

Original Article

EVALUATION OF TIP HOLED SPINAL NEEDLE - A COMPARATIVE STUDY

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Background: The performance and post dural puncture headache were assessed in this randomised clinical study.

Methods. Total 100 patients of ASA physical status I and II undergoing elective caesarean section were enrolled for the study. Patients in the controlled group Group-A. Patients in the trial group (Group-B).

ABSTRACT:

Regional block has its own unique place in modern anesthetic practice increasing popularity over 30-40 years has followed better understanding of the technique and acceptance than the incidence of side effects is low. These depend not only on the correctly performed procedures but the correct design of the needle is also important. The purpose of this clinical study is to evaluate the performance of tip hole spinal needle (25G) in comparison with widely used Quincke spinal needle (25G). Clinical effects, performers satisfaction, side effects and complications were assessed over 100 pts who were decided into group A (Quincke gr) & Group B (tip hole gr) undergoing emergency & elective C.S. under spinal anaesthesia. Ease of insertion of the needle, number of attempts for successful insertion, appearance of CSF flow through needle, bending of needle, quality of analgesia, clinical effects & PDPH were assessed.

No significant changes in pulse, BP. & SPO₂ in 1 minute & 5 minutes were found in pre-operative & per-operative period in Group A & also in Group B.

In terms of ease of insertion there was no significant change in Group A (100%) & Group B (90%). It was found that in less than 1 second no CSF fluid appeared in Group A but in Group B, CSF appeared in 30%, in less than 2 seconds, the values among Gr A & Gr B were 4% & 52%, in less than 3 seconds. 50% & 18% respectively. In less than 4 seconds & 5 seconds in Group A 38% & 8% respectively and no CSF fluid appeared in Group B in that period.

In Group A 52% cases required 1 attempt, 28% cases 2 attempts, 16% of cases 3 attempts & 4% cases 4 attempts were required. In Group B it was 86%, 14% & no 3rd & 4th attempts required. In terms of bending of needles during insertion, the performance of Group B was better (7% in Group A and no in Group B). The incidence of PDPH was found absolutely nil among the gr B & negligible (2%) in gr A subjects.

INTRODUCTION:

First planned spinal anaesthesia for surgery in human performed by August Bier in 1899 with cocaine. In the beginning of the 20th century, intradural injection was carried out for many procedures. But the popularity waned in the late 1940s following reports of neurological damage²² as well as other complications like severe hypotension, nausea, vomiting, PDPH etc.

Again increasing popularity over the last 30-40 years has followed better understanding of the technique & acceptance that the incidence of side effects is low. These depend not only on the correctly performed procedures but the correct design of the needle is also important⁷. Spinal needles are manufactured with no surface irregularities and with a tight fitting removable stylet which completely occlude the needle lumen. Equally diverse are the shapes of the bevel and the tips of the needles. The needles are either end or side injection and either sharp or rounded bevel edges.

The most widely used spinal needle is Quincke needle which has a bevel length, with sharp cutting edges, a sharp point and end injection port. Spott, Greene and Whitacre are pencil point needles, have a rounded bevel, no cutting edges and side hole proximal to the bevel, which causes less damage to the tissues during puncture with less chance of PDPH. But clinical studies suggest that, it gives

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rise to the newer problems with lateral bending of the tip², the side hole being obstructed by the tissues, and delayed appearance of CSF.

That causes damage to the dural tissue with more chance of PDPH, but early appearance of CSF fluid.

Analyzing the performance of the existing needles, the conclusion was drawn that the criteria of an ideal spinal needle may be as follows. The external diameter of the needle should be as thin as possible and the tip should be of a dural fiber-spreading variety. The tip and the shaft should be capable of with standing forces during needle placement. It should also have a drug delivery hole that does not weaken the needle nor become obstructed by tissue.

Easy and quick flashback of CSF is another important desired feature.

Considering these aspects, a new tip holed spinal needle has been designed and produced by Doctor Japan co. Ltd. Japan and Willy Rusch AG, Germany. The tip of the needle proper is actually the blunt end of the needle shaft and the hole for end injection. The stylet that projects beyond the tip of the needle finally form the penetrating part of the tip of the complete needle⁴.

There is report of the performance of new tip holed needle⁴ but there is no comparison of its clinical performance and side effects with other types of spinal needles commonly used (Quincke, Whitacre, Sprotte). In these clinical study evaluation the tip holed spinal needle in comparison with widely used Quincke spinal needle.

METHODS AND MATERIALS:

100 ASA physical status I and II patients having elective caesarean section, aged between 20 to 35 years and weighted between 45 to 60 kg, were randomised by card sampling for this study in Bangabandhu Sheikh Mujib Medical University (BSMMU). A total of hundred cards, fifty for each group were prepared by another person who was not aware of the study. Every patient included in the study was allowed a card preoperatively. According to the card number, patients were

grouped. Group A and Group B (experimental group)

Preoperative

All patients preoperative base line data like pulse rate, blood pressure, respiratory rate and oxygen saturation were measured and recorded. Informed consent was taken from all patients.

PEROPERATIVE

Intravenous channel for routine infusion was started and monitor attached for measuring pulse, blood pressure and arterial oxygen saturation.

Data processing

All statistical analyses were carried out using SPSS statistical package (SPSS 11.0 for Windows Version). All results are expressed as mean \pm standard deviation (SD) or in frequencies as applicable. The results were compiled and analysed using Unpaired 't' or Chi square (χ^2) as appropriate. Results were considered statistically significant if $p < 0.05$ (Confidence Interval; CI-95%).

RESULTS

Observation of the present study was analyzed in the light of comparison among the subject groups, each group having $n = 50$. All results are expressed as mean \pm standard deviation (SD) or in frequencies as applicable. The studied groups became statistically matched for age ($p = 0.705$), weight ($p = 0.599$) and height ($p = 0.642$).

Table-I
Demographic characteristics of the study

Characteristics / Groups	Group-A	Group-B	P value
Age in years	27.5 \pm 0.65	28.15 \pm 0.66	0.705
Weight in kg	62.38 \pm 1.02	64.09 \pm 1.32	0.599
Height in cm	152.5 \pm 6.0	151 \pm 7.1	0.642

Values are expressed as mean \pm SD, analysis were done by unpaired student's 't' test. Values are regarded as significant if $p < 0.05$ (CL-95%).

The demographic characteristics are summarized in Table-1. The mean age was found 27.5 ± 0.65 in group-A and 28.15 ± 0.66 in group-B. The mean weight was 62.38 ± 1.02 in group-A and 64.09 ± 1.32 in group-B. The mean height was 152.5 ± 6.0 in group-A and 151 ± 7.1 in group-B.

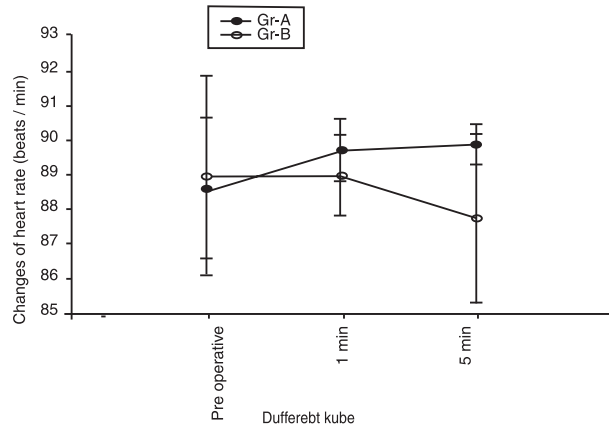


Fig. 1: Changes of heart rate

Changes of heart rate are displayed in Fig-1. The heart rate has significantly ($p < 0.001$) and $p < 0.70$ changed in 1 and 5 min after block.

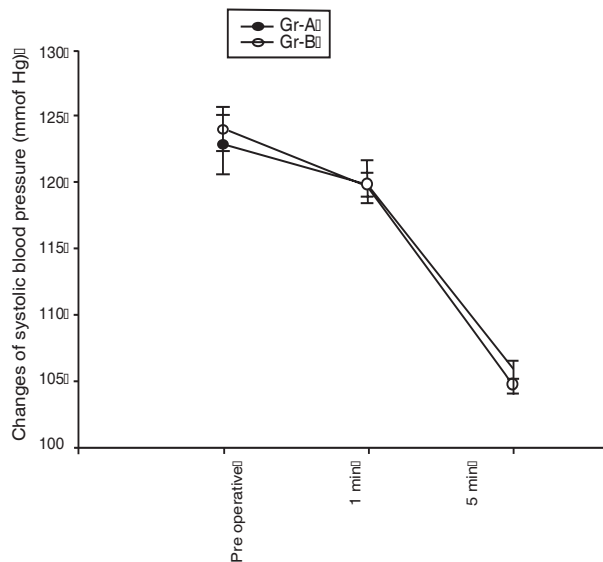


Fig.-2: Changes of systolic blood pressure in different time

Table-II
Performance of the needle

Characteristics	Group-A	Group-B	P value
Insertion			
Smooth	50	47(94%)	
Difficulty	0	3(6%)	
Appearance of CSF in seconds	3.54 ± 0.10	1.84 ± 0.13	0.000
No of attempt			
One	26(52%)	43(86%)	0.002
Two	14(28%)	7(14%)	
Three	8(16%)	0	
Four	2(4%)	0	
Bending of needle	7(14%)	0	0.050

Values are expressed as mean \pm SEM or in frequencies. Within parenthesis are percentages over column total. Values are expressed as significant if $p < 0.05$

Table-III

No of patient complaints of post dural puncture headache and back pain

Characteristics	Group-A	Group-B	P value
PDPH	0	2(4%)	0.000

Values are expressed in frequencies. Within parenthesis are percentages over column total. Values are expressed as significant if $p < 0.05$

DISCUSSION:

In caesarean section operation spinal anaesthesia is popular for various reason. During the spinal anaesthesia various type of spinal needles are used. In our country due to cheap and availability 25 gauge and 26 gauge Quincke needles are mostly used. This cutting bevel have some disadvantages like bending of the needle, delay appearance of CSF and PDPH. To overcome this disadvantages a newly designed tip-holed spinal needle was made. The present work was designed to made a comparison between 25 gauge Quincke spinal needle with the 25 gauge newly designed tip holed spinal needle in obstetrical patient during spinal anaesthesia.

There are few studies^{5,6} which examine the technical difficulties involved in the use of different spinal needles. In our study formed the impression that distinctive click (better sensation with the loss of resistance upon dural puncture) is very much apparent with newly designed tip holed needle than

Quincke needle. Whereas a few recorded distinctive click with 25 gauge whitacre needle which less than Quincke needle⁷.

Regarding the number of attempts of needle insertion it was found that 86% of group B subjects required only one attempt, while group A subjects required more than two or more attempts for insertion. Similar type of study reported 64% incidence of successful dural puncture at first attempt using 25 gauge whitacre needle⁷. The present study demonstrate that the difference of attempts of insertion among two procedures were statistically significant (Table 2, Fig. 3). We had no failure to puncture the dura in both type of needle whereas, Levy JH et al. Found failure to confirm dural puncture with 25 gauge needle.

Recently bending of the needle has been reported with certain fine gauge needles^{2,8}. This bending may occur both at the level of the shaft and at the tip. Shaft bending typically occurs in Quincke needles with unilateral tip bevel. When the bevel encounters tissue resistance, it may change its trajectory and become bent; however this is usually not persistent. This altered needle track, may fail to reach the dural sac, or may enter far laterally⁹.

It was hypothesized that a needle of spreading bevel (cone-shaped) with the drug delivery port at the tip would overcome most of these problems. The mechanical weakness imposed by some needle tip designs caused by the presence of a delivery orifice on or near the tip of the spinal needles-has been removed. As such, it is expected that the needle will not bend under usual placement circumstances To create these modified tip holed spinal needles, 26 gauge Quincke bevel needles (B.Braun) were modified⁴.

In our opinion number of attempts of insertion and bending of the needle was very likely due to unilateral tip bevel of the quincke spinal needle.

Quick appearance of the CSF at the hub contribute to easy identification of the sub-arachnoid space with a reduction in failure rate¹⁰. However similar gauge needles do not always ensure the same CSF flow rate^{5,11}. A major contributing factor to CSF flow rate is internal diameter, which for any given needle size varies between manufacturers¹⁰.

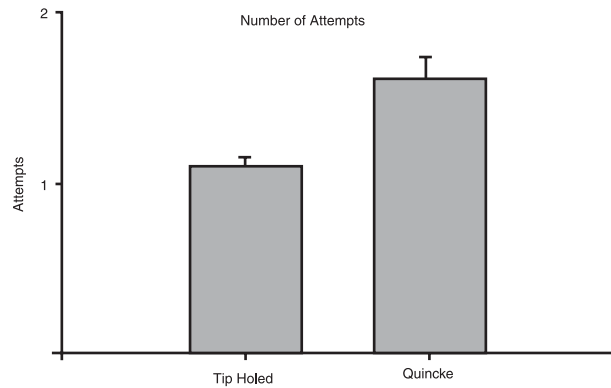


Fig.-3

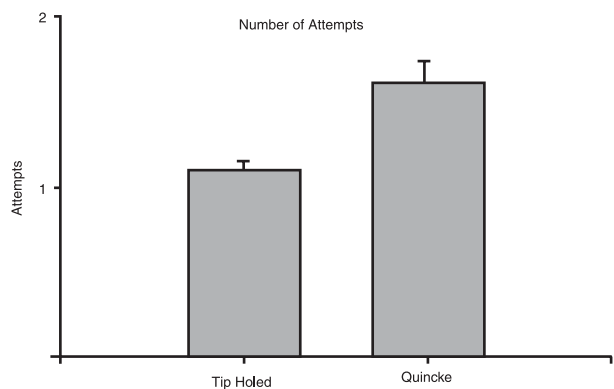


Fig.-4

In this study about the appearance of CSF, it was found that there was highly significant difference among group A and group B subjects. The appearance of CSF was comparatively late in group A subjects (Table 2, Fig. 4). Our work supports the previous study of two seconds of CSF flash back to appear has been suggested as ideal time¹¹.

In another study of 29 gauge needles, cerebrospinal fluid (CSF) was not detected, and therefore anaesthesia was not possible in 8% patients¹¹. Because of CSF at the hub is expected with side holed needles compared with open tipped needles (like Quinckes). These modifying factors have been eliminated altogether in the new design and thus, laminar flow of CSF is maintained throughout.

PDPH has always been present following spinal anaesthesia^{12,13} and incidence is greatest in obstetric patient^{14,15} The frequency of PDPH seems affected by needle size and tip configuration.

Recent report suggest that the pencil-tip configuration seems to be the single most important factor in reducing the incidence of PDPH and related symptoms^{16,17,18}. PDPH remains frequent complication in obstetric population in spinal anaesthesia, it occurs most commonly in young, female patients (particularly parturients^{15, 19} and correlates with the size of the spinal needle used^{20,21,22}. Mayer et al^{23,24} reported to similar incidence of PDPH with 27 gauge Quincke needle and 24 gauge Sprotte needle¹⁵.

The incidence of post dural puncture headache (PDPH) was found absolutely nil among the group B subjects, however negligible (2%) PDPH was observed among group A subjects (Table 3) in our study. Similar findings was also observed with 24 gauge Sprottee needle in a similarly controlled study in obstetric patient²⁵ and with 25 gauge Whitacre needle⁷. The Sprotte needle was compared to 25 gauge cutting bevel needle, the use of which was associated with 14.5% incidence (eight patients) of PDPH²⁵. Other controlled studies in obstetric patients have appeared and reported headache frequencies of 4% (one patient) with 22 gauge whitcre needle against 25% (six patients) with 26 gauge Quincke needle²⁶ and 3.6% (two patients) with 24-gauge sprotte needle compared with 1.75% (one patient) with a 22 gauge sprotte needle²⁷.

Our finding is near the study of sprotte 24 gauge and whitacre needle 25 gauge. Incidence of PDPH in both the study and our study is $\leq 2\%$ ⁷ 25 gauge cutting bevel needle was associated with 14.5%²⁵ incidence of PDPH while comparing with Sprotte needle 24 gauge. Looking at the finding of low PDPH in our study we agree with other pencil point needle study observers and the spreading of dural fibre seems to be the main reason.

CONCLUSION

The study shows a difference in performance between 25 gauge Quincke needle with the 25 gauge newly designed tip holed spinal needle. Both the needles are quite acceptable regarding ease of insertion. But regarding number of attempts at insertion, about the appearance of CSF, in terms of bending, the newly designed tip holed spinal needle is better than Quincke spinal needle.

The incidence of PDPH was found also absolutely nil with the tip holed group.

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