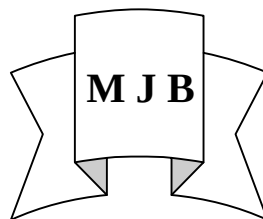


Incisional local anesthesia for pain control after abdominal surgery.

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Abstract

Bach ground:-The optimizing of postoperative pain control is an important aspect in perioperative patient care the use of inscional local anaesthesia in post operative pain control after abdominal operations was proved effective method of analgesia

Aim:-to evaluate the efficacy of postoperative incisional infusion of local anaesthesia (bupivacain) in reduction of postoperative pain in abdominal surgical wounds as well as the need for systemic analgesia and possible side effects of local anaesthesia.

method:- a prospective randomized placebo controlled clinical trial on 80 patients (39 male 41 female) between 13 –54 years old of different abdominal operations, admitted to El- furat hospital in kufa city from December 2005 to October 2006. The patients were divided in tow groups, intervention group 40 patients and placebo group: 40 patients. The study involve the use of incisional intermittent injection of local anesthesia bupivacaine 0.25% via thin subfascial catheter (B/BRAUN Melsungen AG), in intervention group , for relieve of postoperative pain and assess need for systemic analgesia (especially opiate) as compared to placebo group in which we inject normal saline via the incisional catheter.

Result:-The study had been discusses age, sex distribution, types of incision, pain assessment by visual analogue score, the need for systemic analgesia & complications of local anesthesia.

The mean visual analogue score of pain was measured in 1st 6th, 12th, 18th, 24th hours after surgery in every patient in both groups were significantly decreased in bupivacaine group in comparism to normal saline group P<0.005.

There is significant decrease for systemic analgesia requirements after operation in intervention group as compared with placebo group (P<0.05).

There is only one minor complication (seroma or wound infection) was reported in each group (2.5%).

Conculsion:-Study concludes the effectiveness of incisional bupivacaine intermittent injection in relieve of postoperative pain and decrease need for systemic analgesia.

Key words: incisional local anesthesia, abdominal surgery.

الخلاصة

الأهداف: إن هدف الدراسة هو تقييم واختبار فعالية التخدير الموضعي في شق العملية في تقليل الألم بعد العملية في عمليات البطن وكذلك الاحتياج الى مسكنات الألم النظامي والمضار الجانبية المحتملة للتخدير الموضعي.

الطرق: دراسة مستقيلية عشوائية أجريت على (٨٠) مريض (٣٩) ذكر و (٤١) انثى تتراوح اعمارهم بين (١٣-٥٤) سنة أجريت لهم عمليات البطن المختلفة ادخلوا الى مستشفى الفرات في الفترة بين كانون الأو ٢٠٠٥ الى تشرين الأول ٢٠٠٦. قسم المرضى الى مجموعتين: مجموعة التدخل (العلاج بالبليو بيفاكائين) (٤٠) مريض ومجموعة العلاج المموه (العلاج بالمالح العادي) (٤٠) مريض.

الدراسة استعملت الحقن المتقطع للمخدر الموضعي في جرح العملية بواسطة (قنطر) تحت اللقافة في كلا المجموعتين لغرض تقييم الألم بعد العملية وتقييم الاحتياج لمسكنات الألم النظامي خاصة (المستحضرات الليفونية) والمقارنة مع مجموعة العلاج المموه التي استعملت فيها حقن المالح العادي بواسطة القنطر.

النتائج: هذه الدراسة ناقشة توزيع الأعمار والجنس وأنواع فطوح العمليات وتقييم الألم بواسطة قياس المماثل البصري والاحتياج الى مسكنات الألم النظامي ومضاعفات التخدير الموضعي ان معدل قياس المماثل البصري قد قيس في الساعة الاولى والساعة السادسة والساعة الثانية عشر والساعة الثامنة عشر والساعة الرابعة والعشرون بعد الجراحة لكل مريض في كلتا المجموعتين. وقد لوحظ انخفاض القيمة المعنوية في مجموعة (البوبيفاكاين) بالمقارنة مع مجموعة العلاج بالمالح العادي (مقدار p) اقل من (٠,٠٥) هنالك انخفاض القيمة المعنوية في احتياج مسكنات الألم النظامي بعد العملية في مجموعة التدخل بالعلاج بالبوبيفاكاين بالمقارنة مع مجموعة العلاج بالمالح العادي (مقدار P) اقل من (٠,٠٥) هنالك حالة واحدة مسجلة لحدوث مضاعفات صغرى في كلتا الحالتين.

Introduction

Acute pain management is main action in postoperative period care; Patients vary greatly in their requirements for analgesia, even after identical surgical procedures. Under treatment result in non acceptable level of pain with tachycardia, hypertension, vasoconstriction and splinting of affected part. Painful abdominal and thoracic wounds restricts inspiration, decrease in tidal volume, tachypnoea, increase risk of chest infection, delayed mobilization, deep venous thrombosis, muscle wasting and pressure sores.(1).

However, over treatment result in increase risk of side effects, such as nausea, vomiting, dizziness or CNS toxicity with respiratory center depression ^[1]. It is evidenced that intense noxious stimulation can sensitize portion of system to subsequent input. Such stimulation in the form of surgical incision may lead to functional changes in the dorsal horn of the spinal cord and other consequences that later causes postoperative pain more painful than it would otherwise have been(wind up phenomena) ^[2]. Several postoperative pain control methods are available including local anesthesia infiltration by infusion or intermittent injections through intraincisional fine catheter ^[2,3].

The infiltration of the wound with long acting anesthesia such as

bupivacaine(0.25% or 0.5%) can provide analgesia for several hours. Further pain relief can be obtained with repeated injections by infusion via a thin catheter ^[3].

Continuous or intermittent perfusion of surgical wound with local anesthesia is highly effective method in pain relief after operation. Recently this technique has been modified to allow for (patient controlled analgesia) at home by pump device ^[4].

So by using postoperative local anesthesia, we can provide prolong pain relief and decrease risk of side effects of systemic analgesia.

Advantages of Incisional local anesthesia

- 1- Pain relief can start in operating room before patient awareness.
- 2- Pain relief provided at surgical or operative site.
- 3- Local anesthesia works locally not systemic, so avoid side effects like nausea, vomiting, loss of appetite, allergic reaction and respiratory center depression.
- 4- Keep clear head during recovery, so no headache, no dizziness and no confusion.

5- Local anesthetics have less side effects, are inexpensive, potent and available

Many local anesthetic drugs are available and can be used to provide local anesthesia such as lidocaine, bupivacaine, ropivacaine and levobupivacaine. Bupivacaine is the commonest drug used because its potency, effectiveness and long duration of action [5,6].

The bupivacaine 0.25% solution has slow onset of action (15 minutes), and high potency with duration of action equal to 240-480 minutes (4-8 hours) [3].

The assessment or measurement of PAIN:

There are many instruments or scales which can be used for pain assessment in health care researches, these are (visual analogue scale or score, quadruple visual analogue score and numerical rating scale).

The most frequently used and most commonly known scale is the visual analogue scale (VAS). VAS measures the intensity or magnitude of sensations and subjective feeling, and the relative strength of attitudes and opinions about specific stimuli [7].

The patients and methods

The study is a prospective randomized placebo controlled clinical trial. Eighty patients of different abdominal operations are the total number of the trial.

The study was done in El-furat general hospital in Kufa city from December 2005 to October 2006.

The patients were divided randomly in two groups; the first group was the (intervention) group which consists of

40 patients. The second group was the (placebo) group which consists of 40 patients.

In both groups the patients were underwent clean and clean-contaminated abdominal operations. Contaminated or dirty operations were excluded because local anesthesia usually not effective in presence of infection.

All operations were done under the effect of general anesthesia.

We insert sterile fine fenestrated plastic catheter (B/BRAUN Melsungen AG) in the operative site of every patient of both groups.

The site of insertion was in subfascial plane of the surgical wound (i.e. under rectus sheath or external oblique aponeurosis), and fixed to the skin (through separate stab wound), before skin closure and separated from wound dressing.

In the 1st group we injected 5-10 ml of bupivacaine 0.25% via the intra-incisional catheter immediately. After skin closure, (5 ml for small wounds and 10 ml for large one).

In the 2nd group we injected 1 ml of normal saline.

We repeat the injections every six hours after pain assessment.

The assessment of postoperative pain was by one method which is (visual analogue scale).

The visual analogue scale (VAS) has a horizontal or vertical line of 100 mm with 2 ends as shown below

!-----!

No pain
pain as bad as it can

If it was vertical line (which is less preferable), NO PAIN is placed at

the bottom and WORST PAIN at the top.

Linear horizontal scales have been found to be preferred by subjects and more reliable in general [4,7].

There should be no other marking or words in this line that can influence the results. It is important to ensure that patient understand the two end points, so we explain to each patient what does it mean each end point and we ask him to mark on the line what he feel about level of his wound pain right now.

Small percentage of patients including elderly patients and those with limited education has difficulty with (VAS).

Children below 10 years were excluded from the study because they have difficulty with (VAS).

After patient marking on the line we measure the distance of that marking from the left end point and the number can be used to compare changes with pain levels. We asses the severity of pain when the patient active (move or cough) and not only at rest. Pain assessment had been done at 6 hourly intervals in the 1st 24 hours postoperative. So, we use (VAS) at 1st hour, 6th hour, 12th hour, 18th hour and 24th hour postoperatively.

After each assessment when the score was 4 cm and the patient not satisfied from the analgesia, so we use one of the systemic analgesic drugs; narcotic opiates (pethidine or morphine), weak opiates (tramadol), or NSAID (diclofinac injection). So we try to avoid the use of systemic analgesia as we can. The maximum (bupivacaine) dose was 40 ml in 24 hours by intermittent injections.

The injection of the (bupivacaine) was by one of members of same surgical team. It had been done by slow infusion by a sterile syringe connecting to the intraincisional catheter.

1st injection was given in operating room while the consequent doses were given in surgical ward. The catheter removed after 24 hours.

In addition to pain assessment ,we asses the need of every patient in each group for systemic analgesia ,as well as the possible complications of local anesthetic and catheter on each patient.

The comparison between the 2 groups was by chi sequare and T-test.

We followed the ethics and rules of clinical research, so we get the permission of each patient for the use of the catheter and local anesthesia before patient signature on the informed consent of the operation.

Results

Eighty patients were randomly divided in to placebo group (n=40) and intervention group (n=40)

Age & sex distribution

There were (41) female patients (51.2%) and (39) males patients (48.8%) with age range between (13-54) years. Most of them (36) patient (45%) were between (13-20), as shown in tables 1-A & 1-B. Mean age of patients in both groups was 24.8 years.

Table 1-A :- distribution of tow groups (placebo and intervention) according to age group.

Age group		13-20	21-30	31-40	41-50	51-60	Total
Intervention group	No	15	15	7	2	1	40
	%	18.75	18.75	8.75	2.5	1.25	50
Placebo group	No	21	15	4	----	----	40
	%	26.25	18.75	0.05	----	----	50
total	No	36	30	11	2	1	80
	%	45	37.5	13.75	2.5	1.25	100

Table 1-B :- distribution of tow groups (placebo and intervention) according to sex.

sex		Intervention group	Placebo group	total
Male	No	20	19	39
	%	25	23.8	48.8
Female	No	20	21	41
	%	25	26.2	51.2
Total	No	40	40	80
	%	50	50	100

TYPES OF INCISIONS

Abdominal incisions in placebo and intervention groups are shown in table 2.

Table 2: distribution of two groups (placebo and intervention) according to the type and sit of incision

Type of operation	Incision	placebo groups	intervention groups	Total	%
Appendicectomy	Gridiron	31	31	62	77.5
Cholecystectomy	Right subcostal	4	4	8	10
Laparotomy	Midline	2	2	4	5
Inguinal herniotomy	Inguinal	3	3	6	7.5
Total	0	40	40	80	100

Pain assessment by VAS

Mean VAS of pain during 1st hour was (1.8487) (SD=0.8444) in the intervention and (6.2750)(SD=1.3994)in the placebo group (p=0.0001). Mean VAS of pain during 6th hour was (2.1641) (SD=1.1396) in the intervention and (5.8475) (SD=0.2042)

in the placebo group (p=0.00001). Others 12th, 18th, 24th hours as shown in tables 3, 4 and figure (1).

Mean VAS of pain 1st, 6, 12, 18, 24 hours after surgery was significantly decreased in bupivacaine group in comparison to placebo group.

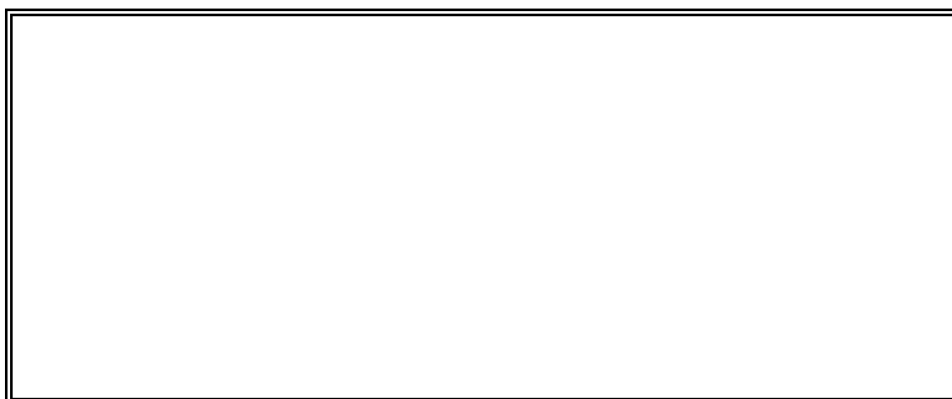
Table 3- comparison of postoperative mean pain score in two groups

Time	intervention groups			placebo groups		
	Mean	Standard Deviation	Standard. error mean	Mean	Standard Deviation	Standard. error mean
1st hour	1.8487	0.8444	0.1352	6.2750	1.3994	0.2213
6 th hour	2.1641	1.1396	0.1825	5.8475	1.2916	0.2042
12 th hour	2.2103	1.0691	0.1712	5.0125	1.2005	0.1898
18 th hour	2.0513	1.1299	0.1809	4.8800	1.3923	0.2201
24 th hour	1.5949	0.9567	0.1532	3.9200	1.4424	0.2281

P value < 0.005

The intensity of pain was more intense in placebo group for 1st 6th hours after operation. the mean VAS score was significantly less in 1st 6th hours after operation in intervention group(p=0.0001).

Figure 1: comparison of postoperative VAS in the two groups



Hr = hour

Hr:hour

The need for systemic analgesia

In the 1st hour (2.6%) of the intervention and (97.6%) of placebo group needed systemic analgesics. In the 6th hour, (7.4%) of the intervention and

97.6 of placebo group needed systemic analgesics. In the 12th hour, (10%) of the intervention and (91%) of placebo group needed systemic analgesics. in the 18th

hour, (12.4%) of the intervention and (80%) of placebo group needed systemic analgesic.in 24th hour after surgery

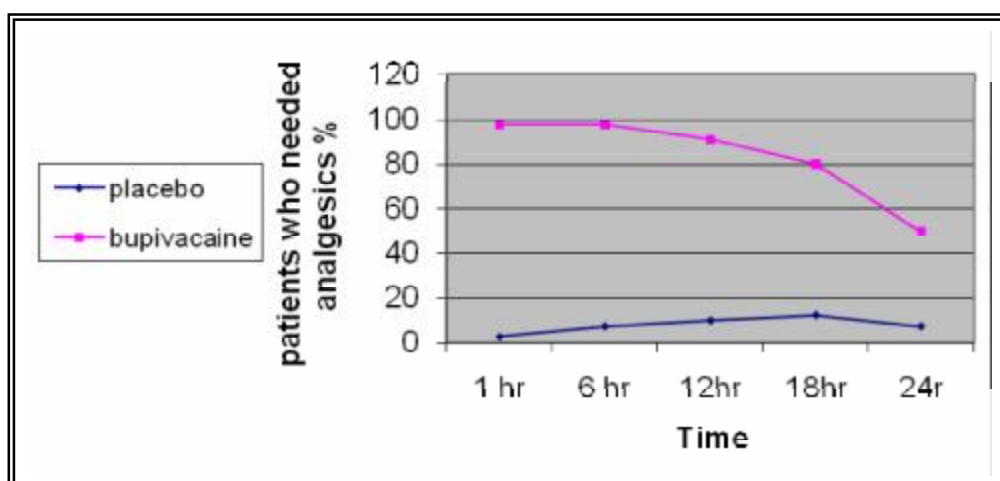
(7.4% of intervention & 50% of placebo need systemic analgesia
As shown in table 5 & figure 2.

Table 5 comparison of post operative systemic analgesic requirement in the two group

Time	intervention groups % n=40	placebo groups % n=40
1 st hour	2.6	97.6
6 th hour	7.4	97.6
12 th hour	10	91
18 th hour	12.4	80
24 th hour	7.4	50

P<0.005

Figure 2: comparison of postoperative analgesic requirement in the two groups



Hr: hour

So more need for systemic analgesia was in the 1st 6th hours post operative in placebo group but was much less in 1st 6th hours post operative in intervention group. So there is significant decrease for systemic analgesia requirements after operation in the intervention group as compared with placebo group.

Complications of local anesthesia & catheter

Regarding the complication there was one patient of intervention group got wound infection & one patient of placebo group got seroma .Both condition were self-limited complication. & treated conservatively as in table 6.

Table 6:-type of complications regarding placebo & intervention groups

Types of complications	placebo group	%	intervention groups	%
seroma	1	---	---	2.5
Wound infection	---	2.5	1	---

There was no reported systemic complication of local anesthesia in both groups.

Discussion

We found significant opioid-sparing effect in patient receiving bupivacaine as compared with placebo injection for the first 24 hours after the operation.

There was no major difference in age and sex distribution in the tow groups of the study.

Pain after abdominal operation can be multifactorial. incision pain is the main factor. Visceral pain and dynamic pain are other factors.

So we concerned about incisional pain and by using frequent injections of bupivacaine 0.25% through multihole catheter placed in the surgical incision between abdominal wall muscles, we can decrease pain intensity after operation.

The site of catheter insertion depends on nerves anatomical distribution in the abdominal wall which lies between internal oblique and transverses abdominus muscles^[8].

As mentioned by Yudgaard et al, that subfascial administration of local anesthesia was significantly more effective in reducing pain than subcutaneous injections^[9].

So we think that site of insertion is more effective than subcutaneous site.

We found in our study that reinjections of bupivacaine in the operative incision

was of great value as reported in many studies Hannibal K, et al , Fredman B, et al, Zohar E, et al, ^[10, 11, 12], where as other studies show no effect ^[13, 14].

In a systematic review of the use of incisional local anesthesia, Moiniche etal,^[15], found inconclusive results for all abdominal operations except inguinal herniorraphy, for which local anesthesia provided up to seven hours of analgesia.

Many studies use single dose of local anesthetic subcutaneously ,found that placement of catheter inserted in the site of incision and injecting local anesthesia is more effective than single dose of local anesthetic given subcutaneously^[11,12].

In our study, the pain intensity was significantly less after using bupivacaine ($p < 0.005$) and it was less intense in the first 6 hours postoperatively in the intervention group.

When the pain was inadequately relieved by local anesthesia and VAS >4cm, so systemic analgesia was given which was morphine , pethedine, tramadol or diclofenac sodium injections.

All of these analgesics has duration of action less than 6 hours ^[5,6], so they will not affect VAS assessment in the next 6 hours.

Cheong WK, et al study had been studied local bupivacaine perfusion versus paenteral mophin for pain relief after laparotomy , and they concluded that local anesthesia(bupivacaine) is safe and feasible alternative to parenteral opioids^[16].

Maliha Arab, et al study, concludes that injection of bupivacaine 0.5% in subcutaneous and intratubal tissue in minilaparotomy tubal ligation led to significant reduction of postoperative pain and consumption of opioid analgesia^[17].

The requirement for systemic analgesia was significantly reduced in the first 6 hours (3%) in intervention group if compared with placebo group(>90%) , $p < 0.05$.

So our study showed that local anesthesia (by intermittent injections) can reduce the need for additional analgesia (especially opiates) in the first 6 hours as well as next 18 hours.

Most of studies evaluate the effect of incisional anesthesia in one type of abdominal operation. In our study ,4 types of abdominal operations involved(appendicectomy,open cholecystectomy,inguinal herniorraphy and midline laparotomy).

In the present study neither subcutaneous nor intraperitoneal injections of local anesthetic were used. Fredman B,et al and Zohar E,et al studies [11 ,12] used patient- controlled bupivacaine instillation in lower abdominal surgery and results were strongly support local anesthesia which was effective and decrease requirement for systemic analgesia.

Good technique should not result in an increase in incidence of side effects in the patients.

Local anesthesia is well tolerated by most patients and if used in appropriate dose, have minimal side effects.

In our study only one complication reported in intervention group which was wound infection grade 3 and also one complication occurred in placebo group which was wound seroma .both of conditions was self limited and treated conservatively. No systemic side effects or toxicity of local anesthesia were reported in our study. Minimal or negligible complications also reported by other studies^[9].

Conclusion

In conclusion, in this randomized placebo controlled clinical trial, we were able to demonstrate significant decrease in pain intensity and significant decrease in the need for supplementary systemic analgesia in the intervention group (when bupivacaine intermittent injections given in the site of incision, that lasted for the first 24 hours after surgery.

Our study is limited in its conclusion, because we studied small group of patients undergoing elective abdominal operations. However the beneficial effect of local anesthesia seen in this study can be translated to other patients undergoing different types of surgery. More studies in more patients are thus needed.

However, we recommend the use of incisional local anesthesia after abdominal operations, because it is safe, simple, effective and can decrease the requirement for systemic analgesia specially opiates and can avoid their unwanted side effects.

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