EFFICACY OF PATIENT CONTROLLED ANALGESIA (PCA) DURING THE FIRST STAGE OF LABOR ANDPREGNANCY OUTCOME

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ABSTRACT

Objective: *To evaluate the efficacy of intravenous (IV) paracetamol versus pethedine via patient-controlled analgesia (PCA) as intrapartum analgesia during the active phase of labour and to evaluate maternal, fetal and neonatal adverse effects of both paracetamol and pethidine.* ***Methods:*** *It is an interventional prospective comparative randomized study which comprised 100 pregnancies of 37 – 42 weeks' gestation that were selected form tertiary Maternity Hospitals to assess the use ofparacetamol IV- PCA as analgesia in the first stage of labor in comparison with pethidine IV-PCA.Pain was evaluated using a 0- to 100-mm visual analog scale (VAS)at 15 min, 1, 2, 3 and 4hours after start of treatment.****Results:*** *Our study found statistically significant reduction in both groups (P < 0.001) of mean VAS score at 15 minutes, 1, 2, 3 and 4 hours after treatment with that of initial VAS at the beginning of the study. Our study found statistical significance (P < 0.05) was detected at 15 minute in favor to pethidine when compared to the initial VAS denoting its more rapid action. Our study found no significant difference between both groups (P > 0.05) as regard need for additional analgesia. Our study found that; as regard maternal side effect there is statistically significant results (P < 0.001), as 27 (54%) of 50 women received pethidine developed maternal side effects with no*

side effects with paracetamol. Our study found a significant difference in favor of paracetamol group where delivery occurs at earlier period than pethidine group (P = 0.023). As regard mode of delivery, our study found no significant difference between both groups. As regard fetal adverse effects it is not significant (P > 0.05) between both groups. And as regard neonatal side effects, there were no neonatal side effects detected in the 2 groups. ***Conclusion:****Our study showing no significant difference between administration of paracetamol and pethidine hydrochloride IV- PCA as intrapartum analgesia in the first stage of labor. Maternal adverse effects were with pethidine hydrochloride, but there were neither fetal nor neonatal adverse effects with both paracetamol and pethidine hydrochloride.*

INTRODUCTION

Labor pain is not life-threatening during normal conditions; on the contrary, it is life-giving and includes components that differ completely from pain in general. It is an acute pain that is neither dangerous nor threatening during a normal delivery; rather, it provides information on a normal process ***(Lowe, 2002).*** The pain of labor produces physiological changes in addition to emotional distress and suffering. These changes have an impact on many maternal systems, and also affect the fetus ***(Gilbert, 2012).***

Pain originates from different sites as the process of labor and delivery progresses. First stage of labor: Pain at this time occurs during contractions, is visceral or cramp-like in nature, originates in the uterus and cervix, and is produced by distention of uterine and cervical mechanoreceptors and by ischemia of uterine and cervical tissues ***(Lowe, 2002).*** The pain signal enters the spinal cord after traversing the T10, T11, T12, and L1. Second stage of labor: Somatic pain from distention of the vagina, perineum, and pelvic floor and stretching of the pelvic ligaments is the hallmark of the second stage of labor. The pain signal is transmitted to the spinal cord via three sacral nerves (S2, S3,

and S4), which comprise the pudendal nerve. Second stage pain is more severe than first stage pain and is characterized by a combination of visceral pain from uterine contractions and cervical stretching and somatic pain from distention of vaginal and perineal tissues***(Gilbert, 2012).***

Labor pain can be assessed verbally or non- verbally ***(Capogna et al., 2010)***. The Visual Analogue Scale (VAS) is a rating scale routinely used in health care to evaluate the patient‘s experience of pain. Visual Analogue Scale (VAS): In this technique, the patient is shown a ten cm line which represent at one end ―no pain and the other worst pain, and the patient is asked to point on the line where his pain lies. This scale has the added advantage that the pain can be given a numerical value ***(Jensen and Karoly, 2001)***.

The management of labor pain is a major goal of intrapartum care. There are two general approaches: pharmacologic and nonpharmacologic***(Penny and Michael, 2012).***

Pethidine can provide short-term relief of acute pain but it is not effective for everyone. During labour, intramuscular or intravenous pethidine sedates women but may not give them adequate analgesia. Pethidine and its active metabolite norpethidine have adverse effects on the neonate as well as the mother, especially if repeated doses are given during labour. Pethidine has a short duration of action (2–4 hours) ***(Bricker and Lavender, 2002).***

Acetaminophen is a very frequently used painkiller and antipyretic drug, also among pregnant women. Acetaminophen crosses the placenta in its unconjugated form and is considered a drug without teratogenic effects. IV paracetamol was an effective analgesic after surgery ***(Sinatra et al., 2005)***. Intravenous acetaminophen (1 g) has been demonstrated to be as efficacious as intramuscular morphine (10 mg) following dental extractions, ***(Van et al., 2004),*** although there was evidence of a ceiling effect ***(Hahn et al, 2003).*** IV-

PCA is an effective method for the treatment of post-operative pain both in adults and children***(Ismail et al, 2012).*** The literaturereview reveals that there are a few studies conducted withnon-opioid analgesics by IV-PCA for treatment of postopera-tive pain in only adults ***(Rodriguez et al, 1993, Torres et al, 2001, Stamer et al, 2003, Karaca etal, 2006 and Sener et al, 2008)***

The intensity of the pain experienced during labor affects maternal psychology, labor progress and fetal well-being. For this reason, one of the basic principles of modern obstetrics is to provide adequate analgesia. An analgesic should have potent analgesic efficacy and minimal side effects to be suitable for use in pain relief during labor. In response to the need for effective labor pains management, we designed this prospective randomized comparative study to compare the efficacy of administration of paracetamol IV-PCA versus pethidine hydrochloride IV-PCA as intrapartum analgesia during the active phase of labour.

PATIENTS AND METHODS

1. Study site: tertiary Maternity Hospitals.

2. Study design: It is an interventional prospective comparative randomized study which comprised 100 pregnancies of 37 – 42 weeks‘ gestation that were selected according to inclusion and exclusion criteria to assess the use of IV-PCAby paracetamol versus pethidine hydrochloride as analgesia in the first stage of labor.

2.1. Population: The study comprised 100 pregnant women in labor. The study population was divided randomly into two groups of patients each group comprised 50 pregnanciessubjected to administration of IV-PCA (Abbott Pain Management Provider,Abbott Laboratories, Abbott Park, Ill, USA):

1st Group:Paracetamol: Loading dose of 5 mg / kg IV, followed by 0.5 mg / kg / h basal infusion, 1 mg /kg bolus dose, lockout interval of 30 min for the time of the study (total dose of paracetamol was limited to 10 mg / kg / 4 h).

2nd Group:**Pethidine hydrochloride**: loading dose of 0.5 mg / kg IV given over 2 minutes with no background infusion and bolus of 0.15 mg / kg body weight with lockout interval of 10 minutes. All patients were subjected to complete examination which includes menstrual history, clinical examination and ultrasound assessment. Each participant was reported pain intensity according to change in the 100-mm VAS "visual analogue scale" pain intensity score where the minimum score is no pain and the maximum score is the worst pain, patients were followed and recordings were also taken at 15 minutes, 1 hour, 2 hours, 3 hours, and 4 hours after drug administration.

2.2. Study entry and duration:

2.2.1. Recruitment and initial assessment: During the pre-selection visit, exclusion and inclusion criteria were applied.

2.2.2. Statistical analysis: Data were analyzed using Statistical Program for Social Science (SPSS) version 18.0. 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.Paired sample t-test of significance was used when comparing between related samples.Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters.Kaplan-Meier Survival Analysis: is a descriptive procedure for examining the distribution of time-to-event variables.Log rank test to compare time-to-event variables by levels of a factor variable.

Probability (P-value): P-value <0.05 was considered significant. P-value <0.001 was considered as highly significant. P-value >0.05 was considered insignificant.

2.2.3. Study duration:

The duration of the study was 6 months from September 2012 to April 2013.

2.3. Selection of patients:

2.3.1. Subjects' recruitment:

The patients were approached on admission. The study was discussed with the laboring woman and consent was taken by the investigator involved with the patient.

2.3.2. Inclusion criteria:

The eligibility criteria for the trial: primiparous, low risk parturients aged 18 – 35 years, term live singleton pregnancy, vertex presentation, spontaneous onset of labor at term “37 – 42 weeks” gestation, cervix dilatation between 4 and 6 cm and requirement of active management of labor.

2.3.3. Exclusion criteria:

The exclusion criteria include: clinical evidence of cephalopelvic disproportion, use of any kind of analgesia prior to study, any medical disorder during pregnancy (liver or kidney impairment), induction of labor, intrauterine fetal death, evidence of fetal distress, antenatal diagnosis of congenital malformation, previous history of hypersensitivity to either drug, extreme of age (i.e. below 18 or above 35), multiparity, multiple pregnancies, malpresentation and cervical dilatation more than 6 cm.

2.4. Data collection and schedule:

2.4.1. Enrollment (recruitment data):

Following admission, all patients were undergone complete clinical examination and detailed medical history was obtained. Assessment of labor pain at

the first stage of labor by VAS at start of study and 15 minutes, 1, 2, 3 and 4 hours after drug administration.

Maternal, fetal and neonatal side effects recorded during study and also time and mode of delivery.

2.4.2. Efficacy and safety data:

2.4.2.1. Efficacy data

Efficacy was assessed on the basis of improved pain perception as evidenced by visual analogue scale and the need of additional analgesia.

Visual Analogue Scale (VAS): In this technique, the patient is shown a ten cm line which represent at one end no pain and the other worst pain, and the patient is asked to point on the line where his pain lies. This scale has the added advantage that the pain can be given a numerical value. It consists of 100 mm horizontal or vertical straight line with anchors indicating for example "no pain and the worst pain imaginable"***(Seymour et al., 1985)***. The pain experience is recorded by marking the appropriate point on the line.

2.4.2.2. Safety data

Spontaneously observed and reported adverse events, either maternal or neonatal.

Maternal: The symptoms of nausea, vomiting, fatigue and drowsiness were compared between the two groups.

Neonatal: Apgar score at 1 & 5 minutes, administration of naloxone, respiratory distress and admission to transitional, special, or intensive care unit.

RESULT

Table (1): Pain assessment by VAS at 15 minutes, 1, 2, 3 and 4 hours after administration of IV-PCA by Paracetamol or Pethidine compared to initial VAS score in both groups.

VAS	Paracetamol group A			t	P	Pethidine group B			t	P
	Mean	95% CI				Mean	95% CI			
		Lower	Upper				lower	Upper		
At start of the study	83.95	81.43	86.47	1.31	0.150	81.26	77.95	84.58	1.31	0.230
After 15 minutes	72.82	69.46	76.16	9.41	**<0.001**	64.45	60.88	68.01	11.20	**<0.001**
After 1 hour	66.97	63.66	70.27	12.42	**<0.001**	66.36	62.17	70.55	11.67	**<0.001**
After 2 hours	65.29	60.22	70.36	4.69	**<0.001**	63.24	59.17	67.30	3.86	**<0.001**
After 3 hours	63.66	58.18	69.13	5.81	**<0.001**	69.65	65.45	73.85	5.73	**<0.001**
After 4 hours	64.29	60.20	68.38	4.42	**<0.001**	71.05	66.39	75.71	4.20	**<0.001**

- 95%CI: 95% confidence interval.
- (t- Paried sample t-test)

This table proves that at start of treatment, the mean VAS score was (83.95) in paracetamol group and (81.26) in pethidine group with statistical insignificance between both groups.The comparison between mean VAS score at 15 minutes, 1 hr., 2 hrs., 3 hrs, and 4hrs after treatment with that of pretreatment revealed statistically significant reduction in both groups (P < 0.001).

Table (2): The difference between both groups according to the VAS in relation to the initial VAS at 15 minutes, 1 hr., 2 hrs., 3 hrs. and 4 hrs.

VAS	Paracetamol group A			t 1	P	Pethidine group B			t 2	P	t*	P
	Mean Diff. from initial	95% CI				Mean Diff. from initial	95% CI					
		Upper	Lower				Upper	Lower				
After 15 minutes	11.13	11.97	10.31	9.48	<0.05	16.81	17.07	16.57	11.20	<0.001	2.98	0.004
After 1 hour	16.98	17.77	16.20	12.51	<0.001	14.90	16.78	14.03	7.67	<0.001	0.60	0.554
After 2 hours	18.66	21.21	16.11	4.72	<0.001	18.02	18.78	17.28	3.86	<0.001	0.08	0.947
After 3 hours	20.29	23.25	17.34	3.82	<0.001	11.61	12.50	10.73	3.50	<0.001	0.12	0.916
After 4 hours	19.66	21.23	18.09	3.43	<0.001	10.21	11.56	08.87	3.20	<0.001	0.89	0.383

- 95%CI: 95% confidence interval.

- Difference between VAS at15min, 1, 2, 3 and 4 hrs. with the initial VAS.
- (t 1) paired t test between VAS 15 min, 1, 2, 3 and 4 hours after administration of Paracetamol in relation to initial pain score.
- (t 2) paired t test between VAS 15 min, 1, 2, 3 and 4 hours after administration of Pethidine in relation to initial pain score.
- (t *) Unpaired (student's) t-test comparing the difference in both groups.

This table shows statistical significance ($P < 0.05$) was detected at 15 minute in favor to pethidine denoting its more rapid action.

Table (3): The difference in need for additional analgesia in both groups is illustrated in that table:

Item		Paracetamol group A		Pethidine group B		P	Sig.
		No.	%	No.	%		
Need for additional analgesia	-ve	41	82	36	72	0.903	NS
	+ve	9	18	14	28		

This table shows that 9 (18%) of 50 women received paracetamol need additional analgesia whereas 14 (28%) of 50 women received pethidine need additional analgesia in the form of ketorolac 30 mg iv injection over 1 minute in both groups, so no significant difference detected between both groups ($P > 0.05$).

Table (4): Comparison between both groups as regard the duration from drug administration till delivery.

Item	*Paracetamol Group A*		*Pethidine Group B*		*z*	*P*	Sig.
	Median	IQR	Median	IQR			
Duration from administration till delivery	5.25	3.14-6.62	7.11	4.66-9.38	1.98	**0.023**	**S**

- Mann-Whitney test = z

According to duration of labor, the mean interval between drug administration & delivery was 5.25 hrs. in paracetamol group but it was 7.11 hrs. in pethidine group. A significant difference in favor of paracetamol group where delivery occurs at earlier period than pethidine group ($P = 0.023$).

Table (5): Comparison between the two groups as regard maternal, fetal and neonatal side effects.

Item		Paracetamol group A		Pethidine group B		χ^2	P	Sig.
		N	%	N	%			
Maternal side effects	-ve	50	100	23	46		**<0.001***	**HS**
	+ve	0	0	27	54			
Fetal side effects	-ve	50	100	47	94	2.01	0.16	NS
	+ve	0	0	3	6			
Neonatal side effects	-ve	50	100	50	100	0.4	0.843	NS
	+ve	0	0	0	0			

- Chi-square test = χ^2
- Fisher's Exact Test*

It is noticed that 27 (54%) of 50 women received pethidine developed maternal side effects with statistical significant results (P < 0.001). These effects are in the form of one or more of the followings (tachycardia, dyspnea, vomiting, dryness of the mouth, dizziness or blurring of vision).Fetal adverse effects in the form of fetal bradycardia were recorded in 3 women (6%) but it is not significant (P > 0.05).On the other hand, there is no maternal or fetal side effects detected in paracetamol group.As regard neonatal side effects, there were no neonatal side effects detected in the 2 groups.

Table (6): Apgar score in both groups.

Item	Paracetamol group A		Pethidine group B		Z	P	Sig.
	Median	IQR	Median	IQR			
Apgar score at 1 minutes	7	6.2-7.4	6	6.3-7.6	2.890	**0.004**	**S**
Apgar score at 5 minutes	9	9.1-9.6	9	9.4-9.5	0.926	0.363	NS

- Mann-Whitney test = z
- (IQR: Interquartile Range).

At 1 min., the median Apgar score for paracetamol group was 7 but it was 6 for pethidine group.At 5 min., it was 9 for both groups.A significant higher Apgar score at 1 min (P = 0.004) was noticed in paracetamol group but no significance between both groups at 5 min.No neonatal ICU admission recorded in both groups.

DISCUSSION

I. Maternal outcomes: Our study found similarity between both groups as regard the demographic data as the mean maternal age by years was 25.60 in paracetamol group and 24.59 in the pethidine group, and their BMI was 30.75 and 29.42 respectively. The mean gestational age at delivery by weeks in paracetamol group was 39.84 and in pethidine group was 40.11, the cervical dilatation at time of recruitment by cm was 4.25 in paracetamol group and 4.37 in pethidine group and the frequency of uterine contraction in 10 minutes was 3.95 in paracetamol group and 3.73 in pethidine group, which had insignificant statistical result (p > 0.05), and these values denotes proper randomization and proper selection due to similarity between both groups.

Satisfaction with pain relief: As regard the mean VAS score at beginning of the study, it was (83.95) in paracetamol group and (81.26) in pethidine group with statistical insignificance between both groups. Our study found statistically significant reduction in both groups (P < 0.001) of mean VAS score at 15 minutes, 1, 2, 3 and 4 hours after treatment with that of initial VAS at the beginning of the study. Our study found statistical significance (P < 0.001) was detected at 15 minute in favor to pethidine when compared to the initial VAS denoting its more rapid action. After exclusion of women who delivered before 4 hours, secondary analysis was done. A significant lower in mean VAS after 15 minutes in pethidine group was detected in comparison to paracetamol group (P < 0.05), whereas no considerable differences in the VAS scores at 1, 2, 3 and 4 hrs. (P>0.05). As regard pethidine results; in another study ***(Keskina et al., 2003)***, which compressed 59 laboring women to evaluate and compare the analgesic efficacy and adverse effects

of tramadol and pethidine in labor, the results of the study indicated that administration of 100 mg i.m. pethidine was more effective in pain relief at 30 and 60 min after administration when compared with 100 mg tramadol. In another study ***(Prasertsawat et al., 1986),*** 100 mg tramadol administered intramuscularly has an analgesic effect equivalent to that of 100 mg pethidine or 10 mg morphine, administered intramuscularly. But in another studies ***(Viegas et al., 1993)*** and ***(Fieni et al., 2000)***, using of 75 mg pethidine showed that this dosage is as effective as 100 mg tramadol. As regard paracetamol results; in another study ***(El-Bohoty and El-Shorbagy, 2010)***, which compressed 35 laboring women in Ain Shams University Maternity Hospital to assess the efficacy of IV paracetamol as intrapartum analgesia, it showed a significant reduction of pain perception at 1 hour, 2 hours and 3 hours after drug administration, but not after 15 minutes. In another study ***(Hyllested et al. 2002)***, which designed to compare the effect of paracetamol, NSAIDs or their combination in postoperative pain management, the study found that; paracetamol is an alternative to the NSAIDs, especially because of the low incidence of adverse effects. In contrast to this study; there were three trials involving a total of 178 patients after episiotomy ***(Schachtel et al. 1989)*** and ***(Skovlund et al. 1991)*** (103 patients) or tubal occlusion ***(Huang et al. 1986)*** (75 patients). In two placebo-controlled studies, ibuprofen (400 mg) ***(Schachtel et al. 1989)*** and meclofenamate (100 and 200 mg) ***(Huang et al. 1986)*** improved pain scores compared with paracetamol. In the third study ***(Skovlund et al. 1991)***, which included only 30 patients, paracetamol was equivalent to naproxen 500 mg but the study sensitivity was not proven.

Need for additional analgesia: Our study found no significant difference detected between both groups ($P > 0.05$) as regard need for additional analgesia in the form of ketorolac 30 mg iv , 9 (18%) of 50 women received paracetamol need additional analgesia whereas 14 (28%) of 50 women received pethidine need

additional analgesia. In another study (***Philipsen and Jensen, 1990),*** which conducted to evaluate maternal opinion about analgesia in labour and delivery, they found higher rates of painless labor in both the epidural and the intramuscular pethidine.

Maternal adverse effects: Our study found that; as regard maternal side effect there is statistically significant results (P < 0.001), as 27 (54%) of 50 women received pethidine developed maternal side effects with no side effects with paracetamol. These effects are in the form of one or more of the followings (tachycardia, dyspnea, vomiting, dryness of the mouth, dizziness or blurring of vision). As regard pethidine results; in another study ***(Fieni et al., 2000)***, with 100 mg tramadol and 75 mg pethidine, the incidence of side effects including nausea, vomiting, fatigue and drowsiness has been found to be significantly higher in the pethidine group. As regard paracetamol results; in another study ***(El-Bohoty and El-Shorbagy, 2010)***, there is no maternal side effects with paracetamol during study.

Progress of labor and delivery: Our study found a significant difference in favor of paracetamol group where delivery occurs at earlier period than pethidine group (P = 0.023). In paracetamol group, the mean interval between drug administration and delivery was 5.25 hrs. But in pethidine group, the mean interval between drug administration and delivery was 7.11 hrs. As regard pethidine results; in another study ***(Viegas et al., 1993)***, the mean duration of labor was 7.9 hrs. after administration of 100 mg tramadol intramuscularly and 7.8 hours after administration of 75 mg pethidine intramuscularly. In contrast to our study; in another study **(Abdulwahab et al., 2012)** which compressed 73 laboring women in Malaysia to study the effect of pethidine on the neonatal outcome with regards to the interval between pethidine administrations to delivery of the fetus, the mean duration from pethidine administration to delivery was 296.48 ± 173.65 minutes (4

hours and 56 minutes). In another study ***(Keskina et al., 2003)***, there was no difference between tramadol and pethidine with respect to the effects on the duration of labor, the mean duration of labor was approximately 2 hrs. in both groups, and all the vaginal deliveries occurred within 4 hrs. of analgesic administration but in another study ***(Prasertsawat et al.,1986),*** in which the same drugs were used with similar dosages, 10 of the 45 patients in pethidine group and nine of the 45 patients of the tramadol group delivered after 4 hrs. of analgesic administration. As regard paracetamol results; in another study ***(El-Bohoty and El-Shorbagy, 2010)***, 15 out of 35 women delivered before 3 hours from administration of paracetamol till delivery.

Mode of delivery: Our study found, as regard mode of delivery, normal vaginal delivery in 45 women (90%) of paracetamol group and 44 women (88%) of pethidine group was recorded. In pethidine group, lower segment cesarean section (LSCS) was performed in 6 women (12%), it was secondary to fetal distress in 2 women and failure of cervical dilataion in 4 women. In paracetamol group, LSCS was performed in 5 women (10%) due to failure of cervical dilatation. As regard pethidine results; in another study ***(Keskina et al., 2003)***, which compressed 59 laboring women in Turkey to evaluate and compare the analgesic efficacy and adverse effects of tramadol and pethidine in labor, two patients (each from one group) were delivered by cesarean section with the indications of fetal distress and cephalopelvic disproportion, and the remaining 57 women delivered vaginally. As regard paracetamol results; in another study ***(El-Bohoty and El-Shorbagy, 2010)***, in which of the 35 included women, 29 (82.9%) delivered vaginally and 6 delivered by CS. All of them were due to 2ry arrest of cervical dilatation.

II. Fetal and neonatal outcomes: Our study found; as regard fetal adverse effects it is not significant ($P > 0.05$) between both groups, it was recorded in 3 women (6%) in pethidine group in the form of fetal bradycardia. On the other hand,

there is no fetal side effects were detected in paracetamol group, and as regard neonatal side effects, there were no neonatal side effects detected in the 2 groups. As regard pethidine results; in another study ***(Abdulwahab et al., 2012)***, sixteen (21.9%) cases were admitted to the Neonatal Intensive Care Unit (NICU). Eleven (68.75%) cases were admitted due to neonatal sedation from the delivery group less than 4 hours after pethidine. Five (31.25%) cases from the delivery group more than 4 hours, 4 cases with a diagnosis of transient tachypnea of newborn and 1 secondary to meconium aspiration syndrome (MAS). All discharge to mother after 24 hours. Despite of the higher number of those require admission in the less than 4 hours group, it was not statistically significant with P value of 7.44. As regard paracetamol results; in another study ***(El-Bohoty and El-Shorbagy, 2010)***, there are no fetal or neonatal side effects with paracetamol during study.

Apgar score: Our study found a significant higher Apgar score at 1 min (P = 0.004) was noticed in paracetamol group but no significance between both groups at 5 min. At 1 min., the median Apgar score for paracetamol group was 7 but it was 6 for pethidine group but at 5 min., it was 9 for both groups. As regard to pethidine results; in another study ***(Abdulwahab et al., 2012)***, all neonates delivered with good Apgar Score (AS), 8 at 1 minute and 9 at 5 minute except 1 with AS of 5 at 1 min and 7 at 5 min which delivered more than 4 hours after pethidine. In another study ***(Keskina et al., 2003)***, it has been reported that Apgar scores are not altered, and respiratory depression requiring resuscitation is not observed with pethidine and tramadol. There was no statistically significant difference in mean Apgar scores at 1 and 5 min when two groups were compared (P=0.093, P=0.895, respectively), and the result was supported by previous studies: ***(Prasertsawat et al.,1986; Viegas et al., 1993and Bredow, 1992).*** In another study ***(Mansoori et al., 2000)***, which designed to examine the use of pethidine, epidural or no analgesia during labour on neonatal outcomes, delivery and maternal satisfaction with pain relief, showed that

difference between the type of analgesia (pethidine and epidural) women had during labour and the corresponding neonatal Apgar scores measured at 1 minute. Regardless of type of analgesia, the majority of Apgar scores (99%) at 5 minutes were within the normal range. And these findings are supported by another study ***(Howell, 1997)***, in which no differences between epidural and other forms of analgesia (including pethidine) on neonatal Apgar scores were found.

III. Limitations of the study: Being assessment of satisfaction with pain relief is subjective, context- specific, and influenced by a number of factors including culture, environment, and previous expectations; our limitations in this study were not including these factors in the research.

CONCLUSION

Our study showing no significant difference between IV-PCA administration of paracetamol and pethidine hydrochloride as intrapartum analgesia in the first stage of labor as regard maternal satisfaction, need for additional analgesia and mode of delivery. Pethidine hydrochloride had rapid onset of action and paracetamol administration had a remarkably shorter mean duration of labor.

Maternal adverse effects were with pethidine hydrochloride, but there were neither fetal nor neonatal adverse effects with both paracetamol and pethidine hydrochloride.

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