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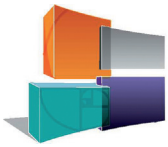

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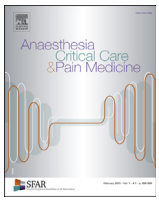

Original Article

Influence of needle diameter on spinal anaesthesia puncture failures for caesarean section: A prospective, randomised, experimental study

Fausto Fama' [b,1,*], Cecile Linard [b,1], Damien Bierlaire [a], Maria Gioffre'-Florio [b], Jacques Fusciardi [a], Marc Laffon [a]

[a] University Hospital of Tours, Department of Anaesthesiology and Intensive Care, Hôpital Bretonneau, 2, boulevard Tonnellé, 37044 Tours cedex 9, France
[b] University Hospital of Messina, Department of Human Pathology, Via Consolare Valeria, 1, 98125 Messina, Italy

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ABSTRACT

Objectives: Spinal anaesthesia represents the technique of choice for elective caesarean section. The purpose of this study was to compare the puncture failure rates with 25, 26 or 27 gauge (G) pencil-point, Whitacre type (with introducer) needles during spinal anaesthesia for caesarean section.
Study design: Prospective, randomised, experimental study in healthy subjects.
Patients and methods: We recruited 330 adults, consecutively scheduled parturients, randomised into three groups. The subarachnoid puncture procedure was standardised. The flexibility of the three needle types was assessed in vitro, and a force was applied using a dynamometer. The occurrence of postdural puncture headache was also evaluated.
Results: The number of spinal puncture failures was significantly higher in the 27 G group, than in the 25 G ($P = 0.006$) group and the 26 G ($P < 0.001$) group, but did not differ between the 25 G and 26 G groups ($P = 0.606$). Ten postdural puncture headaches were observed without significant differences among the groups.
Conclusions: This prospective study showed that puncture failures occur less frequently with the use of 25 G or 26 G pencil-point needles as compared to 27 G needles, probably due to the higher flexibility of the latter. This characteristic was demonstrated in vitro, in a reproducible model. This experiment suggests that a 26 G pencil-point needle is the optimal gauge for performing spinal anaesthesia for scheduled caesarean sections.

1. Introduction

Spinal anaesthesia (SA) is used more and more frequently and has become a technique of choice in elective surgery as well as in obstetrics [1–3]. One of its complications is the occurrence of postdural puncture headache (PDPH), especially in parturients who are more vulnerable for their age and gender [4–6]. The use of fine, pencil-point needles can reduce such effects [1,4,6]. A meta-analysis estimated the incidence of PDPH at 2.2% when using 25 gauge (G) needles compared to an estimation of 1.7% for 27 G needles [4]. Yet, the finer the needle, the greater the risk of puncture failure. In a prospective study on more than 200 parturients undergoing a caesarean section, the impact of puncture failures ranges from 0 to 7.4% with 25 G and 27 G fine, pencil-point needles, respectively [7]. The probable mechanism is an increase in needle flexibility inversely proportional to size [8–10]. Therefore, the more a needle is flexible, the less its path is rectilinear when it passes through tissues [9,11]. To our knowledge, there are no data presenting a standardised model describing needle flexibility as a function of calibre. In addition, the risk for puncture failure and PDPH has not been evaluated for 26 G pencil-point needles.

The purpose of this prospective, randomised study was to compare the puncture failure rates with 25 G, 26 G or 27 G pencil-point needles during SA for caesarean section, as well as to study needle flexibility in vitro.

2. Patients and methods

2.1. In vivo study

We prospectively included 330 adults parturients consecutively scheduled for a caesarean section under SA. All subjects gave

* Corresponding author at: Complesso MITO - Residenza Ginestre F/2, 98151 Messina, Italy. Tel.: +39 090 2402767; fax: +39 090 2402767.
E-mail address: famafausto@yahoo.it (F. Fama').
[1] Equal contributors.

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their written informed consent, and the local ethics committee (University Hospital of Tours, France) approved the study. Exclusion criteria were the woman's refusal of SA, body mass index superior to 30, acquired or congenital coagulation disorders, systemic or localised infection at the puncture site, pregnancy complicated with preeclampsia and eclampsia, neurological diseases, major kyphoscoliosis, and a history of migraine headaches. Caesarean sections performed under emergency conditions were not included to avoid statistical interferences, i.e., failures due to technical difficulties related to the context: procedurally incorrect assessments, difficulty to maintain the required position, and increased anaesthetic stress of the parturients. The SA was performed by 5 trained anaesthetists, 2 with 10 years and 3 with 6 years of experience in obstetrics and gynaecology anaesthesia. The calibre of the pencil-point needle, 25, 26 or 27 G, commonly utilised in clinical practice or for obstetrics SA, was assigned on the base of a computer-generated randomisation table. The subarachnoid puncture procedure was standardised. All parturients were in a sitting position, leaning forward, feet on a stool and shoulders maintained by an assistant. The puncture was done on the lowest palpable space according to the operators' experience, most frequently at levels L4–L5, notwithstanding the lack of ultrasounds, which are mainly suggested by French guidelines. In all cases, after a cutaneous local anaesthesia, each lumbar puncture was performed using a 20 G diameter introducer. Two high sensory levels were observed, once in the 25 G (C4) group and once in the 26 G (C6) group. In the present study, a single brand of needles was tested to ensure uniformity as concerns technical characteristics and manufacturing qualifications. The pencil-point spinal needle (Whitacre™ type with introducer, length 90 mm, Laboratories Vygon®, France) was driven through the introducer sheath and then advanced until a change in resistance was felt, corresponding to the passage of the dura mater. The stylet was withdrawn until the appearance of cerebrospinal fluid (CSF). Once this flow was clear, the anaesthetic solution was injected: hyperbaric bupivacaine 0.5% and sufentanil, associated or not with morphine according to the practitioner's preferences. Drugs were selectively adjusted for each woman and dosages were administered as indicated in Table 1. At the end of the injection, the persistence of a CSF flow was checked to detect anaesthesia failure due to a possible accidental needle displacement during the injection.

The study-data, anaesthetic and demographic features, were collected in the operating room. The occurrence of PDPH (diffuse and/or localised in the fronto-occipital area, and enhanced in an orthostatic position) was assessed via a questionnaire directly addressed to women in bed by an outside observer, up until five days after the surgical procedure.

For an alpha risk at 0.05 and a beta risk at 0.20, the number of women to be included in each group was 108. It was therefore decided to randomise a total of 330 parturients into three groups of 110 each.

Table 1
Anaesthetic and demographic characteristics of the three parturient groups studied. The results are expressed as means ± standard deviations (SD), as medians (interquartile range) and as median [extreme] values.

Group	25 G (n = 109)	26 G (n = 121)	27 G (n = 98)
Age (years)	31 ± 5	31 ± 5	31 ± 6
BMI (kg.m^{-2})	29 ± 7	28 ± 5	29 ± 6
Injected volume (mL)	2.9 ± 0.3	3.0 ± 0.3	3.2 ± 0.3
Bupivacaine (mg)	10.9 ± 1.3	10.7 ± 1.2	10.9 ± 1.2
Sufentanil (μg)	3 ± 1	3 ± 1	3 ± 1
Morphine (μg)[a]	100	100	100
Dermatome[b]	T3 [C4–T8]	T3 [C6–T10]	T4 [T1–T11]

G: Gauge; BMI: body mass index.
[a] Median (interquartile range [IQR]).
[b] Median [extremes].

2.2. In vitro study

The flexibility of the three needle types was assessed in vitro (n = 60, 20 for each needle type) after the positioning of a 20 G introducer. Needles were driven into the introducer. A perpendicular force starting at 0.1 and then moving up through 0.2 - 0.3 - 0.4 Newton (N) was applied to each type of needle using a dynamometer, either at a centimetre after the distal end of the introducer sheath (n = 10 needles per group; proximal force) or at the distal end of the needle (n = 10 needles per group; distal force). Flexibility was assessed by measuring the distance between the ends of the needle before and after the dynamometer application. The applied force was limited to a maximum of 0.4 N because a preliminary experiment in this study demonstrated a 90° deformation for a 27 G needle with 0.5 N. For each force applied in the proximal and distal extremities of the needles, flexibilities were compared calculating the quotient between the deviation of the 27 G needle in relation to the 25 G and 26 G needles.

2.3. Statistical analysis

In vivo, qualitative variables were compared with a Chi^2 test with a Yates correction, and the most relevant statistical events were also investigated by means of a Fisher's exact test. The quantitative variables were analysed using ANOVA or Kruskall-Wallis tests, and then integrated by a Fisher's test, if statistically significant. In vitro, a Kruskall-Wallis test was utilised, and integrated by a Student-Newman-Keuls test, if statistically significant.

The level for statistical significance was set at $P < 0.05$. The results are expressed as means ± standard deviations (SD) for normally-distributed, continuous variables or as median values (with indication of extreme values) for non-normally-distributed continuous variables and as medians (interquartile range) for discontinuous variables. The statistical software utilised was *Primer of Biostatistics*, version 4.02 by Stanton A. Glantz.

3. Results

3.1. In vivo

Anaesthetic and demographic characteristics were not significantly different between groups (Table 1). The study lasted 18 months. The American Society of Anaesthesiologists (ASA) physical status classification system was assessed for all patients; 223 were ASA 1, and 107 ASA 2. Puncture failure was defined as such only after three consecutive failures to obtain CSF flow with the same needle. When a first failure occurred, our protocol indicated a new attempt with the upper diameter needle (i.e. passing from 27 G to 26 G or from 26 G to 25 G), which was reinserted at the same spot, and in case of failure, general anaesthesia (GA) was then performed. In the 25 G group, two cases with failed punctures required general anaesthesia (GA). In the 26 G group, there was only one puncture failure, and the SA was easily performed by means of a 25 G needle. In the 27 G group, 12 failures were followed by SA with a 26 G needle. In summary, the 27 G group included 98 women, the 26 G group 121, and finally, the 25 G group 109 because 2 were submitted to GA (Table 2). The percentages of anaesthetic punctures failures were 1.8%, 0.9% and 10.9%, in groups 25 G, 26 G and 27 G, respectively, and their comparison was statistically significant ($P < 0.001$). The number of spinal puncture failures was significantly higher in the 27 G group as compared to the 25 G (P = 0.006) and 26 G ($P < 0.001$) groups, but was not different between the 25 G and