The Egyptian Journal of Hospital Medicine (October 2019) Vol. 77 (5), Page 5589-5596

Intradermal Sterile Water Injection versus Epidural Bupivacaine in Painless First Stage of Labor

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ABSTRACT

Background: Many women have moderate to severe low back pain during labor. It has been shown that injection of sterile water can reduce the pain of 1st stage. This method is very cheap, easy to learn and can be used as alternative method for reducing the labor pain.
Objectives: The aim of this study was to compare the effectiveness, women satisfaction safety and safety of intradermal sterile water injection and epidural bupivacaine in decreasing the pain of1st stage of labor.
Patients and Methods: After approval of Institutional Ethical Committee and obtaining written informed consent from eligible parturient women, 120 healthy parturient divided into 3 groups. 1st group epidural bupivacaine plus fentanyl, Initiated with 10 ml of bupivacaine 0.125% with 2 micrograms/ ml of fentanyl and maintained with 10 ml/ h of the same mixture. 2nd group intradermal injection of sterile water 0.1 ml, while 3rd group intradermal injection of 0.1 ml normal saline.
Results: The study reported good pain relief in epidural and sterile water group compared to normal saline group. Pain relief was comparable in both the epidural and sterile water group. Complications were more demonstrated in epidural compared to the sterile water and the normal saline groups. A good maternal satisfaction in epidural and sterile water group with no satisfaction in the normal saline group.
Conclusion: The evidence from this study suggests that sterile water injections are safe and effective method for relieving pain of the 1st stage of labor similar to epidural bupivacaine analgesia.

Keywords: Sterile Water, Labor Pain.

INTRODUCTION

Normal vaginal delivery pain is drastically hard to tolerate, especially during the first stage. Some women experience abdominal pain, some others have lower back pain, and some have both types. Although the pain of giving birth usually appears with the onset of uterine contractions, sometimes lower back pain is also experienced in the intervals between uterine contractions. About 30% of women suffer from constant back pain simultaneously to contractions and apparently lack of rest in the intervals between contractions makes tolerance of pain much more difficult [(1)].

Visual analogue score that usually used as scoring system for pain assessment in different studies, is used also for assessment of labor pain [(2)].

Recently, epidural analgesia has become one of the most frequently used analgesic techniques for birth. The advantage of this technique is its ability to provide analgesia during labor as well as excellent anesthesia for delivery, as it is titrated to maintain the patient's sense of touch and motor ability, facilitating participation in the birth process. Epidural analgesia reduces pain-induced maternal hyperventilation during labor, preventing left shift of the hemoglobin dissociation curve in the mother, which can have detrimental effects on fetal hemoglobin saturation [(3)]. Stress intensity is influenced by numerous factors such as previous pain experiences, education, culture, expectations, environmental factors and support from caregivers [(4)]. Some draw backs are linked with regional analgesia techniques as pain at the puncture site, fear of needles and recall of the procedure [(5)].

Stress response leads to release of catecholamines and other vasopressors. At full term, uterine vasculature is maximally dilated, but still responds to these vasopressors causing uterine vasoconstriction and decrease the uterine and placental blood flow which adversely affect the neonates [(3)]. Therefore, the prevention from maternal stress is potentially important. This can be prevented by giving patients detailed information

Received: 11/8/2019
Accepted: 11/8/2019

about their operation and with preoperative pharmacological medications [6].

The use of epidural analgesia is not without consequences and is associated with increased frequency of instrumental delivery (forceps or vacuum) and some degree of motor weakness in the parturient [7].

Sterile water injected lateral to the lumbosacral spine is a simple approach to ameliorate the visceral pain of labor including that of low back. This approach is easy to administer, inexpensive, has minor side-effects and can be administered without care specialist. Intracutaneous sterile water injection is associated with acute pain that lasts for 30 seconds but as the pain subsides so does the visceral referred pain of low back. The effect begins quickly and has been shown to be effective for 2 to 3 hours, long after the acute pain of the injection has subsided [5]. Physiologically the hypotonic, sterile water does not act as a local anesthetic and does not directly inhibit the visceral pain fibres. In fact, sterile water will cause firing of the C fibres as well as A-delta fibres normally associated with somatic pain. The leading hypothesis explaining the efficacy of sterile water is that the firing of A-delta fibres overwhelms the visceral pain input from C fibres such that the visceral pain is not noticeable. This hypothesis relies somewhat on gate control theory of pain although it may also be that intracutaneous sterile water leads to endorphin release similar to that found in acupuncture [8].

The aim of our study was to compare the effectiveness, safety and women satisfaction of intradermal sterile water injection and epidural bupivacaine to decrease pain in 1st stage of labor.

PATIENTS AND METHODS

The study was conducted in the Obstetrics Department of Al-Azhar University Hospitals "Al-Hussein and Bab-Al-Shaarya", Cairo, Egypt, from December 2018 till September 2019.

Patients:

After informing the women about the advantages and disadvantages of each method and discussing with them, which way is suitable for each one.

One hundred and twenty parturients were enrolled in this study. Parity in the first group was 15 /40 primipara & 25/40 multipara (less than 5 deliveries), while in the second group, parity was 11/40 primipara & 29/40 multipara and in third group, it was 13/40 primipara & 27/40 Multipara respectively.

Patients randomly assigned to either of three groups (40 patients each).

Group I: Epidural with bupivacaine plus fentanyl

Group II: Intradermal sterile water

Group III: Intradermal normal saline.

Ethical approval and written informed consent:

An approval of the study was obtained from Al- Azhar University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of the operation.

Inclusion criteria

1. Request for analgesia, only patient how needed analgesia.
2. Null parity
3. Age 25-35 years,
4. Body mass index < 30 kg per square meter,
5. American anathesiology association ASA I or II,
6. Gestational age > 37 weeks.
7. Single fetus in cephalic presentation.
8. Normal fetal heart rate and true labor with cervical dilatation > 4 cm.

Exclusion criteria

1. Patients receiving analgesia prior to enrolment.
2. Presence of complicated pregnancies with hypertension, diabetes mellitus, neurological disease, recent hemorrhage, preeclampsia, eclampsia.
3. Suspicion of fetal malformation and intrauterine growth retardation.
4. Fever and history of allergy to local anesthetics.
5. Body mass index above 35.
6. ASA class III
7. Gestational age less than 37 weeks.
8. Any patient turned to caesarian section.

Prepartum evaluation:

Pre labor maternal assessment to fulfill patients criteria for study by full history taking physical examination including chest and heart examination routine labs was done as (complete blood count , random blood sugar, INR) ,

Methods:

Study protocol was explained to the patients taking their consent. Explanation of visual analog scale (VAS) scoring system for all patients. Patient arterial blood pressure was recorded and O2 saturation and heart rate were recorded by automatic monitor with pulse oximetry. Wide bore 18 gauge cannulae was inserted for receiving ringer solution

Study groups:

Group I: Epidural (E)

Each parturient was preloaded with 500 ml of lactated ringer solution before the initiation of epidural analgesia. A 20 gauge epidural catheter (prefix epidural set) was inserted under aseptic precautions in the lateral position at L3-L4 or L4-L5 interspaces with the loss of resistance to saline technique. The epidural catheter was then secured and the parturient placed in the supine position with left uterine displacement with the head of the bed elevated 20 -30 degrees. 3 ml test dose of 2% lidocaine containing epinephrine 15 µgm used to exclude intravascular or subarachnoid placement. Epidural analgesia will be initiated with a 15 ml bolus of bupivacain 0.125% with 2 µgms/ml of fentanyl and maintained with 10 ml/hr of same mixture. This infusion maintained throughout the first stage of labor. Maternal blood pressure recorded every 5 minutes for 30 minutes after initiation of epidural analgesia and then every 15 min. Until delivery.

Group II- Intradermal sterile water injection (S.W.)

Parturient of this group received four intradermal injections of sterile water in the lumbo-sacral region (Michael's rhomboid).

1. The volume of each injection was 0.1 ml. The injections administered using 1 ml insulin syringe with fine needle (30 gauges). The injections were given during contraction. The treatment was repeated every 90 min intradermal injection of sterile water 0.1 ml, in the lumbo-sacral region (Michael's rhomboid).

Group III – Intradermal normal saline injection: patients received injections of 0.1 ml isotonic saline in the same region using an insulin needle.

The following parameters were assessed:

1. Demographic data include (age in years, gestationl age in weeks and BMI).
2. Mode of delivery incidence if vaginal or instrumental delivery.
3. Pain assessment: pain was assessed with 10 cm visual analogue scale with 0 representing no pain and 10 being the worst pain imaginable, pain assessed before initiation of analgesia and at 5,10,15, 30 min then every 30 min .
4. Maternal blood pressure and heart rate were recorded using monitor with automatic noninvasive intermittent blood pressure monitoring and pulse oximeter was recorded before starting and at 5, 10, 15, 30 then every 30 min.
5. Side effects of epidural administration, intradermal sterile water injection and intradermal saline injection.
6. Degree of parturient satisfaction:
   Overall satisfaction with analgesia will be assessed by using a 4-point verbal scale ranging from excellent to poor satisfaction:
   A. Excellent satisfaction.
   B. Good satisfaction.
   C. Fair satisfaction.
   D. Poor satisfaction.

Statistical analysis:

Recorded data were analyzed 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.
- Chi-square (x^2) test of significance was used in order to compare proportions between two qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. The p-value was considered significant as the following:
- 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.

RESULTS

A total of 120 parturients were eligible for our procedure. They were randomized into the epidural, sterile water and normal saline groups, 40 parturients for each. No statistically significant difference was found between the three groups, regarding the patients' demographic characteristics as shown in table (1).

Table (1): Characteristics and demographic data expressed as mean ± SD.

Demographic character and mode of delivery		GROUPS						P-VALUE
		Group E		GROUP SW		GROUP NS		
		Mean	SD	Mean	SD	Mean	SD	
AGE		29.8	± 4.8	28.65	±4.8	27.05	±4.8	>0.05
BMI		27.32	± 1.7	27.28	±1.8	27.08	±1.6	>0.05
GESTATION		39.6	±1.2	39.62	±1.2	39.58	± 1.1	>0.05
Mode of Delivery	VAGINAL (%)	92.50%		97.50%		97.50%		>0.05
	Number of cases	n(37)		n(39)		n(39)		
	INSTRUMENTAL (%)	7.50%		2.50%		2.50%		
	Number of cases	n(3)		n(1)		n(1)		

Our study showed significant difference between all groups, regarding pain relief as shown in table (2). There was a significant decrease in pain score after 5 min in sterile water group compared to other groups. Furthermore, there was significant decrease in pain score in epidural group compared to normal saline control group after 15 minutes while it was not significant after 5 minutes.

Table (2): Comparison between groups according to visual analogue pain score

Groups	**group I**		**group II**		**group III**		**P-VALUE**
Vas	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation	
Pre injection	5.93	±1.207	6.25	±1.256	5.85	±1.122	<0.005
5 min	3.83	±1.615	1.78#en	±1.459	6.05*w	±1.28	<0.005
10min	4.55	±1.797	1#en	±0.847	5.73*w	±1.261	<0.005
15 min	1.47#n	± 0.96	0.82#n	±0.844	5.93*ew	±1.207	<0.005
30 min	0.55#n	±0.504	0.88#n	±0.853	6*ew	±1.301	<0.005
60 min	0.55#n	±0.504	0.82#n	±0.874	5.78*ew	±1.23	<0.005
90 min	0.43#n	±0.501	0.82#n	±0.844	6.03*ew	±1.291	<0.005
120 min	0.48#n	±0.506	1.05#n	±0.815	5.93*ew	±1.207	<0.005
150 min	0.55#n	±0.504	0.88#n	±0.853	5.85*ew	±1.189	<0.005
180 min	0.73#n	±0.679	1.00#n	±0.847	5.93*ew	±1.207	<0.005

Data expressed as mean ± SD. Group I (Epidural group). Group II (Sterile water group). Group III (Normal saline group)
(*) significant higher compared to other group.(#) significant lower compared to other group; (e) significantly compared to epidural group ; (w) significantly compared to water group ; (n) significantly compared to normal saline group.

Regarding the mean arterial blood pressure, our study showed significant difference between all groups as shown in table (3). There was a significant decrease in mean arterial blood pressure after 5 min in sterile water group compared to other groups. Furthermore, there was significant decrease in mean arterial blood pressure in epidural group compared to normal saline control group after 15 minutes while it was not significant after 5 minutes (Table 3).

Table (3): Comparison between groups according to mean arterial BP after injection.

	group I	**group II**	**group III**	

	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation	P-VALUE
Pre Inject	105.25	±3.193	105.78	±2.991	106.08	±3.377	<0.005
BP 5 MIN	95.20	±2.766	81.45#en	±2.342	104.23*w	±2.896	<0.005
BP 10 MIN	87.93	±1.655	81.88#en	±2.399	105.73*w	±2.810	<0.005
BP 15 MIN	81.55#n	±2.062	81.23#n	±2.236	104.83*ew	±2.745	<0.005
BP 30 MIN	81.43#n	±2.541	81.63#n	±2.415	104.70*ew	±3.421	<0.005
BP 60 MIN	81.83#n	±2.135	82.15#n	±2.045	104.75*ew	±3.119	<0.005
BP 90MIN	80.95#n	±2.112	81.38#n	±2.559	105.30*ew	±3.502	<0.005
BP120MIN	80.95#n	±2.112	81.38#n	±2.559	105.30*ew	±3.502	<0.005
BP150MIN	81.70#n	±2.420	82.00#n	±2.364	104.68*ew	±2.990	<0.005
BP180MIN	81.30#n	±2.255	80.58#n	±2.147	105.38*ew	±3.078	<0.005

Data expressed as mean ± SD. Group I (Epidural group). Group II (Sterile water group). Group III (Normal saline group)(*) significant higher compared to other group.(#) significant lower compared to other group; (e) significantly compared to epidural group ; (w) significantly compared to water group ; (n) significantly compared to normal saline group.

Regarding the heart rate, our results showed significant difference between all groups as shown in table (3). There was a significant decrease in heart rate after 5 min in sterile water group compared to other groups. Furthermore, there was significant decrease in heart rate in epidural group compared to normal saline control group after 15 minutes while it was not significant after 5 minutes (Table 3).

Table (4): Comparison between groups according to heart rate after injection

	group I		group II		group III	
GROUPS	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
HR Pre injection	95.23	±3.416	94.75	+2.994	94.83	+2.943
HR 5	88.03	±1.510	72.73#en	±4.070	94.68*w	±3.308
HR 10	82.70	±1.667	72.60#en	±5.153	95.35*w	±3.043
HR 15	72.98#n	±4.215	72.68#n	±4.654	95.40*ew	±2.808
HR 30	73.53#n	±4.782	73.60#n	±4.018	94.60*ew	±2.762
HR 60	72.20#n	±4.842	73.53#n	±4.772	94.70*ew	±2.997
HR 90	72.78#n	±4.312	71.28#n	±4.523	95.15*ew	±3.438
HR 120	72.33#n	±4.022	72.28#n	±4.987	94.65*ew	±2.685
HR 150	72.95#n	±4.437	72.85#n	±4.365	94.48*ew	±2.996
HR 180	70.83#n	±3.928	72.75#n	±5.222	95.03*ew	±3.092

Data expressed as mean ± SD. Group I (Epidural group). Group II (Sterile water group). Group III (Normal saline group) (*) significant higher compared to other group.(#) significant lower compared to other group; (e) significantly compared to epidural group ; (w) significantly compared to water group ; (n) significantly compared to normal saline group.

Furthermore, our study showed significant difference between epidural group and other groups as shown in table (5). Regarding the complications, indeed, no complications were demonstrated in the 2nd and 3rd group. Nevertheless, 3 cases in the epidural group developed backache and received non-steroidal anti-inflammatory drugs for 10 days. Two cases developed mild pruritus with no need for treatment. One case developed shivering after 30 min and received 20 mg pethidine.

Table (5): Comparison between groups according to complications.

Groups	Group E	Group SW	Group NS	P-value
	Complications	complications	complications	

Number of cases	6	0	0	**0.001**
Percent	15%**	0%	0%	

Data expressed as (n) and (%).

** highly significant difference compared to other groups

Maternal satisfaction was demonstrated and compared between the groups. Table (6) showed highly significant difference between normal saline group and other groups as majority of cases showed excellent satisfaction in the epidural and sterile water group but in normal saline group the majority of cases showed poor satisfaction.

Table (6): Comparison between groups according to maternal satisfaction.

Maternal Satisfaction (%)	**Group E**		**Group S.W**		**Group N.S**		**P-VALUE**
	Frequency	Percent	Frequency	Percent	Frequency	Percent	
Excellent	30	75%	25	62.5%	0	0%**	<0.001
Good	10	25%	12	30%	0	0%**	<0.001
Fair	0	0%	3	7.5%	12	30%**	<0.001
Poor	0	0%	0	0%	28	70%**	<0.001

Data expressed as frequency and percentage

** Highly significant difference compared to other groups

DSCUSSION

Central neuraxial blockade in labor in the form of walking epidurals is routinely practiced in many institutions. However, central neuraxial blockade has certain absolute and relative contraindications and in patients where it cannot be offered one must know what other modalities of labor analgesia can be used in the best interest of the patient. Uterine contractions are felt as back pain because rami of T10- L1 supplying the uterus are also supplying the skin over the lumbosacral area [(9)].

Many studies showed that epidural analgesia was associated with increased number of cesarean delivery. However increased use of epidural analgesia did not change the overall dystocia and cesarean delivery rate where dystocia was more common with epidural anesthesia [(10)].

In our study, instrumental delivery was more in epidural group than other groups but nonsignificant statistically (Table 1). In another study done to 20 women had sterile water injection (SWI) against placebo showed that sterile water injection was effective as analgesic with few side effects. About 4 women complained of pain of injection but the pain associated with the injection of sterile water was weighed against the likelihood of rapid, effective pain relief. So, the net result showed satisfaction on 95% of cases. Some maternity practitioners advocated administering the injections during a uterine contraction to mitigate the intensity of the pain. Additionally, SWIs can be administered at any time during labour, including early labour [(11)].

In our study, VAS started to reduce to significant level in sterile water group within 5 min and in the epidural group within 15 min (Table 2). Another double-blinded, placebo-controlled trial had been done, where sixty laboring patients were randomly allocated into one of two groups. Group I (40 patients) received four injections of sterile water while group II (20 patients) received four injections of normal saline as a placebo intracutaneous to Michaelis' rhomboid during active first stage of labor. Pain scores were similar between both groups at time of injections but significantly lower at 10, 45 and 90 minutes in group I compared to group II, with maximal difference at 10 minutes following injections. Also, participants requesting more pain relief were more among group II with a statistically significant difference. Moreover, significantly more participants of group I accepted this technique to be used in their future labors [(12)].

Our study showed significant difference between epidural group and other groups regarding the complications. Indeed, no complications were demonstrated in the 2nd and 3rd group. Nevertheless, 3 cases in the epidural group developed backache and received non-steroidal anti-inflammatory drugs for 10 days. Two cases developed mild pruritus with no need for treatment. One case developed shivering after 30 min and received 20 mg pethidine.

Women in another study done to 20 women had sterile water injection against placebo largely viewed sterile water injections as an effective analgesia with few side effects. About 4 women complained of pain of injection but the pain associated with the injection of sterile water was

weighed against the likelihood of rapid and effective pain relief. So, the net result showed satisfaction on 95% of cases. Some maternity practitioners advocated administering the injections during a uterine contraction to mitigate the intensity of the pain. Additionally, SWIs can be administered at any time during labour, including early labour [(12)].

One of the disadvantages of dermal injection of sterile distilled water is feeling pain at the site of injection for 20–30 sec as a result of which women may refuse re-injection. This pain probably results from the creation of high osmotic pressure in the skin and edema in the superficial layers. To reduce the pain in the injection area while retaining the effectiveness, several modifications in the injection technique should be studied. We chose a single bolus based on body weight, however, in clinical practice, some may prefer to titrate intra venous (IV) drugs to affect. Thus, our results cannot be compared to other studies with repeated doses or IV infusion. **In Hosseini *et al.* [(13)]** study, the use of subcutaneous injection of sterile distilled water has been proposed as an alternative to intracutaneous injection due to its lower rate of pain. They, showed that substitution of intradermal injection with subcutaneous injection of sterile distilled water was better outcomes regarding pain of injection. Other recent study also, recommend using the technique of intradermal injection at time of uterine contraction, either to reduce the effect of the stinging sensation or to mask differences between the sterile water and normal saline solutions, which is associated with markedly less pain. Moreover, women also expressed a preference for receiving the injections during a contraction [(14)]. **Choudhary and East [(15)]** showed that sterile water group patients were visibly happier after receiving the intradermal injection and the effectiveness increased when used as part of multimodal analgesia as paracetamol.

In our study, women were very satisfied with this technique and declared that they will use it again, although 96% indicated good satisfaction, where in our study maternal satisfaction was better in epidural and sterile water as compare to normal saline group. However, there is a fact must be carefully explained to the women that like other pain relief measures, it may not be 100% effective or last for hours but it can be repeated, also it may be an option for women who do not want to use narcotics or who refuse to have an epidural.

CONCLUSION

The evidence from this study suggests that sterile water injections are safe and effective method to relieve pain in the 1st stage of labor similar to epidural bupivacaine analgesia. Additionally, it is simple and safe technique and is associated with women satisfaction, which may provide women with an alternative method to narcotics and epidurals.

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