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

Dr. Mostafa Abdulla Elsayed
Lecturer in Obstetrics and Gynecology department - IVF division. Ph.D in Obstetrics and Gynecology - Benha faculty of medicine. Qalubia district. Cairo Egypt

Objective: 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 (P value < 0.0001).

Conclusion: infiltration of lidocaine in Douglas pouch intra-operatively in elective cesarean sections significantly lower visceral pain scores and allow early ambulation and breast feeding.

INTRODUCTION

Pain after caesarean section (CS) is still a common and important source of patient dissatisfaction in many obstetric centers. Although it is always essential to relieve patient discomfort, the management of post-CS pain differs from that in the general surgical population because mothers need to recover quickly in order to take care of their babies and breastfeed successfully. (1)

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

Infiltration of the incision wound with local anesthetic has been claimed to be safe and effective in reducing postoperative pain. (4, 5)

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

With the dramatic rise in the rate of cesarean deliveries in the last two decades; postoperative pain management of these patients has become a major medical and nursing challenge. (7)
Although advances have been made in the understanding of pathophysiology of postoperative pain and development of new analgesics and delivery techniques, many patients still suffer from moderate to severe postoperative pain. (8, 9)

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

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

Materials and methods

Study type: prospective, double-blind, placebo-controlled, randomized clinical trial

Sample size: one hundred candidates for elective CS with uncomplicated 37 weeks’ gestation) divided into two equal groups singleton pregnancies each one consisted from fifty participants

Sample size calculation: (Daniel formula)

\[
\text{Sample Size} = \frac{n}{1 + (n/\text{population}) \times Z^2 \times (1 - P)/(D^2)}
\]

Population Value = 800

Expected Frequency of the Factor under Study = 95%

Worst Acceptable Frequency = 85%

\[P = \text{Expected Frequency Value} = 95\%
\]

\[D = (\text{Expected Frequency} - \text{Worst Acceptable}) = 95\% - 85\% = 10\%
\]

\[Z = 1.960 \text{ with a Confidence Level of 95%}
\]

\[S = 18.24 / [1 + (18.24 / 800)
\]

\[S = 17.8, \text{ or 18 to decrease error the minimal sample size will be 25 cases and for easy simple calculation the number for each group was elevated to 50.}
\]

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 cesarean delivery under general anesthesia using a transverse lower abdominal incision.

Exclusion Criteria: More than two previous cesarean deliveries, other abdominal 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 gynecology department (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 a sealed envelope in which was a syringe containing a 10 ml solution of 1% lidocaine with 1:100000 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 in the study. Each envelope was marked with a randomization number that was disclosed 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 into the posterior cul de sac (Douglas pouch).

**Placebo (P) group:** 10 ml 0.9% sodium chloride (saline) was infiltrated in Douglas pouch. The instillation of lidocaine or saline done after cleaning of the gutters from blood and meconium after complete suturing of the uterus and assurance of hemostasis. by pushing the uterus anteriorly and stretching of the uterosacral ligaments as shown in (figure 1).

Based on a standard protocol, all patients received general anesthesia.

Standard monitoring included electrocardiography, arterial hydration with blood pressure and pulse oximetry.
All the patients received post-CS pain relief, i.e. diclofenac sodium (100 mg rectal suppository Novartis Pharmaceuticals), starting immediately after the operation at the operating table and then the rescue analgesic after that recorded. (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 that elapsed between discharge from the recovery room and the first postoperative demand for rescue analgesia was also documented.

Patients were encouraged to move around and to breastfeed their babies as soon as possible, and the times of first post-operative ambulation and first breastfeeding (in the women who wanted to breastfeed) were recorded.

Healing of the incision wound was assessed one week after discharge when the 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 for analysis used to produce the data.

Results
The current work studied the effect of local lidocaine infiltration in Douglas pouch in elective caesarean sections done under general anesthesia.

The rationale of the study based upon passage of the hypogastric nerve plexus in the uterosacral ligament, this ligament surround the Douglas pouch, so infiltration of lidocaine in Douglas pouch will resolve visceral pain transmitted by the hypogastric plexus.

The two groups were comparable with regard to patient age, weight, and gravidity, operative time.

Post-operative pain scores are summarized in (Table 1) and revealed significant differences between the groups in terms of post-operative pain scores (p<0.0001 for all Patients in the placebo group demanded significantly more rescue analgesia after the operation.

There were significant differences between the two groups regarding the early ambulation and early breastfeeding in the first two hours (Table 2)

### Tables

**Table (1) Difference in pain scores and rescue analgesia among studied groups**

<table>
<thead>
<tr>
<th>item</th>
<th>Lidocaine group</th>
<th>Placebo group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean SD</td>
<td>2.1</td>
<td>6.06</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>1.3</td>
<td>1.57</td>
<td></td>
</tr>
<tr>
<td>Rescue analgesia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(more than one</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>postoperative)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table (2) early ambulation and breastfeeding in the first two hours**

<table>
<thead>
<tr>
<th></th>
<th>Lidocaine group</th>
<th>Placebo group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early ambulation</td>
<td>43</td>
<td>22</td>
<td>0.00001</td>
</tr>
<tr>
<td>Early breast feeding</td>
<td>45</td>
<td>30</td>
<td>0.0005</td>
</tr>
</tbody>
</table>
**Discussion**

This present work investigated the influence of infiltration site on post-CS pain scores and analgesic requirement. The findings showed that infiltration of lidocaine in Douglas pouch was effective in reducing pain and demand for rescue analgesia in comparison with patients who received placebo (Table 1).
Although studies investigating the effect of local anesthetic infiltration on postoperative pain management have been reported in the literature, the results are widely heterogeneous and the debates have largely been focused on the appropriate time and site of injection. (17, 18, 19)

Church described a regular controlled infusion of pethidine at a rate of 0.3 mg/kg/h (20). Stepleton et al assessed intravenous infusion of pethidine. They gave an opening 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 h study period. (21)

Rutter et al. (22) assessed morphine requirement immediately after surgery and used each patient’s individual requirement as a guideline for comparing intravenous 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 could not identify an ideal dose that would provide adequate analgesia. (23)

The post-operative pain relief obtained after infiltration of a short-acting anesthetic such as lidocaine (1 - 2 hours) cannot be due to peripheral neural blockade alone, because its analgesic effect is superior to placebo as much as 24 hours after infiltration. Likewise, it is proposed that amide local anesthetics have potent and long-lasting anti-inflammatory qualities. (24, 25, 26).

Many studies focus their work on the parietal pain after cesarean section but 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 pain postoperatively even after lidocaine infiltration in the vicinity of the skin wound. It was the first time to try this work, all of the previous works focus on lidocaine local wound infiltration (in the anterior abdominal wall) so this work may add a benefit for women delivered by cesarean sections.

It is my routine work to instil lidocaine in Douglas pouch and it makes the pain scores less and allows the early ambulation and breast feeding and the important advantage was the less use of frequent non-steroidal anti-inflammatory drugs.

Lidocaain infiltration in Douglas pouch alleviate visceral pain due to uterine contraction (after pain) through anesthetic effect on the hypogastric nerve plexus passing through the uterosacral ligament. This allowed early ambulation and breast feeding after delivery. P value for difference in early ambulation and breast feeding were 0.00001 and 0.0005 respectively with very 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.

Acknowledgement
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References


15-Yang T, Breen TW, Archer D, Fick G. Comparison of 0.25 mg and 0.1 mg intrathecal morphine for analgesia after caesarean section. Can J Anaesth. 1999; 46(9):856-860.


