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RESEARCH ARTICLE

Douglas pouch lidocaine infiltration in reducing pain scores in elective cesarean sections: randomized clinical trial

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Abstract

Objectives: to compare the effects of infiltration of lidocaine into the Douglas pouch on postoperative pain scores in elective cesarean sections done under general anesthesia compared to infiltration with saline only.

Methods: a randomized clinical trial done in obstetrics and gynecology department-Benha faculty of medicine in which one hundred cases scheduled for elective CS were randomly allocated . the cases allocated to receive infiltration of either 1% lidocaine (in the Douglas pouch) or saline .The pain intensity and analgesic demand after CS, as well as the time to ambulation and breast feeding, were documented and compared between the groups.

Main outcome measures: reduction of pain scores after labour. .Secondary outcomes: early ambulation and breast feeding and reduced need for rescue analgesia.

Results: Post cesarean section pain intensity and analgesic demand were significantly lower, and the time to ambulation was significantly less in the lidocaine group than in the placebo group. Pain score mean was 2.1 in lidocaine group .compared to 6.06 in placebo group with (Pvalue<0.0001).

Conclusion: infiltration of lidocaine in Douglas pouch intra-operatively inelective cesarean sections significantly lower visceral pain scores and allowearly ambulation and breast feeding

INTRODUCTION

Pain after caesarean section (CS) is still a common and important source ofpatient dissatisfaction in many obstetric centers. Although it is alwaysessential to relieve patient discomfort, the management of post-CS paindiffers from that in the general surgical population because mothers need torecover quickly in order to take care of their babies and breastfeedsuccessfully.(1)

There are various ways to manage pain after CS, ranging from the traditionaladministration of opioid/non-opioid medications to novel technologies such ascontinuous epidural analgesia and patient-controlled methods.(2, 3)

Infiltration of the incision wound with local anesthetic has been claimed to besafe and effective in reducing post-operative pain. (4, 5)

Although the exact mechanism is unknown, it is generally believed that post-incisionallocal anesthetic infiltrations act through peripheral neural blockadeand an anti-inflammatory effect. (6)

With the dramatic rise in the rate of cesarean deliveries in the last twodecades; postoperative pain management of these patients has become amajor medical and nursing challenge. (7)

Although advances have been made in the understanding of pathophysiologyof postoperative pain and development of new analgesics and deliverytechniques, many patients still suffer from moderate to severe postoperativepain. (8, 9)

Cesarean delivery patients have even more compelling reasons to achieveoptimal postoperative pain relief, as they present with unique challenges; suchas, a higher risk for thromboembolic events, which may also be precipitatedby immobility from inadequate pain control or excessive sedation associatedwith the use of opioids. (10, 11)

All of the studies focused on the parietal pain and lidocaine infiltration in thewound itself. The current study was an attempt to alleviate the postoperativepain after elective cesarean sections through infiltration of lidocaine in theDouglas pouch so anesthetizing the hypogastric plexus in the uterosacral ligament.

Materials and methods

Study type: prospective, double-blind, placebo-controlled, randomizedclinical trial
Sample size: one hundred candidates for elective CS with uncomplicated37 weeks' gestation) divided into two equal groups singleton pregnancieseach one consisted from fifty participants
Sample size calculation :(Daniel formula)
Sample Size = n / [1 + (n/population In which n = Z * Z [P (1-P)/(D*D
Population Value = 800
Expected Frequency of the Factor under Study =95%
Worst Acceptable Frequency = 85%
P = Expected Frequency Value = 95%
D = (Expected Frequency - Worst Acceptable) = 95%- 85% = 10%
Z = 1.960 with a Confidence Level of 95%
S = 18.24 / [1 + (18.24 / 800
S = 17.8, or 18 to decrease error the minimal sample size will be 25 casesand for easy simple calculation the number for each group was elevated to50.
Method of randomization: Randomization created by software named (DatInfRandList version 1.2 /2013).

Setting: cases recruited from Benha university hospital, Benha, Egypt.
Study duration: from January 2013 through July 2013.
Inclusion Criteria:
Women who are scheduled for an elective cesareandelivery under general anesthesia using a transverse lower abdominalincision.
Exclusion Criteria: More than two previous cesarean deliveries Otherabdominal operations in the past, morbid obesity diabetes mellitus,neurological diseases, systemic vascular disease,mental disability and lidocaine sensitivity
Patient's approval: written informed consent was obtained from all the participants.
IBA approval: study approved by IB of the obstetrics and gynecologydepartment (Benha School of medicine) in January 2013.
Anesthesia: general anesthesia which is popular in Egypt.
Intervention: On the day of the operation, the surgeon was provided with asealed envelope in which was a syringe containing a 10 ml solution of 1%lidocaine with 1:100 000 adrenaline or 10 ml 0.9% sodium chloride,accompanied by an instruction.
All the 100 syringes were prepared by a pharmacist who was not involved inthe study. Each envelope was marked with a randomization number that wasdisclosed to the investigators only after completion of data analysis.

Each participant was allocated to one of the following two groups:
lidocaine group:10 ml of local anesthetic mixture including was injected intothe posterior cul de sac (Douglas pouch).
Placebo (P) group: 10 ml 0.9% sodium chloride (saline) was infiltrated in DouglaspouchThe instillation of lidocaine or saline done after cleaning of the gutters fromblood and meconium after complete suturing of the uterus and assurance ofhemostasis .by pushing the uterus anteriorly and stretching of the uterosacralligaments as shown in (figure 1) .
Based on a standard protocol, all patients received general anesthesia.
Standard monitoring included electrocardiography, arterial hydration withblood pressure and pulse oximetry.

All the patients received post-CS pain relief, i.e. diclofenac sodium (100 mgrectal suppository Novartis Pharmaceuticals), starting immediately after theoperation at the operating table and then the rescue analgesic after thatrecorded. (12, 13)

Post-operative pain was assessed by a self-rating 10 point visual analogue scale (VAS) (0 no pain, 10 = the worst pain imaginable). (14.15.16)

Pain was assessed at predetermined intervals of 2, 3, 4, 6, 8, and 12 and 24 hours after surgery. Duration of analgesia was defined as the time thatelapsed between discharge from the recovery room and the first postoperativedemand for rescue analgesia was also documented.
Patients were encouraged to move around and to breastfeed their babies assoon as possible, and the times of first post-operative ambulation and firstbreastfeeding (in the women who wanted to breastfeed) were recorded.
Healing of the incision wound was assessed one week after discharge whenthe patient returned for removal of the stitches. If there was any redness, hotness, edema, discharge or dehiscence healing was considered inadequate.
Data were analyzed with SPSS for Windows version 18.0 (SPSS Inc., Il,USA); p-values <0.05 were considered to be significant. Students T test foranalysis used to produce the data.

Results

The current work studied the effect of local lidocaine infiltration in Douglas pouch in elective cesarean sections done under general anesthesia.
The rationale of the study based upon passage of the hypogastric nerveplexus in the uterosacral ligament, this ligament surround the Douglas pouchso infiltration of lidocaine in Douglas pouch will resolve visceral paintransmitted by the hypogastric plexus.
The two groups were comparable with regard to patient age, weight, andgravidity, operative time.
Post-operative pain scores are summarized in (Table 1) and revealed significant differences between the groups in terms of post-operative painscores ($p<0.0001$ for all Patients in the placebo group demanded significantlymore rescue analgesia after the operation.
There were significant differences between the two groups regarding the earlyambulation and early breast feeding in the first two hours (table 2)

Tables

Table (1) Difference in pain scores and rescue analgesia among studiedgroups

item		Lidocaine group	Placebo group	P value
Pain scores	Mean SD	2.1 1.3	6.06 1.57	<0.0001
Rescue analgesia(more than one postoperative				=0.0005

Table (2) early ambulation and breast feeding in the first two hours

	Lidocaine group	Placebo group	P value
Early ambulation	43	22	0.00001
Early breast feeding	45	30	0.0005

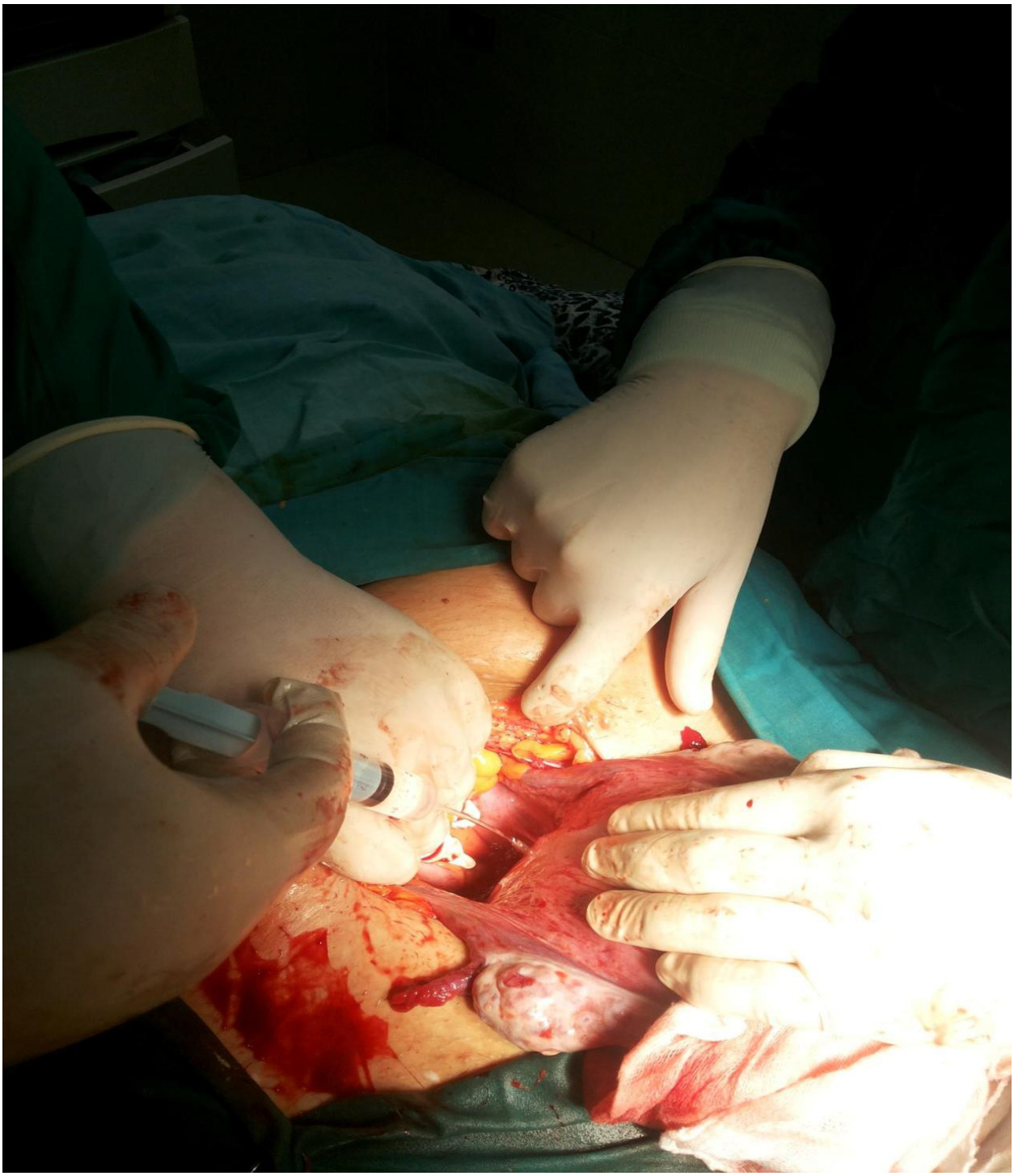

Figure (1) instillation of lidocaine in Douglas pouch intraoperative in elective cesarean section.

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Discussion

This present work investigated the influence of infiltration site on post-CS painscores and analgesic requirement. The findings showed that infiltration oflidocaine in Douglas pouch was effective in reducing pain and demand forrescue analgesia in comparison with patients who received placebo (Table1).

Although studies investigating the effect of local anesthetic infiltration on postoperativepain management have been reported in the literature, the resultsare widely heterogeneous and the debates have largely been focused on theappropriate time and site of injection. (17, 18, 19)
Church described a regular controlled infusion of pethidine at a rate of 0.3mg/kg/h (20).
Stepleton et al assessed intravenous infusion of pethidine. They gave aloading dose of 1 mg/min for 45 min followed by 0.53 mg/min for 28 min. A maintenance infusion of 0.4 mg/min was used for the remainder of the 32 hstudy period. (21)
Rutter et al. (22) assessed morphine requirement immediately after surgeryand used each patient's individual requirement as a guideline for comparingintravenous infusion, scheduled intramuscular injection .Despite the use of a continuous opioid infusion injection on patient request (either as a fixed dose or a dose based on weight), these investigators couldnot identity an ideal dose that would provide adequate analgesia. (23)

The post-operative pain relief obtained after infiltration of a short-actinganesthetic such as lidocaine (1 - 2 hours) cannot be due to peripheral neuralblockade alone, because its analgesic effect is superior to placebo as muchas 24 hours after infiltration. Likewise, it is proposed that amide localanesthetics have potent and long-lasting anti-inflammatory qualities. (24, 25, 26).
Many studies focus their work about the parietal pain after cesarean sectionbut still the visceral pain has its impact after delivery especially with general anesthesia commonly requested in developing countries like Egypt.
The visceral pain felt after labour (after pains) still produce a significant painpostoperatively even after lidocaine infiltrationin the vicinity of the skin wound. It was the first time to try this work, all of theprevious works focus on lidocaine local wound infiltration (in the anteriorabdominal wall)so this work may add a benefit for women delivered bycesarean sections.
It is my routine work to instill lidocaine in Douglas pouch and it makes the painscores less and allows the early ambulation and breast feeding and theimportant advantage was the less use of frequent non-steroidal anti-.inflammatory drugs.
Lidocaininstillation in Douglas pouch alleviate visceral pain due to uterinecontraction (after pain) through anesthetic affect on the hypogastric nerveplexus passing through the uterosacral ligament. This allowed earlyambulation and breast feeding after delivery. P value for difference in earlyambulation and breast feeding were 0.00001 and 0.0005 respectively withvery high significant statistical difference.The current work gave a good offer for pregnant women who want to be .delivered by cesarean section with general anesthesia.

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