with the magnifying effect at the needle hub, Pajunk[®] is claimed to provide rapid CSF gain and clear visualization(²). The size recommended is 25-gauge to make room for a larger opening eye and research confirmed this size not to increase PDPH incidence(¹¹). Because of the bigger size and the rather blunt tip, this entails in more force in skin needling, even rotating the needle just to get through the skin did not seem to help much(¹¹). That is why the needle also comes in the package together with the cutting introductory needle. Parker RK et al concluded from their microscopic study that

Table 1. Demographic data (mean \pm SD)

Group	C n = 59	S n = 32	p
Age (years)	59.03 \pm 18.87(22-86)	58.34 \pm 14.24(27-83)	0.85
Body weight (kilograms)	61.90 \pm 13.60(39-103)	60.54 \pm 10.61(46-83)	0.62
Height (centimeters)	162.03 \pm 6.92(142-180)	163.06 \pm 5.48(148-172)	0.47
History: medications	5	2	0.58
backache	-	1	
hard of hearing	-	-	
blurred vision	-	-	
headache	-	-	-
anesthesia	-	2	
Systolic Blood Pressure(mm.Hg.)	131.47 \pm 20.90	136.18 \pm 21.18	0.30
Diastolic Blood Pressure (mm.Hg.)	74.86 \pm 14.06	81.28 \pm 15.16	0.04*
Heart rate/min	73.91 \pm 13.39	75.59 \pm 13.34	0.63
Types of surgery:			
orthopedics	27	16	0.12
general surgery	18	14	
urology	13	2	
0.5% hyperbaric bupivacaine(ml)	2.98 \pm 0.36 (2-3.8)	3.10 \pm 0.30 (2.5-3.5)	0.13
Needling times	1.59 \pm 1.47 (1-7)	2.03 \pm 1.78(1-10)	0.20
1	47	15	0.005*
2	7	12	
≥ 3	5	5	
Anesthetic level(median)	T8	T8	0.54
T4	5	7	
T8	16	9	
T10	5	3	
T12	14	5	
Systolic BP < 100 mm.Hg.(cases)	18	12	0.49
Ephedrine (mg)(max)	4.09 \pm 5.44 (21)	8.54 \pm 10.48 (31)	0.02*
IVfluid(ml) (max)	1,344.88 \pm 1,073.99(4,600)	1,456.81 \pm 870.45(3,500)	0.65
Blood loss(ml) (max)	201.19 \pm 511.33 (2,050)	213.88 \pm 357.19(1,500)	0.91
Tourniquet time(min) (max)	24.05 \pm 34.77 (120)	22.35 \pm 31.87 (80)	0.86
Sedative supplements(cases)	19	9	0.68
Surgeon rating			
excellent	23	10	
good	33	20	
Postoperative complications			0.96
blurred vision	1	-	
headache	4	2	
hard of hearing	2	-	
others	1	1	
Patient comments			0.86
favor	47	21	
disfavor	6	4	

*Significant \pm Refere \pm Refere at p-value < 0.05

most pencil-point spinal needles are manufactured in better quality; for example the strength to stand bony contact and the less deformation of the shaft. They suggested this goodness could help in difficult situa-

tion when the needle is hard to get past stiff bony structure⁽¹²⁾. But the work of Aboul-Eish *et al* pointed out that the blunt tip is poor for penetration sensation⁽¹³⁾. Lynch and the team compared how fast to get

CSF between these two needles in 27-gauge, timing from dural feel to CSF flow and they found similar for both within 10 seconds⁽¹⁴⁾. However, the single lateral eye opening on the tip can slow down the CSF flow when passing into the subarachnoid and theoretically it could happen that only the tip part gets through the dura leaving the eye still outside the space. Thanks to the bigger opening of Pajunk[®] the local anesthetics tend to spread and mix well with CSF, lowering the chance of TNS which involves local anesthetic localization around the former pencil-point tip⁽¹⁵⁻¹⁷⁾.

The sample size of the study was 59 cases for group C and 32 cases for group S, not exactly the number calculated (36 cases per group). We increased group C to over 36 to maintain power strength in case the study group lacked behind. Success rate for the first-time needling in group S was 46% (15/32) while group C 79% (47/59) ($p = 0.005$). This was far lower than Pan PH et al study of 25-gauge Whitacre to be 62%³ in 215 gynecological patients. The tip of Whitacre is called stepping; from the long straight shaft, the needle has a rim and then tapering to an end. Such an appearance could get deep through the space easily without knowing. Failure rate of Whitacre ranges from 5-8.5 and in this study, only one case was switched from Pajunk[®] to cutting. The difficulty could not be explained with the body stature, since our monks weighed average 60.5, 61.9 kg, had average height of 163, 162 cm and aged 58.3 and 59 years for group S and C respectively. The baseline characteristics did not count for any statistical difference. Failure was mainly from unfamiliarity with the needle itself. Our anesthesiologists kept calling for the routine spinal needle when running into procedural problems or the patient back looked tough. We suggested using the cutting introductory needle after subcutaneous local anesthetics, not worth trying rotating from the beginning. Even though Pajunk[®] was not preferred, we admitted CSF flow was impressively quick and easily visualized for the right case. Median anesthetic level was T8; hypotensive cases and volumes of intravenous fluids of both groups were not different but why group S was administered more ephedrine (8.5 vs. 4 mg, $p = 0.02$). We thought that S patients had markedly higher diastolic blood pressure (BP) and the same trend for systolic BP, in addition to the higher amount of the local anesthesia (3.1 vs. 2.8 ml, $p = 0.13$), BP fluctuations could be more abrupt. To maintain near baseline BP, the vasopressor was therefore used. Sedative supplements were not different between both groups. One S patient did not like the procedure and would like

to sleep while 1 C patient had to be continued with general anesthesia for prolonged surgery. For mortality not anesthesia-related, one case was diagnosed as necrotizing fasciitis and got septic shock afterwards; the other one underwent hip surgery with suspected concealed bleeding. Both with full resuscitation, they passed away the same day of operation. Other complications were minor like headache, blurred vision, hard of hearing as in Table 1. One C patient has nausea-vomiting, probably from intrathecal narcotic side-effect and 1 S patient has backache. All were relieved before discharge. Interestingly, postdural puncture backache (PDPB) incidence is 5.91-22 from pencil-point needles; it is usually mild and related to type of surgery, immobilization and SA posture⁽¹⁸⁾. Postoperative interviews revealed patient satisfaction to a certain degree; over 80% still would like the same anesthetic technique while those of surgeons were good to excellent (Table 1). This study was carried on only male patients, Thai monks. The good part was that they were good shaped-subjects for regional anesthesia but the limitation was lack of data to compare gender influence. The Pajunk[®] costs almost 7 times the Quincke on the Thai market. From literature, this new profiled tip is properly indicated in selected patients who are at risk of PDPH like obstetric and young patients. It is also another alternative for diagnostic/therapeutic lumbar puncture for malignancy children⁽¹⁹⁾.

Conclusions

The study was done to compare the use of cutting and newly-designed, pencil-point tips for spinal anesthesia on 91 Thai priests at the Priest Hospital. The control group of 59 cases underwent the procedure with 27-gauge Quincke while the study group of 32 cases and with 25-gauge Pajunk[®]. Operations were mostly orthopedic and patient characteristics were not statistically different. The success rate in first-time spinal needling in the study group was only 46%, far less than reported. For the right patient, it was admitted that CSF flow visualization was very impressive. Discussion about the good and adverse result of the design, both theoretically and practically were done. It was recommended for use in indicated patients at risk of postdural puncture headache because of its high cost. It could be stated that Pajunk[®] spinal needle adds another armamentarium to anesthesia practice.

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การศึกษาเปรียบเทียบเข็มฉีดยาชาเข้าช่องน้ำไขสันหลังชนิดปลายตัดกับปลายดินสอแบบใหม่

รังสิมา แสงหิรัญวัฒนา, กักร ตันติวิทยาพันธ์, วัฒนา ชำนาญเวช, สุภาภรณ์ ตั้งสุขเกษมสันต์,
ประไพ ศิริทองถาวร

วัตถุประสงค์: การศึกษาแบบ single blinded randomized เพื่อเปรียบเทียบประสิทธิภาพของเข็มฉีดยาชาเข้าช่องน้ำไขสันหลังชนิดปลายตัดกับปลายดินสอ Pajunk[®] ในเรื่องความสำเร็จของการแทงเข็มครั้งแรกให้น้ำไขสันหลังภาวะแทรกซ้อนต่างๆ ตลอดจนความพึงพอใจของพระสงฆ์ที่มารับการผ่าตัดศัลยกรรมกระดูก ศัลยกรรมทั่วไป และศัลยกรรมทางเดินปัสสาวะ ที่โรงพยาบาลสงฆ์

วิธีการ: การศึกษาผ่านคณะกรรมการจริยธรรมเพื่อการวิจัยของโรงพยาบาลสงฆ์ และได้รับการยินยอมจากผู้ป่วยทุกราย ได้ทำการศึกษาในช่วงเวลาตั้งแต่สิงหาคม พ.ศ. 2549 - ตุลาคม พ.ศ. 2550 ในพระสงฆ์จำนวน 91 ราย ซึ่งแบ่งสุ่มเป็น กลุ่มควบคุม (C) ใช้เข็มปลายตัด Quincke ขนาด 27 และกลุ่มศึกษา (S) ที่ใช้เข็ม Pajunk[®] ขนาด 25 ในการระงับความรู้สึกแบบฉีดยาชาเข้าช่องน้ำไขสันหลัง บันทึกจำนวนครั้งของการแทงเข็มจนได้น้ำไขสันหลัง และความสำเร็จ ในการระงับความรู้สึก สัมภาษณ์ผู้ป่วยหลังผ่าตัดทุกวันโดยผู้ร่วมศึกษาที่ไม่ทราบชนิดของเข็มที่ใช้

ผลการศึกษา: ความสำเร็จในการแทงเข็ม Quincke ครั้งแรก ร้อยละ 79 แต่ของเข็ม Pajunk[®] ร้อยละ 46 ซึ่งต่ำกว่าที่เคยรายงานไว้ อุบัติการณ์ภาวะแทรกซ้อนที่ไม่รุนแรงพบน้อย แม้จะมีผู้ป่วยเสียชีวิต 2 ราย แต่ไม่เกี่ยวข้องกับสาเหตุทางวิสัญญี และมากกว่าร้อยละ 80 ของผู้ป่วยทั้งสองกลุ่มยังต้องการวิธีระงับความรู้สึกแบบที่ได้รับ และศัลยแพทย์มีความพึงพอใจระดับดีถึงดีมาก

สรุป: เข็มฉีดยาชาเข้าช่องน้ำไขสันหลังปลายดินสอที่มีการออกแบบใหม่ เป็นตัวอย่างของการพัฒนาทางวิสัญญีให้ถึงระดับคุณภาพควรมีข้อบ่งชี้ในการใช้เข็มแบบนี้กับผู้ป่วยที่เสี่ยงต่อภาวะแทรกซ้อนที่เกี่ยวข้องกับการรั่วของน้ำไขสันหลัง เพื่อความปลอดภัยและความคุ้มค่า
