INCIDENCE OF POSTDURAL PUNCTURE HEADACHE IN ELECTIVE CESAREAN SECTION PATIENTS FOLLOWING SPINAL ANESTHESIA AT TIKUR ANBESSA SPECIALIZED HOSPITAL.

THESIS SUBMITTED TO ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE, SCHOOL OF MEDICINE IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR SPECIALITY CERTIFICATE IN ANESTHESIOLOGY.

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LIST OF ABBREVIATIONS

ASA - American Society of Anesthesiologists

BP - Blood pressure

CC - cubic centimeter

C/S - Caesarean section

CSF - Cerebral Spinal Fluid

EBP - Epidural blood patch

IDDS – Intratechal drug delivery system

IM - Intramuscular

IV - Intravenous

NSAIDS - Non-steroidal anti- inflammatory drugs

PDPH - Post Dural Puncture Headache

PLPH - Post Lumbar Puncture Headache

SPSS - Statistical Package for Social Sciences

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Abstract

Background

PDPH is common in the obstetrical population, who frequently receives epidural or spinal analgesia and anesthesia during labor and delivery. Female sex and young age are reported risk factors adding additional risks.

Objective

This study will assess the incidence, onset time and severity of PDPH and other symptoms associated with PDPH, in elective cesarean section patients undergoing spinal anesthesia at TAH.

Methods

A prospective observational descriptive study was done on ASA I and ASAII patients scheduled for elective C/S under spinal anesthesia after an informed consent is obtained. The study was carried out at the maternity operating theatre and maternity wards of TAH. Patients were contacted by telephone, on the 7th day postoperatively after discharge from hospital. The study was conducted for a period of 4 months. Approval to conduct the study was obtained from ethical committee. An interviewer administered data sheet was used as the main instrument for data collection. Data was analyzed using Statistical package for social sciences version 20 and presented in tables and pie charts.

Results and conclusion

The incidence of PDPH in elective C/S mothers following spinal anesthesia at TAH maternity theatre was 38.7%. There was very significant association between needle size and PDPH incidence. P (0.000), Orientation of the needle bevel perpendicularly to the longitudinal dural fibres was associated with more risk of develop PDPH compared to parallel orientation p(0.01). Multiple dural puncture attempts during administration of anesthesia were also associated risk of development of PDPH as compared to one dural puncture (p=0.02).

The incidence of PDPH is higher in obstetric patients of TAH

CHAPTER ONE INTRODUCTION

1.1 Background

The signs and symptoms of PDPH result from loss of cerebrospinal fluid, traction on the cranial contents, and reflex cerebral vasodilatation (1). As female sex, young age and pregnancy are purported risk factors, the complication is common in the obstetrical population, who frequently receives epidural or spinal analgesia and anesthesia during labor and delivery. Young women with a lower body mass index (BMI) and those who are pregnant have the highest risk of developing headache after lumbar puncture(3,4).

PDPH occurs twice as often in women as in men. Most of the increased frequency in women is during the child-bearing years. The highest frequency is in the 18- to 30-years age group. The frequency is less in children younger than 13 years and in both men and women older than 60 years (2, 3).The incidence of post-dural puncture headache was 66% in 1898 (5, 6). This alarmingly high incidence of post-spinal headache was likely attributable to the use of large gauge, medium bevel, cutting spinal needles. Today the use of fine gauge pencil-point needles, such as the Whitacre and Sprotte has produced a greater reduction in the incidence of post-dural puncture headache, which varies with the type of procedure and patients involved. It is related to the size and design of the spinal needle used, the experience of the personnel performing the dural puncture, and the age and sex of the patient (5, 7, 8). Reducing the size of the spinal needle has made a significant impact on the incidence of post-spinal headaches (5). The incidence is 40% with a 22G needle; 25% with a25G needle; 2%—12% with a 26G Quincke needle; and <2% with a 29G needle (5, 9, 10, 11).

1.2 Rationae of the study

Regional anesthesia is the favored methods of cesarean section delivery due to their safety to the mother, simplicity of the technique, lesser maternal risk and satisfactory postoperative analgesic effect**.** The concern of the new born and bond of family member may be affected by the post operative PDPH.

The findings of this study will be used in:-

- Suggesting means of further reducing the incidence of PDPH.

- Improving the existing methods of management of PDP
- Providing a window for future research on this subject.

–

1.3. Statement of the Problem

The use of neuraxial anesthesia for c/s has dramatically increased in last 2 decades because it is easier to perform,safe to the mother and the fetus, and has a high degree of success rate. The period from 1930 to 1950 has often been referred to as the ‘dark ages of obstetric anaesthesia’, when natural childbirth and psycho -prophylaxis were encouraged .In 1951, Whitacre and Hart developed the pencil-point needle. Developments in needle design since that time have led to a significant reduction in the incidence o f post-dural puncture headache. However, post-dural puncture headache (PDPH) is a common and incapacitating complication following dura-arachnoid puncture. It results in increased morbidity, prolonged hospital stay, increased cost, and patient dissatisfaction.

CHAPTER TWO: LITERATURE REVIEW

The history of spinal anesthesia can be traced back to the late 1800s when Wynter and Quincke aspirated cerebrospinalfluid from patients with tuberculous meningitis in an attempt to lower

intracranial pressure. (5)

Spinal anaesthesia developed in the late 1800s (5). In 1891, Wynter and Quincke aspirated cerebrospinal fluid (CSF) from the subarachnoid space for the treatment of intracranial hypertension associated with tuberculous meningitis. (5) The catheters and trochars used were probably about 1 mm 15in diameter and would certainly have led to a post-dural puncture headache.(2) However, all Quincke and Wynters' subjects died soon after. In 1895, John Coming, a New York physician specializing in diseases of the mind and nervous system, proposed that local anaesthesia of the spinal cord with cocaine may have therapeutic properties (3). In August 1898, Karl August Bier, a German surgeon, injected cocaine 10-15 mg into the subarachnoid space of seven patients, himself and his assistant, Hildebrandt(5, 6). Bier, Hildebrandt and four of the subjects all described the symptoms associated with post-dural puncture headache. Bier surmised that the headache was attributable to loss of CSF (5). By the early 1900s, there were numerous reports in the medical literature of the application of spinal anaesthesia using large spinal needles. Headache was reported to be a complication in 50% of subjects. At that time, the headache was said to resolve within 24 hrs (5). Ether anaesthesia was introduced into obstetric practice in 1847, shortly after Morton's public demonstration (5). Despite the obvious advantages of regional anesthesia for the relief of labour pain, it was not until a Swiss obstetrician in 1901 used intrathecal cocaine for the relief o f pain in the second stage of labour that regional anaesthesia for obstetrics was popularized (1). Though both vomiting and a high incidence of post-dural puncture headache were noted, it was the high mortality rate in Caesarean deliveries performed under spinal anaesthesia (1) in 139) that led to the abandonment of this technique in the 1930s. The period from 1930 to 1950 has often been referred to as the 'dark ages of obstetric anaesthesia', when natural childbirth and psycho - prophylaxis were encouraged (1). In 1951, Whitacre and Hart developed the pencil-point needle, based on the observations of Greene in 19263. Developments in needle design since that time have led to a significant reduction in the incidence o f post-dural puncture headache (1). However, dural puncture headache remains a disabling complication of needle insertion into the subarachnoid space (2).

Anatomy and pathophysiology

Anatomically, the spinal dura mater extends from the foramen magnum to the second segment of

the sacrum. It consists of a dense connective tissue matrix of collagen and elastic fibers.(4) The average adult produces about 500 mL of CSF per day, or 21 mL per hour (0.3 mL/kg/hr), with 90% coming from the choroid plexus, and 10% from the brain substance itself. (2, 4) A total of about 150 mL of CSF circulates at any one time and is absorbed by the arachnoid villi. The cause of PDPH is not entirely certain. The best explanation is that low CSF pressure results from CSF leakage through a dural or arachnoid tear; a leakage that exceeds the rate of CSF production. (4) As little as 10% loss of CSF volume can cause an orthostatic headache. There are two basic theoretical mechanisms to explain PDPH. (1, 4) One is reflex vasodilatation of the meningeal vessels due to the lowered CSF pressure. The other is traction on the pain-sensitive intracranial structures in the upright position. Traction on the upper cervical nerves including C1, C2, and C3, causes pain in the neck and shoulders. Traction on the fifth cranial nerve causes a frontal headache. Traction on the sixth cranial nerve causes visual symptoms. Pain in the occipital region is due to the traction of the ninth and tenth cranial nerves. (1, 4)

Needle size and incidence of PDPH

There are several spinal needle designs, but four of them are commonly used in clinical practice (5).

1. Quincke needle: It is a standard needle with a medium cutting bevel and an orifice at the needle tip. Its advantages are that CSF is identified as soon as it enters the subarachnoid space, paraesthesias and neurotrauma are less likely and it is cheaper compared to atraumatic needles. Its disadvantages include a high incidence of PDPH compare to atraumatic needles (5).
2. Sprotte needle: It is also atraumatic needle and is a modification o f the whitacre needle with a longer lateral opening. It has a conical tip and the orifice is up to 0.5mm from the needle tip. The advantages o f atraumatic needles include, less incidence of PDPH than the medium bevel cutting needles. However, paraesthesias have been observed with the use of pencil point needles (5).
3. Whitacre needle: It is a pencil point or atraumatic needle. It has a small orifice and a diamond shaped tip (2,3)
4. Atraucan needle: It has a narrow cutting tip and atraumatic bevel and orifice at the tip o f the needle. It has less paraesthesia compared to whitacre and sprotte needles. It is easy

to use and has low PDPH rates.(5)

The incidence of PDPH is directly related to the needle diameter that pierces the dura mater. (7) Diagnostic lumbar puncture (LP) requires 22-gauge needles to facilitate measurement of opening pressure and withdrawal of CSF over a reasonably brief time period. With needles smaller than size 22-gauge, collection of 2 mL of CSF may take 6 minutes or longer and measurement of CSF pressure may be less accurate.8 An addendum to the American Academy of Neurology (AAN) practice guidelines advocated the use of 22-gauge needles, but reported a case series where 25-gauge needles were used successfully. (9)

Although smaller diameter needle punctures used for subarachnoid block decrease the risk of PDPH, these needles are technically difficult to use and are associated with a lower success rate in spinal anesthesia, especially in inexperienced hands. (10) This is due to failure to recognize dural puncture secondary to slow flow through a small needle, leading to multiple and repeated puncture attempts. The incidence of PDPH with the 25-gauge Whitacre (non-cutting) needle is less than with the 27-gauge Quincke (cutting) needle.7 Morbidity associated with lumbar puncture can be decreased by the proper selection of an appropriate needle gauge and needle tip configuration.(11,12)

Direction of bevel

Spinal needles are designed as cutting bevels, as in the Quincke-type, or pencil point, as in the Whitacre-type spinal needle. Dural fibers were once believed to run longitudinally; (13) however microscopic dissection of the dura mater from cadavers revealed that dural fibers do not run longitudinally or in a parallel fashion. The dura is a laminated structure built up from well-defined layers oriented concentrically around the medulla spinalis. (14) Orienting the bevel of a cutting needle probably needs further consideration before making absolute, blanket statements regarding the etiology of dural puncture leaks. The use of a paramedian approach to the subarachnoid space has been suggested as a means of reducing PDPH particularly when using cutting needles. (15)

Electron microscopy has shown that pencil point needles are more traumatic to the dura than the cut bevel needles. It ispostulated that a pencil point needle produces an irregular tear in the dura and the subsequent inflammatory reaction reduces CSF leakage more effectively than the clean

U-shaped puncture seen with a cutting-bevel needle, which decreases the risk of PDPH. (16)

Anju et al noted an incidence of PDPH of 20% in a group of 25 C/S mother in whom G25 Quincke needles were used for spinal anesthesia. All had one dural puncture attempt and all the procedures were performed by the same anesthesiologist with enough experience.(38)

Dura mater and response to trauma

After perforation of the dura there will be leakage of CSF. In neurosurgical experience even minor perforations need to be closed, either directly or through the application of synthetic or biological dural graft material. Failure to close the dural perforation may lead to adhesions, continuing CSF leak, and the risk of infection. It was thought that the closure was facilitated through fibroblastic proliferation from the cut edge of the dura. Work published in 195917 dismissed the notion that the fibroblastic proliferation arose from the cut edge of the dura. This study maintained that the dural repair was facilitated by fibroblastic proliferation from surrounding tissue and blood clots. The study also noted that dural repair was promoted by damage to the pia arachnoid, the underlying brain and the presence of blood clots. It is therefore possible that a spinal needle carefully placed in the subarachnoid space does not promote dural healing, as trauma to adjacent tissue

is minimal. Indeed, the observation that blood promotes dural healing agrees with Gormley's original observation that bloody taps were less likely to lead to a post dural puncture headache as a consequence of a persistent CSF leak. (18)

Symptoms

PDPH typically manifests as a postural, frontal, frontotemporal, or occipital headache, worsened by ambulation and improved by assuming the decubitus position, occurring within 48 hours after dural puncture. The accompanying symptoms are usually nausea, vomiting and neck stiffness.(1, 19)

Atypical symptoms after accidental dural puncture have been infrequently described. Other nonspecific symptoms may occur such as nausea, vomiting, ocular complaints such as photophobia and diplopia, and auditory complaints like tinnitus and hyperacusis.

The first case of diplopia after dural puncture was reported by Quincke more than 100 years ago. (19) Diplopia or extraocular muscle paralysis (EOMP) after dural puncture has been reported occasionally, primarily in the neurology and ophthalmology literature. Because there seems to be

a window period before diplopia manifests after dural puncture, the patient and physician may not always believe that the symptom is secondary to dural puncture, particularly when it occurs after resolution of PDPH. Diplopia usually occurs 4–10 days after dural puncture but can manifest as late as 3 weeks. Full recovery can generally be expected in 2 weeks to 8 months, although permanent cases have rarely been reported. (20)

Factors influencing incidence

Women, particularly during pregnancy and especially after vaginal delivery, are considered at increased risk for PDPH. The incidence of PDPH is highest between 18 and 30 years of age and declines in children younger than 13 years and adults older than 60 years. The incidence is greater in patients with lower body mass index.2 Women who are obese or morbidly obese may actually have a decreased incidence of PDPH. The decreased incidence is due to the increase in intra-abdominal pressure which may act as an abdominal binder helping to seal the defect in the dura and decreasing the loss of CSF. Younger women may be at a greater risk because of increased dural fiber elasticity that maintains a patent dural defect compared to a less elastic dura in older patients.4 Patients with a headache before lumbar puncture and a prior history of PDPH are also at increased risk. There is no known relationship between the diagnosis of migraine headaches and increased incidence of PDPH after regional anesthesia. (21) There may be some correlation between a history of motion sickness and PDPH. Another important factor is the experience of the person doing the procedure leading to the puncture of the dura. Continuous spinal infusion reduced the incidence of PDPH when compared to single shot spinal, at least according to one study. (22)

A study conducted in Department of Obstetrics and Gynecology, Tehran University of Medical Sciences, the incidence of PDPH was higher than studies which used pencil – tipped needles and determined that the occurrence of PDPH is not associated to some factors like the previous history of nonspecific headache, Body Mass Index, age, type of local anesthetic, previous history of PDPH, experience of operator, history of habitual tea and coffee drinking (26).

The incidence of PDPH in elective C/S mothers following spinal anesthesia at Kenyatta National hospital maternity theatre, Nairobi, Kenya was 47.5%. Orientation of the needle bevel perpendicularly to the longitudinal dural fibres was associated with 2.6 times more risk of develop PDPH compared to parallel orientation. This was statistically significant, p-value 0.013. Multiple dural puncture attempts during administration o f anesthesia were associated with 1.2

times more risk of headache development**.**

A comprehensive history and physical exam must be carried out before making the diagnosis of PDPH. Spinal abscess, spinal hematoma, septic or aseptic meningitis, intracranial mass lesion, cerebral aneurysm, cerebral edema, myofascial syndrome, arachnoiditis caused by intrathecal steroids, transient neurologic syndrome or related symptoms, unspecific post-dural puncture lumbalgia, neural toxicity of the drugs, and anterior spinal artery syndrome, post-partum cerebral angiopathy and cerebral thrombophlebitis should all be ruled out. (10, 23, 24|) Additional tests such as a cerebral CT scan, or magnetic resonance imaging could be performed in cases with atypical post-dural puncture symptoms, to exclude the possibility of developing serious complications. (25)

Few cases of atypical post-dural puncture symptoms have been reported in the literature. Lybecker et al cited interscapular pain as a "related musculoskeletal symptom," however; no instances of upper back pain are cited among the 75 cases of PDPH reported by the authors.19 McGrady and Freshwater reported a case of posterior neck pain without headache after spinal anesthesia.26 Schabel et al reported a case of arm pain with dysesthesia after an unintended dural puncture, and explained it as irritation of the C5 and C6 nerve roots caused by central traction.24

Treatment

Conservative/symptomatic therapy

The treating clinician must provide emotional support and reassurance to patients with PDPH. Bed rest has been advocated in cases of dural puncture by some clinicians.

However, a recent meta-analysis failed to show that bed rest after dural puncture was better than immediate mobilization in reducing the incidence of PDPH. (27) Bed rest can be associated with a higher incidence of PDPH in particular patient groups. (28) Bed rest may postpone the occurrence of the headache but does not prevent it.

Pharmacotherapy

Oral and intravenous medications

Oral hydration remains a popular therapy for PDPH, but there is no evidence that vigorous hydration has any therapeutic benefit, or that it encourages an increased production of cerebrospinal fluid. However, no patient with PDPH should be allowed to become dehydrated.

The efficacy of oral caffeine for the treatment of PDPH was evaluated in 40 postpartum patients.

(29) A single oral dose was demonstrated to be safe, effective and should be considered in the early treatment of mild PDPH. Caffeine sodium benzoate, as an intravenous bolus or an infusion can be used to treat PDPH. Caffeine was 75% to 80% effective in the initial treatment of PDPH; however, follow-up 48 hours later revealed that all patients had a return of their headache. (30) Cosyntropin, a synthetic form of adrenocorticotropic hormone, has been used in the treatment of refractory PDPH. Adrenocorticotropic hormone is believed to work by stimulating the adrenal gland to increase CSF production and □-endorphin output. Caution should be used in patients with diabetes. (31)

The serotonin type 1-d receptor agonist sumatriptan is effective in the treatment of PDPH, with complete resolution of symptoms. (31, 32). The drug is expensive, and side effects include pain at the site of injection and chest tightness.

Caution must be used in treating patients with ischemic heart disease using sumatriptan. (32,) Controlled trials are needed to further evaluate the use of sumatriptan for PDPH. A trend away from conservative management to the use of the blood patch has appeared in recent years. This is based on the relative ineffectiveness of the conservative treatment. For example, over 80% of postpartum patients who are conservatively treated will still have a headache after 1 week.

Epidural injections

The autologous epidural blood patch (AEBP) has become the 'gold standard' in the treatment of PDPH. Prior to considering the use of epidural injections of blood or other substances to relieve the symptoms of PDPH, there needs to be a clearly negative history of sepsis and coagulopathy. HIV infection is not considered to be a contraindication to AEBP. (32)

Dextran and 0.9% NaCl (saline) injections into the epidural space transiently increase pressure in the epidural space, which subsequently decreases the leakage of CSF and restores subarachnoid pressure.34–36 Not only is the success rate moderate, but also anaphylaxis has been reported following the use of dextran for this purpose. Epidural patching with non-blood substances, eg, saline or colloid, are ineffective for prolonged relief, Epidural saline: It was noted that after a blood patch treatment, there was a rapid resolution of symptoms, which could not be explained purely by the sealing effect on the puncture site (4, 5). This brought the concept of possible compression of the thecal sac with presumed increase in subarachnoid pressure owing to the volume of blood introduced (4, 5). The same effect was expected on using saline, which is relatively inert and sterile, and epidural saline bolus or infusions were advocated in some

regimens based on this hypothesis, with variable results (4, 5).

Epidural dextran 40: It has not been extensively studied for the treatment of headache after lumbar puncture and is not in current use4. However, in a series of 56 patients with headache, who failed to respond to treatment including epidural blood patch, relief of headache was accomplished in all patients within 24 h after injection with 20 ml of dextran 40 epidurally. Although other substances

such as fibrin glue have been used.38 The utility of epidural morphine was investigated in one RCT.39,40,41 Epidural morphine 3 mg was given after the end of anesthesia and another 3 mg was given on the following day. This reduced the incidence ofPDPH from 48% (12/25) to 12% (3, 25), which translates to a statistically significant reduction in the relative risk of 0.25 (0.08–0.78). There was no respiratory depression, but nausea was numerically more frequent in the morphine group (44% versus 16%, P=0.06).

Autologous epidural blood patch (AEBP)

The AEBP was first described by Gormley in 1960 for use in PDPH, and was later popularized by DiGiovanni et al.32 The suspected mechanism of action of AEBP is tamponade of the dural leakage while simultaneously raising the subarachnoid pressure. Elevation of subarachnoid and epidural pressures remains for only about 20 minutesMRI evidence confirms a mass effect after injection of epidural blood, with gradual resolution over about 7 hours. Unlike saline, dextran or other fluids, blood is not removed quickly from the epidural space, and it potentially exerts a tamponade effect for much longer periods of time. The autologous blood is thought to form a fibrin clot over the dural rent, allowing CSF volume and hence pressure to normalize as new CSF is generated. (14)

Abouleish et al, summarized 524 cases of AEBP reported by eleven centers.45 Persistent symptomatic relief of PDPH following epidural blood patch was .95%, particularly when using volumes of blood .15 mL. In this review, using volumes of blood greater than 20 mL offered no advantages, as it is known that 20 mL spreads about 9–10 spinal segments when administered to patients in the sitting position. (12)

Some studies have demonstrated lower success rates, with only 61%–75% of patients demonstrating sustained benefit.

These lower success rates may reflect dural puncture occurring with large-bore epidural needles

versus smaller-gauge spinal needles. In obstetrical studies, the success rate of epidural blood patching for PDPH is lower because the dural hole made by 18 gauge Tuohy needles results in a large leakage of CSF, necessitating a second blood patch in as many as 29% of patients. (33)

On a Retrospective Review of Post Dural Puncture Headache Following Intrathecal Drug Delivery System Placement in Myo clinic the development of PDPH after IDDS implantation was found to be fairly common (23% incidence), the majority of these patients had self-limited symptoms that resolved with conservative medical management. Epidural blood patch or application of epidural fibrin glue was therapeutically successful for the remainder of PDPH patients who were refractory to conservative measures (27).

CHAPTER 3: SIGNIFICANCE OF THE STUDY

Regional anesthesia is the favored methods of cesarean section delivery due to their safety to the mother, simplicity of the technique, lesser maternal risk and satisfactory postoperative analgesic effect**.** The concern of the new born and bond of family member may be affected by the post operative headache **(**32) The actual incidence of PDPH in elective C/S after spinal anesthesia at TAH is not known since no study has been carried out previously to address this subject. The findings of this study will be used in:

-Suggesting means of further reducing the incidence of PDPH.

-Improving the existing methods of management of PDPH.

-providing a window for future research on this subject.

CHAPTER FOUR: OBJECTIVES

4.2. General objective:

To assess the Incidence of post dural puncture headache in elective cesarean section patients following spinal anesthesia at TAH from April 1-June 30, 2018

4.2. Specific objectives:

1. State the incidence of PDPH.
2. Determine the onset time of postdural puncture headache.
3. Evaluate the severity of post dural puncture headache.
4. Evaluate other symptoms associated with post dural puncture headache.

CHAPTET FIVE: METHODS AND MATERIALS

5.1 Eligibility criteria and ethical considerations

5.1.1 Inclusion criteria

ASA I and ASA II mothers scheduled for elective cesarean section and who had spinal anaesthesia.

5. 1.2. Exclusion criteria

ASA I and ASA II elective cesarean section mothers who had spinal anesthesia that:

- Failed spinal anesthesia and general anesthesia substituted,

-developed complication, other than PDPH, during or/ after surgery that required ICU admission.

-Mothers who have pre-existing chronic or recurrent headache.

5.1.3 Ethical considerations

Before the data collection, consent is obtained from each patient. The study participants were informed about the purpose of the study, why and how they were selected. Moreover, patients were told that they are free to withdraw from the study at any time during the research. Any specific patient identifiers are not included in the data collection tool and this is assured by using code numbers to each data.

1.1. Study setting

The study is conducted at Addis Ababa University, College of Health Sciences, TikurAnbessa Specialized Hospital. It is the largest public specialized hospital in Ethiopia located at Addis Ababa under the Ethiopian Federal Ministry of Education (FMOE).

5.3. Study period: - The study period is from October 10, 2018 to October 15, 2018

5.4. Study design: - This is a prospective hospital based observational cross-sectional study.

5.5. Population

5.5.1. Source population- All admission to Obstetric wards of TAH.

5.5.2. Study population – All ASA 1 and ASA2 patients admitted to TAH for elective C/S

5.6. Sample size and technique

The Sample size was determined by the following formula

Part I; n = t2 x p (1 -p)/m2

Part II; n f= n / (l+ n /N)

Part I ; n = t2 x p (l-p)/m2

Description

n = required sample size.

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

P = estimated prevalence o f PDPH which is put at 25% (The quoted incidence of PDPH after spinal anesthesia in obstetric patients using 25G Quincke point needle is 25%5,910).

The 25G Quincke point spinal needle is the type of spinal needle that is commonly used for spinal anesthesia at Tikur Anbessa Hospital.

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

Therefore:

n = (1.96)2x 0.25(1-0.25)/(0.05)2

n = 3.8416 x 0.25x 0.75/0.0025

n = 0.7203/0.0025

n = 288.

Part II

If the population to be studied in a year is less than 10,000 (In our case 364 which is the number of elective C/S patients that undergo spinal anesthesia at the maternity theatre per year), then part II of the formula which uses the required sample size got from part I of the formula will be applied,

nf = n/ (1+n/N)

Description:

nf = is the desired sample size when the population studied is less than 10,000.

n: the sample size required if the population would have been more than 10,000(288 in our case got from part I of the formula).

N = the estimated population size, in our case which is the estimated number o f C/S that undergo spinal anesthesia in TAH per year which is 364.

Therefore

nf=n/(1+n/N)

= 288/(1+288/364)

= 160

Hence the estimated number of patients required to achieve the desired sample size is 160.

5.7. Data collection

5.7.1 Data collection process - The relevant information was filled in the structured checklist by respective data collectors provided that consent is obtained from patients.

5.7.2 Data collectors-The data was collected by principal investigator and anesthesia residents assigned in the obstetric OR. Patients will be seen in the obstetric ward by the principal investigator till discharge. Finally they will be called in the 7th post operative day.

5.7.3 Quality assurance – The data was foreseen checked for completeness and edited every day after collection.

5.8. Data analysis and interpretation –After data is collected, it was entered to a computer soft ware (SPSS Windows version 25.0). Percentages, means, median, and standard deviation were used for elementary data analysis. Data is presented by Frequency tables..

Data presentation

Data presentation is in the form of tables, charts, and graphs.

Bias minimization:

Sampling bias

The study involved all consenting elective cesarean section patients scheduled for spinal anesthesia in maternity theatre at TAH. Patients were consecutively enrolled in the study and stood equal chances of being included in the study.

Measurements bias

This was minimized by using a well coded and standardized data sheet.

Information bias

This was minimized by adhering strictly to the definition of terms outlined in the study.

5.9 Variables

5.9.1 Dependent Variable

- Post dural puncture headache

5.9.2. Independent Variable

- Age
- BMI
- Type of spinal needle
- Size of spinal needle
- Orientation of the needle bevel to the long axis of the spine
- Time spinal anesthesia given
- Technique of spinal anesthesia
- Number of attempts during puncture
- Prior post dural puncture headache

CHAPTER SIX: RESULT AND DISCUSSION

RESULT

Of the 160 patients were able to collect data for 137 patients due to limited time.

The mean age of the participants was 27.8 ranging from 18 to 43. Age was not associated with occurrence of PDPH P (0.41).

Thirty six mothers have prior PDPH history of whom 17 (42.2%) develop PDPH. However this was not significantly related with PDPH (P- 0.37).

74 (54%) cases was done by size 25G Quincke needle of which 20% encounter PDPH. The rest 63(46%) by 23G Quincke needle and 60.3% of them had PDPH. Only Quincke point needles were used to administer spinal anesthesia in all the cases. There is very strong association between needle size and PDPH (P-0.000).

Spinal anesthesia performed with the needle orientation in relation to the long axis of the spine was parallel in 98 (71.53%) patients and perpendicular in 39(28.47%) patients There is strong association between orientation of the needle bevel in relation to longitudinal dural fibers and presence of PDPH (p=0.01)

Thirty five (25.5%) patients had only one dural puncture attempt; the rest, (74.5%) patients had multiple dural punctures ranging from 2-6 attempts.

Patients who had more than one attempt were more likely to develop PDPH. There was statistically significant correlation between number of attempts and presence of postdural puncture headache (p=0.02).

The results are summarized in the table below.

Table 1: Age and Spinal anesthesia related parameters of the study participants who underwent spinal anesthesia cesarean section, in the period of June 25, 2018 – October 10, 2018.

Factors		PDPH present		Absent		P value
		Frequency	%	n	%	
Age	16-24	15	28.3	22	26.2	0.410*
	25-29	21	39.6	41	48.8	
	30-34	5	9.4	7	8.3	
	35-39	7	38.9	11	61.1	
	40-44	5	9.4	3	3.6	
Prior PDPH	Yes	17	47.2	19	52.7	0.237
	No	36	35.6	65	64.4	
Spinal needle size	23	38	60.3	25	39.7	0.000
	25	15	20.3	59	79.7	
Orientation of blevel needle	parallel	31	31.6	67	68.4	0.01
	perpendicular	22	56.4	17	43.6	
No. of attempts	1	6	17.1	29	82.9	0.02
	>=2	47	46	55	64	

* Linear by linear association

Of the 53 mothers who had PDPH, majority (71.2%) developed headache in the first 24hr, eight (15.1%) mothers developed headache on the second day post dural puncture. 4 (2.9%) mother developed headache on the third day post dural puncture and only two mothers complain onset of headache on the fourth post op day.

Out of the 53 mothers who developed PDPH, 24 (45.3%) mothers had mild headache, 29(54.7%) mothers had moderate headache and none had severe headache. All the mothers responded well to conservative management of bed rest, good rehydration, and NSAID. Of the 53 mothers who developed PDPH, 41 (77.3%) had no other symptoms associated with PDPH. 14 mothers had at least one symptom associated with PDPH. One mother had both neck stiffness and low back pain. The frequencies of symptoms were as follows: Six (11.3%) for Neck stiffness, four (7.5%) for nausea, two (3.8%) for vertigo, one (1.9%) for low back pain, one (1.9%) for blurred vision. These results are summarized in the table below.

Table 2: characteristics of PDPH and its management of the study participants who underwent spinal anesthesia cesarean section, in the period of June 25, 2018 – October 10, 2018

		Frequency	Percent
Onset of headache	Within 24hrs	38	71.7
	b/n 24 to 48 hrs	8	15.1
	48-72hrs	4	7.5
	After 3 days	2	3.7
Headache sevirity	Mild	24	45.28
	Moderate	29	54.72
	Severe	0	0
Complication	none	41	77.3
	Neck stiffness	6	11.3
	Nausea	4	7.5
	Vertigo	2	3.8
	Low backpain	1	1.9
	Blurred vision	1	1.9
Measures	Take rest	49	92.4
	Fluid diet	22	41
	Iv fluid	2	3.7
	Caffeine	13	24.5
	Analgesic		
	PCM	31	58.5
	Diclofenac	12	22.6
	Ibuprofen	7	13.2
	Opoids	0	0

Discussion

The study has shown the incidence of PDPH in elective C/S patients following spinal anesthesia at TAH to be 38.7%, which is higher than expected.

The mean age of study patients was 27.8 years. This mean age group lies within 18-30 years age group which is associated with the highest frequency of PDPH (2, 9).

There was, however, no statistical significance in the occurrence of PDPH between the two groups (p-value=0.41).

Only Quincke point needles were used to administer spinal anesthesia in all the cases. In this study there was strong association between needle size and PDPH (p=.000). In a prospective study conducted over 2 years by Lubusky*et al.*[34] revealed in 2003 an incidence of 16.3%, where 85.2% of the blocks were performed using Quincke needles. Tarekegn et al on their study done in 248 patients FelegeHiwot Hospital, Bahir dar, Ethiopia in 2017, the prevalence of PDPH was 42.6%. They used needle size from 20-25G Quincke spinal needle. They have found association b/n needle size and occurrence of PDPH. (28)

The frequency of PDPH was related to the direction of the bevel during introduction of the spinal needle. In this study the needle orientation in relation to longitudinal dural fibres during lumbar puncture was parallel in 98 (71.5%) of whom 31.6% developed PDPH and perpendicular in39 (29.5%) of the cases of whom 56.4% developed spinal anesthesia.

Patients where spinal anesthesia administered were more likely to develop PDPH compared to when the needle bevel was oriented parallel. There was statistically significant correlation between the direction of spinal needle bevel and PDPH incidence. (p=0.002).

Lybecker et al had a similar observation. They noted that the incidence of PDPH among patients in whom the bevel was inserted parallel to the longitudinal dural fibres was 0.56 times the incidence among patients in whom the bevel was inserted perpendicularly to the longitudinal dural fibres.

In this study 35(25.5%) patients had only one dural puncture attempt. The rest 42.6% had multiple dural punctures ranging between 2-6 times. This was found to be statistically significant p=0.002.

Anju et al in their study in a group 25 patients, who had spinal anesthesia using 25G Quincke needles, all had one dural puncture attempt. In their study all the procedures were performed by

the same anesthesiologist with enough experience (38). In our study different providers performed the procedures and some of them with little experience. At the Tikur Anbessa Hospital, being a teaching hospital, some of the spinal anesthesia procedures were performed by junior postgraduate (anaesthesia) students and nurse anesthetists some of whom had little experience. This is reflected in the high frequency of dural puncture attempts noted in this study. Vallejo et al in their study done in Magee hospital (a teaching hospital) in a group of 172 C/S mothers who had spinal anesthesia using G25 Quincke needle only 5 patients had 2 dural puncture attempts the rest had one attempt (39).

In our study, onset of headache occurred in 71.2% of the patients in the first day, 15.1 of patients on the second day and 2.9 on the third, 2 patients on the fourth day after dural puncture. Anja et al in their study noted that the onset of headache was within 24 hrs to 72hrs after dural puncture35. The onset of headache after lumbar puncture is usually within 24-48hrs after dural puncture, but could be delayed up to 12days4. This is consistent with our study.

Of the 53 mothers who developed headache, 54.7 had moderate headache, 45.3 had mild headache and none had severe headache. Similar studies have classified headache according to severity. Nafiii et al in their study most patients rated their headache as mild to moderate on a 10-cm visual analog scale. Kuntz et al in their study, of the 107 patients who developed headache, the severity of PDPH on the 1st day of occurrence was mild in 54%, moderate in 31% and severe in 15%. The criterion for the determination of the severity of headache was different for each of the studies quoted above thus they are not easy to compare though there is some consistency with our study.

Out of 53 mothers who developed PDPH, 14 had at least one symptom associated with PDPH. One mother had both neck stiffness and blurring of vision

Chapter seven: Conclusion and Recommendations

Conclusion

There was a higher incidence of PDPH in elective C/S mothers following spinal anesthesia at TAH maternity theatre(38.7%).

Spinal needle size, perpendicular orientation of needle bevel to the long axis of the dural fibers and repeated no of dural puncture attempts were found to be associated with occurrence of PDPH.

Headache severity generally was from mild to moderate and responded well to conservative management.

STRENGTH AND LIMITATION

STRENGTH

This is the firist research done it TAH on the incidence of PDPH, which will be taken as initiative for further researches in the topic

LIMITATION

It is a single hospital based study, which didn't allow comparison between different institutions in the country.

The fact that different anesthesia providers administered spinal anesthesia for the study patients, the study being observational, may decrease the uniformity of the techniques and the results.

Recommendations

To Ministry of health

1. National protocol should be provided for administration of spinal anesthesia which should be applicable nationwide including TAH
2. Simulation centers awareness creation programs should be provided for trainees on the correct administration of spinal anesthesia.

To Department of Anesthesiology

1.Institutional Protocol should be provided for administration of spinal anesthesia in maternity Theatre of TAH.

2. Introduction of small gauge atraumatic spinal needles to be used for mothers undergoing spinal anesthesia in TAH will reduce the incidence of PDPH.

To department Anesthesiology and OBG/YN

5. There should be interdepartmental collaboration on classifying PDPH and managing it accordingly

6. A long term prospective study on the risk factors associated with severity of headache and duration of PDPH in C/S mothers undergoing spinal anesthesia in TAH should be conducted. This will help the anesthetists to minimize the severity of PDPH and to be able to estimate the duration of follow-up for those mothers that will have developed PDPH.

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ANNEXS

Annex 1: American Society of Anesthesiologist (ASA) Physical status Classification.

Class I: A normal healthy patient.

Class II: Patient with mild systemic disease.

Class III: Patient with severe systemic disease that is not incapacitating.

Class IV: A patient with incapacitating life threatening systemic disease.

Class V: A moribund patient who is not expected to survive for 24 hours with or without operation.

Class E: A patient undergoing an emergency operation (the 'E' added to the classification number)

Annex 2: Criteria of post dural puncture headache ".

1. Occurred after mobilization.

2. Aggravated by erect or sitting position and coughing, sneezing or straining

3. Relieved by lying flat.

4. Mostly localized in occipital, frontal or generalized.

Annex 3: Headache severity

Mild: No limitation o f activity, No treatment required.

Moderate: Limited activity, regular analgesic required.

Severe: Confined to bed, anorexic, unable to feed the baby.

Annex 4: Consent Explanation

My name is Dr. Nura Nasser, a postgraduate student in anesthesia at Addis Ababa University. You will undergo an elective C/S under spinal anesthesia. I am doing a study of which you are about to be explained to in full details before agreeing to participate in it.

Study

The purpose of the study is to assess the incidence of post dural puncture headache in elective C/S patients following spinal anesthesia at TAH.

What is PDPH?

This is the headache which can occur any time within 2weeks after spinal anesthesia. It is a common minor complication which the anesthetist aims at preventing. Although different prevention methods have been used to reduce its incidence it still continues to occur. This is why more research continues to be done in order to prevent it.

Reasons for the study

The incidence of PDPH after elective C/S following spinal anesthesia is known is some hospitals elsewhere. We do not know the incidence of PDPH after elective C/S following spinal anesthesia at TAH.

The finding of this study will be used to suggest means o f further reducing the incidence of PDPH and to improve the existing methods of management of PDPH.

Participation in the study

Your participation in this study will be voluntary and you can decide to withdraw at any stage without any penalty. The study is purely observational, non invasive and there will be no cost associated with participating in the study. Participating in this study will not interfere with the regular management before, during, and after operation.

Confidentiality

Your identity will be protected with utmost confidentiality during the study and only initials will be used in reference to the participants of the study

Thank you.

Annex 5: Questionnaire

Section A: Patient Identification

Serial number.....In patient number.....

Name.....Date..... Contact Telephone number.....

Section B: Sociodemographic Data

Age in years.....Sex.....Parity.....BMI.....

Previous history of spinal anesthesia: Yes…….. No…….. (Tick where appropriate V)

If yes prior post dural puncture headache : Yes……, No…… (Tick where appropriate V)

Section C: Maternity Theatre Data

Time at which the spinal anesthesia is given.....

Spinal needle used a) Type (design)..... b) Size.....

Approach to the spinal anesthesia (Tick where appropriate V)

a) Midline…… b) Paramedian……..

Orientation of the needle bevel to the long axis of the spine

a) Parallel...b) perpendicular..... (Tick where appropriate V)

Number o f dural puncture attempts.....

Section D: Follow Up Data In Maternity Wards.

(Tick where appropriate V)

PDPH is a) Present..... b) Absent.....

Time of onset of PDPH after spinal block (Tick where appropriate V)

a) Within the 1st 24hrs.....b) After 24hrs within 48hrs.....c) After

48hrs within 72hrs.....

d) After 3 days within 14 days.....

Severity o f headache (as per appendix 2): (Tick where appropriate V)

a) Mild..... b) Moderate..... c) Severe.....

Other symptoms associated with post dural puncture headache: (Tick where appropriate V)

a) Neck stiffness..... b) Low back pain..... c) Nausea.....

d) Vomiting..... e) Vertigo.....f) Tinnitus.....g) Doplopia.....

What measures do you take for your headache? (Tick where appropriate V)

A) Take rest_____
B) Fluid diet _____
C) IV fluid _____
D) Caffine(Coffee, Tea, Cola) _____
E) Analgesic

   Paracetamol_____

   Diclofenac _____

   Ibuprofen _____

   Opoids (specify) _____

   Other (Specify) _____