



“A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE INCIDENCE OF POSTDURAL PUNCTURE HEADACHE FOLLOWING SPINAL ANAESTHESIA IN OBSTETRIC PATIENTS USING 25 GAUGE WHITACRE SPINAL NEEDLE AND QUINCKE SPINAL NEEDLE.

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ABSTRACT

BACKGROUND: PDPH causes considerable morbidity, with symptoms lasting for several days, at times severe enough to immobilize the patients. Our study is to compare the incidence and the severity of PDPH in obstetric patients using 25 gauge cutting tip Quincke spinal needle and 25 gauge pencil tip Whitacre spinal needle.

MATERIALS AND METHODS: 240 Obstetric patients posted for elective caesarean section were randomly allocated into Group A and Group B using a computer generated randomization table. Group A received subarachnoid block with 25 gauge Whitacre needle and Group B with 25 gauge Quincke needle. Number of attempts and number of failed spinal anaesthesia noted. All patients were enquired about onset, duration, severity and associated symptoms for 3 days postoperatively. Severity of headache was categorised as mild, moderate and severe.

RESULT: The occurrence of PDPH was meaningfully less (3.3%) when pencil-point 25G Whitacre spinal needles is used compared to Cutting bevelled 25G Quincke spinal needle (10.8%). It was mild in 6%, moderate in 12% and severe in 6% of patients in pencil-point 25G Whiteacrespinal needle group. It was mild in 29%, moderate in 35% and severe in 12% of patients in Cutting bevelled 25G Quincke spinal needle group. This difference is true and significant and has not occurred by chance.

CONCLUSION : We conclude that use of 25 gauge pencil tip, Whitacre needle is associated with significant reduction in the incidence of PDPH than 25 gauge cutting needle Quincke needle in obstetric patients.

KEYWORDS : Postdural puncture headache (PDPH), Whitacre spinal needle, Quincke Babcock spinal needle.

INTRODUCTION

Subarachnoid block is the widely used technique by the anaesthesiologist worldwide. Spinal anaesthesia dates back to late 1800 with the work of Wynter, Quincke and Corning. However Dr.Karl August Bier is given the credit for introducing spinal anaesthesia in clinical practice in 1898. The main advantage of SAB is due to its simplicity, ease of performance, requirement of minimal apparatus, minimal effect on blood biochemistry, conscious patient maintaining airway, good immediate postoperative pain relief, blunts stress response to surgery, decreased thromboembolic events. Though popular still, subarachnoid block is not without complications. One of the common complication is Postdural puncture headache. Bier gained first-hand experience of the disabling headache related to dural puncture. He correctly summarized that the headache was related to excessive loss of CSF.

PDPH increases the duration of hospital stay. In addition to this, it warrants a battery of investigations to rule out different causes of headache. This PDPH is more distressing to the mother who is supposed to take care of the newborn baby. There are lot of studies done regarding the measures for the reduction of PDPH. It is said that with the help of fine gauge spinal needle and needle tip modification can reduce the incidence to a greater extent. The 25 gauge Quincke babcock with medium cutting bevel is the most popular and widely used spinal needle. A balance has to be done between the incidence of PDPH and the technical difficulties with the use of fine gauge spinal needle. In this study we compared 25 gauge Pencil tip whitacre needle with 25 gauge cutting bevelled Quincke babcock needle for the incidence of PDPH.

AIM OF THE STUDY

The aim of the study is to compare the incidence of PDPH, using 25 gauge Quincke spinal needle and 25 gauge Whitacre spinal needle in obstetric patients.

PRIMARY AIM -Incidence and Severity of PDPH.

SECONDARY AIM -Number of attempts for successful blockade and number of failed blocks.

MATERIALS AND METHODS

The study is to compare the incidence and severity of PDPH, number of attempts for successful block and number of failed spinal in using 25 gauge Quincke and 25 gauge Whitacre spinal needles in 240 obstetric patients after getting approval by the Institutional Ethical Committee. It is a double blind study where the patient is unaware of the needle type used and the postoperative assessment of headache is done by a person unaware of the needle type used. 240 obstetric patients posted for elective LSCS under Subarachnoid block were

randomly allocated into group A and group B by using a computer generated randomization table.

SELECTION CRITERIA

INCLUSION CRITERIA -Age 20 to 36 years, weight 58 to 87 kilograms, height 148 to 170 cms, ASA 1, elective surgery, valid informed consent.

EXCLUSION CRITERIA-Not satisfying inclusion criteria, lack of Written informed consent, contraindication for neuraxial anaesthesia, H/O Recurrent headache in the past, H/O Occipital neuralgia/Migrain.

A thorough history taking and clinical evaluation done to include patients who satisfy inclusion and exclusion criteria. Preoperative investigations done as all cases posted for elective surgery. All patients were briefed about the nature of the study, procedure to be performed and a valid written informed consent obtained. The patients were instructed fasting from midnight, atleast for 8 hours. The patients transported to the operation theatre in left lateral position. Monitors of pulse oximeter, electrocardiogram (ECG) and non-invasive blood pressure (NIBP) attached before performing subarachnoid block and monitored throughout the procedure. An intravenous access established over the dorsum of left hand with 18 gauge venflon. Preloading with 20ml/kg of Ringer lactate done for all patients. Premedication with injection Ranitidine and injection metaclopramide given 1 hour prior to surgery.

240 patients were randomly allocated into group A and group B.

Group A patients received subarachnoid block with 25 gauge Whitacre needle and Group B received SAB with 25 gauge Quincke needle.

After preloading, patients were placed in right lateral position. The back of the patient was cleaned with Povidone iodine and spirit and draped with sterile towel. A skin wheel was raised with 2ml of 2% Lignocaine and SAB performed with 10mgs of 0.5% hyperbaric bupivacaine at L3-L4 space. The patient was turned supine after giving the drug, with a wedge under the right hip.

Anaesthesia considered adequate when the sensation to cold is lost at the level of T4, tested with alcohol. Oxygen administered with Hudsons mask at 4litres/min throughout the procedure. Mean blood pressure monitored every 5 minutes intervals and any decrease more 20% from baseline was treated with a 100ml bolus of crystalloids and incremental bolus of 6mgs intravenous Ephedrin. 10units Syntocinon administered as intramuscularly and as intravenous infusion after the delivery of the baby.

In case of failure of SAB or inadequate analgesia, patients were administered General anaesthesia. Failure of block is defined as either an inability to produce a free flow of CSF after 3 attempts or inadequate analgesia for surgery at 15 minutes after giving the local anaesthetic agent.

The number of attempts required for successful blockade was also noted for both the type of needles.

Postoperatively all the patients were enquired about the onset, characteristics, duration, severity and associated symptoms of any headache for three days. PDPH is characterized by postural headache, aggravated by sitting or standing and relieved by lying supine. It may be dull aching or throbbing, mostly in the occipital or frontal region, accompanied by nausea, vomiting, neck stiffness, diplopia and tinnitus.

The patients with features suggestive of PDPH were treated with iv fluids, bed rest and oral paracetamol 15mg/kg, four times daily.

The severity of headache was categorized as mild PDPH (Slight restriction of physical activity, these patients are not restricted to bed and had no associated symptoms), Moderate PDPH (The patient is forced to stay in the bed for part of the day, resulting in restricted physical activity, not necessarily associated with symptoms) and Severe PDPH (The patients were bedridden for most of the day, associated symptoms always present).

Treatment Groups

| Treatment Groups | Name of Group | Treatment | Number of Subjects |
|------------------|---------------|--|--------------------|
| Group A | 25 GW | PDPH using pencil-point 25G Whitacre spinal needle in obstetric patients | 120 |
| Group B | 25 GQ | PDPH using Cutting bevelled 25 G quincke spinal needle in obstetric patients | 120 |

STATISTICS

Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t-test and categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as P < 0.05. The data was analysed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

Sample Size Calculation

Sample size was determined on the basis of a pilot study in which the incidence of Post Dural Puncture Headache was measured as 18%. We calculated a minimum sample size of 113 patients was required in each group, assuming a type 1 error (two-tailed) of 0.05 and a margin of error of 5%. Therefore, the final sample selected was n=120 in Group A and n=120 in Group B.

$$n = \frac{t^2 \times p(1-p)}{m^2}$$

Description:

n = required sample size

t = confidence level at 95% (standard value of 1.96)

p = estimated prevalence of malnutrition in the project area

m = margin of error at 5% (standard value of 0.05)

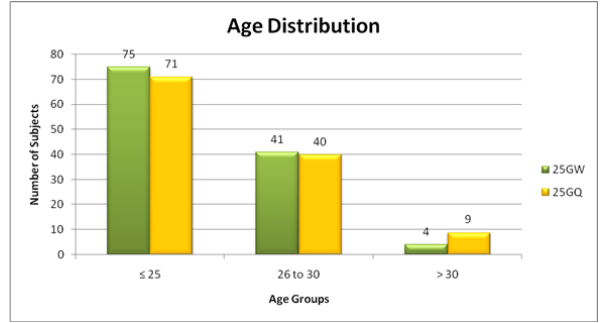
$$n = \frac{(1.96)^2 \times 0.18(1-0.18)}{(0.05)^2}$$

$$n = \frac{3.8146 \times 0.1476}{0.0025}$$

= 226

= 113 per group

Age

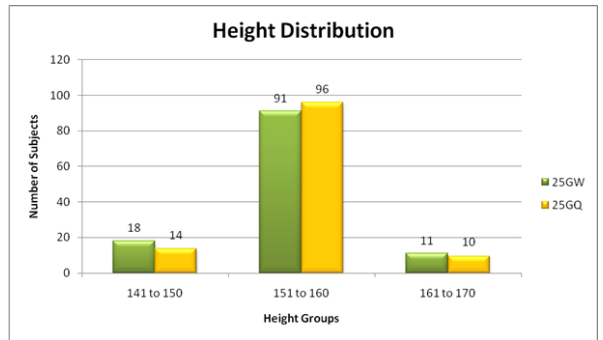


| Age | 25GW | 25GQ | % |
|--------------|------------|------------|------------|
| ≤ 25 | 75 | 71 | 59.17 |
| 26 to 30 | 41 | 40 | 33.33 |
| > 30 | 4 | 9 | 7.50 |
| Total | 120 | 120 | 100 |

| Table -1 | 25GW | 25GQ |
|-------------------------|----------|----------|
| N | 120 | 120 |
| Mean | 25.00833 | 25.03333 |
| SD | 2.891587 | 3.159442 |
| P value Unpaired t test | 0.94907 | |

By conventional criteria the association between the Spinal Needle groups and age is considered to be not statistically significant since p > 0.05.

Height

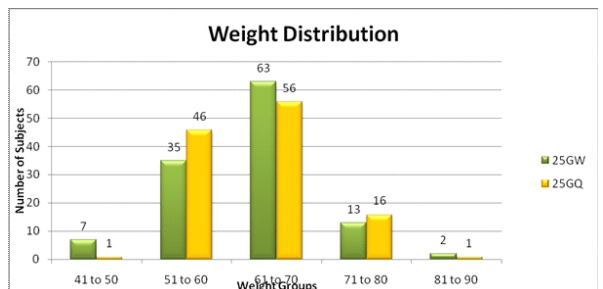


| Height in CMs | 25GW | 25GQ | % |
|---------------|------------|------------|------------|
| 141 to 150 | 18 | 14 | 11.67 |
| 151 to 160 | 91 | 96 | 80.00 |
| 161 to 170 | 11 | 10 | 8.33 |
| Total | 120 | 120 | 100 |

| Table-2 | 25GW | 25GQ |
|-------------------------|----------|----------|
| N | 120 | 120 |
| Mean | 155.4333 | 155.7083 |
| SD | 4.166157 | 4.013414 |
| P value Unpaired t test | 0.603023 | |

By conventional criteria the association between the Spinal Needle groups and Height is considered to be not statistically significant since p > 0.05.

Weight

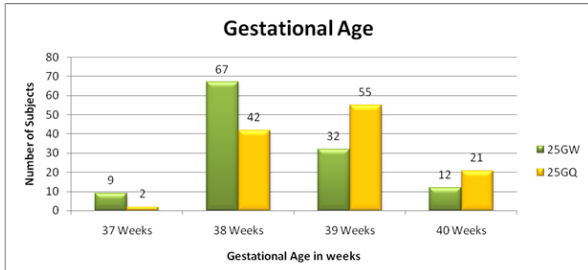


| Weight in Kg | 25GW | 25GQ | 25GW | 25GQ |
|--------------|------|-------|------|-------|
| 41 to 50 | 7 | 5.83 | 1 | 0.83 |
| 51 to 60 | 35 | 29.17 | 46 | 38.33 |
| 61 to 70 | 63 | 52.50 | 56 | 46.67 |
| 71 to 80 | 13 | 10.83 | 16 | 13.33 |
| 81 to 90 | 2 | 1.67 | 1 | 0.83 |
| Total | 120 | 100 | 120 | 100 |

| Table -3 | | 25GW | 25GQ |
|-------------------------|--|----------|----------|
| N | | 120 | 120 |
| Mean | | 63.85833 | 63.51667 |
| SD | | 7.515022 | 6.713818 |
| P value Unpaired t test | | 0.710668 | |

By conventional criteria the association between the Spinal Needle groups and Weight is considered to be not statistically significant since $p > 0.05$.

Gestational age

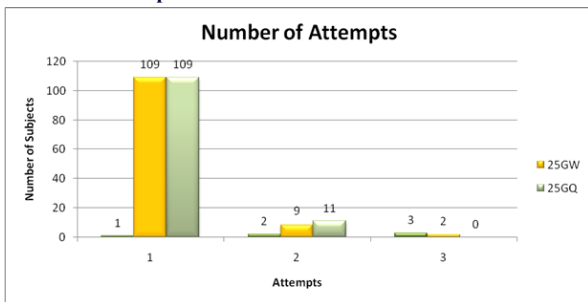


| Gestational Age | 25GW | 25GQ | 25GW | 25GQ |
|-----------------|------|-------|------|-------|
| 37 Weeks | 9 | 7.50 | 2 | 1.67 |
| 38 Weeks | 67 | 55.83 | 42 | 35.00 |
| 39 Weeks | 32 | 26.67 | 55 | 45.83 |
| 40 Weeks | 12 | 10.00 | 21 | 17.50 |
| Total | 120 | 100 | 120 | 100 |

| Table -4 | | 25GW | 25GQ |
|-------------------------|--|----------|----------|
| N | | 120 | 120 |
| Mean | | 37.88542 | 38.31083 |
| SD | | 3.586618 | 3.60578 |
| P value Unpaired t test | | 0.3604 | |

By conventional criteria the association between the Spinal Needle groups and Gestational age is considered to be not statistically significant since $p > 0.05$.

Number of attempts

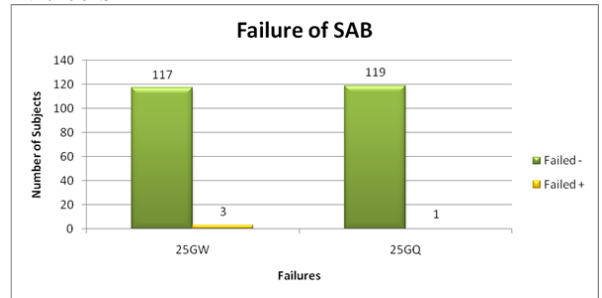


| Number of Attempts | 25GW | 25GQ | 25GW | 25GQ |
|--------------------|------|-------|------|-------|
| 1 | 109 | 90.83 | 109 | 90.83 |
| 2 | 9 | 7.50 | 11 | 9.17 |
| 3 | 2 | 1.67 | 0 | 0.00 |
| Total | 120 | 100 | 120 | 100 |

| Table -5 | | 25GW | 25GQ |
|-------------------------|--|----------|----------|
| N | | 120 | 120 |
| Mean | | 1.108333 | 1.091667 |
| SD | | 0.36197 | 0.289765 |
| P value Unpaired t test | | 0.6941 | |

By conventional criteria the association between the Spinal Needle groups and number of attempts is considered to be not statistically significant since $p > 0.05$.

Failure of SAB



| Table -6 | | 25GW | 25GQ |
|--------------------------|--|-------|-------|
| Failed - | | 117 | 97.50 |
| Failed + | | 3 | 2.50 |
| Total | | 120 | 100 |
| chi-square | | 1.02 | |
| degrees of freedom | | 1 | |
| P value Chi-squared test | | 0.313 | |

By conventional criteria the association between the Spinal Needle groups and failure of SAB is considered to be not statistically significant since $p > 0.05$.

Accompanying Symptoms

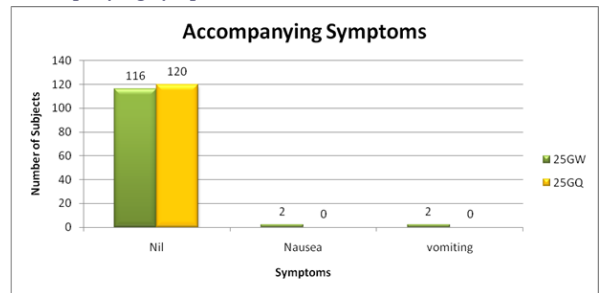


Table -7

| Accompanying Symptoms | 25GW | 25GQ | 25GW | 25GQ |
|--------------------------|------|-------|------|--------|
| Nil | 116 | 96.67 | 120 | 100.00 |
| Nausea | 2 | 1.67 | 0 | 0.00 |
| Vomiting | 2 | 1.67 | 0 | 0.00 |
| Total | 120 | 100 | 120 | 100 |
| chi-square | | 2.91 | | |
| degrees of freedom | | 2 | | |
| P value Chi-squared test | | 0.233 | | |

By conventional criteria the association between the Spinal Needle groups and accompanying symptoms is considered to be not statistically significant since $p > 0.05$.

Post Dural Puncture Headache

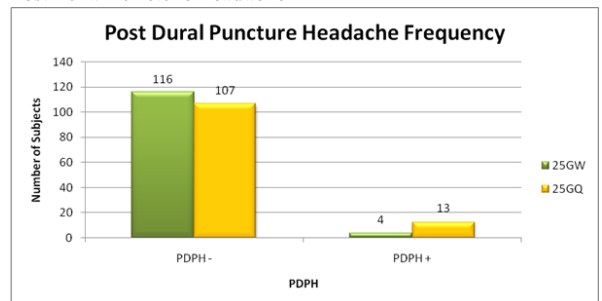


Table -8

| Frequency of PDPH | 25GW | 25GQ | Total -Row |
|--------------------------|------|-------|------------|
| PDPH - | 116 | 107 | 223 |
| PDPH + | 4 | 13 | 17 |
| Total - Column | 120 | 120 | 240 |
| chi-square | | 5.13 | |
| degrees of freedom | | 1 | |
| P value Chi-squared test | | 0.024 | |

Severity of PDPH - Table-9

| | | | |
|--------------------|------|----|----|
| Mild | 2 | 4 | 6 |
| Moderate | 1 | 7 | 8 |
| Severe | 1 | 2 | 3 |
| Total - Column | 4 | 13 | 17 |
| chi-square | 1.02 | | |
| degrees of freedom | 2 | | |

| Table -10 | 25GW | 25GQ | Total -Row |
|--------------------------|-------|------|------------|
| 1st POD | 0 | 0 | 0 |
| 2nd POD | 3 | 9 | 12 |
| 3rd POD | 1 | 4 | 5 |
| Total - Column | 4 | 13 | 17 |
| chi-square | 0.327 | | |
| degrees of freedom | 2 | | |
| P value Chi-squared test | 0.849 | | |

By conventional criteria the association between the Spinal Needle Groups and Post Dural Puncture Headache is considered to be statistically significant since $p < 0.05$.

STATISTICAL SIGNIFICANCE

This indicates that there is a true difference among groups and the difference is significant. In simple terms, in obstetric anaesthesia, the incidence of PDPH is less when pencil-point 25G Whiteacrespinal needle is used compared to Cutting bevelled 25G Quincke spinal needle. It is statistically significant with a p-value of 0.005 according to Chi-squared Test.

CLINICAL SIGNIFICANCE

The occurrence of PDPH was meaningfully less (3.3%) when pencil-point 25G Whiteacrespinal needles is used compared to Cutting bevelled 25G Quincke spinal needle (10.8%).

It was mild in 6%, moderate in 12% and severe in 6% of patients in pencil-point 25G Whiteacrespinal needle group. It was mild in 29%, moderate in 35% and severe in 12% of patients in Cutting bevelled 25G Quincke spinal needle group.

This difference is true and significant and has not occurred by chance.

DISCUSSION

An Anaesthesiologist is one who renders the patient insensitive to pain. SAB is the commonest technique performed for LSCS. The pregnant patients are more prone for PDPH because of their young age, gender and greater use of walking Epidural technique. Development of fine gauge spinal needles and needle tip modification has reduced the incidence of PDPH. Technical difficulty in identifying the space and risk of failed blocks should be balanced against the morbidity associated with PDPH. Now-a-days 25gauge, 26gauge and 27 gauge needles are recommended for SAB. Needles of 29 gauge or less are associated with increased failure rate and therefore not recommended.

12% claims of malpractice filed against anaesthesiologist providing obstetric anaesthesia care were because of postdelivery headache in patients who received epidural anaesthesia and probable dural puncture. There are many studies demonstrating the reduced incidence of PDPH with fine gauge needle and needle tip modification.

Landau R et al in 2001, studied 400 patients with 25 gauge Whitacre and 27 gauge Whitacre needle. The incidence of PDPH was 1.32% with 25gauge and 0.03% with 27gauge Whitacre needle. (Int.J.Obstet Anaesth;2001,10:168-71)

75 female patients scheduled for LSCS were grouped into 3 of 25 each. Group 1,2,3 received SAB using 25 gauge Quincke, 27 gauge Quincke and 27 gauge Whitacre needles respectively. The patients were assessed for the severity of PDPH and the technical difficulties with the needle insertion. All the patient had mild form of PDPH. 25 gauge needle had 100% successful dural puncture and 27 gauge Whitacre had 12% failure rate. (Indian J. Anaesth 2002;46(5):373-377).

Tabedar in 2006, studied 60 patients with 25 gauge Quincke and 26gauge Whitacre needle. Incidence was 8% with Quincke and 2.2% with Whitacre. (Kathmandu Uni. Med.J.;2003,1:263-6)

Bano F et al in 2004, studied 100 patients with 25 gauge Quincke and 25gauge Whitacre. The incidence of PDPH was 4% with Quincke and 0.75% with whitacre. (Dow University of Health science hospital, Karachi; 2004, 14:647-50)

In a study 480 obstetric patients were included as group 1-(25 gauge Quincke, n=168), group 2(27 gauge Quincke, n=160) and group 3(27 gauge Whitacre, n=152). The study comparing 25 gauge Quincke, 27 gauge Quincke and 27 gauge Whitacre needle showed the incidence of PDPH as 8.3%(14/168) with 25 gauge Quincke, 3.8%(6/160) with 27 gauge Quincke, 2%(3/152) with 27 gauge Whitacre needle. The severity of PDPH was mild in 5, moderate in 7 and severe in 2 patients in group 1. In group 2, it was mild in 2, moderate in 3 and severe in 1 patient. In group 3, 2 patients had mild headache and 1 patient had moderate headache. (Med Coll Abbottabad 2008;20:10-3)

INCIDENCE:

| Needle design | Gauge | Incidence |
|---------------|-------|-----------|
| Quincke | 22 | 36% |
| | 25 | 3-25% |
| | 26 | 0.3-20% |
| | 27 | 1.5-5.6% |
| | 29 | 0-2% |
| Whitacre | 20 | 2-5% |
| | 22 | 0.6-4% |
| | 25 | 0-14.5% |
| | 27 | 0% |
| Sprotte | 24 | 0-9.6% |
| Atraucan | 26 | 2.5-4% |

The incidence of PDPH is directly proportional to the gauge of the needle and inversely proportional to the experience of the anaesthetist. The incidence is less if the bevel of the needle is oriented parallel to the direction of dural fibres. The loss of resistance with air increases the risk of PDPH than loss of resistance with saline during epidural anaesthesia.

In summary, a randomized study in comparing the incidence of PDPH in obstetric patients posted for Elective LSCS, Using 25 gauge Quincke and 25 gauge Whitacre spinal needles showed the following results.

- In the present study of 240 obstetric patients, Age, Height, Weight, Gestational age are not statistically significant and are comparable.

-The occurrence of PDPH was meaningfully less when 25 gauge Whitacre (3.3%) is used compared to cutting bevelled 25 gauge Quincke needle (10.8%).

-It was mild in 6%, moderate in 12% and severe in 6% in Whitacre group.

-It was mild in 29%, moderate in 35% and severe in 12% in Quincke group.

-No difference in the number of attempts for successful blockade and number of failed blocks.

The difference is true and significant with a p value of 0.005.

CONCLUSION

We conclude that use of 25 gauge pencil tip, Whitacre needle is associated with significant reduction in the incidence of PDPH than 25 gauge cutting needle Quincke needle in obstetric patients.

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