

Postdural Puncture Headache and Spinal Needle Design

Metaanalyses

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Background: Attempts have been made to reduce the incidence of postdural puncture headache (PDPH) after spinal anesthesia by changing the size and design of the needle. We wished to determine whether these strategies are effective in reducing PDPH and whether they affect the incidence of back pain and the failure rate of spinal anesthesia.

Methods: The literature was searched for trials comparing noncutting spinal needles with cutting needles and larger spinal needles with smaller needles. Trials were included if they were randomized or blinded and if outcomes included PDPH, backache, or failure of the method. The pooled odds ratio for each side effect was computed, and the results were considered statistically significant if the 95% confidence interval excluded 1.

Results: Four hundred fifty articles were identified by title using computerized search strategies. Thirty-one abstracts, 25 correspondences, 44 original articles, and 12 reviews were assessed. There was a reduction in the incidence of PDPH when noncutting spinal needles rather than cutting needles were used ($P < 0.05$), unless the discrepancy in needle size was very large. There also was a reduction in PDPH when a small spinal needle was used compared with a large needle of the same type ($P < 0.05$). There was no difference in the incidence of failure of spinal anesthesia or the incidence of back pain.

Conclusions: We conclude that a noncutting needle should be used for patients at high risk for PDPH, and the smallest gauge needle available should be used for all patients. (Key words: Anesthesia, spinal; adverse effects; headache; instrumentation; metaanalysis; needles.)

SPINAL anesthesia is commonly used for surgical procedures but is often followed by postdural puncture headache (PDPH) particularly among young patients

and obstetrical patients. Two strategies have arisen to reduce the incidence of PDPH. The first is to reduce the size of the needle.¹ The second is to change the design of the needle presumably to reduce the leak of cerebrospinal fluid. This has been accomplished by using a noncutting rather than a cutting point.² Whether or not these strategies are successful in reducing the incidence of PDPH is controversial. Some studies show a reduction in PDPH when a noncutting needle²⁻⁴ rather than a cutting needle is used, whereas others do not.⁵⁻¹⁰ Similarly, some studies show a reduction in PDPH when a small needle is used^{1,11-14} compared with a larger needle, whereas others show no difference.¹⁴⁻¹⁶

Several reviews have considered this problem but have come to different conclusions, depending on the literature cited.¹⁷⁻²⁶ Metaanalysis can be helpful in resolving these issues.

The purpose of this metaanalysis is to answer two questions. First, is there a lower incidence of PDPH when a noncutting spinal needle is used for spinal anesthesia compared with the same size or smaller cutting needle. Second, is there a lower incidence of PDPH when a small needle is used compared with a larger needle of the same type.

Although PDPH was the focus of this metaanalysis, other outcomes, such as the incidences of postoperative back pain and failure, also were studied.

Materials and Methods

A computer search of MEDLINE from January 1966 to December 1993 was performed independently by two observers. The following terms were used: anesthesia, spinal, adverse effects. The text term "headache" was also used. Excerpta Medica was scanned in a similar fashion. Abstracts from major anesthesia meetings from 1989-1993 were searched, and an attempt was made to locate articles in the Scientific Ci-

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Received from the department of Anaesthesia, Women's College Hospital, Toronto, Ontario, Canada. Accepted for publication August 11, 1994.

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Table 1. Assessment of Quality

Randomization				
Were the patients assigned randomly?	1 Yes	0 No		
Randomization adequately described?	2 Yes	1 Partly	0 No	
Was treatment group concealed to investigator?	1 Yes	0 No		
	Total/4			
Description of outcome measurement				
adequate?	1 Yes	0 No		
Outcome measurements objective?	2 Yes	1 Partly	0 No	
Were the assessors blind to treatment?	1 Yes	0 No		
	Total/4			
Were inclusion/exclusion criteria well defined?				
	2 Yes	1 Partly	0 No	
Number of patients excluded and the reason?				
	2 Yes	1 Partly	0 No	
	Total/4			
Was the therapy fully described for the treatment group?				
	2 Yes	1 Partly	0 No	
Was the therapy fully described for the controls?				
	2 Yes	1 Partly	0 No	
	Total/4			
Statistics				
Was the test stated and was there a P value?	1 Yes	0 No		
Was the statistical analysis appropriate?	2 Yes	1 Partial	0 No	
If the trial was negative, were confidence intervals or post hoc power calculations performed?	1 Yes	0 No		NA
Sample size calculation before the study?	1 Yes	0 No		
	Total/5*			
	Total/4 if positive trial			

Adapted from reference 27.

* The total possible is 21 for a positive trial and 22 for a negative trial.

tation Index by the authors of those abstracts. The Oxford database of Perinatal Trials was searched to find references for spinal anesthesia in pregnancy. The International Journal of Obstetrical Anaesthesia was searched separately for 1992 and 1993 because it is not an indexed journal. Finally, the references from review articles were retrieved. All articles, correspondence, reviews and abstracts considered to be potentially relevant by either author were retrieved for further evaluation.

All material considered for inclusion were evaluated to ensure that they met the following criteria: (1) the trial was randomized and controlled; (2) there was a comparison of two types or sizes of needles; (3) PDPH was an outcome; and (4) the definition of PDPH avoided confusion with or inclusion of other types of

headache. Studies comparing spinal anesthesia with another type of anesthesia were discarded as were studies that did not state that the bevel orientation of a cutting needle was parallel to the dural fibers.

The authors then rated the articles for quality using a previously published scale.²⁷ The agreement between authors was measured using the intra class correlation coefficient and a final quality score was obtained by averaging the two scores. The rating scale is shown in table 1. Because articles with a significant difference between groups have a different denominator than those that showed no difference, we expressed the scale as a fraction of the possible total. We decided to discard articles with a score of less than 0.5 *a priori*. Authors of abstracts that met the above criteria for quality were contacted to obtain more information if it was available.

Data from the articles were abstracted independently by the two authors using predesigned forms. This included population descriptors, the intervention, and outcome measurements.

The articles were then divided into two groups. Articles in the first group compared a noncutting needle (Sprotte or Whitacre) with a cutting needle. In this group the noncutting needle was considered "experimental" and the cutting needle "control". The articles in the second group compared a smaller needle with a larger needle of the same class. In this group the smaller needle was considered "experimental" and the larger "control". These two groups of articles were analyzed separately and the odds ratio was calculated. The odds ratio was defined as the odds of the event occurring in the experimental group divided by the odds of it occurring in the control group. An odds ratio of less than one implies that the experimental group has a reduced incidence of the outcome in question.

The studies were analyzed to determine whether there was significant heterogeneity using graphical methods and the Breslow-Day method.²⁸ The data were then combined using the Mantel-Haenszel method. When significant heterogeneity among studies was found, the data were treated in two ways. First, data were reanalyzed using a random effects model.²⁹ Second, if the reason for the heterogeneity could be identified, the data were reanalyzed with the heterogeneous study or studies dropped from the analysis.

The following outcomes were identified as important before the literature search was started: the incidences of (1) PDPH, (2) severe PDPH (as defined by a rating scale as "severe" or by the use of a blood patch), (3) back pain, and (4) difficulty using the needle as defined

by a rating scale, failure rate, or the incidence of more than two attempts at dural puncture. The failure rate was analyzed separately and failure was said to occur if a different needle was substituted for the needle assigned by randomization, or if spinal anesthesia was abandoned and another form of anesthesia was used. The 95% confidence interval of the odds ratio for each outcome of each study was calculated and a pooled odds ratio computed. The results were considered statistically significant when the 95% confidence interval did not include 1.

Results

Four hundred fifty articles were retrieved from the search strategy and 31 abstracts, 25 correspondence, 44 original articles and 12 reviews were assessed. Four of the abstracts met the inclusion criteria. Of these, the authors supplied full manuscripts for two. These were subsequently published.^{8,15} None of the correspondence met the inclusion criteria. Two of the reviews did not discuss the effect of either needle size or needle design on the incidence of PDPH.^{30,31} None of the reviews was quantitative, although one outlined the search strategy.²⁰ None gave criteria for exclusion or inclusion of articles.

Of the 46 articles evaluated, 30 were rejected for the reasons shown in the appendix.

Of the 16 articles accepted for analysis, 15 were written in English and 1 was written in German. One article included two studies.¹⁴ All studies used in the analyses were identified using MEDLINE except for 2 retrieved from abstracts^{8,15} and 1 that was identified using a hand search of anesthesia journals.⁴ The patients were identified as mixed,^{4,5,8,9} young,^{1,7,11,14} elderly^{10,14} and obstetrical^{2,3,6,12,15} patients. The data from the studies are shown in tables 2 and 3.

The correlation between observers for the quality of the articles was high ($r = 0.97$). The mean quality score was 0.61. (standard deviation 0.08 and range 0.50–0.79). All patients were randomized and assessed by observers blinded to the type of needle used. In addition, all had a measure that differentiated PDPH from non-PDPH. However, in none of the articles was the randomization scheme used described, and so it was not possible to assess whether bias could be introduced at this stage. The other major flaw in all articles was inadequate description of patients who were dropped from the studies for any reason. It was impossible to assess how many patients from each group

were dropped, their characteristics or their clinical outcome. In none of the articles was described either a sample size justification before the study or a *post hoc* power analysis if the study was negative.

There was significant heterogeneity of results in odds ratios for the incidence of PDPH in the cutting *versus* noncutting needle group ($P = 0.03$), but there was none in any of the other analyses. Only one study showed a higher incidence of PDPH in patients with a noncutting needle compared with a cutting needle.⁷ This study compared the largest noncutting (22-G) with the smallest cutting (29-G) needle. When this study was eliminated, heterogeneity of results could no longer be demonstrated ($P = 0.28$). We chose to calculate the pooled odds ratio with and without this result included (fig. 1A).

The odds ratios for the studies that examined PDPH, back pain and failure for cutting *versus* non cutting needles are shown in figures 1A–1C. Noncutting needles were associated with a lower incidence of PDPH, the P value being significant whether the fixed or random model was used. The pooled odds ratios are shown in figure 1A with and without the study that accounted for the heterogeneity in this group of studies. Noncutting needles were also associated with a lower incidence of severe PDPH ($P < 0.05$, pooled odds ratio 0.26, 95% confidence interval 0.11–0.62). There was no difference in the odds ratios related to back pain (fig. 1B). The incidence of difficulty with the needle was greater with the cutting needles (pooled odds ratio 0.48, 95% confidence interval 0.24–1.00, $P = 0.05$) and the actual failure rate also appeared to be greater (pooled odds ratio 0.52, 95% confidence interval 0.27–1.01) (fig. 1C). One study reported the time to administer the spinal anesthetic and found that it took significantly longer when a 29-G Quincke was used compared with a 24-G Sprotte (8 min *vs.* 4 min, $P < 0.05$).⁹

The odds ratios for the comparison of larger *versus* smaller needles are shown in figure 2. The incidence of PDPH in those who received a smaller needle was less compared with those who received a larger needle (fig. 2A). There was also a statistically significant reduction in the incidence of severe headache (pooled odds ratio 0.18, 95% confidence interval 0.09–0.36, $P < 0.05$). There was no difference in the incidence of back pain (fig. 2B) or the incidence of failure (fig. 2C).

Discussion

These metaanalyses of randomized trials showed that smaller needles produce a lower incidence of PDPH

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Table 2. Incidence of Complications: Noncutting Versus Cutting Needles

Reference	Quality Score	Needle Type		Sample Size		Headache (%)		Severe Headache (%)		Backache (%)		Difficulty with Needle or Failure (%)	
		E	C	E	C	E	C	E	C	E	C	E	C
Sundberg ¹⁰	0.71	22W	22Q	25	25	0	0	0	0	NA	NA	NA	NA
Lynch ⁷	0.55	22W	29Q	200	200	3.5	2	0	0	2.0	2.5	2.0	8.5
Tarkkila ⁵	0.61	24S	25Q	83	89	2.4	4.4	0	1.1	19.2	14.6	6.0	3.3
Cesarini ²	0.59	24S	25Q	55	55	0	14.5	0	5.5	NA	NA	1.8	0
Mayer ⁸	0.68	24S	27Q	151	147	0.7	3.4	0	0	38.0	45.5	0	0.6
Shutte ³	0.76	22W	26Q	93	48	1.1	10.4	0	6.2	16.1	8.3	4.3	4.1
Buettner ⁴	0.64	25W	25Q	200	200	3	8.5	0	1.0	NA	NA	NA	NA
Lim ⁹	0.62	24S	29Q	28	28	10.7	25	3.5	7.1	35.7	32.1	NA	NA
Weisel ⁶	0.65	24S	27Q	47	46	13.0	13.0	6.3	6.5	NA	NA	NA	NA

NA = not available; E = experimental group; C = control group; W = Whitacre needle; Q = Quincke needle; S = Sprotte needle.

than larger needles of the same type. When noncutting needles were used, they produced a lower incidence of PDPH than cutting needles even though the cutting needle was smaller. Only one study reported that the cutting needle had a lower incidence of PDPH.⁷ In this study, 4 of 200 patients who received a 29-G Quincke needle had a PDPH, compared with 7 of 200 who received a 22-G Whitacre (fig. 1A). The difference was not statistically significant. None of those patients reported a severe headache and none received a blood patch. However, because of this study, it is not possible to conclude that a noncutting needle will produce less headache than a cutting needle regardless of size difference.

An early prospective study by Vandam and Dripps demonstrated a decrease in PDPH in patients who had

spinal anesthesia with smaller needles compared with those who had larger needles.³² Despite the large number of patients and careful follow-up described in this study, it is appropriate to reexamine this issue: their study design was flawed in several ways (such as non-random assignment and nonblinded observers), and the smallest needle used in the study would be considered "large" today. In addition, only cutting needles were evaluated at that time.

Previous reviews about PDPH and other complications of spinal anesthesia have not included statistical analysis of the reviewed articles, nor have they discussed the selection criteria for the articles. The conclusions presented therefore are subject to bias. Kestin²¹ concluded that there was little advantage to using smaller than 26-G needles to prevent PDPH. This

Table 3. Incidence of Complications: Small Versus Large Needles

Reference	Quality Score	Needle Type		Sample Size		Headache (%)		Severe Headache (%)		Backache (%)		Difficulty with Needle Insertion or Failure (%)	
		E	C	E	C	E	C	E	C	E	C	E	C
Flaatten ¹	0.50	29Q	26Q	50	99	0	10.1	0	4.0	NA	NA	8.0	0
Geurts ¹¹	0.59	29Q	25Q	40	40	0	25	0	10.0	10	12.5	2.5	2.5
Kang ¹³	0.73	27Q	26Q	336	332	1.4	9.3	0.3	3.6	20.2	17.8	0.6	0.9
Lynch ¹⁸	0.55	25W	22W	100	100	2.0	4.0	0	1.0	9.0	9.0	0	0
Campbell ¹⁵	0.79	25W	24S	150	150	0.7	4.0	0.7	1.3	NA	NA	2.7	3.3
Barker ¹²	0.50	26Q	25Q	49	51	2.0	17.6	0	11.7	NA	NA	NA	NA
Rasmussen ¹⁴	0.56	25Q	20Q	95	98	12.6	27.5	NA	NA	NA	NA	NA	NA
Rasmussen ¹⁴	0.56	25Q	20Q	90	93	11.1	10.7	NA	NA	NA	NA	NA	NA

NA = not available; E = experimental group; C = control group; W = Whitacre needle; Q = Quincke needle; S = Sprotte needle.

opinion was based on a single study with insufficient power to detect a large difference in the incidence of this complication. Morewood²⁰ concluded, without supporting data that the 25-G Whitacre needle was the "best" needle to use, although he also concluded that there was no clear advantage over a 26-G Quincke needle. Another reviewer¹⁹ concluded that the noncutting needles did not reduce the incidence of PDPH. This conclusion was based on two studies but these cannot be located because of misreferencing. In addition, the review was written before the randomized trials of this metaanalysis had been published.

None of the authors of studies examined in this review reported a power analysis in their study. The incidence of PDPH in the studies quoted above using control needles is about 7% and the incidence of severe PDPH is between 2% and 4% (tables 2 and 3). To achieve a power of 0.8, with $\alpha = 0.05$, the sample sizes would have had to be 700 and 2,500 per group for PDPH and severe PDPH respectively to detect a 50% difference in incidence of these complications. None of the studies approached that sample size. When combining studies with similar intervention (noncutting *vs.* cutting; large *vs.* small gauge), the required sample size is approached for PDPH but not for severe PDPH. A difference in severe PDPH was detected because the reduction in incidence was more than 50%. We refrained from doing subgroup analysis (by age or sex, for instance) because the sample sizes were insufficient.

Very-small-gauge spinal needles may be more difficult to use and have a greater failure rate than larger needles of either type. Although the differences approach statistical significance, care must be taken in interpreting these data. The judgment of difficulty with using a particular needle is somewhat subjective and the anesthetist was not blinded to the type of needle used. Therefore this outcome is more subject to bias than the others.

One of the major weaknesses of all articles reviewed was a lack of follow-up of patients dropped from the study. Some authors may have simply reassigned the randomization number of patients who failed to have adequate anesthesia rather than reporting them. In addition, subjective difficulty with the needle may be difficult to interpret because the anesthetist could not be blinded to the type and size of needle used.

In contrast to headache, back pain is a much more frequent side effect (tables 2 and 3). Approximately 200 patients per group would be required to detect a difference in incidence of 50% in this outcome mea-

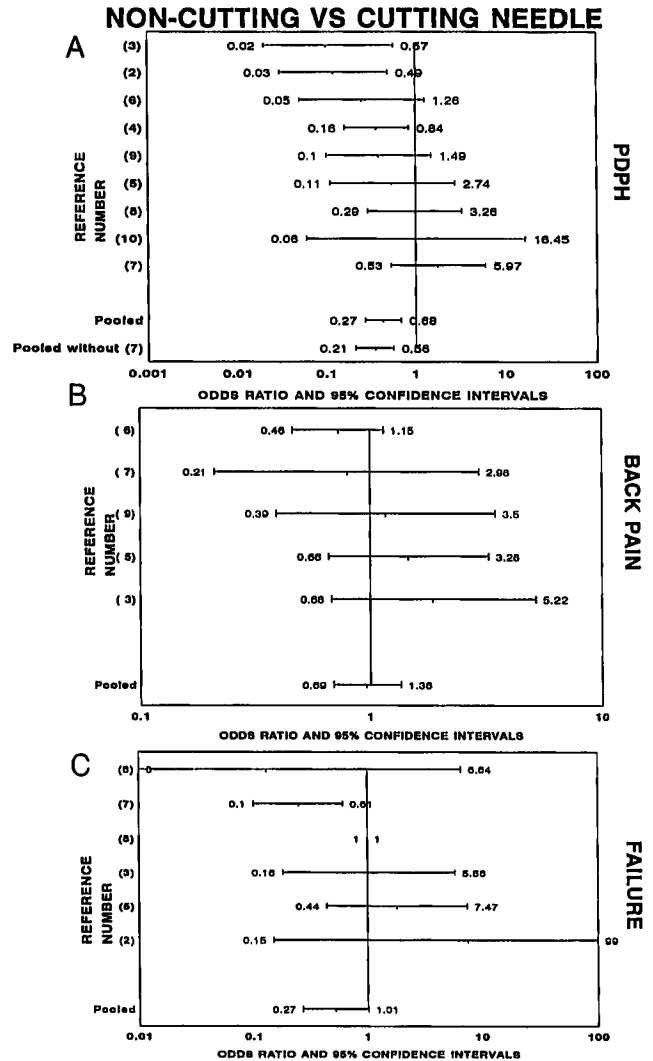


Fig. 1. Point estimate and 95% confidence intervals for the odds ratios for (A) postdural puncture headache, (B) back pain, and (C) failure rate: noncutting *versus* cutting needles. Pooled values are the combined odds ratios.

surement. Several articles had the required numbers but none showed any difference between groups.

In summary, these metaanalyses show that noncutting needles for spinal anesthesia produce a lower incidence of PDPH than cutting needles. In addition, smaller needles produce less headache than larger needles of the same type. Very-small-gauge cutting needles may be more difficult to use and may have a higher failure rate than larger noncutting needles. Finally the size or design of needle has no influence on the incidence of postoperative back pain.

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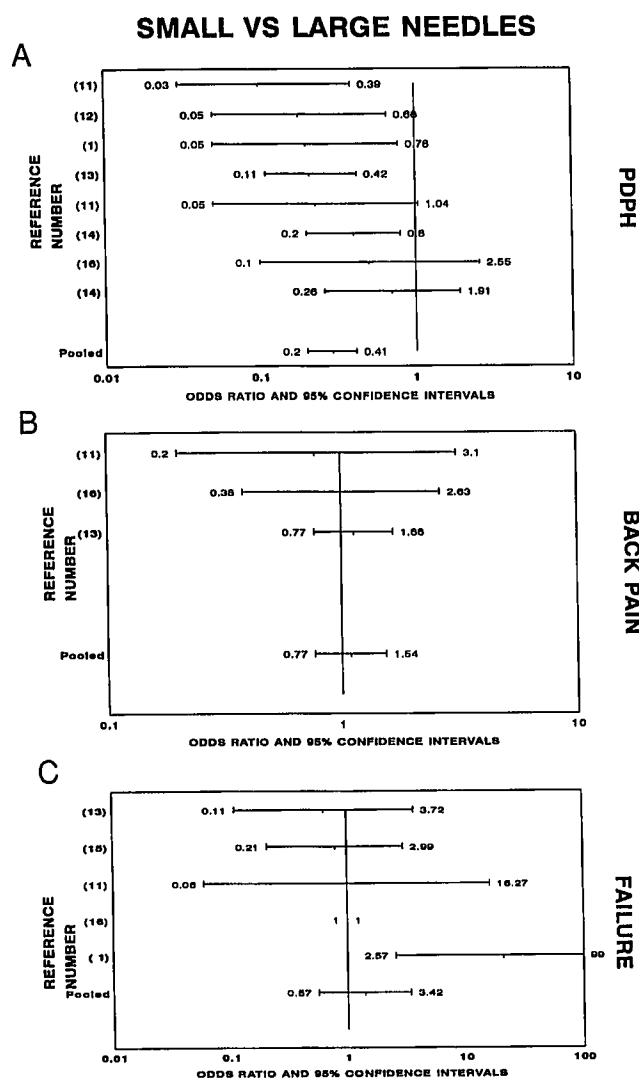


Fig. 2. Point estimate and 95% confidence intervals for the odds ratios for (A) postdural puncture headache, (B) back pain, and (C) failure rate: small *versus* large needles. Pooled values are the combined odds ratios.

We conclude that a noncutting needle should be used for patients at high risk for PDPH and that the smallest-gauge needle available should be used for all patients.

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Appendix

Table A1. Studies Not Included in Meta-analysis, and Reasons for Exclusion

Reference	Not Randomized	Maneuver Other Than Change in Needle	No Anesthesia or General Anesthesia in Control Group
Thornbury ^a		×	
Ravindran ^b		×	
Mihic ^c		×	
Michie ^d		×	
Abboud ^e		×	
Abboud ^f		×	
Milligan ^g		×	
Russel ^h		×	
Huffman ⁱ	×		×
Tourtellote ^j			×
Mazze ^k		×	
Naulty ^l	×	×	
Westbrook ^m	×	×	
Silvanto ⁿ	×	×	
Denny ^o	×	×	
Quaynor ^p	×	×	
Lesser ^q	×		
Lybecker ^r	×		
Pitkänen ^s	×		×
Flaaten ^t		×	

(Table continues)

Table A1. Continued

Reference	Not Randomized	Maneuver Other Than Change in Needle	No Anesthesia or General Anesthesia in Control Group
Kaukinen ^u	×	×	
Brownridge ^v	×		
Ross ^w	×		
Clarke ^x	×		×
Flaatten ^y	×	×	
Maffull ^z	×		
Sarma ^{aa}	×		
Tarkkila ^{bb}	×		
Harrison ^{cc}	×		
Crawford ^{dd}	×		

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