Atraumatic versus conventional lumbar puncture needles: a systematic review and meta-analysis

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Summary

Background **Atraumatic needles have been proposed to lower complication rates after lumbar puncture. However, several surveys indicate that clinical adoption of these needles remains poor. We did a systematic review and meta-analysis to compare patient outcomes after lumbar puncture with atraumatic needles and conventional needles.**

Methods **In this systematic review and meta-analysis, we independently searched 13 databases with no language restrictions from inception to Aug 15, 2017, for randomised controlled trials comparing the use of atraumatic needles and conventional needles for any lumbar puncture indication. Randomised trials comparing atraumatic and conventional needles in which no dural puncture was done (epidural injections) or without a conventional needle control group were excluded. We screened studies and extracted data from published reports independently. The primary outcome of postdural-puncture headache incidence and additional safety and efficacy outcomes were assessed by random-effects and fixed-effects meta-analysis. This study is registered with the International Prospective Register of Systematic Reviews, number CRD42016047546.**

Findings **We identified 20 241 reports; after exclusions, 110 trials done between 1989 and 2017 from 29 countries, including a total of 31 412 participants, were eligible for analysis. The incidence of postdural-puncture headache was significantly reduced from 11·0% (95% CI 9·1–13·3) in the conventional needle group to 4·2% (3·3–5·2) in the atraumatic group (relative risk 0·40, 95% CI 0·34–0·47, p<0·0001; I^2=45·4%). Atraumatic needles were also associated with significant reductions in the need for intravenous fluid or controlled analgesia (0·44, 95% CI 0·29–0·64; p<0·0001), need for epidural blood patch (0·50, 0·33–0·75; p=0·001), any headache (0·50, 0·43–0·57; p<0·0001), mild headache (0·52, 0·38–0·70; p<0·0001), severe headache (0·41, 0·28–0·59; p<0·0001), nerve root irritation (0·71, 0·54–0·92; p=0·011), and hearing disturbance (0·25, 0·11–0·60; p=0·002). Success of lumbar puncture on first attempt, failure rate, mean number of attempts, and the incidence of traumatic tap and backache did not differ significantly between the two needle groups. Prespecified subgroup analyses of postdural-puncture headache revealed no interactions between needle type and patient age, sex, use of prophylactic intravenous fluid, needle gauge, patient position, indication for lumbar puncture, bed rest after puncture, or clinician specialty. These results were rated high-quality evidence as examined using the grading of recommendations assessment, development, and evaluation.**

Interpretation **Among patients who had lumbar puncture, atraumatic needles were associated with a decrease in the incidence of postdural-puncture headache and in the need for patients to return to hospital for additional therapy, and had similar efficacy to conventional needles. These findings offer clinicians and stakeholders a comprehensive assessment and high-quality evidence for the safety and efficacy of atraumatic needles as a superior option for patients who require lumbar puncture.**

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Introduction

Postdural-puncture headache is the most common complication after lumbar puncture, affecting up to 35% of patients.[1] This type of headache is postural and can be debilitating in some patients, resulting in discomfort that results in patients returning to hospital for controlled analgesia or invasive therapy. Postdural-puncture headache is presumed to be due to sustained leakage of cerebrospinal fluid from the dural defect, which is created by the spinal needle during puncture.[2] The incidence of headache after lumbar puncture is thought to be influenced by multiple factors, including needle gauge, needle tip design, patient position, use of prophylactic intravenous fluid or bed rest, and experience of the clinician.[3] To date, needle tip design has received the most attention in view of the proposed mechanism of postdural-puncture headache.

Spinal needles can be broadly classified as atraumatic or conventional on the basis of their tip configuration.[4] Conventional needles are the most frequently used in clinical practice and have a sharp slanted tip designed to cut through the dura with a distal opening that enables the injection of therapeutics or collection of cerebrospinal fluid. In comparison, atraumatic needles are blunt with a

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Research in context

Evidence before this study

Several surveys show that clinicians' knowledge about the existence of atraumatic needles and their adoption in clinical practice is poor. More than 100 trials have compared atraumatic needles and conventional needles, but these trials were largely single-centre with a small sample size, which even if powered to detect the effect of needle tip design for the primary outcome of postdural-puncture headache, were not sufficiently powered to examine key additional outcomes. Moreover, previous trials were underpowered to detect interactions between needle tip design and important clinical subgroups. Previously published meta-analyses also failed to reach consensus on this topic because of methodological limitations.

Added value of this study

To the best of our knowledge, our systematic review and meta-analysis is the most broad and robust analysis comparing atraumatic and conventional needles to date. Our study was not only powered to detect a difference in the primary outcome of postdural-puncture headache, but also 11 additional outcomes. Moreover, evidence from this study was not limited to a single clinical discipline and was obtained from a large sample size (>30 000 participants), which enhanced generalisability and enabled the interaction between needle tip design and key predefined patient subgroups and procedural characteristics to be assessed. Prespecified subgroup analyses for the primary outcome revealed no interactions between needle type and patient and care delivery characteristics suggesting that our findings indicate a true effect of the atraumatic tip design.

Implications of all the available evidence

Evidence from this study suggests that atraumatic needles are associated with significant reductions in the risk of postdural-puncture headache and other complications, with similar efficacy to their conventional counterparts. Additionally, atraumatic needles reduced the need for patients to return to hospital for medical or invasive therapy. Our findings offer clinicians and health-care policy makers a comprehensive assessment and high-quality evidence for the safety and efficacy of atraumatic needles as a superior option for patients who require lumbar puncture.

closed pencil point tip and a side port for injection or collection (figure 1).[5] Post-mortem studies[6] have shown that conventional needles cut through tissues, causing irregular lacerations that can increase the potential for cerebrospinal fluid leakage. By contrast, atraumatic needles separate and dilate dural fibres, resulting in a smaller pinpoint opening after needle removal and contracture of the dura.[6] Therefore, atraumatic needles are postulated to reduce the incidence of postdural-puncture headache by limiting the leakage of cerebrospinal fluid after lumbar puncture. In-vitro studies[7] that further support this theory have shown that the rate of cerebrospinal fluid leakage due to dural perforations is decreased with atraumatic needles compared with the conventional needle type.

See Online for appendix

Although atraumatic needles were first developed nearly 70 years ago,[8] they are not routinely used in clinical practice.[9] In fact, few surveyed clinicians reported awareness of their existence because evidence describing the safety and efficacy of atraumatic needles has not reached consensus.[10,11] Previous studies have largely been single centre trials with a small sample size, only powered to detect the effect of needle tip design on the primary outcome of postdural-puncture headache. Additionally, these trials were not powered to assess the true effect of needle tip design and whether it interacts with important clinical subgroups. Therefore, we did a systematic review and meta-analysis of randomised controlled trials to compare atraumatic and conventional lumbar puncture needles across important outcomes and prespecified subgroups of patient and procedural characteristics.

Methods

Search strategy and selection criteria

For this systematic review and meta-analysis, we searched 13 databases, including MEDLINE, Embase, and Web of Science from inception to Aug 15, 2017, using a combination of relevant keywords and medical subject heading terms. We searched for randomised controlled trials that compared the use of atraumatic needles with conventional needles for any lumbar puncture indication. Full search terms and search strategy are provided in the appendix (p 1). Database searching was supplemented by manually screening references of relevant articles, proceedings of pertinent meetings, and contacting clinical experts in the field. Search strategies were developed and implemented by an independent multidisciplinary team, which included librarians and researchers with diverse clinical expertise from numerous countries. Our search had no publication type (ie, abstracts *vs* complete reports), language, or date restrictions.

Articles were included if they were randomised controlled trials comparing atraumatic needles and the conventional type for lumbar puncture. We excluded observational studies, reviews, commentaries, and letters. Randomised trials comparing atraumatic and conventional needles in which no dural puncture was done (epidural injections) or without a comparative conventional needle control group were also excluded. Disagreements about inclusion were resolved through discussion and consensus by the research team, including an impartial reviewer, and by contacting the trial authors. Where necessary, we contacted authors of relevant studies

to obtain additional information, article texts, and resolve questions about eligibility. This study is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement[12–14] and the Cochrane Handbook for Systematic Reviews of Interventions.[15] Our detailed study protocol is available online and has been previously published.[16] No institutional review board approval was required for this meta-analysis because the study included data that had been published previously.

Data analysis

Data pertaining to patient and study characteristics, treatment regimens, and safety and efficacy of both atraumatic and conventional needles for lumbar puncture were extracted from included studies independently by the research team using data abstraction forms. For studies published more than once (duplicates), we included only the report with the most informative and complete data.

The primary outcome was the incidence of postdural-puncture headache, defined as a headache that fulfilled the international classification of headache disorders (ICHD) III criteria[17]—ie, an orthostatic headache occurring within 5 days of lumbar puncture, secondary to cerebrospinal fluid leakage into the epidural space. Four diagnostic criteria are defined by the ICHD III for postdural-puncture headache: headache is secondary to cerebrospinal fluid leakage, dural puncture was done, headache developed within 5 days of dural puncture, which remits spontaneously within 2 weeks or after sealing of the puncture site with an autologous epidural blood patch, and all other causes of headache were excluded.[17] For identified studies that did not explicitly list the full ICHD III criteria, our team searched for terminology that fitted the criteria without it being entirely stated. For cases in which we were unable to assess whether headaches fitted the ICHD III definition, we contacted study authors for clarification.

Additional outcomes were the severity of postdural-puncture headache, incidence of any headache, backache, hearing disturbance, nerve root irritation, and traumatic tap, and the need for intravenous fluid or controlled analgesia, the need for epidural blood patch for treatment of headache, and the failure rate and success rate of lumbar puncture on the first attempt. The mean number of attempts required to obtain cerebrospinal fluid was also evaluated.

The additional outcome of any headache encompassed postdural-puncture headache and all headaches not fulfilling the above criteria for postdural-puncture headache (ie, non-specific headaches). Non-specific headaches differed from the ICHD III definition and were largely secondary to anaesthetics. Severity of postdural-puncture headache was assessed on the basis of intensity using a numerical ranking of 0–10 on the visual analogue scale and the required treatment regimen. Intensity ranged from mild (visual analogue scale score 1–3 or responds to over the counter analgesics and bed rest, or both) to moderate (visual analogue scale score 4–7 or responds to intravenous fluid or controlled analgesics and bed rest, or both) to severe (visual analogue scale score 8–10 or requires epidural blood patch, or both). Backache was defined as any pain in the lumbar region after puncture. We defined nerve root irritation as pain radiating to lower limbs after puncture. Hearing disturbance was defined as tinnitus or hearing loss after puncture. We defined traumatic tap as the presence of blood in the cerebrospinal fluid on visual inspection. Failure rate included all instances in which a puncture attempt was made but cerebrospinal fluid could not be obtained. Lumbar puncture was defined as successful on the first attempt if cerebrospinal fluid was obtained during the first puncture.

Figure 1: **Atraumatic and conventional needle tip designs**
A schematic of magnified atraumatic (left) and conventional (right) lumbar puncture needle tips.

Analyses for all outcomes were done on an intention-to-treat basis. We pooled population-level data from included studies and calculated relative risks (RRs) with corresponding 95% CIs. The DerSimonian and Laird random-effects model[18] was used for our meta-analysis. Weights of included studies were calculated using the inverse variance method. Pooled estimates for all incidences were computed separately for the atraumatic group and the conventional group. The number needed to treat to prevent harm was calculated for the primary outcome as outlined in the protocol. We considered a p value of less than 0·05 statistically significant. We assessed heterogeneity using the I^2 statistic.[19]

We examined eligible studies independently using the Cochrane risk of bias assessment tool.[15,20] Publication bias was assessed qualitatively by visual inspection of funnel plots and quantitatively by calculation of the Begg-Mazumdar rank correlation[21] and Egger's

For the **study protocol** see www.almenawer.com

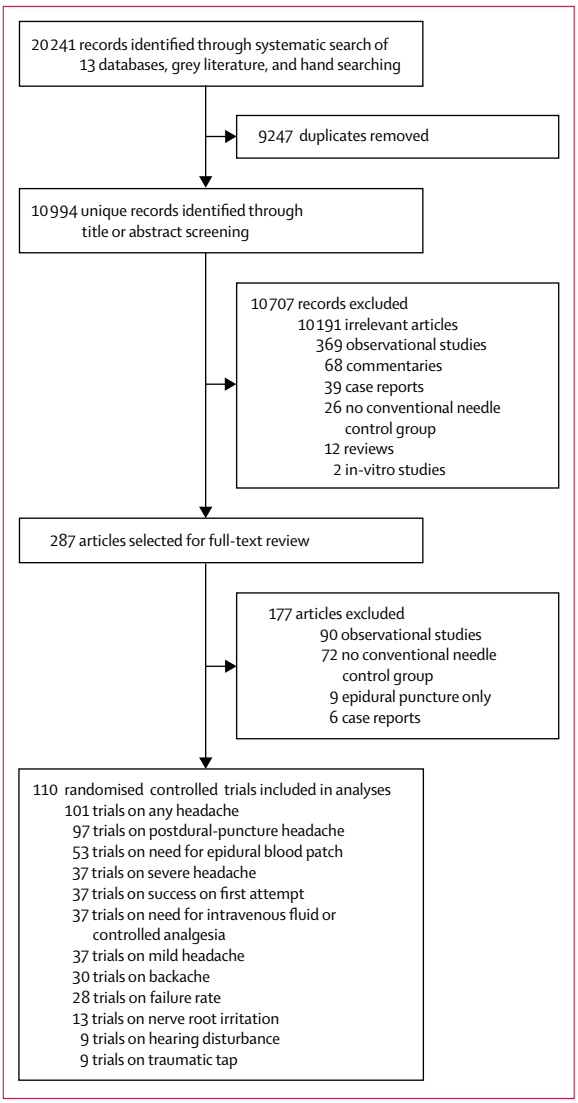

Figure 2: **Study selection**
Of the 110 trials included, several reported multiple outcomes for lumbar puncture.

	Atraumatic needle (n=13 264)	Conventional needle (n=18 148)
Age		
Overall (years)	37·3 (16·9)	39·5 (17·7)
<18	554 (4·2%)	511 (2·8%)
≥18	12 710 (95·8%)	17 637 (97·2%)
Sex		
Female	8706 (65·6%)	10 689 (58·9%)
Male	4558 (34·4%)	7459 (41·1%)
Needle gauge*		
20–22	1824 (13·8%)	1963 (10·8%)
23–26	7184 (54·1%)	6479 (35·7%)
>26	4256 (32·1%)	9706 (53·5%)
Indication for lumbar puncture		
Myelography	612 (4·6%)	655 (3·6%)
Diagnosis	954 (7·2%)	727 (4·0%)
Anaesthesia	11 698 (88·2%)	16 766 (92·4%)

Data are mean (SD) or n (%). *Smaller gauge needles are larger in diameter than larger gauge needles.

Table: **Baseline characteristics of study participants and procedural measures**

regression intercept.[22] We assessed heterogeneity between studies included in the meta-analysis using the I^2 statistic. The quality of evidence for outcomes was rated using the grading of recommendations assessment, development, and evaluation (GRADE) approach.[23]

We did sensitivity analyses using the Cochrane assessment tool (low *vs* high risk of bias) and to compare random-effects with fixed-effects meta-analysis. Furthermore, trial sequential analysis was used to account for the risk of type I error secondary to sparse data through cumulative significance testing.[24] Trial sequential analysis implements a frequentistic approach by sequentially adding data from eligible studies.[25] A diversity (D^2)-adjusted information size, whereby D^2 is the relative variance when the meta-analysis model is changed from random-effects to fixed-effects, was calculated for each outcome. D^2 values were subsequently used to establish whether the required sample sizes were reached.[26] We constructed monitoring boundaries for the amount of data needed to establish benefit or futility using the conventional test and O'Brien-Fleming boundaries.[27] Trial sequential analysis (version 0.9.5.5 beta) was used with the aim of maintaining an overall 5% risk of type I error and 80% power.[28]

Prespecified subgroup analyses were done for the primary outcome of postdural-puncture headache to explore potential heterogeneity. We assessed subgroups associated with patient characteristics, use of prophylactic measures (eg, bed rest or administration of intravenous fluid after puncture), needle gauge, patient position, indication for lumbar puncture, and clinician specialty. We did all statistical analyses using R (version 3.4.0) and Stata (version 14). This study is registered with the International Prospective Register of Systematic Reviews, number CRD42016047546.

Role of the funding source

There was no funding source for this study. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Our systematic search of the literature identified 20 241 records. Of these, 110 trials totalling 31 412 patients, done between 1989 and 2017 in 29 different countries, met our inclusion criteria (figure 2). Eight (7%) of 110 eligible studies were conference abstracts and the remainder were full-text articles. All articles were written in English with

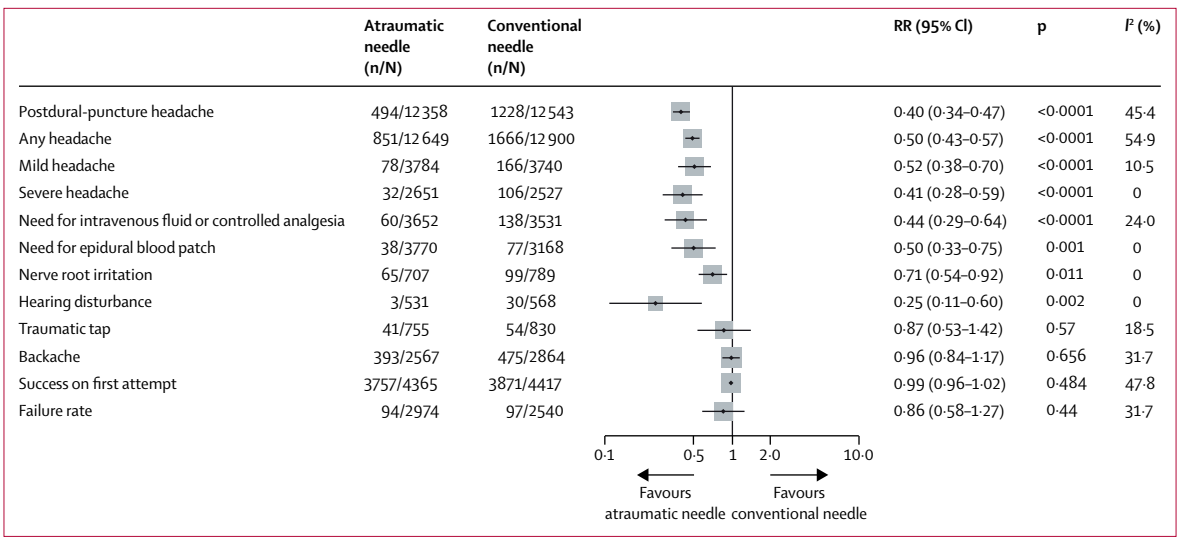

Figure 3: **Pooled analysis of relative risk according to outcome**
Group sizes do not equal the total number of participants because not all studies reported on all outcomes. n=number of events. N=group size. RR=relative risk.

the exception of 25 that were published in German (n=7), Spanish (n=5), Mandarin (n=4), Turkish (n=3), Danish (n=2), Dutch (n=1), Japanese (n=1), Polish (n=1), and Portuguese (n=1). Study characteristics, quality assessment, outcomes, and references of all 110 included trials are shown in the appendix.

The mean age of all participants was 38·6 years (SD 17·4), of whom 19 395 (61·7%) were women (table). Most patients had lumbar puncture for spinal anaesthesia, followed by diagnostic purposes and then myelography. Patient and care delivery characteristics were similar between atraumatic and conventional needle groups, with the exception of needle gauge, whereby larger gauge (smaller diameter) needles were more commonly used in the conventional needle group than in the atraumatic group.

The incidence of postdural-puncture headache differed significantly between the atraumatic and conventional needle groups. Postdural-puncture headache occurred in 494 (4·2% [95% CI 3·3–5·2]) of 12 358 patients in the atraumatic group and in 1228 (11·0% [9·1–13·3]) of 12 543 patients in the conventional group (appendix pp 149–50). The risk of postdural headache was 60% lower when atraumatic needles were used than when conventional needles were used (RR 0·40, 95% CI 0·34–0·47, p<0·0001; I^2=45·4%; figure 3). The number needed to treat to prevent harm was five.

A significant reduction in the need for epidural blood patch was also observed with atraumatic needles. Overall, 1·1% of patients in the atruamatic needle group required epidural blood patch compared with 3·0% in the conventional group (p=0·001; figure 3, appendix p 149). Similarly, the need for intravenous fluid or controlled analgesia was reduced significantly (2·2% of patients in the atraumatic needle group *vs* 4·5% of patients in the conventional needle group; p<0·0001; figure 3, appendix p 149). Significant reductions in the incidence of both mild and severe postdural-puncture headache, of any headache, of nerve root irritation, and of hearing disturbance were also observed (figure 3, appendix p 149). The incidence of backache and traumatic tap, the success rate on first attempt, and failure rate did not differ significantly between the atraumatic and conventional needle groups. The mean number of attempts required to obtain cerebrospinal fluid also did not differ (weighted mean difference –0·006, 95% CI –0·026 to 0·014, p=0·537; I^2=0; appendix p 148). Forest plots of all outcomes are shown in the appendix (pp 111–22).

Visual inspection of funnel plots and quantitative assessments revealed no evidence of publication bias for the examined outcomes (appendix pp 123–34). The overall quality of evidence was rated as high, which was examined using the GRADE approach (appendix p 150). Predefined sensitivity analyses comparing low risk of bias studies with high risk of bias studies revealed no difference ($p_{interaction}$=0·721; appendix p 147). Additionally, results from random-effects versus fixed-effects meta-analysis showed no significant differences (appendix p 148). Trial sequential analysis showed that the required sample sizes were reached, and thus the meta-analysis had sufficient power to assess the specified outcomes. Results from trial sequential analyses mirrored those of primary analyses, with the cumulative *Z* curve crossing the O'Brien-Fleming boundary for benefit or futility (appendix pp 135–46).

Subgroup analyses revealed no significant interactions with needle type for the primary outcome of postdural-puncture headache (figure 4). No evidence of heterogeneity of treatment effect was observed for patient age (<18 years *vs* ≥18 years), sex, use of prophylactic intravenous fluid, needle gauge (20–22 *vs* 23–26 *vs* >26), patient position (sitting *vs* lateral), indication for lumbar puncture

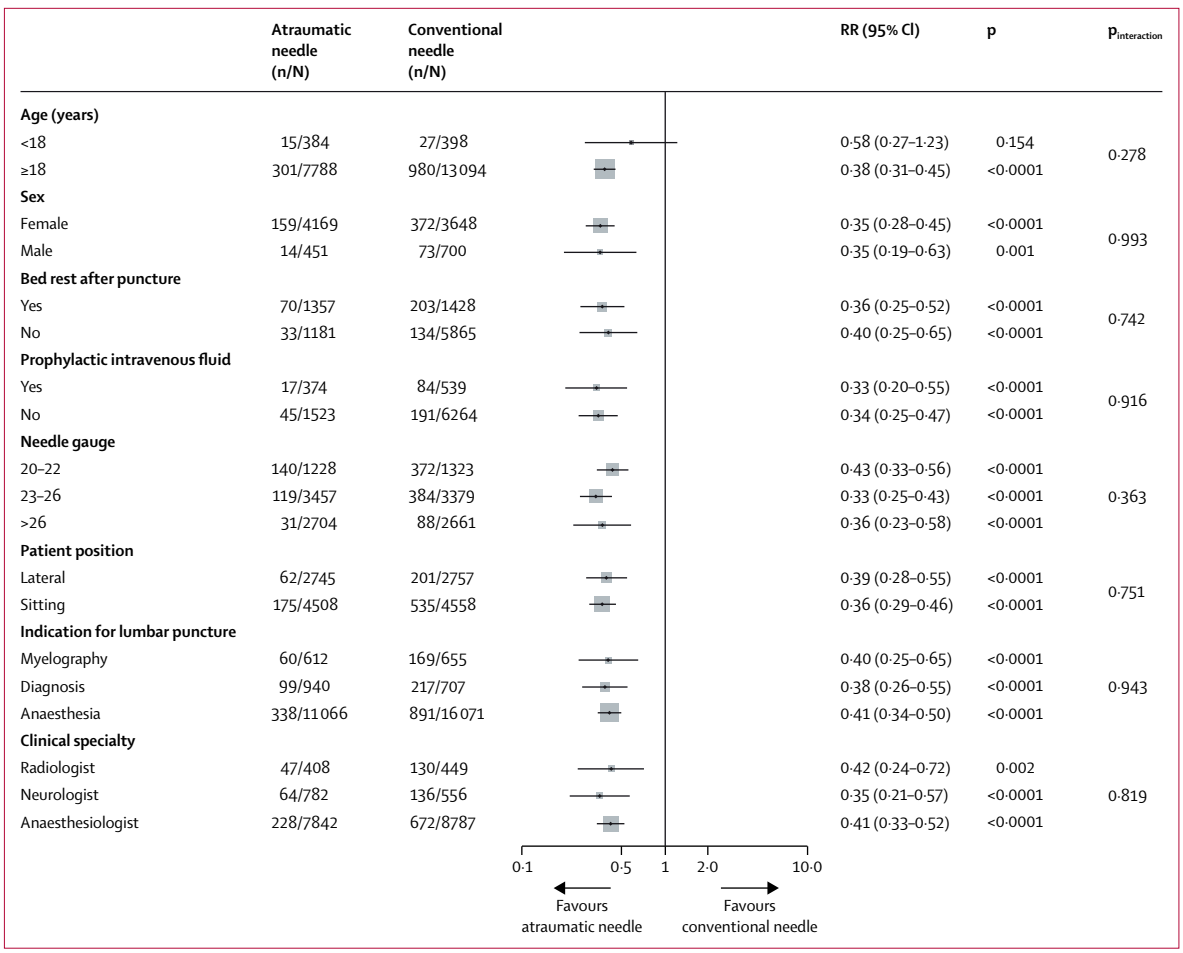

Figure 4: **Pooled relative risk of postdural-puncture headache according to subgroup**
Group sizes do not equal the total number of participants because not all studies reported on all outcomes. n=number of events. N=group size. RR=relative risk.

(anaesthesia *vs* diagnostic *vs* myelography), bed rest after puncture, or clinician specialty (anaesthesiologist *vs* neurologist *vs* radiologist; figure 4).

Discussion

Our study indicates that patients who have lumbar puncture with atraumatic needles have a significantly lower incidence of postdural-puncture headache than those punctured with the conventional type. Furthermore, the need for patients to return to hospital for controlled analgesia or intravenous fluid was reduced in patients punctured with atraumatic needles. Need for invasive therapy (ie, epidural blood patch) was also significantly decreased in the atraumatic group compared with the conventional group. Performance characteristics, including failure rate, rate of success on the first attempt, and the mean number of attempts were similar between both groups, indicating that atraumatic needles have similar efficacy to conventional needles.

Reduced risk of postdural-puncture headache in the atraumatic needle group was maintained across important subgroups associated with patient demographics, needle gauge, patient position, indication for lumbar puncture, clinician specialty, and use of prophylactic measures, such as bed rest or intravenous fluid. This observation suggests that our findings reflect a true effect of atraumatic needles, rather than an artefact of statistical heterogeneity or specific patient or procedural characteristics. Notably, smaller gauge (larger diameter) needles were used more frequently in the atraumatic group than in the conventional needle group. Despite this difference, the therapeutic advantage of atraumatic needles was maintained, suggesting that the effect of needle tip design supersedes that of needle gauge in reducing postdural-puncture headache.

Several surveys done worldwide have indicated that atraumatic needles are rarely used by clinicians because many individuals in the profession are unaware of their existence.[9–11,29] Clinicians who were surveyed reported unfamiliarity, concerns about cost, and questions regarding the ease of use of atraumatic needles. Moreover, clinicians were concerned about the true effect of atraumatic needles and the generalisability of the existing literature. Previous trials comparing

atraumatic with conventional needles examined specific atraumatic (eg, Cappe and Deutsch, Eldor, Gertie-Marx, Microtip, Sprotte, and Whitacre) and conventional (eg, Atraucan, Bainbridge, Barker, Brace, Hingson-Ferguson, Labat, Lemmon, Quincke, and Rovenstine) needle subtypes. These trials were further limited to a specific needle gauge and lumbar puncture indication (eg, anaesthesia, diagnostic, myelography, or therapeutic). Our large sample size (>30 000 participants) enhances generalisability and precision in the assessment of our primary and multiple additional outcomes, and key subgroups.

Our findings stand in clear distinction from those of past studies that have failed to reach consensus on this topic. Previous meta-analyses[30–32] had limitations and focused on the application of atraumatic needles for a specific clinical discipline, whereas our study is broad in its scope with robust analyses done by a multidisciplinary team. A Cochrane systematic review[33] aimed to assess both needle gauge and needle tip design. However, the review only included 36 trials (33% of eligible studies) comparing atraumatic and conventional needles without examination of important clinical outcomes and subgroups, such as patient return to hospital for medical or invasive therapy and efficacy measures (ie, failure and success rates). As a result, this review lowered the confidence in the estimate of effect of needle tip design. After careful examination of our meta-analysis using the GRADE approach,[23] the quality of evidence on the safety and efficacy of atraumatic needles was rated as high. Thus, future research is unlikely to change our confidence in the estimate of effect. Further research is required to inform and improve clinical decision making, but such studies will not alter our certainty regarding the safety and efficacy of atraumatic lumbar puncture needles.

However, our study is not without limitations. First, we did not do a cost-effectiveness analysis, which is of importance for informing health-care policy. Atraumatic and conventional needles remain variable in cost, with prices differing on the basis of the specific needle subtype and manufacturer. The cost of atraumatic needles can be similar to, double that of, or occasionally triple that of the conventional type.[34] Past studies[35] have shown that atraumatic needles are cost-effective because they reduce the need for additional care, such as intravenous fluid, controlled analgesia, or invasive therapy, resulting in better allocation of health-care resources. Cost-effectiveness of atraumatic needles is further realised by reductions in lost work hours for patients, attributed to fewer sick days, leading to better economic outcomes overall.[36]

Second, because the trials assessed varied outcomes, not all of our outcomes were represented in an equal number of participants. For example, our primary outcome of postdural-puncture headache was assessed in 24 901 patients, compared with 5431 for backache and 1585 for traumatic tap. Moreover, most patients were adults, with only 1065 paediatric participants, and analysis of elderly patients as an independent subgroup was not possible because data were not sufficiently granular. Sensitivity analyses showed that our meta-analysis was sufficiently powered to assess outcomes and to make decisions about benefit and futility.

Third, we were unable to quantify the ease of use of atraumatic needles among clinicians who did lumbar puncture. Use was reported largely as a subjective measure, with some clinicians indicating difficulty with the atraumatic type, citing unfamiliarity. Notably, most practitioners reported that their first encounter with atraumatic needles was in the context of the randomised trial. Most clinicians, however, found atraumatic and conventional needles similar to use, especially when the atraumatic needle was inserted through the same skin puncture used for local anaesthesia. Furthermore, no significant differences in the rates of failure and success were identified between the two needle groups.

Finally, we identified heterogeneity in our primary outcome, calling into question the validity of our results. However, we investigated eight predefined subgroups associated with patient and procedural characteristics and found no significant interaction with needle type, suggesting a true effect of the atraumatic tip. In particular, bed rest—which is often recommended after lumbar puncture—was not found to influence the incidence of postdural-puncture headache.

In conclusion, we found that atraumatic needles were associated with significant reductions in the risk of postdural-puncture headache and other complications, and had similar efficacy to their conventional counterparts. Patients who were punctured with atraumatic needles were also less likely to return to hospital for additional medical therapy or an invasive procedure than those punctured with conventional needles. Our findings suggest that atraumatic needles retain a favourable balance between safety and efficacy when compared with the conventional type. In fact, these results provide clinicians and health-care policy makers with a comprehensive assessment and high-quality evidence on the safety and efficacy of atraumatic needles as a superior option for patients who require lumbar puncture.

Contributors

SN, JHB, WA, and SAA conceived and designed the study. SN, AK, JHB, WA, SSh, LB, EB-C, MMB, FA, MK, IE-I, RK, ON, and SAA did the data searches, data extraction, and quality assessment. SN, AK, JHB, WA, FF, and SAA did the quality analyses and statistical analyses. SN, AK, and SAA created the tables and figures and prepared the supplementary material. SN, AK, and SAA drafted the manuscript. All authors critically revised and approved the final manuscript.

Declaration of interests

We declare no competing interests.

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