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Continuous spinal anaesthesia: A retrospective analysis of 318 cases

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ABSTRACT

Background and Aims: Continuous spinal anaesthesia (CSA) is an underutilised anaesthetic technique. Our objectives were to evaluate the use of CSA in our institution, its efficacy, ease to use and safety. Methods: This was a retrospective analysis conducted in a tertiary centre. Records of all patients who underwent surgery and received CSA between December 2008 and July 2017 were reviewed. Their demographic profiles, type and duration of surgery were analysed. The outcomes measured were the success of CSA, technical evaluation and difficulties encountered, intraoperative haemodynamics, usage of vasopressors and any reported complications. Statistical analysis was done using Chi-square test. Results: Three hundred and eighteen patients (94%) successfully underwent surgery using CSA. Twenty cases (6%) had failed CSA, of which five of them had CSA insertion failure, while the rest failed to complete the operation under CSA, thus requiring conversion to general anaesthesia. Patients who have had an initial intrathecal local anaesthetic (LA) volume ≥ 1.5 ml had higher odds (odds ratio (OR) 2.78; 95% confidence interval [CI], 1.70-4.57) of developing hypotension compared to those who had <1.5 ml (P < 0.001). There were no reported post-dural puncture headache, neurological seguelae or infection. Conclusion: CSA is a useful anaesthetic technique with low failure rate. The key to achieving haemodynamic stability is by giving a small initial bolus, then titrating the block up to required height using aliquots of 0.5 ml of intrathecal LA through the catheter.

Key words: Continuous spinal anaesthesia, haemodynamic stability, high-risk

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INTRODUCTION

Continuous spinal anaesthesia (CSA) is an under-utilized anaesthetic technique[1] suitable for surgeries of the lower extremity, perineum and lower abdomen. CSA has several advantages over a single-shot spinal anaesthesia (SSA) and continuous epidural anaesthesia (CEA), such as the ability to administer small, titrated and incremental doses of local anaesthetics (LA) through the catheter that may provide haemodynamic stability and the ability to achieve adequate level of dense block for indefinite duration.[1-3] Despite these advantages, CSA does not appear to be popular among anaesthesiologists as reflected by the paucity of references in the literature and it is usually reserved for fragile high-risk cases. Due to the lack of sales, one of the main manufacturers for CSA set had stopped producing Spinocath® (BBraun, Melsungen, Germany) worldwide since 2017.

CSA, when compared to SSA, can be technically challenging^[1,4] with failure of the technique (requiring conversion to general anaesthesia [GA]), difficulty in threading the catheter especially with the microcatheters (25–32 G), catheter kinking leading to inability to aspirate or administer the LA through the catheter. CSA potentially has a higher risk of post-dural puncture headache (PDPH)^[5-7] due to cerebrospinal fluid (CSF) leakage through the dural

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puncture and the use of larger bore needle. The development of microcatheters has significantly reduced the incidence of PDPH.^[5,7-9] Unfortunately, the use of spinal microcatheters has been associated with case reports of cauda equina syndrome^[10,11] leading to a further drop in popularity of the CSA. This resulted in lack of exposure and training among the younger anaesthesiologists.

We have had considerable numbers of CSA performed in our institution in the past 9 years. Our objectives were to evaluate the use of CSA, its efficacy, ease to use and safety over the above duration.

METHODS

This retrospective analysis was conducted with a waiver of informed consent approved by SingHealth Centralised Institutional Review Board [CRIB Ref: 2017/2663, https://research.singhealth.com.sg]. We adhered to the applicable STROBE statement checklist in the reporting of this manuscript.

Records of all patients who underwent surgery and received CSA between December 2008 and July 2017, in a non-obstetrics and gynaecology tertiary centre, were reviewed. Data collection source included patients' hospital electronic medical records and anaesthesia records. Patients' demographic profiles, American Society of Anesthesiologists (ASA) physical status, comorbidities and clinical outcome were retrieved from the hospital electronic records. Details of the CSA, performance parameters, type and duration of surgery, intraoperative haemodynamic status and the usage of vasopressors were obtained from the anaesthesia records.

We evaluated the success of the CSA and its performance details; observing lumbar interspace level, patient position during procedure, type of CSA set, number of attempts, technical difficulty (if present), initial intrathecal spinal LA volume and dose, additives to LA, subsequent intrathecal spinal top-up volume, dose and frequency. The success of CSA was defined as ability to complete the surgery with the anaesthetic technique without conversion to GA.

We also identified the problems associated with the failed CSA cases such as failure to insert the CSA catheter or failure to complete the surgery under the CSA technique, thus conversion to GA. The intraoperative haemodynamic status for the first

60 min after CSA was performed was evaluated and the usage of vasopressors was determined.

Patients' various comorbidities were further evaluated using Charlson comorbidity index, a validated scoring system. This scoring index contains 19 categories of comorbidity and predicts the 1- and 10-year mortality for a patient who has a range of comorbid conditions. [12] Mortality rate increased with increasing Charlson score. We also recorded the value of the left ventricular ejection fraction for those who had recent echocardiography (within the previous 6 months).

We analysed the initial intrathecal LA volume and incidence of hypotension in our study population, which we further categorised into low- (ASA I and II) and high-risk (ASA III and IV) groups. For the purpose of the study, hypotension was defined as a decrease in mean arterial pressure of >20% from the baseline value and required vasopressors.

We used 1.5 ml as the cut-off point for the initial intrathecal volume of bupivacaine 0.5% to distinguish the two subgroups: the first with initial intrathecal volume below 1.5 ml and the second with initial intrathecal volume 1.5 ml or more. This value was obtained from the prospective UK Anaesthesia Sprint Audit of Practice (ASAP-2).^[13]

Descriptive statistics for categorical data were presented as frequency and percentage. Numerical data were presented as median (interquartile range [IQR]) unless otherwise specified. Chi-square test was adopted for analysing the initial intrathecal spinal LA volume and incidence of hypotension in low- and high-risk group. We also calculated the odds ratio (OR), positive predictive value and negative predictive value (NPV) for the incidence of hypotension in the subgroup analysis. A predictive value of greater 70% was considered as clinically significant. A two-tailed, P value <0.05 was considered statistically significant. Statistical data analysis was performed with SPSS statistical software, version 19.0 (IBM Corp. Armonk, New York, NY).

RESULTS

Three hundred and thirty-eight patients underwent surgery using CSA during the study period [Table 1]. Of these, 217 (64%) were females. The median age (IQR) of the patients was 77 (67–84) years. More than 70%

of patients were ASA III and IV, and most patients underwent orthopaedic surgeries (89.6%), especially hip surgeries. The median duration of surgery (IQR) of the patients was 105 (75–135) min. The duration of surgery was measured from the time of surgical incision until the end of surgery (the last surgical stitch). This excluded the time taken to position, and to clean and drape the patient, which often take more than 30 min in most cases.

Most patients had multiple comorbidities. As assessed by the Charlson comorbidity index, the median score is 5 (IQR 3–6). The score indicates high risk of 1-year mortality. The most common comorbidities

Table 1: Patient and su	rgical characteristics
Age, years	
Median (IQR)	77 (67-84)
Gender, n (%)	
Male/Female	121 (35.8)/217 (64.2)
BMI kg/m ²	
Median (IQR)	24.4 (21.2-29.2)
ASA physical status, n (%)	
I/II/III/IV	2 (0.6)/99 (29.3)/209 (61.8)/28 (8.3)
Charlson Comorbidity Index	
Median (IQR)	5 (3-6)
Comorbidities, n (%)*	
IHD	92 (27.2)
CCF	19 (5.6)
Hypertension	254 (75.1)
Diabetes mellitus	107 (31.7)
Chronic pulmonary disease	41 (12.1)
CVA	68 (20.2)
Dementia	61 (18.0)
CKD, CKD III-V	58 (17.2)
Discipline, n (%)	
Orthopaedic/Vascular/Surgical/ Urology	303 (89.6)/4 (1.2)/13 (3.8)/18 (5.3)
Type of surgery, n (%)	
Lower abdomen	11 (3.2)
Pelvic (include perineal, TURP)	21 (6.2)
Hip	205 (60.7)
Femur (includes AKA)	29 (8.6)
Knee	63 (18.6)
Leg (includes BKA)	8 (2.4)
Foot	1 (0.3)
Duration of surgery, minute [†]	
Median (IQR)	105 (75-135)

*We only list some of the most common comorbidities from the Charlson comorbidity index list; 2 cases had moderate-to-severe aortic stenosis; One hundred and sixteen patients had recent transthoracic echocardiography (performed within the last 6 months) or during the current hospital admission; 95 (28%) had preserved left ventricular function (ejection fraction ≥50%), average ejection fraction=55±12% and lowest ejection fraction 15% *Only those cases with successful CSA were included. TURP − Transurethral resection of prostate; AKA − Above knee amputation; BKA − Below knee amputation; CSA − Continuous spinal anaesthesia; SD − Standard deviation; ASA − American Society of Anesthesiologists; IHD − Ischaemic heart disease; CCF − Congestive cardiac failure; CVA − Cerebrovascular accident; CKD − Chronic kidney disease; IQR − Interquartile range; BMI − Body mass index

are hypertension (75%), diabetes mellitus (32%), ischaemic heart disease (27%), cerebrovascular accident (20%), dementia (18%), moderate or severe kidney disease (17%), chronic pulmonary disease (12.1%) and congestive cardiac failure (6%). One hundred and sixteen patients had recent transthoracic echocardiography (performed within the last 6 months) or during the current hospital admission [Table 1]. Most of them had preserved left ventricular function (mean ejection fraction $55 \pm 12\%$).

Ninety-four per cent (318) successfully underwent surgery with CSA [Table 2]. Only 20 cases (6%) had failed CSA. Most CSAs were inserted at L3L4 lumbar interspace level (61%), in the lateral decubitus position (87%), and using the Intralong CSA set with Sprotte® special cannula (Pajunk, Geisengen, Germany) (91.4%).

Table 3 shows median initial intrathecal LA volume and dose was 1.5 ml bupivacaine 0.5% (7.5 mg). Majority used plain bupivacaine (95%) and additive fentanyl in the spinal solution. The median (IQR) fentanyl dose was 10 (10–15) mcg. Seventy-two cases did not require top-up during the surgery. As for the cases that required subsequent top-up through the catheter, the average top-up volume per bolus was 0.5 ml bupivacaine 0.5% (2.5 mg) and the median (IQR) frequency of top-up was 2 (1–3) depending on the duration of surgery.

Table 3 and Figure 1 showed patients who had initial intrathecal volume 1.5 ml or more were 2.78

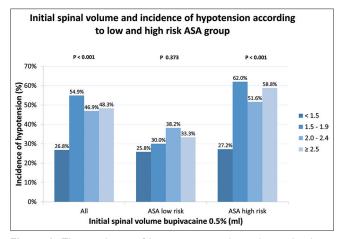


Figure 1: The incidence of hypotension and initial spinal volume by low- and high risk There was a trend of increasing incidence of hypotension for initial spinal volume of 1.5 ml and above in both low- and high-risk groups. This trend was statistically significant in the high-risk group as well as in the total study population (P < 0.001)

(OR; 95% confidence interval [CI] 1.70–4.57) times more likely to have hypotension as compared to those who had less than volume 1.5 ml (P < 0.001). The evidence was strongest in the high-risk group, OR 3.60 (95% CI, 2.00–6.48; P < 0.001). The NPV was good, 73.2% for the overall group. From further analysis, we found none of our patients had incidence of hypotension with initial intrathecal LA volume of 0.5 and 0.8 ml.

These hypotensive episodes were transient and reversible. There was no reported intra-operative severe hypotension that required administration of adrenaline, noradrenaline or dopamine. There was no patient who suffered from cardiovascular collapse.

Table 2: Continuous spinal anaesthesia performance				
CSA success, n (%)				
Success	318 (94)			
Failed	20 (6)			
Failure to insert CSA (n=5)				
Failure to complete the operation				
using CSA technique which required				
conversion to general anaesthesia *(n=15)				
Lumbar interspace, <i>n</i> (%) [†]				
L2L3/L3L4/L4L5	7 (2.1)/208 (61.4)/91			
L2L3/L3L4/L4L3	(26.8)			
Position, n (%) [†]	(/			
Sitting/Lateral	38 (11.2)/295 (87.3)			
Type of CSA set, n (%) [†]	, , , ,			
Pajunk Intralong/BBraun Tuohy Epidural	309 (91.4)/24 (7.1)			
Number of attempts, n^{\dagger}	, , , ,			
Median (IQR)	1 (1-2)			
Initial spinal				
Volume (bupivacaine 0.5%, ml [‡]),	1.5 (1.0-2.0)			
median (IQR)				
Dose (bupivacaine 0.5%, mg [‡]),	7.5 (5.0-10.0)			
median (IQR)	00/000/0			
Additive (nil/fentanyl/morphine), n	38/283/8			
Fentanyl dose (mcg), median (IQR)	10 (10-15)			
Subsequent top up via catheter	0.00 (0.5.4.4)			
Total volume (bupivacaine 0.5%, ml), median (IQR)	0.80 (0.5-1.1)			
Total dose (bupivacaine 0.5%, mg),	4.0 (2.5-5.5)			
median (IQR)	4.0 (2.0-0.0)			
Successful CSA placement but no top-up	72			
required				
Frequency of top-up, median (IQR)	2 (1-3)			
Average top-up volume per	0.4			
bolus (bupivacaine 0.5%, ml)				
Average top-up dose per	2.0			
bolus (bupivacaine 0.5%, mg)				

^{*}Among the failure to complete the operation using CSA technique, thus requiring conversion to general anaesthesia – eight cases experienced pain, inadequate anaesthesia despite able to top-up via catheter, seven cases experienced catheter kinked, unable to aspirate or bolus and operation extended beyond the initial spinal effect; *Excludes cases with failure to insert CSA. *Only 18 cases (5.3%) used hyperbaric bupivacaine. IQR – Interquartile range; CSA – Continuous spinal anaesthesia

The median dose of ephedrine used was 12 mg with IQR from 9.75 to 20 mg. The median dose of phenylephrine used was 400 mcg with IQR from 200 to 700 mcg. Overall, CSA provided stable haemodynamic throughout the operation despite the incidence of transient hypotension which was correctible with vasopressors [Figure 2].

There were a total of 20 cases (6%) of failed CSA [Table 2]. Five cases had failure to insert the CSA catheter while 15 cases failed to complete the operation solely under CSA and had to be converted to GA. Of the 15 cases that had to be converted to GA, 8 cases experienced inadequate anaesthesia despite LA bolus top-ups via the catheters, while the other 7 cases had complete catheter occlusion.

None of the patients who underwent surgery with CSA, including those in the failed CSA group experienced serious post-operative complication related to neuraxial anaesthesia. Only one patient had low back pain which resolved during the hospital stay. There were no reported PDPH, catheter breakage during removal, infection, or any neurological sequelae like nerve injury and cauda equina syndrome.

DISCUSSION

This study shows that CSA is a useful anaesthetic technique for various types of surgery. The failure rate was low (6%) and is comparable with many previous studies [Table 4]. The failure rate for the procedure may vary from institution to institution. Most data

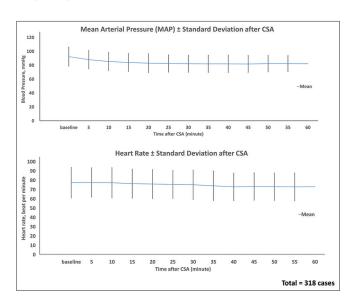


Figure 2: Changes of mean arterial pressure and heart rate from induction of continuous spinal anaesthesia to 1 h after

Table 3: Initial intrathecal volume and incidence of hypotension								
Initial intrathecal volume, bupivacaine 0.5%	% Hypotension, n (%)		Remarks					
	No	Yes						
Total group, n=328								
<1.5 ml	82 (73.2)	30 (26.8)	PPV 50.5%; NPV 73.2%; OR 2.78 (95% CI 1.70-4.57); *P<0.001					
≥1.5 ml	107 (49.5)	109 (50.5)						
Low-risk group (ASA I and II), n=97								
<1.5 ml	23 (74.2)	8 (25.8)	PPV 34.8%; NPV 74.2%; OR 1.54 (95% CI 0.59-3.98); *P=0.373					
≥1.5 ml	43 (65.2)	23 (34.8)						
High risk group (ASA III and IV), n=231								
<1.5 ml	59 (72.8)	22 (27.2)	PPV 57.3%; NPV 72.8%; OR 3.60 (95% CI 2.00-6.48); *P<0.001					
≥1.5 ml	64 (42.7)	86 (57.3)						

*Chi-square test. Hypotension was defined as decreased in MAP >20% from baseline value and required vasopressors; vasopressors dose administered throughout operation duration – Ephedrine (mg), median (IQR), 12 (9.75–20); phenylephrine (mcg), median (IQR), 400 (200–700). PPV – Positive predictive value; NPV – Negative predictive value; OR – Odds ratio; CI – Confidence interval; MAP – Mean arterial pressure; IQR – Interquartile range; ASA – American Society of Anesthesiologists

Table 4: Failure rate of continuous spinal anaesthesia								
Study (year)	Sample size Catheter (ga)		Failure (%)	Study design				
Beh et al. (2018)	338	25	6	Retrospective				
Aksoy et al. (2014)[14]	38	22	7.9	Prospective				
Horlocker <i>et al.</i> (1997) ^[15]	127	28	3.9	Retrospective				
	476	20-474 cases; 24-2 cases	3.2					
Van Gessel et al. (1995)[16]	100	20	6	Prospective				
Petros et al. (1993)[17]	90	28	4.4	Prospective				
Mahisekar <i>et al.</i> (1991)[18]	226	20	4	Retrospective				
Sutter et al. (1989)[19]	457	20	1.7	Retrospective				
Denny et al. (1987)[7]	117	20	5.1	Prospective				

in Table 4 were old studies, which visibly reflect the paucity of new data and lacking popularity of CSA over the years. The utilisation rate of CSA technique in our institution remained the same over the past 9 years and on average 40 patients would require surgery using CSA annually. We understand that some institutions rarely use CSA and Spinocath® (BBraun, Melsungen, Germany) has been discontinued from the market.

In our institution, CSA has been successfully used for various types of surgery including abdominal, urological, peripheral vascular and lower extremity operations [Table 1]. The majority of patients selected for CSA techniques were high risk, elderly, multiple comorbidities and ASA class III and IV. The demographic profiles were fairly similar to other studies.[15,17,19,20] Charlson comorbidity scoring index contains 19 categories of comorbidity and predicts the 1-year mortality for a patient who has a range of comorbid conditions.[12] This scoring index has been widely cited by nearly 3000 papers till date describing various comorbidities and mortality risk. Mortality rate increased with increasing Charlson score (12): none (0), 7% (95% CI, 5.4–8.5%); low (1–2), 22% (95% CI, 19-24%); moderate (3-4), 31% (95% CI, 26.8-34.7%); and high (≥ 5), 40% (95% CI, 35.5–43.8%). Our study population had median Charlson score of 5, which indicates high risk.

A review of the literature has shown that CSA has been successfully used in various types of major surgeries involving high-risk patients. Examples include one patient with congestive heart failure and hypertension who underwent femoral-femoral bypass under CSA[21] and the CSA being used in patients with severe aortic stenosis undergoing lower extremity surgery.[22-24] CSA may obviate the complications associated with GA and positive pressure ventilation in patients with severe respiratory problem.^[25] Sixty-eight high-risk patients underwent abdominal surgeries under CSA.[26] Our study population had considerable number of high-risk cases and they successfully underwent surgery with CSA. A recent systematic review^[27] advocated the use of regional anaesthesia whenever possible, especially in patients susceptible to developing post-operative cognitive dysfunction, [28,29] for example, the elderly, dementia, stroke and chronic renal failure.

Some studies utilised the spinal catheter for post-operative analgesia for abdominal, vascular and hip surgery^[20,30] but this was not practiced in our institution and all catheters were removed at the end

of surgery. CSA has also been used in parturient and it has also been shown to be highly useful in many obstetric situations^[31,32] such as previous spinal surgery, significant cardiac disease, morbid obesity, difficult airway and difficult epidural catheter placement.

In our study, most CSAs were inserted at the L3L4 lumbar interspace level (61%) and with the patients in lateral decubitus position (87%); these findings were similarly demonstrated in other studies. [16,33] The median number of attempts was one time and this may reflect the technical ease of performing this procedure and contradict the common misconception about the difficulty of performing CSA. The most commonly used CSA set was Intralong (Pajunk, Geisingen, Germany), 91.4%, which is a catheter-through-needle set that comes with 22G Sprotte needle and 25G nylon catheter. Some used Tuohy epidural set (BBraun, Melsungen, Germany) (8.6%) for CSA which has 18G Tuohy needle and 20G nylon catheter. Both sets had been described in other studies using CSA. [33-35]

CSA using small titrated dose provides better haemodynamic stability than SSA^[36,37] and CEA^[38] in elderly patients. A study^[39] reported that CSA had better intraoperative blood pressure control than GA using propofol TCI or sevoflurane in elderly patients with cardiac comorbidities. Our study showed that CSA indeed provides haemodynamic stability [Figure 2]. Although transient hypotension occurred, it was easily reversed with vasopressors without any major adverse event reported.

To ensure haemodynamic stability in patients with the CSA, it is important to administer intrathecal LA in small aliquots. The prospective UK ASAP-2 study[13] showed a significant correlation between hypotension, mortality and dose of intrathecal LA. That study proposed that the dose of intrathecal LA should be decreased to the lowest possible, which may potentially reduce mortality for high-risk and elderly patients. They concluded that intrathecal dose of bupivacaine 0.5% should be reduced "towards 1.5 ml". Our study supported the use of lower spinal volume, especially in fragile, elderly patient. We found that none of our patients had incidence of hypotension with initial intrathecal volumes of 0.5 and 0.8 ml. With an intrathecal catheter, small aliquots of intrathecal LA could be administered at intervals to achieve adequate level of block; it would also allow regular intrathecal LA administration to extend the intrathecal anaesthesia in case the surgery is prolonged. Another study^[37] showed that CSA produced fewer episodes of hypotension and severe hypotension than single injection small-dose isobaric bupivacaine (7.5 mg) for surgical repair of hip fracture in elderly patients.

A total of 20 cases (6%) had failed CSA, where 5 of them (1.5%) had failure to insert the CSA catheter (unable to thread the catheter) while others failed to complete the operation under CSA technique and required conversion to GA [Table 2]. The incidences of inability to thread the CSA as reported in other studies were De Andres^[33] (3%), Hurley^[8] (10%) and Silvanto^[40] (25%). Our study had a relatively lower failure rate due to inability to thread the catheter. Difficulty in threading the catheter can be due to inserting the needle too far, making the catheter impossible to bend at the anterior wall of the dura mater.[41] One should try to slightly withdraw the needle, maintain good CSF flow and re-attempt threading the catheter. After the catheter tip leaves the needle, the catheter should be advanced only 2-3 cm to avoid coiling, possible damage of the nerve roots or mal-positioning. [42,43] Other common catheter problems include catheter kinking and blockage leading to the inability to aspirate or inject LA via the CSA catheter. Such incident is prone to occur with the microcatheter due to its small size and flimsiness. We tried to reduce these problems by ensuring that the CSA catheters are secured and taped carefully.

None of our patients suffered from significant complications like severe neurological complications, spinal infections and PDPH. There were case reports of cauda equina syndrome after CSA technique with microcatheters.[10,11] Subsequent evidences showed that cauda equina syndrome was not caused by the microcatheter itself, but instead by high concentration and maldistribution of LA.[10,11,44-46] The risk of infection with spinal catheters is low. A large retrospective review^[15] of 603 continuous spinal anaesthetics reported only one case of aseptic meningitis. We had no reported PDPH. The use of smaller bore pencil point Sprotte needle, microcatheter and elderly population could explain the low incidence. The PDPH rates as reported in other studies using CSA with microcatheters on elderly population were Standl^[9] (1%), Kumar^[26] (5.6%) and Lux^[2] (1.5%). Obstetrics populations are at higher risk of PDPH than the general population, with reported incidences[31,32,47] of 29-33%.

Another problem with CSA was catheter breakage during removal, especially with the microcatheters.

This was reported in several studies: Petros^[17] (1 case) and Hurley^[8] (3.4%). None of our patients had CSA catheter breakage, and this could be due to our practice of removing the CSA catheter with the patient's spine in a flexed position, and the slow removal of the catheter. We also advocate that the CSA catheter should be pulled out as close to its insertion point as possible, so as not to overstretch and break the CSA catheter. An experimental study^[48] tried comparing the mechanical properties of microcatheters between BBraun Spinocath, Pajunk Intralong and Portex Microcatheter system and found that Spinocath 22G had the highest maximal tensile strength, which was defined as the force applied before rupture of the catheter. However, Pajunk 25G and 27G showed the highest distensibility values, meaning the catheters can be extended nearly four to sixfold the initial length at room temperature before they rupture.

The main weakness of this study was principally the retrospective data collection. Consequently, some of the analysed variables were incomplete or missing. We did not evaluate the level of anaesthesia achieved with the spinal volume administered.

CONCLUSION

Our study showed that CSA is a useful anaesthetic technique with low failure rate. It is not as technically difficult as many may previously perceive. The median number of attempts is 1 and the incidence of failure to thread the catheter is very low (1.5%). The key to achieving haemodynamic stability is by giving a small initial bolus, then titrating the block up to required height using aliquots of 0.5 ml of intrathecal LA through the catheter. No major complications reported.

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Conflicts of interest

There are no conflicts of interest.

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