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#### RESEARCH SUBMISSION

# The effect of needle size on cerebrospinal fluid collection time and post-dural puncture headache: A retrospective cohort study

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# Abstract

**Objective:** The main objective of this study was to compare cerebrospinal fluid (CSF) collection time and patient's discomfort between 20G (a)traumatic and 22G atraumatic needles.

**Background:** Risk of post-dural puncture headache (PDPH) is decreased using atraumatic needles. Smaller needles may give lower risk but possibly at the cost of increased CSF collection time (due to lower flow), leading to additional patient's discomfort.

**Methods:** We performed a retrospective study of lumbar puncture data from a research program on CSF metabolomics and compared traumatic 20G (n = 210) with atraumatic 20G (n = 39) and 22G (n = 105) needles. In this cohort, incidence of PDPH was prospectively registered with other procedure details. Primary outcome was CSF collection time (time to fill the tube). Secondary outcomes were pain and stress scores during procedure, and incidence of PDPH.

**Results:** The time to collect 10 mL of CSF was longer for 22G needles (6.1 minutes; 95% CI 5.8–6.5) than for 20G traumatic (2.2 minutes; 95% CI 2.1–2.2) and 20G atraumatic needles (2.9 minutes; 95% CI 2.8–3.1). There were no differences in pain and stress scores. PDPH was lower for 22G atraumatic needles: odds ratio 0.41 (95% CI 0.25–0.66) versus 20G traumatic needles and 0.53 (95% CI 0.40–0.69) versus 20G atraumatic needles. Absolute PDPH rates were 69/210 (32.9%) for 20G traumatic, 13/39 (33.3%) for 20G atraumatic, and 19/105 (18.1%) for 22G atraumatic needles.

**Conclusions:** CSF collection time is slightly longer for smaller 22G needles, but this does not lead to more discomfort for the patient.

#### KEYWORDS

atraumatic, gauge, lumbar puncture, needle, traumatic

Michel D. Ferrari and Gisela M. Terwindt shared authorship.

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# INTRODUCTION

Post-dural puncture headache (PDPH) is defined as headache occurring within 5 days of a lumbar puncture, caused by cerebrospinal fluid (CSF) leakage through a dural puncture. It is usually accompanied by neck stiffness and/or subjective hearing symptoms (hearing loss, tinnitus, hyperacusis) and remits spontaneously within 2 weeks, or after sealing of the leak with autologous epidural lumbar patch.<sup>1</sup> Sometimes it can develop into a chronic headache.<sup>2</sup> PDPH is a frequent complication of lumbar puncture and can be very debilitating in some patients. There is extensive literature to support that neurological sequelae are reduced using atraumatic needles,<sup>3,4</sup> but studies have differed on the effect of needle size on the risk of post dural puncture headache.<sup>4,5</sup> Furthermore, the smaller diameter might reduce the CSF flow, thereby increasing sampling time and possibly leading to additional discomfort for the patient. We hypothesized that the potential increase in sampling time and discomfort is minor and that PDPH incidence is lower for smaller atraumatic 22G needles compared to 20G needles and aimed to quantify this.

# METHODS

We performed a retrospective study of lumbar puncture data from our Leiden University MIgraine Neuro-Analysis (LUMINA) research program, in which CSF was collected for biochemical profiling migraine patients and healthy controls. This LUMINA program was performed in a research setting in the Leiden University Medical Centre between April 2008 and May 2016. In this cohort, incidence of PDPH and other complications of lumbar puncture were prospectively registered for safety monitoring and details of CSF collection were also recorded in a protocolized manner, including collection time and patient-reported pain and stress scores. More details on LUMINA participants can be found in the online supplement. At the start of this study, 20G traumatic needles (90 mm, Quincke, MediPlast<sup>®</sup>) were used. On 16 December 2010, we stopped using traumatic needles and switched to 20G atraumatic needles (90 mm, Sprotte, Pajunk<sup>®</sup>) because of published evidence that atraumatic needles had lower PDPH incidence. Later, some physicians gradually switched to 22G atraumatic needles (90 mm, Sprotte, Pajunk<sup>®</sup>) because of additional evidence that this might reduce PDPH. Finally, 22G became the new standard for the final part of the study. In this post hoc analysis, we compared the effects of needle size and gauge on CSF collection time and patient's discomfort in addition to PDPH risk. After formulating the research question, we investigated the required data. Data were not studied beforehand, except that lumbar punctures with 20G traumatic data were used in the past to investigate a different research question, namely whether migraine was a risk factor for PDPH.<sup>6</sup>

Volunteers (aged 18-65 years) were included via the general population and our headache clinic, two third of participants had episodic migraine, remaining participants were controls (see e-methods for more information). Punctures were performed between the L3-L4/L4-L5/L5-S1 interspace, preferably in left lateral decubitus position. All lumbar punctures were performed by experienced physicians. The amount of CSF that was collected ranged from 14.6 to 18.0 mL per participant. This depended on the original study purposes. We used CSF data from two biochemical studies ("study 1" and "study 2") and the sampling tubes differed between these studies. For "study 1," 1× 3.0, 1× 3.0, 1× 3.8, and 1× 4.8 mL were collected, resulting in time points 3.0, 6.0, 9.8, and 14.6 mL. For "study 2," 1× 3.0 mL, 1× 3.0, 1× 4.0, and 1× 8.0 mL were collected resulting in time points 3.0, 6.0, 10.0, and 18.0 mL. For each sampling tube that was filled, the sampling time was registered by stopwatch. The stopwatch was started when the first drop of CSF fell in the first tube and round times were recorded (in seconds) for each tube that was filled.

After lumbar puncture, participants filled out a standardized questionnaire on experienced pain and stress during the procedure (numeric rating scale 0–10 with "0" meaning "no pain/stress" and "10" meaning "worst pain/stress imaginable"). Incidence and severity<sup>7</sup> of PDPH were evaluated by a standardized telephone interview 3 days after lumbar puncture. Participants who were still free of PDPH after these first 3 days were instructed to contact researchers if PDPH developed. PDPH was diagnosed based on the clinical criteria of the ICHD-III (Supplementary Table e-1).<sup>1</sup>

#### Statistical analysis

CSF collection time at 10 mL was defined as primary outcome. We chose to compare needle types at 10 mL of CSF because this volume is regularly collected in clinical practice. For "study 1," the time to collect 10 mL was calculated from 9.8 mL data ([collection time of 9.8 mL]  $\times$  10/9.8). Secondary outcomes were pain and stress scores during lumbar puncture and PDPH incidence. No statistical power calculation was conducted prior to the study. Sample size was based on the available data.

CSF collection time in minutes was described with median and interquartile range (IQR) because of the skewed distribution of data. Next, needle types were compared using a generalized estimating equations (GEE) model with an exchangeable correlation structure. Collection time was set as a dependent variable, after log-transformation, and needle type and opening pressure as predictors. Opening pressure was included as a covariate because it was associated with both the outcome (the higher the pressure, the higher the CSF flow) as the predictor of interest (needle type; not similar between the three groups). Physician was included as additional repeated measure variable since different (n = 11) physicians performed lumbar punctures in multiple patients and they were not evenly distributed among groups. To adjust for physician effects, we included this variable in the model (one physician is handier than the other and, e.g., creates better contact with the spinal canal or damages the needle tip less by maneuvering between the vertebrae). Persons who had lumbar puncture in sitting

position were excluded from this analysis, because opening pressure data were not available for these participants. The model excluded cases with missing data.

Pain and stress scores were described with median and IQR because of the skewed distribution of data. The same GEE model was used with pain and stress scores as dependent variables, needle type and opening pressure as predictors, and physician as a repeated measure variable. Data were ranked because of the non-normal distribution (log-transformation was not possible since some values were zero).

PDPH incidence was calculated by the absolute event rate (% of persons who developed PDPH) per needle type. To compare needle types, a logistic regression model was used with PDPH as a dependent variable, and needle type, age, sex, body mass index (BMI), and position as predictors. Age, sex, BMI, and sitting position,<sup>6</sup> are known to influence PDPH risk and were therefore included as covariates, because needle groups were not randomized. Again, the GEE function was used to include physician as a repeated measure variable and to adjust for physician-related factors (i.e., a less-skilled physician could damage the dura mater more when maneuvering the needle).

Unadjusted data were studied after reviewer's request. Baseline characteristics were compared with one-way ANOVA (for numerical variables) and Pearson chi-square for categorical variables. SPSS version 23.0 was used for statistical analysis. Two-tailed significance testing was performed and values of p < 0.05 were considered significant.

All participants gave written informed consent. The study was approved by the Leiden University Medical Centre ethical committee.

#### RESULTS

In total, 354 lumbar punctures resulted in CSF collection, 210 with 20G traumatic, 39 with 20G atraumatic, and 105 with 22G atraumatic needles (Table 1).

#### **CSF** collection time

There was a linear increase in CSF collection time for increasing volumes (Figure 1). The time to collect 10 mL was longer for 22G atraumatic needles than for 20G atraumatic and 20G traumatic needles (Figure 2), with a median of 6.2 minutes (IQR 5.2–7.1) versus 2.4 minutes (20G atraumatic; IQR 3.0–3.4) and 2.1 minutes (20G traumatic; IQR 1.8–2.7). Adjusted for opening pressure and physician performing the puncture, estimated means from the GEE model were 2.2 minutes for 20G traumatic needles (95% CI 2.1–2.2), 2.9 minutes for 20G atraumatic needles (95% CI 2.8–3.1), and 6.1 minutes for 22G atraumatic needles (95% CI 5.8–6.4). The GEE model excluded cases with missing data: n = 19 with no opening pressure because lumbar puncture was performed in sitting position, n = 5 with no opening time was not registered and 14 because sampling time was not registered. Unadjusted data were similar (Supplementary Table e-2).

#### Pain and stress scores during lumbar puncture

Experienced pain ranged from 0 to 9 with a median of 3.0 (IQR 2.0– 5.0). Experienced stress ranged from 0 to 10 with a median of 2.0 (IQR 1.0–5.0). No differences were found in pain and stress scores between the three needle types (Figure 3), also not with unadjusted data (Supplementary Table e-3).

#### Post-dural puncture headache

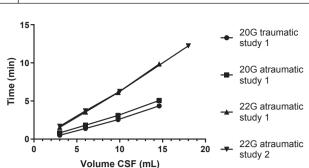
PDPH incidence was lowest for 22G atraumatic needles (Figure 4). Absolute PDPH rates were 69/210 (32.9%) for 20G traumatic, 13/39 (33.3%) for 20G atraumatic, and 19/105 (18.1%) for 22G atraumatic needles. Adjusted for age, sex, BMI, position, and physician, odds ratios were 0.41 versus 20G traumatic needles (95% CI 0.25–0.66; p < 0.001) and 0.53 versus 20G atraumatic needles (95% CI 0.40–0.69; p < 0.001). There was no difference in PDPH for 20G atraumatic

#### TABLE 1 Clinical characteristics and lumbar puncture characteristics

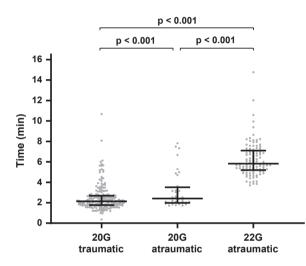
Variable	20G traumatic	20G atraumatic	22G atraumatic	p-value <sup>a</sup>
Number of LPs attempted, n	224	39	110	
Number of LPs succeeded, n	210	39	105	
Age in years, mean (SD)	42.2 (±14.2)	38.5 (±13.1)	41.0 (±12.5)	0.284
Females, n (%)	130 (61.9%)	18 (46.2%)	67 (63.8%)	0.134
BMI in kg/m <sup>2</sup> , mean (SD)	24.1 (±3.0)	23.8 (±2.5)	23.5 (±2.4)	0.143
LP effort >1, n (%)	52 (24.8%)	6 (15.4%)	21 (20.0%)	0.345
CSF RBCs >5/µL, n (%)	73 (32.6%)	17 (15.5%)	7 (17.9%)	0.004
Sitting position, n (%)	19 (9.1%)	0 (0.0%)	0 (0.0%)	0.001
Opening pressure, cm H <sub>2</sub> O, mean (SD)	17.7 (±4.3)	20.6 (±4.9)	18.5 (±4.4)	0.002

<sup>a</sup>One-way ANOVA was used for numerical variables, and Pearson's chi-square test for categorical variables.

Abbreviations: BMI, body mass index; G, gauge; LP, lumbar puncture; RBC, red blood cell count.



**FIGURE 1** CSF collection times. For each sampling tube, the time to fill the tube was recorded by stopwatch. For original study purposes, different sampling tubes were used in "study 1" and "study 2." In participants from "study 1," this resulted in time points 3.0, 6.0, 9.8, and 14.6 mL. In participants from "study 2," this resulted in time points 3.0, 6.0, 10.0, and 18.0 mL



**FIGURE 2** Time to collect 10 mL of CSF (in minutes) compared between the three needle types: 20 gauge (G) traumatic, and 20G and 22G atraumatic spinal needles. Gray dots indicate individual participants, and black lines indicate median ± interquartile range

versus 20G traumatic needles (odds ratio 0.77; 95% CI 0.41–1.44). Unadjusted for physician the odds ratios were 0.46 (95% CI 0.25–0.84; p = 0.011) and 0.47 (95% CI 0.20–1.10; p = 0.082), respectively (Supplementary Table e-4).

In total, n = 20 blood patches were required, all resulting in remission of headache, 14/210 (6.7%) in the 20G traumatic group, 2/39 (5.1%) in the 20G atraumatic group, and 4/105 (3.8%) in the 22G atraumatic group. There were no participants who contacted us with new chronic headache after lumbar puncture. Supplementary Table e-5 in the online supplement shows PDPH severity. No difference was observed in initial opening pressure between persons who later developed PDPH and those who did not (Supplementary Figure e-1).

# DISCUSSION

Using 22G atraumatic needles instead of 20G needles increased CSF collection times with 3-4 minutes (for 10 mL of CSF) but this

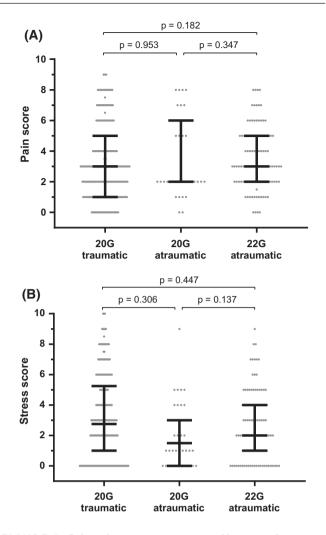
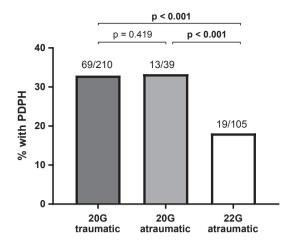


FIGURE 3 Pain and stress scores compared between the three needle types. After lumbar puncture, participants filled in a standardized questionnaire with a numeric rating scale from 0 to 10. (A) Pain scores ("How much pain did you experience during the lumbar puncture?"). (B) Stress scores ("How much stress did you experience during the lumbar puncture?"). Gray dots are individual participant scores, and black lines indicate median scores ± interquartile range (for pain scores of the 20 gauge (G) atraumatic needle, the 25th percentile was similar to the median because of the majority of patients scoring "2.")

did not lead to additional discomfort for the patient. Participants reported similar pain and stress scores for 22G atraumatic needles as for 20G needles. PDPH incidence was halved using 22G atraumatic needles compared with 20G atraumatic and traumatic needles.

Our observations on PDPH incidence are in line with previous studies. First, there is extensive evidence, including meta-analysis, that PDPH risk is reduced using atraumatic needles.<sup>3,4</sup> However, unfortunately many physicians still use traumatic needles.<sup>8,9</sup> Second, there is increasing evidence that smaller atraumatic needles have less of PDPH risk than larger atraumatic needles,<sup>5,10</sup> although other studies have differed on this.<sup>4</sup> Our study adds to this evidence.

There is less evidence on CSF collection times and patient discomfort. In an experimental study using a fluid column, flow rates



**FIGURE 4** Incidence of post-dural puncture headache (PDHP) compared between the three needle types. Numbers above bars indicate absolute numbers of cases with PDPH per the total number of participants in whom the specific needle type was successfully used

differed less than 10% when comparing 20G traumatic versus 22G atraumatic needles.<sup>11</sup> However, in the experimental study, needles were inserted in a pre-drilled hole. This could have led to an oversimplification, ignoring other factors of influence on fluid mechanics such as needle tip damage due to the puncture. Only one other clinical study investigated collection time.<sup>10</sup> No difference was found in flow velocity between 20G traumatic needles and 22G atraumatic needles, but collection time did increase for 25G needles, where active withdrawal with a syringe was necessary to collect the CSF. Pain scores were similar for all needle types, similar to our observations. Experienced stress was not investigated. Based on our study and this previous study, we believe it can be concluded that the increase in CSF collection time for a smaller needle is only minor and that this increase does not lead to additional discomfort for the patient.

The following limitations are important for generalizability of these findings. This study was non-randomized and therefore prone to confounding bias. By adjusting for several covariates, we aimed to eliminate some confounders (i.e., opening pressure, physician) but this could not be done for unknown confounders. Furthermore, adjusted data may be more difficult to interpret. Although we believe the used corrections were necessary, one could argue evidence for sitting position and PDPH risk is still limited.<sup>6,12</sup> Additionally, the study is at risk of confounding by indication. The switch from 20G traumatic needles to 20G atraumatic was a direct and full switch and therefore less prone to this type of confounding, but the switch from 20G atraumatic to 22G atraumatic was more gradual, depending on the willingness of the physician to use a smaller needle. However, we believe this to be of small impact since this was only the case for a minor period: 22/105 (21.0%) of the succeeded 22G punctures were done when physicians could choose between 20G atraumatic and 22G atraumatic. The other n = 83 were done when 22G was obliged. The strength of our study is the standardized strict protocol

that we used for data collection. Although the needle switch was not predefined at the beginning of the study, all other aspects of data collection (PDPH diagnosis, time monitoring of CSF flow, clinical characteristics) were predefined, protocolized, and prospective. Furthermore, the study population consisted of young, non-obese participants, at least half of them females, who are at increased risk of PDPH and are, therefore, an important group to investigate.<sup>6</sup> We believe these risk factors in combination with the intensive and proactive follow-up of PDPH (we contacted every participant 3 days after puncture) led to a relatively high percentage of PDPH in our study compared to earlier studies. Participants were also instructed to contact us if headache developed after the telephone interview on day 3; to prevent underestimation of late-onset PDPH occurring on day 4 and 5.

In conclusion, our study showed the increase in CSF collection time is only minor and does not lead to additional discomfort for the patient when using small size atraumatic gauge needles.

#### CONFLICT OF INTEREST

MDF reports consultancy or industry support from Medtronic, Novartis, Amgen, Lilly, and Teva, and independent support from the European Community, NWO, and the Dutch Heart & Brain Foundations. GMT reports consultancy support from Novartis, Lilly, and Teva, and independent support from NWO, European Community, and the Dutch Heart & Brain Foundations. The other authors report no disclosures.

#### AUTHOR CONTRIBUTIONS

Study concept and design: Gisela M. Terwindt and Michel D. Ferrari. Acquisition of data: Robin M. van Dongen, Gerrit L. J. Onderwater, Ronald Zielman, and Nadine Pelzer. Analysis and interpretation of data: Robin M. van Dongen and Erik W. van Zwet. Drafting of the manuscript: Robin M. van Dongen. Revising it for intellectual content: Robin M. van Dongen, Gerrit L. J. Onderwater, Nadine Pelzer, Ronald Zielman, Willibrordus P. J. van Oosterhout, Erik W. van Zwet, Michel D. Ferrari, Gisela M. Terwindt. Final approval of the completed manuscript: Robin M. van Dongen, Gerrit L. J. Onderwater, Nadine Pelzer, Ronald Zielman, Willibrordus P. J. van Oosterhout, Erik W. van Zwet, Michel D. Ferrari, Gisela M. Terwindt.

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#### SUPPORTING INFORMATION

Additional Supporting Information may be found online in the Supporting Information section.

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