AMINOPHYLLINE VERSUS ACETAMINOPHEN IN THE TREATMENT OF POST-DURAL PUNCTURE HEADACHE

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ABSTRACT:

Background: *Post-dural puncture headache (PDPH) is one of the most common complications of lumbar punctures performed for spinal anaesthesia, neurologic investigation or inadvertent Dural puncture during Epidural anaesthesia. Despite acceptance of the postulated cause of CSF leakage and intracranial hypotension, the exact mechanism of developing PDPH is not clear. Many pharmacological options have been advocated as a therapy for PDPH with a varying degree of success, but problem in choosing main drug therapy is the lack of large randomized controlled trials proving efficacy and safety***.**

Aim of the Work: T*o compare the efficacy of aminophylline compared to acetaminophen in management of PDPH.*

Patients and Methods: *The current clinical trial included 70 patients aged between 18-40 years old, class I-II according to the American society of anaesthesiology having a headache that developed after Dural puncture for various surgical procedures under regional anaesthesia. Patients were randomly allocated into 2 groups (35 patients each). Patients in the study Group (A) received 250 mg Aminophylline IV infusion while patients in Group (B) received 1gm paracetamol IV infusion for management of PDPH. Baseline VAS scores were recorded before drug administration &at 2 hours, 6 hours and 12 hours after the treatment administration.*

Results: *Mean VAS scores for PDPH intensity were statistically significant lower in Group A compared to Group B at 2 hours, 6 hours & 12 hours, while baseline VAS Score for PDPH intensity was insignificant statistically between Both Groups. There was also statistically significant improvement in Group A compared to Group B according to the Patient Global impression of change (PGIC) between both groups.*

Conclusion: *IV injection of aminophylline is relatively straightforward and non-invasive, safe and effective treatment for PDPH, and has improved early-stage effectiveness.*

Key words: *aminophylline*, acetaminophen, treatment, post-dural puncture headache

INTRODUCTION:

Spinal anaesthesia is a simple, cost effective and efficient technique that provides complete sensory and motor block, as well as postoperative analgesia with a high success rate[(1)]**.**

Post-dural puncture headache (PDPH) is among the most common complications of lumbar punctures performed for spinal anaesthesia or neurologic investigation, with incidence rates of 8% to 37% reported in different studies[(2)]**.**

It typically begins within 2 days but may be delayed for as long as 2 weeks and almost resolves spontaneously within a few days[(3)]**.**

The classic symptoms of (PDPH) consist of photophobia, nausea and vomiting, neck stiffness, tinnitus, diplopia, and dizziness, in addition to the often severe cephalgia. The headache is usually severe and throbbing, frontal in origin, with radiation to occiput and is exacerbated by sitting or standing. The positional nature of the headache and dramatic improvement on assuming the supine position remains the standard diagnostic criterion for this condition[4].

Preventive strategies of PDPH are developed based on how to reduce CSF leakage by available methods including small size pencil point spinal needle, parallel bevel orientation, and liquid use for the loss of resistance in epidural puncture[5].

Commonly used treatments for PDPH include rehydration, the administration of corticotropin, caffeine, or sumatriptan, and the application of an Epidural blood patch (EBP)[6].

It seems that Methylxanthines' derivateions (e.g. caffeine and theophylline) lead to vascular contraction and can reduce the headache. On the other hand, these drugs may decrease the headache by blocking the purine receptors[7].

Aminophylline, like theophylline and caffeine, can prevent PDPH by adenosine antagonization and vasoconstriction effect[8].

Acetaminophen is one of the most important drugs used in the treatment of mild to moderate pain when an anti-inflammatory effect is not necessary.The drug is one of the most commonly used non-narcotic analgesic agentsfor mild to moderate pain such as headache[9].

AIM OF THE WORK:

To verify the efficacy and the safety of Aminophylline for management of PDPH. Also to compare the efficacy of Aminophylline and Acetaminophen for management of PDPH.

PATIENTS AND METHODS:

This study was carried out in Nasr City insurance hospital and Ain shams University hospitals as a prospective, single-blinded (patients only), randomized, parallel-group clinical trial in 2019. The study was approved by the research ethical committee at Ain Shams University & all subjects provided written informed consent to be enrolled in the study after the procedure, aim and all safety measures were explained to them.

70 patients were included in this clinical trial, the inclusion criteria were patient's ages between 18 – 40 year old, class I – II according to the American society of anaesthesiologists, having a headache that developed after Dural puncture for various surgical procedures under regional anaesthesia (spinal anaesthesia, epidural anaesthesia or combined spinal and epidural anaesthesia).

PDPH was defined according to the international classification of headache disorders, 3rd edition criteria (ICHD-3) as headache occurring within 5 days of a lumber puncture, caused by CSF leakage through the dural puncture.

The diagnostic criteria according to ICHD-3 were: Either Low CSF pressure or Evidence of CSF leakage on imaging or both, Dural puncture has been performed, Headache has developed within 5 days of the dural puncture & not better accounted for any other cause of headache according to ICHD-3 diagnosis.

The exclusion criteria included having a history of headache that could interfere with the PDPH diagnosis, having a history of central nervous system diseases, including intracranial haemorrhage, seizures, intracranial hypertension, or hydrocephalus; having a history of cardiovascular diseases, including coronary heart disease, arrhythmias, or hypertension. The patients with

any history of allergy to or any contra-indication for using Aminophylline, theophylline or Acetaminophen were excluded.

Patients were randomly recruited using computer generated program into 2 groups (35 patients each). Patients in the study Group (A) received Aminophylline (250mg of Aminophylline dissolved in 100ml normal saline for intravenous infusion over 30 minutes) while patients in control Group (B) received paracetamol (1gm of acetaminophen in 100ml for intravenous infusion over 30 minutes). All the patients in the 2 groups were blinded to the group of randomization.

Headache intensity was assessed using Visual Analogue score (VAS) bedside card.VAS scores were recorded with the patients assuming standing position. Patient lies flat for more than 10 minutes and then stands for 5 minutes and then VAS scores were recorded.

Baseline VAS scores were recorded before drug administration. VAS scores were recorded again at 2 hours, 6 hours and 12 hours after the treatment administration.

The primary end point was the headache severity after 8 – 12 hours after treatment

The secondary outcomes were the overall response to treatment measured on the Patient Global impression of change (PGIC) which is a self-evaluation of the patient overall change since the start of the study.

Patients not responding to either treatment were planned to be managed invasively using Epidural Blood Patching or Epidural Saline injection.

Statistical analysis:

Recorded data were analysed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage. The following tests were done: Independent-samples t-test of significance was used when comparing between two means. Mann Whitney z-test: for two-group comparisons in non-parametric data. Chi-square (x2) test of significance was used in order to compare proportions between qualitative parameters. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: Probability (P-value): P-value <0.05 was considered significant.

RESULTS:

Table (1): Demographic data

Demographic data	Group A (n=35)	Group B (n=35)	t/x2#	p-value
Age (years)				
Range	18-40	18-40	0.851	0.619
Mean±SD	32.77±8.85	31.79±8.58		
Sex				
Male	22 (62.9%)	25 (71.4%)	2.194#	0.396
Female	13 (37.1%)	10 (28.6%)		
Weight (kg)	72.76±5.56	75.11±9.31	1.049	0.220
ASA				
I	19 (54.3%)	22 (62.9%)	1.386	0.291
II	16 (45. 7%)	13 (37.1%)		
Duration of surgery (min)	96.30±24.61	99.51±20.33	1.154	0.242
Duration of hospital stay (days)	2.25±0.86	2.02±0.75	1.269	0.267

As table (1) shows, there was no statistically significant difference between the two groups according to demographic data included: Age, Sex, Weight, American

Society of anaesthesiologists' classification (ASA), Duration of surgery & Duration of hospital stay.

Baseline VAS scores were recorded before drug administration. VAS scores were recorded again at 2 hours, 6 hours and 12 hours after the treatment administration in both studied groups.

Table (2): Comparison between group A and group B according to headache intensity.

Headache intensity	Group A (n=35)	Group B (n=35)	z-test	p-value
Baseline	6.17±1.37	6.73±1.24	1.713	0.207
After 2 hrs	5.65±1.62	6.75±1.31	2.592	0.019*
After 6 hrs	3.88±1.78	4.89±1.53	3.576	0.008*
After 12 hrs	2.75±2.42	4.79±2.03	4.196	<0.001**

In Group A the mean baseline VAS Score for PDPH intensity was 6.17±1.37. While the mean VAS scores for PDPH intensity 2 hours, 6 hours & 12 hours after Aminophylline administration were 5.65±1.62, 3.88±1.78 & 2.75±2.42 respectively.

In Group B the mean baseline VAS Score for PDPH intensity was 6.73±1.24. While the mean VAS scores for PDPH intensity 2 hours, 6 hours & 12 hours after Acetaminophen administration were 6.75 ± 1.31, 4.89±1.53 & 4.79±2.03 respectively.

Mean VAS scores for PDPH intensity were statistically significant lower in Group A compared to Group B at 2 hours, 6 hours & 12 hours, while baseline VAS Score for PDPH intensity was insignificant statistically between Both Groups as shown in table (2).

On the Patient Global impression of change (PGIC), 26 patients in Group A reported that their pain symptoms were much improved or very much improved, while 18 patients in Group B reported the same.

Also only 8 patients in Group A stated that there was no change in their pain symptoms while 14 patients in Group B stated the same.

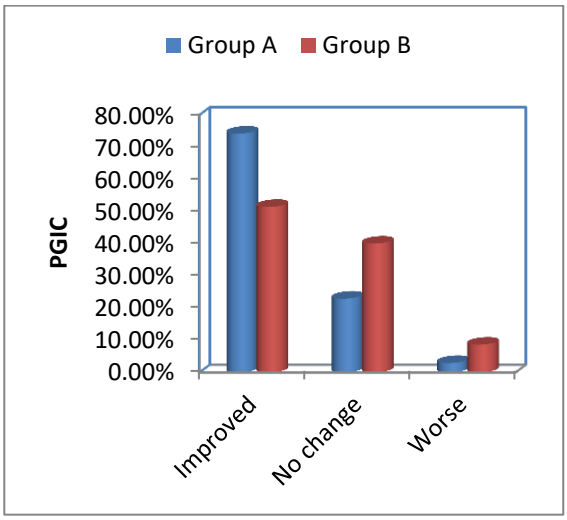
Table (3): Comparison between group A and group B according to PGIC

PGIC	**Group A (n=35)**	**Group B (n=35)**	**x2**	**p-value**
Improved	26 (74.2%)	18 (51.4%)	10.171	<0.001**
No change	8 (22.9%)	14 (40%)	6.012	0.014*
Worse	1 (2.9%)	3 (8.6%)	2.038	0.153

x2: Chi-square test, p-value>0.05 NS; *p-value <0.05 S; **p-value <0.001 HS

There was statistically significant improvement in Group A compared to Group B according to PGIC (improved & no change) as shown in table (3) & diagram. (1).

Diagram (1):



Bar chart between group A and group B according to PGIC.

DISCUSSION:

Lumbar puncture (LP) is a routine technique performed for a variety of procedures, for example diagnosis, administration of drugs, myelography, and spinal anaesthesia. PDPH is a common complication (30–40%) of diagnostic LP [(10)].

However, the exact mechanism of PDPH remains unclear and might be related to the following factors: decreased intracranial pressure leading to the compensatory expansion of the intracranial blood vessels and increased blood flow, resulting in PDPH[(11)].

Moreover, As a result of CSF leakage and CSF volume depletion, the brain descends. This leads to traction or distortion of various anchoring pain-sensitive structures in the brain, causing orthostatic or primarily orthostatic headaches[(12)].

Methylxanthines are beneficial in controlling the compensatory vasodilatation associated with PDPH. Methylxanthines are thought to interfere with the uptake of calcium by the sarcoplasmic reticulum, block activity of phosphodiesterase and antagonize the effects of adenosine. The cerebral vasoconstriction is most likely due to the antagonizing effect of adenosine. In addition, methylxanthines increase CSF production by stimulating sodium-potassium pumps[(13)].

Caffeine and acetaminophen is the most widely accepted pharmacologic treatment for PDPH; it has proven to be effective in decreasing the proportion of participants with PDPH persistence and those requiring supplementary interventions. Traditional therapies such as bed rest and rehydration are usually ineffective when the headache is severe[(14)].

The dose of aminophylline used in this study was lower than that used for regular clinical treatments and would, hence, not have caused an excessive plasma concentration, explaining the absence of adverse reactions related to the drug treatment. Therefore, the study results show that an IV injection of 250 mg aminophylline can be regarded a safe treatment for PDPH.

Our results showed that administration of aminophylline 250 mg produced a great reduction in VAS score for PDPH compared with 1 gm of acetaminophen despite baseline VAS Score for PDPH intensity was

insignificant statistically between Both Groups.

In agreement with our study Camann et al. (1990) evaluated the possibility of oral caffeine for the treatment of PDPHs. The study was randomized, double-blind, and placebo-controlled involving 40 postpartum patients. Each patient was randomized to receive caffeine capsules 300 mg po or placebo. A 100-mm visual analog scale was used to evaluate the pain for the headache at baseline, 4 hours, and 24 hours after caffeine administration. They concluded that caffeine administered orally provides relief, albeit if sometimes transient, from PDPH with minimal side effects[14].

In addition, *Ergün et al.* (2008) evaluated the efficacy of intravenous theophylline treatment for PDPH in comparison with a placebo in randomized, double blinded study. 33 patients with PDPH were randomly allocated into 2 groups : study group (17 patient) received 200 mg intravenous theophylline (200 mg theophylline in 100 mL 5% dextrose) infusion over 40 min, and control group (16 patients) were given 100 mL 5% dextrose intravenously over 40 min. Then the two groups were asked for their VAS values 4 h after the infusion while in the standing position, and then the values were compared. They found that intravenous theophylline infusion was effective for decreasing the painfulness of PDPH compared with the control group[6].

In addition, *Mahoori et al. (2013)* compared the efficacy of oral theophylline to oral acetaminophen. In a single-blind randomized clinical trial, 60 patients with Class I physical status according to ASA classification system, who suffered from PDPH were enrolled. Patients in Theophylline group were received theophylline tablet 250 mg three times per day, and in the other group acetaminophen 500 mg three times per day was administered. The main VAS values were significantly lower in theophylline group in comparison with the acetaminophen with No adverse effects reported[15].

In addition, *Sen & Sen (2013)* studied the efficacy of oral Theophylline for the management of PDPH in comparison to conservative management. Forty patients with PDPH, whose surgeries were done under spinal anaesthesia, were selected randomly and divided into two groups of 20 each. One group received conservative treatment and the other group Theophylline (400 mg) only orally. Intensity of headache was analyzed using a VAS of pain**.** Assessment was done immediately before (0 h) and at 8, 16 and 24th hr of drug administration. Significantly better relief of PDPH was found in Theophylline group than the conservative group Recurrence of headache was found much less in the Theophylline group compared to the other group[16].

In addition *Chuanjie et al. (2016)* studied the efficacy and safety of an intravenous injection of aminophylline in management of PDPH. Thirty-two PDPH patients received Aminophylline (250 mg) was dissolved in 100 mL saline for IV injection and was administered over at least 30 minutes, once daily for 2 consecutive days. The primary and secondary endpoints were the degree of headache and the patient's overall response to the treatment, respectively. VAS scores were determined with the patient's standing position (lies flat for more than 10 minutes and then stands for 5 minutes) before the first aminophylline treatment and at 30 minutes, one hour, 8 hours, one day, and 2 days after treatment. Treatment safety was evaluated based on the occurrence of adverse reactions. They found that Aminophylline significantly reduced the VAS scores for Headache with More than 50% (17/32) of the patients reported that they were "very much improved" or "much improved" 30 minutes after the initial

treatment, increasing to 93.8% (30/32) at 2 days post-treatment[17].

In addition *Chuanjie et al. (2018)* studied the efficacy and safety of an intravenous injection of aminophylline compared with placebo in management of PDPH. 126 patients were enrolled & randomly assigned to groups receiving either IV aminophylline or a placebo within 3 hours of symptom onset once daily for 2 consecutive days. The primary endpoint was headache severity 8 hours after treatment. The aminophylline group received 250 mg aminophylline dissolved in 100 mL saline for IV injection over ≥30 minutes once daily for 2 consecutive days. The placebo group received isochoric, 100 mL isotonic saline injections on the same schedule. They found that Compared to the placebo-treated patients, the aminophylline-treated patients had significantly lower mean VAS scores 8 hours after treatment and were significantly more likely to report improvements on the PGIC. This therapeutic effect was already evident at the 30-minute time point and persisted for 2 days. There was no significant difference in the incidence of adverse events[18].

Also *Sadeghi et al. (2012)* studied whether single dose of intravenous aminophylline can be used as prophylaxis of this complication in cesarean section or not. 120 patients undergoing spinal anesthesia for the elective cesarean section participated. After cord clamping, 1mg/ kg aminophylline injected intravenously in 60 patients but others didn't receive it. At 1st, 4th, 24th and 48th hours after operation, these 120 patients evaluated for PDPH. They found that the incidence of PDPH decreases in those patients who received single dose intravenous aminophylline after cord clamping[19].

In addition, *Chao-Jie et al. (2019)* investigated the effect and safety of the pre-administration with aminophylline on the occurrence of PDPH in women undergoing caesarean section by combined spinal-epidural anaesthesia. 120 women undergoing elective caesarean sections with combined spinal-epidural anaesthesia were randomly allocated into two groups; for 30 min immediately after the infant was delivered, group (A) received 250 mg aminophylline intravenously and group (B) received an equal volume of normal saline. The incidence of PDPH in group A was significantly lower than group B. There were no related side-effects within 24 h after aminophylline administration in group A[20].

In addition, *Naghibi &Hamidi (2014)* studied the effects of combining administration of intravenous aminophylline and dexamethasone on PDPH in patients who underwent lower extremity surgery in comparison with using either drug alone and also comparing them with placebo. 140 patients aged 20-65 years were divided into four groups of 35 each and received aminophylline 1.5 mg/kg i.v. (group A), dexamethasone 0.1 mg/kg (group D), aminophylline 1.5 mg/kg plus dexamethasone 0.1 mg/kg i.v. (group AD), and placebo (group P). The incidences of PDPH and complete response were evaluated at 6-48 h after arrival to the ward in the four groups by using VAS score. Acetaminophen 15 mg/kg i.v. was administered if the patients had VAS score of >5 cm and the total dose of rescue analgesic was recorded. They concluded that Combine administration of aminophylline 1.5 mg/kg plus dexamethasone 0.1 mg/kg significantly reduced PDPH better than using either drug alone in patients who underwent lower extremity surgery. Postoperative analgesic requirement was significantly less in groups A, D, and AD compared with group P. The results of this study did not show any significant adverse effect such as tachycardia or restlessness due to study drug administration[21].

In contrast to the results of our study, *Laleh et al. (2019)* compared the effect of

ondansetron to aminophylline on the incidence and severity of PDPH in women undergoing elective caesarean section surgery. 300 women who were candidates for elective caesarean section surgery were randomly assigned to 3 groups: group (A) receiving 1 mg/kg intravenous aminophylline, or (B) receiving 0.15 mg/kg IV ondansetron or (C) control group receiving 5 cc normal saline as placebo. Afterwards, PDPH and post-operative nausea and vomiting were followed during 24, 48 and 72 h periods since the performance of spinal anaesthesia and the severity of headache was noted by numerical rating scale which had been already explained to the patients. This study shows that although (0.15 mg/kg) ondansetron does not reduce the incidence of PDPH, it significantly reduces the severity of headache also shows that aminophylline has no effect on reduction of incidence nor severity of PDPH. This can be explained by low dose of Aminophylline (1 mg/kg) compared to the present study[22].

Conclusion:

In this study, we administered an IV injection of aminophylline to treat PDPH. The treatment was relatively straightforward and non-invasive, safe and effective treatment for PDPH, and has improved early-stage effectiveness. Therefore, we believe that an IV injection of aminophylline could be the preferred method for the clinical treatment of PDPH.

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مقارنة بين عقار الأمينوفيللين وعقار الأسيتامينوفين في علاج صداع ما بعد ثقب الجافية

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قسم التخدير والرعاية المركزة وعلاج الألم

خَلفِيَّة : يُعد صداع ما بعد ثقب الجافية أحد أكثر المضاعفات شيوعًا للبزل القطني سواءً كان للعلاج أو لإجراء الفحوصات العصبية أو الثقب الغير مقصود للجافية أثناء تخدير فوق الجافية. و بالرغم من التسليم بأن حدوث صداع ما بعد ثقب الجافة يرجع إلى تَسَرُّبالسَّائِلُ النُّخاعِيّ و إنخفاض الضَّغْطِ داخِلَ القِحْف إلا أن الآلِيَّة الدقيقة لكيفية حدوثه غير واضحة. تم تأييد العديد من الخيارات الدوائية كعلاج لصداع ما لعد ثقب الجافية بدرجات نجاح متفاوتة، إلا أنه تكمن المشكله لإختيار علاج ناجع هو نقص الدراسات السريرة الكافية المعتمدة على العينات العشوائية لإثباتَ فاعلية و أمان تلك الخيارات.

الهدف من الدراسة : مقارنة فاعلية عقار الأمينوفيللين بعقار الأسيتامينوفين في علاج صداع ما بعد ثقب الجافية.

المرضى

منهجية البحث: إشتلمت هذه الدراسة على عدد ٧٠ مريض تتراوح أعمارهم بين ١٨-٤٠ سنة و حالتهم الصحية بالمستوى الأول أو الثاني على حسب تصنيف الجمعية الأمريكية لأطباء التخدير. تم تشخيص المرضى بصداع ما بعد ثقب الجافية بعد إجراء جراحات مختلفة تحات تأثير التخدير العصبي المحوري. تم تقسيم المرضى عشوائياً إلى مجموعتين (تحتوي كل واحدة على ٣٥ مريض). المرضى في المجموعة (أ) تلقوا ٢٥٠مجم من عقار الأمينوفيللين بالتسريب الوريدي بينما تلقى مرضى المجموعة (ب) ١ جم من عقار الأسيتامينوفين بالتسريب الوريدي. قمنا بتسجيل شدة الألم بإستخدام الميزان القياسي البصري في بداية التجربة قبل إعطاء أي عقار ثم بعد ٢ و ٦ و ١٢ ساعة بعد تلقى العقاقير المستخدمة.

النتائج : وجدنا أن الميزان القياسي البصري لمرضى المجموعة (أ) أقل بشكل مُعْتَدّ إحصائياً عن مرضى المجموعة (ب) بعد ٢ و ٦ و ١٢ ساعة من تلقى العقاقير بالرغم من أن الميزان القياسي البصري في بداية التجربة بين المجموعتين كان غير مُعْتَدّ إحصائياً. كان هناك تحسن ملحوظ معتد إحصائياً في مرضى المجموعة (أ) مقارنة بالمجموعة (ب) على حسب مقياس الإنطباع الشامل للمرضى عن التغيير بين المجموعتين.

الإستنتاج :يعتبر عقار الأمينوفيللين عن طريق الوريد علاج بسيط و غير غازي و آمن و فعال لصداع ما بعد ثقب الجافية، و قد أثبت فاعلية في علاج المراحل المبكرة للمرض.