

Development of a difficulty score for spinal anaesthesia

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Background. Multiple attempts at spinal puncture may be hazardous. Accurate preoperative prediction of difficulty adds to the delivery of high quality care. This clinical trial was designed to: (i) determine the predictive performance of difficulty variables; (ii) compare senior and junior anaesthetists; (iii) develop a score to predict difficulty during the performance of spinal anaesthesia.

Methods. A total of 300 patients subjected to urological procedures and scheduled for spinal anaesthesia were independently assessed and stratified according to the categories of the difficulty predictors of spinal anaesthesia into one of nine grades (0–8) and randomized according to the experience of the anaesthetist into two groups (group A, staff with more than 15 yrs' experience; group B, resident with more than 6 months but less than 1 yr in training). The number of attempts and levels, and success rate of the technique were the outcome variables. Data were analysed by multivariate analysis and receiver operating characteristic (ROC) curves.

Results. The bony landmarks of the back and the radiological characteristics of the lumbar vertebrae were two independent predictors of difficulty. Multivariate analysis indicated differences between junior and senior staff but ROC curves indicated no difference. Grade 4 was the difficulty score at or above which difficulty was expected whether or not radiological characteristics of the vertebrae were included.

Conclusions. Spinal bony landmarks and radiological characteristics of the lumbar vertebrae are independent predictors of difficulty during spinal anaesthesia. There is no difference between senior and junior anaesthetists. Grade 4 is the difficulty score at or above which difficulty is expected.

Br J Anaesth 2004; **92**: 354–60

Keywords: anaesthetic techniques, subarachnoid

Accepted for publication: October 30, 2003

Spinal anaesthesia is still widely used for many surgical and endoscopic procedures. Multiple attempts at needle placement may cause patient discomfort, higher incidence of spinal haematoma,^{1,2} postdural puncture headache^{3,4} and trauma to neural structures.⁵

Accurate preoperative prediction of potential difficulty can help reduce the incidence of multiple attempts, rendering the technique more acceptable and less risky to the patient. The quality of bony landmarks of the back is an independent difficulty predictor, while the significance of the anaesthetist's level of experience is still unsettled.^{6,7} An objective scoring system might serve as a reproducible quantitative measure of the expected difficulty. This clinical study was designed to: (i) determine the predictive performance of the expected difficulty variables; (ii)

compare senior and junior anaesthetists; (iii) develop a simple, accurate and easy applicable difficulty score.

Methods

Study population

This was a prospective randomized study approved by the hospital research ethics committee and written consents were obtained. The study population included 300 patients undergoing urological procedures. Exclusion criteria were patients with neurological disease or coagulation defects, patients medicated with anticoagulation and patients refusing spinal anaesthesia. Preoperative examination and

routine laboratory and radiographic investigations were completed.

Development of preoperative difficulty score

The preoperative difficulty score for spinal anaesthesia was designed using patient characteristics familiar to the clinicians to make it easily applicable before anaesthesia. The rationale behind the definition of each difficulty category is based on general and accepted knowledge of spinal anaesthesia. For example, the subjective estimation of difficulty is increased in overweight adult patients. This will be greater in elderly obese patient, and even more when lumbar vertebral spinous processes are difficult to palpate. The difficulty categories are shown in Table 1. Age, BMI and spinal bony deformities are totally objective variables. Kyphosis, scoliosis and lordosis were considered as spinal bony deformities. The assessment of the quality of spinal bony landmarks is purely subjective. To avoid bias, this examination was performed separately before surgery by the senior investigator (MMA). The spinous processes of the lumbar vertebrae were assigned as clear and easily palpable, or unclear and difficult to palpate. The radiographic findings of the lumbar vertebrae, performed routinely in urological practice in our hospital, were categorized as in the difficulty score. The presence of osteophytes, ligament calcification or narrow intervertebral spaces were considered difficulty characteristics.

Information gained from preoperative multifactorial difficulty variables gave a score for each patient (Table 1). The scores of all patients were stratified into a wide range of scores (nine levels: 0–8).

Spinal anaesthesia

Patients were randomly allocated, through computer-generated numbers, into two groups. For group A, the anaesthetist had more than 15 yrs' experience; for group B spinal anaesthesia was provided by a resident in training for more than 6 months and less than 1 yr. Spinal anaesthesia is frequently performed in our centre. A resident usually performs approximately five spinal punctures daily. In both groups, spinal puncture was performed with the patient in the sitting position, using a 22G spinal needle and

after establishing the free flow of crystalloid solution in one arm vein. When spinal anaesthesia was complete, patients were laid supine and midazolam 1–3 mg was given.

Outcomes

The difficulty encountered in performing the spinal puncture was evaluated by three variables. First, the number of attempts required for successful needle placement at the initial spinal level. Each new skin puncture was considered another attempt. However, redirecting the needle without a new skin puncture was not considered an additional attempt. Second, the number of spinal levels before completing the puncture. Two levels only were allowed for the resident, after which the senior staff member had to take over and was allowed two more attempts. If they failed, the senior investigator had to complete the puncture. Third, the success or failure of spinal anaesthesia was recorded. Anaesthesia was considered complete and successful if the urological procedure was completed without any analgesic or anaesthetic supplementation.

Statistical analysis

The power of this clinical trial was retrospectively calculated using the GPower analysis program.⁸ Using *post-hoc* power analysis with accuracy mode calculations and assuming type-I error protection of 0.05 and medium effect size convention of 0.3, a total sample size of 300 patients produced a power of 0.99.

Patient characteristics are presented as mean (SD) and range, and were analysed by paired Student's *t*-test. The association between patient predictive difficulty variables and the selected outcome variables was determined by univariate analysis using the Pearson χ^2 goodness-of-fit test. Predictive difficulty variables that were significant with univariate analysis were subjected to logistic multivariate stepwise regression analysis for the determination of preoperative difficulty variables that had an independent impact on the outcome variables.

Predictive accuracy was assessed for all predictive difficulty scores by building receiver operating characteristic (ROC) curves for the outcome variables using the statistical program Accu ROC for windows 95/98/NT version 2.4 (Accumetric corporation, Montreal, Canada). Accu ROC uses non-parametric methods,^{9–11} based on the Mann–Whitney *U*-test: to calculate the area under the ROC curve (AUC), its standard error (SE) and an estimate of its normal symmetric 95% confidence intervals; compare ROC curves from independent samples; and calculate other measures of test performance at all grades with 95% confidence intervals. AUC values of 0.5–0.7 suggest low accuracy and values greater than 0.7 confirm the usefulness of the difficulty classification as a difficulty predictor.¹² In all calculations, $P < 0.05$ was the significance level.

Table 1 Scoring the categories of the difficulty variables. The spinous processes of the lumbar vertebrae were assigned as easy palpable (clear) or difficult to palpate (unclear); spinal bony deformities included kyphosis, scoliosis and lordosis. Difficult radiological characteristics included osteophytes, ligament calcification or narrow intervertebral spaces

	0	1	2	3
Age (yr)	20–40	41–60	>60	
BMI (kg m ⁻²)	<22	22–27	>27–34	>34
Spinal bony landmarks	Clear	Unclear		
Spinal bony deformity	No	Yes		
Radiological characteristics of lumbar vertebrae	Easy	Difficult		

Results

Study population

The characteristics of the patients in both groups and the total study population are shown in Table 2. Both groups were comparable, with no statistical differences between them.

Difficulty predictors

In group A, the anaesthetist required more than one attempt in 12.7% of cases and more than one level in 2.7%, but was able to complete all cases with success. The respective values in group B were 24.7% and 14.7% ($P=0.008$ and $P=0.0002$ respectively), and inability to complete 12 cases.

Univariate analysis of the difficulty predictors revealed that BMI, spinal bony landmarks and deformity, radiological characteristics of the lumbar vertebrae and the experience of the provider had significant impact on outcome variables. The results of the logistic multivariate stepwise regression analysis of these difficulty predictors are shown in Table 3. Two predictors only (spinal bony landmarks and radiological characteristics of the lumbar vertebrae) had a significant impact on attempts, levels and success of the spinal analgesia, while the experience of the anaesthetist had a significant impact only on the number of attempts and levels.

Table 2 Patient characteristics. Data are mean (range) or mean (SD). There were no significant differences between the groups

	Group A (<i>n</i> =150)	Group B (<i>n</i> =150)	Total (<i>n</i> =300)
Age (yr)	53 (23–83)	52 (20–80)	53 (20–83)
Sex (M/F)	124/26	113/37	237/63
Weight (kg)	78 (15)	80 (16)	79 (16)
Height (cm)	168 (7)	168 (6)	168 (7)
BMI (kg m ⁻²)	27.8 (5.6) (18.8–47.7)	28.6 (5.6) (15.4–44.8)	28.2 (6.0) (15.4–47.7)

Table 3 Logistic multivariate stepwise regression analysis of difficulty predictors

	Regression estimate (B)	Standard error	Exp (B)	<i>P</i> value
Attempts				
Bony landmarks	1.9365	0.3927	6.9342	0.0000
Radiological characteristics	1.0536	0.3464	2.8678	0.0024
Randomization (staff/resident)	1.1288	0.3555	3.0920	0.0015
Levels				
Bony landmarks	1.4831	0.5092	4.4065	0.0036
Radiological characteristics	1.1977	0.4728	3.3125	0.0113
Randomization (staff/resident)	2.0999	0.5865	8.1654	0.0003
Complete				
Bony landmarks	1.9566	0.7073	0.70750	0.0057
Radiological characteristics	1.8011	0.7510	6.0561	0.0165
Randomization (staff/resident)	9.9414	33.0566	20773.04	0.7636

Experience of the anaesthetist

The providers of the spinal anaesthesia in both groups, whether staff or resident, had comparable AUC values. For the number of trials, the AUC values were 0.7656 (SE 0.0478) and 0.7088 (0.0550) for groups A and B, respectively, with no significant difference (Fig. 1). The respective AUC values for the number of levels were 0.7038 (0.1069) and 0.6880 (0.0718) ($P=0.9023$) (Fig. 1). With all difficulty predictors, the AUC for trials, levels and success for the whole study population were 0.7235 (0.0396), 0.6816 (0.0619) and 0.7807 (0.0802), respectively.

Determining the difficulty score

The summation of the difficulty predictors in each patient gave the difficulty score. The statistical program Accu ROC stratifies patients according to their difficulty score into nine grades (0–8). It is necessary to determine the appropriate grade at which the true difficulty rate is nearly equal to the true easy rate, above which difficulty is expected. This was performed by exploring the computed other measures of ROC test performance for the three middle grades (3, 4 and 5) in the easy–difficulty score for the three outcome variables of the whole study population (Fig. 2). In this figure, we compared the other measures of ROC test performance for grade 4 with the grade above (grade 5) and the grade below (grade 3) to determine the appropriate grade comparable with a balance between the true difficulty rate and the true easy rate. Below grade 3 and above grade 5 there was a total imbalance between the true difficulty and true easy rates. It became evident that grade 4 is the score value at or above which the score is indicative of difficulty. The rationale for this choice is multivariate. The true difficulty rate (sensitivity) and the true easy rate (specificity) are nearly equal at that grade and include 60–75% of the study population. The false difficulty proportion and the false easy proportion are nearly equal at grade 4 and comprise nearly one third of the study cases. At this grade the difficulty score correctly classified two thirds of the study subjects. The likelihood ratio of a difficulty score is

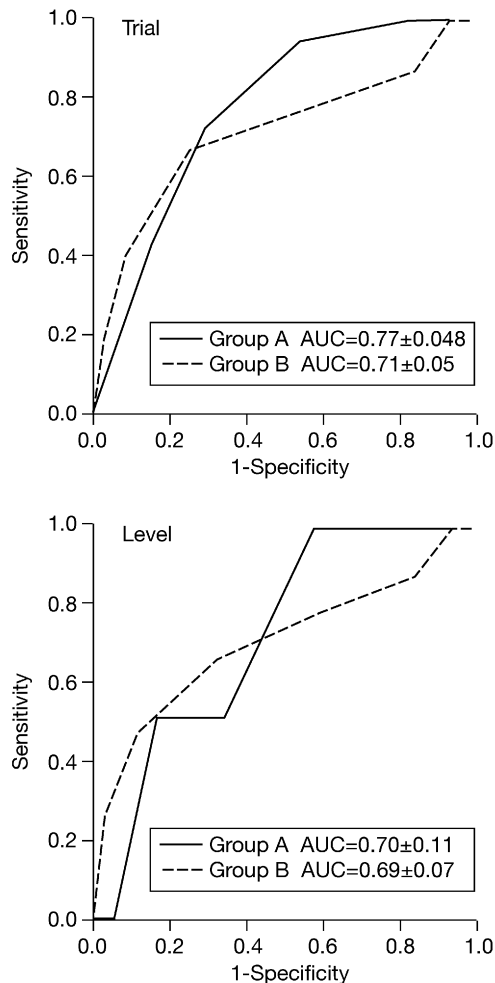


Fig 1 Receiver operating characteristic curves obtained with each group for prediction of more than one attempt (Trial) and more than one level (Level) ($n=150$ patients in each group). AUC=area under the curve.

quite a few times more frequent than the likelihood ratio of the easy score. The predictive value of a difficulty score is low while the predictive value of an easy score is high.

Determining difficulty score without radiological characteristics

Lumbar vertebrae radiology is not routinely available in most cases suitable for spinal anaesthesia. Consequently, we determined the difficulty score without the radiological criteria of the lumbar vertebrae. Grade 4 was still the difficulty score at or above which the score is indicative of difficulty. This is justified by the data elicited from other measurements of ROC test performance for the whole study population (Fig. 3). The true difficulty rate is 0.67 and the true easy rate is 0.72. The false difficulty proportion and the false easy proportion are 0.28 and 0.33, respectively. The correct classification and misclassification proportions are 0.72 and 0.28, respectively. The likelihood ratio of a difficulty score is more than five times that of the easy score.

Discussion

This clinical trial has demonstrated that the spinal bony landmarks and the radiological characteristics of the lumbar vertebrae are two independent predictors of difficulty during spinal anaesthesia. Considering all difficulty predictors of spinal anaesthesia, there is no significant difference between senior and junior anaesthetists. Calculating the difficulty score before spinal anaesthesia, grade 4 is the value at or above which the score is indicative of difficulty, calculated with or without the lumbar vertebral radiological characteristics.

The experienced practitioner develops the tactile sense of needle advancement and completes spinal anaesthesia in a smooth, rapid and effective manner. However, patient characteristics and the anaesthetist's level of experience may culminate in multiple attempts at more than one level, rendering the technique unpleasant to the patient and occasionally with dangerous complications. Neurological complications following neuraxial anaesthesia, leading to temporary or permanent disability have recently been reviewed.¹³ Spinal epidural haematoma,^{14–16} although very rare, caused the US Food and Drug Administration to issue a warning in 1997.¹⁷ Epidural abscesses following neuraxial anaesthesia continue to be reported.^{18,19}

Patient characteristics mostly determine the difficulty during spinal puncture. Patient characteristics have been described as difficulty predictors.^{6,7} Spinal bony landmarks were the only independent predictor of difficulty. In this study, spinal bony landmarks and radiological characteristics of the lumbar vertebrae were the only two independent predictors of difficulty during spinal puncture.

The anaesthetist's level of experience has been evaluated as a predictor of difficulty during spinal puncture. In a study comparing staff/fellow anaesthetists, certified nurse anaesthetists and anaesthesia trainees,⁶ the provider's level of experience had no effect. In another study comparing residents in training with anaesthetists of varying clinical experience,⁷ the provider's level of experience was an independent predictor. In our study, multivariate analysis of difficulty predictors revealed a significant difference between senior and junior providers in the number of trials and levels but there was no significant difference in completing spinal anaesthesia. When the areas under the ROC curves were compared, there was no significant difference between senior and junior providers in either the number of trials or the number of levels. The explanation of this is complex. Multivariate analysis is a collection of techniques appropriate for the situation in which each individual provides observations simultaneously on several variables, and the random variation in these variables has to be studied simultaneously.²⁰ The application of this method will only have produced a useful reduction in the dimensionality of the data if the components have an interpretation that appears to represent some meaningful characteristics. The ROC analysis uses non-parametric

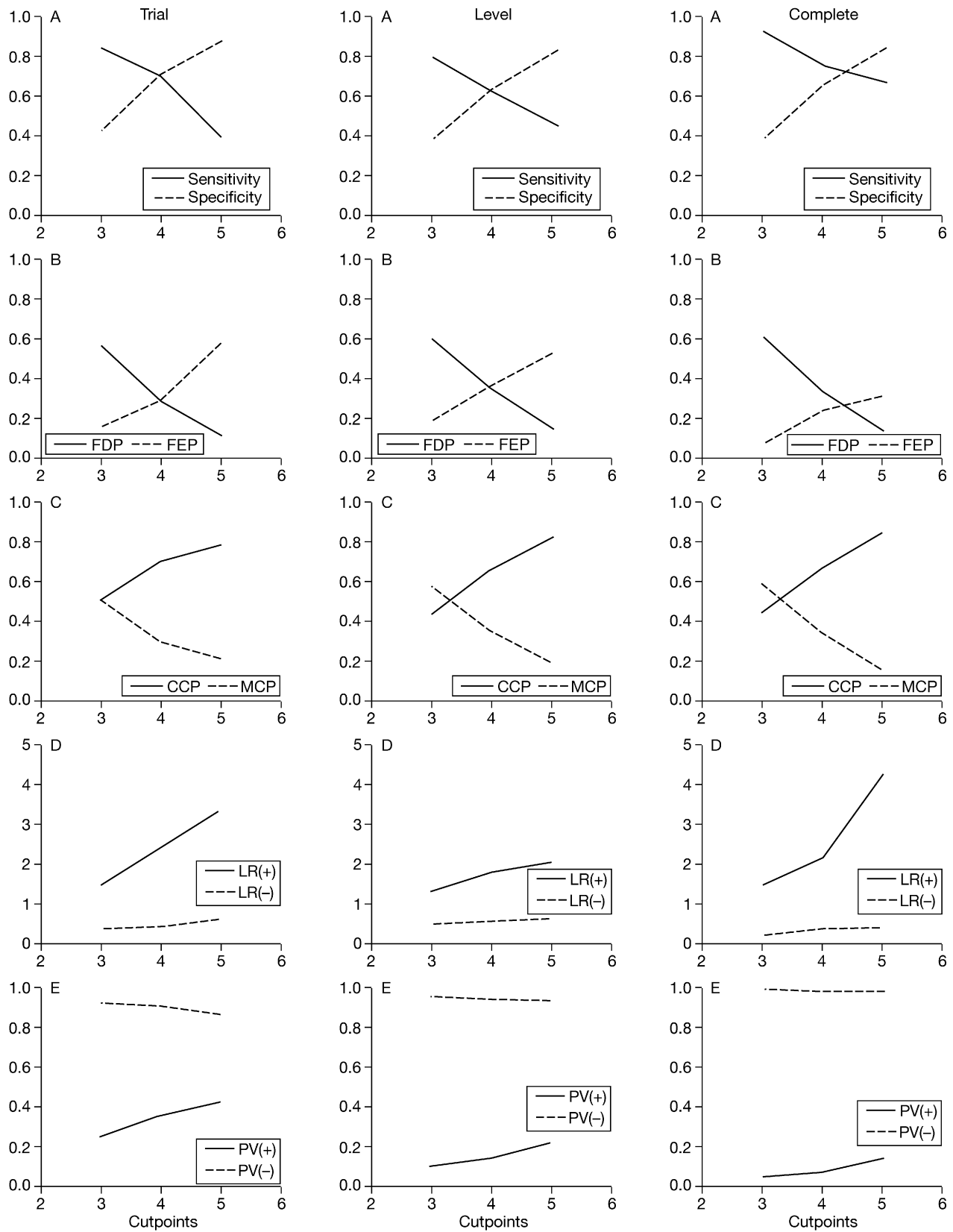


Fig 2 Measurements of the difficulty score performance calculated for more than one attempt (Trial) more than one level (Level), and for the completeness (Complete) of spinal anaesthesia at the difficulty grades 3, 4 and 5 using all difficulty predictors ($n=300$ patients). FDP=false difficulty proportion; FEP=false easy proportion; CCP=correct classification proportion; MCP=misclassification proportion; LR(+)=likelihood ratio of a difficulty score; LR(-)=likelihood ratio of an easy score; PV(+)=predictive value of a difficulty score; PV(-)=predictive value of an easy score.

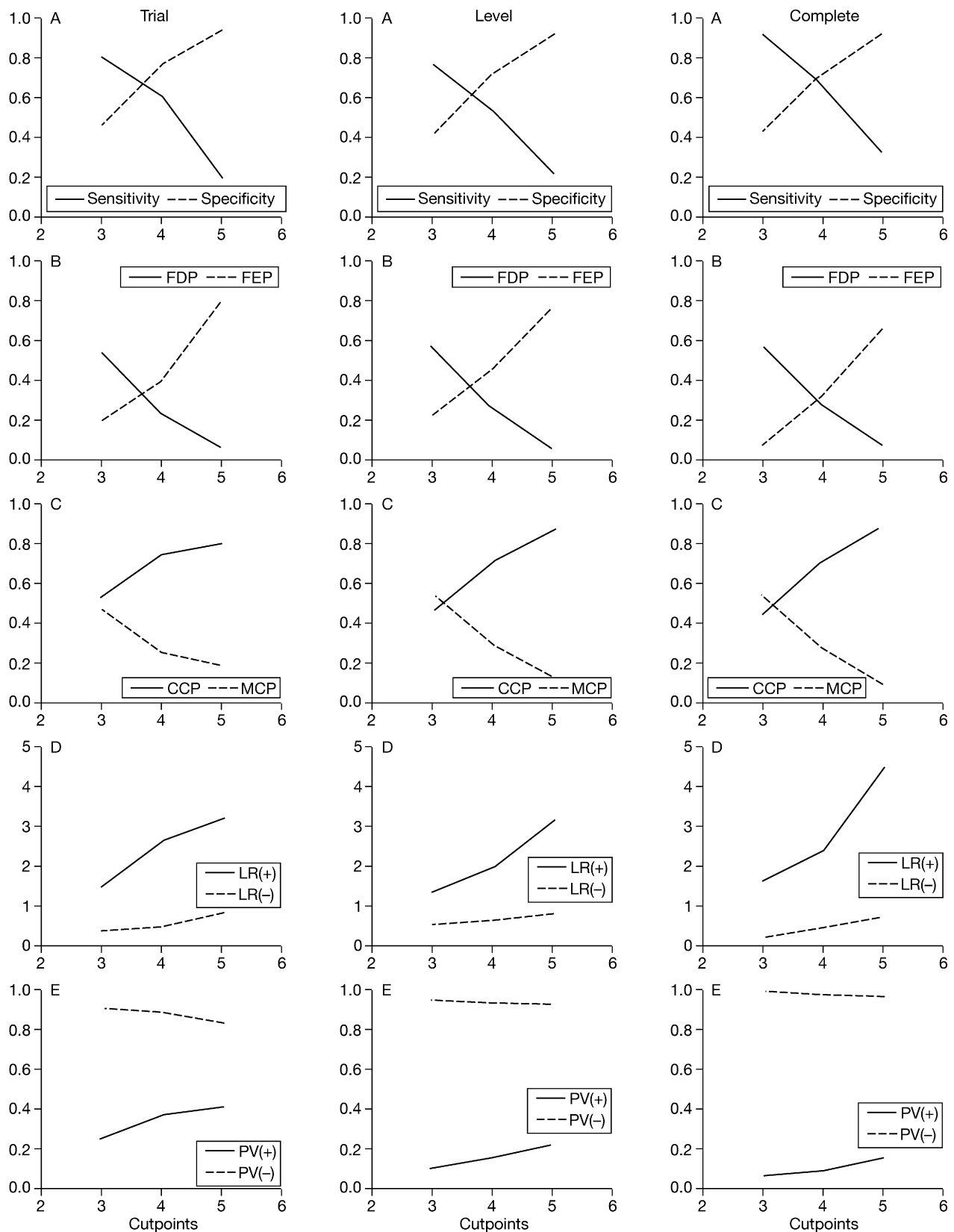


Fig 3 Measurements of the difficulty score performance calculated for more than one attempt (Trial), more than one level (Level), and for the completeness of spinal anaesthesia (Complete) at the difficulty grades 3, 4 and 5 using all difficulty predictors except the lumbar vertebrae radiological characteristics for the whole study population ($n=300$ patients). Abbreviations are explained in Figure 2.

methods^{10 11} which are robust, and the hypotheses to be tested usually relate to the nature of the distribution as a whole rather than to the values assumed by some of its parameters.²⁰ It is one of the most common measures used to describe the performance of the provider over all grades.⁹ Consequently, it can be safely concluded that there was no significant difference between senior and junior anaesthetists in this study.

Grade 4 was the difficulty score at or above which difficulty was predicted. This holds true whether or not the radiological characteristics of the lumbar vertebrae are included. Using this score, nearly two thirds of the patients were correctly stratified and classified. Furthermore, the likelihood ratio of a difficult score is greater than that of an easy score and, being relatively insensitive to changes in difficulty prevalence, it becomes an excellent descriptor of the score performance. The predictive values are sensitive to difficulty prevalence in the study population; this is why the predictive value of a difficulty score is low whereas the predictive value of an easy score is high. The thoughtful use of this difficulty score can stratify patients to the appropriate anaesthetist, reducing the number of trials and levels and improving the performance of spinal puncture.

Acknowledgement

We acknowledge the statistical analysis by Mrs Sahar A. Rahman, statistician at the Urology & Nephrology Center.

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