The effect of honey gel on cesarean incision pain: A triple blind clinical trial

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Honey is considered as a remedial in the Qur'an. Today, honey is used in wound healing and pain relief. This study was designed to assess the effects of honey gel on postoperative pain and analgesic need after cesarean section. This triple blind randomized clinical trial was conducted on women who underwent cesarean section in Imam Ali Hospital, Iran. Patients were categorized into three groups: drug (37 patients), placebo (38 patients), and control (54 patients) by random allocation. Patients in the drug group received 25% local honey gel, while placebo group received similar gel without honey twice a day for 14 days. No intervention was given in control group. Pain was measured using visual analogue scale on the 7 and 14th day after surgery. Data were analyzed using Chi-square and analysis of variance (ANOVA). The mean pain intensity did not differ significantly between groups on the 1st day, but on the 7th day it was 14.44, 26.41 and 25.73 (P=0.01), and on the 14th day it was 0.27, 5.84 and 4.07 (P=0.02) in the drug, placebo and control groups, respectively. The need for analgesics in the first 10 days was 11.5% in drug group, 62.6% in placebo group and 45.9% in control group which was significantly different (P=0.02). Until the 14th day, no patient needed analgesics in the drug group while 40 and 60% of patients in placebo and control groups required analgesic, which did not show a significant different (P=0.09). Honey gel was effective in cesarean wound pain and in reducing the need for analgesics.

Key words: Cesarean section, pain, wound healing, wound infection, honey.

INTRODUCTION

Pain is one of the most important problems in postoperative cares which has received a lot of attention in recent years. Today, pain is considered as the fifth vital sign (Khorgami et al., 2009). Postpartum period is associated with several problems due to the physical and mental stresses of which one of it is pain. Pain may affect the positive sense of being a mother and infant care, and its consistency may lead to a phobia of sexual contact and loss of relaxation and prepare the ground for depression (Yerbi, 2000). One of the most important causes of pain after delivery is cesarean wound pain which is an important concern for most women (Pillitteri, 2003). Cesarean is one of the most important gynecology surgeries, and the most common surgery today (Scott et al., 2002). Women who undergo cesarean section should be able to take care of their infant besides tolerating cesarean wound pain and the postoperative recovering time. Thus, they required intensive cares (Pillitteri, 2003; Samadi et al., 2010).

The most prevalent treatments for analgesia are narcotics (Fredman et al., 1999; Vanessa et al., 2002), oral analgesics like nonsteroidal anti-inflammatory drugs (NSAIDs), codeine-containing products and acetaminophen...
improving mothers' health, and the fact that honey is an easily accessible and cheap material, this study was designed to assess the effects of honey on postoperative pain of cesarean wound measured by visual analog scale (VAS).

MATERIALS AND METHODS

After the written approval of the Ethical Committee of Mazandaran University, this triple blind clinical trial (for intervention and placebo group so that, all participants, investigators and statistical analyzers were not aware of participants’ groups and only the head of research research was aware of groups) was conducted on 132 women who fitted the inclusion criteria in Imam Ali Hospital (in the North of Iran) between 2010 and 2011. The inclusion criteria included education level at least fifth grade class of primary school, gestational age 37 to 42 weeks based on the last menstrual period (LMP) or sonography, Pfannenstiel skin incision and had informed consent to enroll in the study, the maximum time of rupture of membrane was 12 h and health of infants. The exclusion criteria included record of medical and obstetric history, need for transfusion during surgery, and cesarean duration more than 60 min, smoking and diseases or drugs which may affect wound healing.

Based on the study by Mphande et al. (2007), the sample size was calculated considering the confidence level (z1) of 95%, study power (z2) of 95%, improvement rates of 85% in patient and 50% in control group, and also considering loss to follow up to 10%; at least 40 patients were considered for each group. In order to gather required sample size, first, fitted persons were targetedly selected and after studying the information form, giving informed consent were randomly allocated to the three groups of drug, placebo or control using permuted block randomization.

The main drug (honey gel) and placebo were prepared by pharmacist. The types of honey were assessed and compared for components including reducing carbohydrates, sacarose, fructose and glucose and their ration, defining invert sugar, humidity percentage, microscopic evaluation for pollen and finally the most qualified honey (from coriander and Goat’s- thorn flowers) was selected. Honey gel was prepared on the basis of a formulation to do this. The combination of honey, glycercin, crabapple, methylparaben, triethanolamine, propyl paraben, and distilled water was measured for standardization. The amount of honey in the formulations was calculated by using the ointment) arranged on a Likert scale (very satisfied—unsatisfied).

Then, in both the drug and placebo groups, a packet of coded gel was given to the mothers and its instruction was explained. The mothers had to first wash their hand and suture site, then rub the gel over the sutures twice a day (12 ± 2 h) for 14 days, and leave it dried. Moreover, pain intensity was measured using VAS in the supine position.

All forms were filled by a researcher in the first 24 h after the cesarean section in the women ward. The required training regarding care of cesarean wound and sutures, personal hygiene and nutrition were given face to face. Moreover, pain intensity was measured using VAS in the supine position.

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Moreover, the completed check list by the mothers including physical activities, complication in wound site (burn, pruritus, redness and warming in wound) and drug consumption (gel, analgesics and antibiotics) were assessed.

All participants were operated by a gynecologist with 20 years of experiences. The cesarean duration was less than 25 min and the incision length was less than 12 cm in all patients; all the three groups were similar regarding these two variables.

After data collection, they were coded and analyzed using Statistical package for Social Sciences (SPSS) software version 16. The cases under the study were described using descriptive statistics. Qualitative variables in three groups were compared using Chi-square test. Quantitative variables in three groups were compared using one-way analysis of variance (ANOVA). The significance level was considered as P < 0.05.

RESULTS

One hundred and forty-six (146) women were included in the study. After excluding some cases in each group due to intervening factors, finally 37 cases in the drug group, 38 cases in placebo group and 54 cases in control group were studied (Figure 1). The age of patients in the three groups did not differ significantly (27.77 ± 4.97, 26.57 ± 4.88 and 26.14 ± 6.06 years, respectively; P > 0.05). Moreover, there was no significant difference between studied groups regarding the education level of patients, the mother’s job, gravidity and type of cesarean (emergent, elective) (Table 1).

During follow up period, pain intensity decreased significantly in all the three groups from first stage (day 1) to third stage (day 14) of the study (Table 2).

The mean pain intensity in cesarean wound site did not differ significantly on the 1st day between groups, but on the 7th day it was 14.44, 26.41 and 25.73 (P = 0.01), and on the 14th day it was 0.27, 5.84 and 4.07 (P = 0.02) in groups drug, placebo and control, respectively (Table 2).

All participants in the three groups have consumed milk, meat, fruit, vegetables and cereals each day. The need for analgesics in the first 10 days in the drug, placebo and control groups were 11.5, 62.6 and 45.9% respectively (Table 2). The cases under the study were described using descriptive statistics. Qualitative variables in three groups were compared using Chi-square test. Quantitative variables in three groups were compared using one-way analysis of variance (ANOVA). The significance level was considered as P < 0.05.

DISCUSSION

In this study, the pain intensity was measured using VAS which showed that on the 7 and 14th days after cesarean, it was significantly lower in the honey group as compared to placebo and control groups.

Mphande et al. (2007) in a study compared the effects of honey and sugar ointment on surgical wound healing, and concluded that in the group with honey ointment the surgical wounds were healed in a shorter period of time. After 3 weeks, 86% of patients treated with honey ointment versus 72% with sugar felt no pain in the wound site (Mphande et al., 2007). Moreover, a study by Subrahmanyan (1996) showed that honey ointment decreases the required time for wound healing and pain intensity as compared to silver sulfadiazine. These researchers reported that topical application of honey has antioxidant effects and reduce the lipid peroxide serum levels, and leads to better wound healing (Subrahmanyan, 1996). In a study by Omidvari et al. (2011), topical use of honey as compared to daily washing did not have any specific effect on the process of healing in dermatitis related to the breast cancer radiotherapy, nor did it reduce pain intensity in the first 2 weeks of intervention (Omidvari et al., 2011). Meanwhile, a limited number of studies have shown that the use of topical honey leads to pain in the first 12 to 20 min (Subrahmanyan, 1996) which is in conflict with our study. The observed difference may be due to the types of wound. These researchers used honey for infected and inflammatory wounds which may have led to irritation and sensitization of nociceptors and caused pain. But in our study, honey gel was used for uninfected and clean wounds, which led to decrease in pain. Moreover, the honey type and quality of honey may also be effective.

In tissue damage and its healing process, reactive oxygen species (ROS) is produced which is an agent of inflammation and tissue damage. On the other hand, the inflammation itself produces prostaglandins and causes pain, edema and exudation in wound site. It is interesting that by increasing the production of phagocytes, honey restrains the production of ROS in tissue which subsequently results in decrease in pain, edema and exudation (Tonks et al., 2001). Honey through increasing the number of lymphocytes B, T, phagocytes and stimulation of monocytes leads to production of cytokines, interleukins 1 and 6 and tumor necrosing factor. These agents have antimicrobial effects and activate the immune system of the body (Tonks et al., 2001). Meanwhile, the existing antioxidant in honey inhibits concentration of free radicals, which are responsible for its anti-inflammatory effects (Henriquins et al., 2006). Its anti-inflammatory properties through reducing edema, exudation and improving the blood flow may reduce pain in wound site (Molan, 2001b). Results of the present study showed that wound complications like burning, pruritus and redness were lower in the honey group than the other two groups, which imply better wound healing and lower irritating symptoms and less pain. The results of a study by Ozlugedik et al. (2006) showed that pain intensity measured by VAS after tonsillectomy
and the need for analgesics were significantly lower during 14 days after surgery in the honey plus acetaminophen group as compared to acetaminophen alone. Oral honey has an important role in decreasing acute pain and inflammation of wounds through decreasing prostaglandin E2, F2α and thromboxane B2 (Ozlugedik et al., 2006). In this study, besides reducing pain intensity in wound site, the need for analgesic was significantly lower in honey group in comparison with those in the other groups. None of the cases took analgesic up to the end of the 2nd week, but in the other groups the need for analgesics continued, which may be an evidence for decreasing wound pain in honey group. Several studies have illustrated that honey like other topical antibacterial agents is more effective in healing infected (Al-Waili and Saloom, 1999; Ingle et al., 2007) and uninfected wounds and in decreasing pain intensity (Subrahmanyam, 1996; Mphande et al., 2007).

Honey can inhibit the growth of 60 types of bacteria like airborne, non-airborne, negative and positive gram stain (Molan et al., 1992) so that no living organism is able to live in honey. Its anti bacterial effects and the presence of substance called glu nas in honey accelerates healing of tissue lesions (Ashtiyani et al., 2011).

The satisfaction rate also was greater in honey group as compared to that in the other two groups. This may be due to the decrease in pain, inflammation, irritating symptoms of wound healing and rapid relief. Researchers
Table 1. Frequency of some variables in three groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Drug group n (%)</th>
<th>Placebo n (%)</th>
<th>Control n (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother’s education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>11 (29.7)</td>
<td>18 (21.1)</td>
<td>18 (42)</td>
<td>0.25</td>
</tr>
<tr>
<td>Guide school</td>
<td>15 (40.5)</td>
<td>20 (52.6)</td>
<td>28 (52.8)</td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>11 (29.7)</td>
<td>10 (26.3)</td>
<td>7 (13.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Mother’s job</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housekeeping</td>
<td>28 (75.5)</td>
<td>30 (78.9)</td>
<td>50 (92.6)</td>
<td>0.06</td>
</tr>
<tr>
<td>Occupied</td>
<td>9 (24.3)</td>
<td>8 (21.1)</td>
<td>4 (7.4)</td>
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<tr>
<td><strong>Father’s education</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>3 (8.1)</td>
<td>5 (13.2)</td>
<td>11 (20.4)</td>
<td>0.2</td>
</tr>
<tr>
<td>Guide school</td>
<td>23 (52.1)</td>
<td>22 (60.6)</td>
<td>35 (64.8)</td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>11 (29.7)</td>
<td>10 (26.3)</td>
<td>8 (14.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Cesarean type</strong></td>
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<td></td>
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<tr>
<td>Elective</td>
<td>10 (27.02)</td>
<td>13 (34.21)</td>
<td>21 (38.88)</td>
<td></td>
</tr>
<tr>
<td>Emergent</td>
<td>27 (72.97)</td>
<td>25 (65.78)</td>
<td>33 (61.11)</td>
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<tr>
<td><strong>Antibiotic consumption</strong></td>
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<td></td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Regular</td>
<td>32 (88.9)</td>
<td>34 (94.4)</td>
<td>48 (88.9)</td>
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</tr>
<tr>
<td>Irregular</td>
<td>1 (11.0)</td>
<td>2 (5.6)</td>
<td>6 (11.1)</td>
<td></td>
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<td><strong>Numbers of pregnancy</strong></td>
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<td></td>
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</tr>
<tr>
<td>1</td>
<td>15 (40.5)</td>
<td>24 (63.2)</td>
<td>33 (61.1)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>22 (59.5)</td>
<td>14 (36.8)</td>
<td>21 (38.9)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Comparison of pain intensity in cesarean wound in first 7th and 14th days after surgery in three studied groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Drug group n (mean ± SD)</th>
<th>Placebo n (mean ± SD)</th>
<th>Control n (mean ± SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity 24 h after cesarean</td>
<td>37 (78.91 ± 17.44)</td>
<td>38 (78.55 ± 20.95)</td>
<td>54 (62.7 ± 17.68)</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Pain intensity 7th day after cesarean</td>
<td>37 (14.44 ± 15.20)</td>
<td>38 (25.73 ± 18.70)</td>
<td>54 (26.41 ± 21.31)</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Pain intensity 14th day after cesarean</td>
<td>37 (0.27 ± 1.66)</td>
<td>38 (4.07 ± 8.99)</td>
<td>54 (5.8 ± 12.47)</td>
<td>0.02</td>
<td></td>
</tr>
</tbody>
</table>

also found similar findings in previous studies (Ingel et al., 2007). Limitations of this study were: (1) clinical criteria were used, (2) there was no pathologic examination and (3) various concentrations of honey were not compared.

Conclusion

The current study has evaluated the usefulness of honey in postoperative pain relief and wound healing in patients undergoing caesarean section. The strength of the study lies in blinding and objective assessment of pain scores. This paper is interesting, because of the fact that honey is practically devoid of any side effects.

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