Stab Intra-Myometrial Injection (SIMI) of low dose oxytocin versus parenteral oxytocin during LSCS- A comparative clinical study

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Abstract
Background: In an effort to effectively reduce placental site haemorrhage in a number of cases alternative methods were sought and myometrial transfer of oxytocin by insulin syringe is the result.

Aim: This is a comparative study of 4 IU oxytocin by stab intra-myometrial injection (SIMI) and conventional 10 IU parenteral during LSCS with the objective of comparing the blood loss.

Materials & Methods: A prospective study of Group A 100 patients subjected to SIMI by insulin syringe and Group B 100 patients administered 10 IU of oxytocin IV after baby birth. The blood loss and adverse effects of oxytocin during LSCS compared between the 2 groups.

Results: It’s observed that in all the emergency & elective cases of Gr. A the mean blood loss is less by 40.1 ml (482.8 ml) as compared to 522.9 ml in Gr. B cases.

Discussion: The placental site haemorrhage plays the dominant role during caesarean sections to decide the maternal mortality and morbidity. Intra-myometrial uterotonics have the effect of faster action reducing the 3rd stage time and bleeding thereby the total blood loss by 40.1 ml. in this study.

Conclusion: SIMI of low dose oxytocin may be an alternate step for 3rd stage management and more studies may be needed in this regard.

Keywords: Stab Intra-Myometrial Injection (SIMI), Low dose oxytocin, Placental site haemorrhage, caesarean section.

Introduction
More than 5000 caesarean sections are being done throughout the world each day. Excessive haemorrhage has remained a cause of concern for the obstetrician, a nightmare for the patient and herculean task for the management. Enough freedom is given to surgeons to perform the surgery in their way and many steps have alternate methods. Surgical steps are advocated taking into account the short term, long term outcomes as well as the cosmetic aspect. More than 10% cases land in PPH which is severe in emergency
situations threatening life, more or less equally in developed and developing countries. \(^{1-4}\) Postpartum hemorrhage remains to be a major health burden, leading to maternal mortality in the developing and in the developed countries.\(^5\) Defined as blood loss of 500 mL or more and 1000 mL or more within 24 hours of vaginal and cesarean deliveries, respectively, postpartum hemorrhage represents about 25% of all cases of maternal deaths every year worldwide.\(^6-8\)

There is continuous effort to reduce blood loss, hospital stay, BT and optimal use of antibiotics and analgesics. A small breakthrough in any step may be of enormous value because of vast number of cases. Placental site haemorrhage is the cornerstone of management to improve maternal morbidity and mortality of caesarean sections.\(^9\)

Though many steps have been suitably modified for an alternate option, administration of uterotonic drugs – the dose, route & manner of administration have conventionally remained the same. In majority of cases substantial amount of blood loss do not reflect immediately in the clinical condition of the patient or it may cause her anaemic post-caesarean that goes un-noticed and taken care of by itself. Some are readily recognized clinically, some are symptomatic and some pass into a stage of shock. Hence the importances of always saving even a small amount of blood when feasible.\(^10\)

For active management of the 3\(^{rd}\) stage of labour (AMTSL 2012) the WHO has fixed guidelines like CCT for placental delivery and administer Oxytocin 10 IU parenterally in all caesarean cases.\(^11\) AMTSL as a prophylactic intervention is composed of a package of three components or steps: 1) administration of a uterotonic, preferably oxytocin, immediately after birth of the baby; 2) controlled cord traction (CCT) to deliver the placenta; and 3) massage of the uterine fundus after the placenta is delivered. In 2012, the results of a large WHO-directed, multi-centred clinical trial were published and showed that the most important AMTSL component was the administration of a uterotonic.\(^12\), \(^13\) Though oxytocin is used prophylactically and therapeutically its improper use can have deleterious effects as it has extra-uterine actions.\(^14\)

In this study we have administered smaller dose of oxytocin into myometrium by insulin syringe—only 4 IU and compared it with the existing method of parenteral dose of 10 IU and assessed the safety and practicability of such use.

**Materials & Methods**

It was a prospective study of 100 cases (50 elective & 50 emergency) caesarean sections in the study group – Group A and 100 cases (50 elective & 50 emergency) in the control group—Group B. conducted in Gouri Devi Institute of Medical Sciences & Hospital, Durgapur, West Bengal from July 2018 to Jan.2019 with due permission from the institutional ethical committee and consent from the patients. In Group A patients 4 IU of oxytocin (0.8ml) drawn in an insulin syringe was administered into the myometrium by stab injections, 2 IU in the region of each cornu of the uterus just after the baby is taken out before delivery of the placenta. In Gr. B patients 10 IU oxytocin administered by IV route over a period of 2-3 minutes as bolus after delivery of the baby as usual. Placentae delivered in all cases by CCT as per WHO guide lines and 10 IU oxytocin in IV drip continued as usual in both the groups.

Only primigravidae having minimum 10 gm% haemoglobin between 20 to 30 years of age were included in both groups. Multiparous women, primigravidae below 20 and above 30years and Rh negative pregnancies were excluded.

For intra-myometrial injection sterile insulin syringes kept ready with 4 IU of oxytocin (0.8 ml) were used i.e. upto mark 8 of the syringe and 2 IU injected to each cornu immediately after baby birth, at 90 degree to the uterus without waiting for placental separation. The injection is driven full depth of the needle as a stab in a few seconds without any prior withdrawing the piston to see whether blood coming or not. In all cases any
adverse effect of oxytocin like nausea, vomiting, rise in pulse rate (>20/min), significant change in B.P. (>20 mm Hg) in systolic/diastolic recorded by the anaesthetist. For EBL (estimation of blood loss) in both the groups the Glass Jar method, which is a modified volumetric method, is used adding 20% towards evaporation loss in the OT conditions. The amount of bleeding thus calculated was summarised.

**Results**

It was a prospective study of 100 cases (50 elective & 50 emergency) caesarean sections in the study group – Group A, out of which 34 were primigravida and 66 were multigravida. They were mostly belonging to 20–30 yrs age group [58%], followed by 30–40 yrs [26%].

**Table 1: Indications for CS in both study groups**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Group A [N=100] %</th>
<th>Group B [N=100] %</th>
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</thead>
<tbody>
<tr>
<td>Prolonged labour</td>
<td>37</td>
<td>35</td>
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<tr>
<td>CPD</td>
<td>22</td>
<td>26</td>
</tr>
<tr>
<td>PROM</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Breech Presentation</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Oligo-hydramnios</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Postdated Pregnancy</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Fetal distress</td>
<td>18</td>
<td>13</td>
</tr>
<tr>
<td>CS on request</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

Most common indication for caesarean section was prolonged labour (35%) followed by CPD (26%) and fetal distress (13%) in group B subjects [Table 1]. On an average 4–6% of cases caesarean section was conducted on the request of patients or study subjects.

**Table 2: Showing the amount of blood loss in ml during CS**

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Blood loss [ml] (mean)</td>
<td>467.8</td>
<td>498.0</td>
<td>NS</td>
<td>504.6</td>
<td>545.9</td>
<td>NS</td>
<td>476.4</td>
<td>522.8</td>
<td>NS</td>
<td>482.8</td>
<td>522.9</td>
<td>NS</td>
</tr>
<tr>
<td>SD</td>
<td>68.3</td>
<td>57.4</td>
<td></td>
<td>74.3</td>
<td>45.9</td>
<td></td>
<td>62.3</td>
<td>55.1</td>
<td></td>
<td>70.3</td>
<td>49.8</td>
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</table>

In this study it’s observed that the mean amount of blood loss is less but not significantly - 482.8 (±49.8) ml in Group B. The side effects of oxytocin as observed during the surgery are also less in Group A than Group B [Table 2].

**Table 3: Showing adverse effects of oxytocin**

<table>
<thead>
<tr>
<th>Group</th>
<th>Nausea/vomiting</th>
<th>Changes in BP ➢ 20 mmHg</th>
<th>Changes in pulse rate ➢ 20/min</th>
<th>Any other changes medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>7</td>
<td>12</td>
<td>12</td>
<td>Nil</td>
</tr>
<tr>
<td>Group B</td>
<td>8</td>
<td>15</td>
<td>15</td>
<td>Nil</td>
</tr>
</tbody>
</table>

**Discussion**

Many modifications have taken place for many steps of caesarean sections beginning from skin incision, opening the abdomen, peritoneum, uterine incision, delivering the baby, closing the uterus and closing the abdomen; but there has been no significant changes in the guidelines regarding dose, route and manner of administration of uterotonic drugs in spite of numerous publications since WHO guidelines (AMTSL2012) although maternal mortality due to 3rd stage haemorrhage is going unabated. Of course a good proportion of PPH cases are attributed to increasing number of morbid adhesion of placenta for which newer methods are advocated and followed. But for routine care and prophylaxis the same 2012 guidelines hold good. In this study, the mode of administration of oxytocin is by insulin syringe which is factory fitted with an atraumatic needle of only 10 mm long that can be pushed into the whole thickness of uterine musculature to deliver the drug, the thickness of myometrium at term being 10-20 mm in the upper segment. If it pierces into the uterine...
vasculature inside the muscle oxytocin is delivered to the myometrium through small arterioles and a portion of it directly acts on it, its action being faster than if it's administered IV/IM. IV administration takes 30-45 seconds & IM administration takes 3-4 minutes to work. Since the site of action of oxytocic drugs is the myometrium we take the advantage of directly administering the drug into the myometrium near the cornua during CS saving nearly 6 minutes,

and also the amount of oozing of blood for that period throughout the surgical site. It’s the text book teaching that uterine pacemakers are located in the cornua. Secondly, a bigger dose of oxytocin is required to bring about the same effect if given IV/IM. Hence, administering only 4 IU of oxytocin intra-myometrally is similarly effective, thereby reducing the extra-uterine adverse effects. In this study it’s observed that the mean amount of blood loss is less but not significantly - 482.8 (±70.3) ml in Group A as compared to 522.9 (±49.8) ml in Group B. The side effects of oxytocin as observed during the surgery are also less in Group A than Group B. There were no other symptoms that required extra medications in both the groups. Main hemodynamic effect of intramyometrial oxytocin against intravenous oxytocin in terms of blood pressure decrease was reported by two journals. 

Intra-myometrial oxytocic administration requires merely keeping ready an insulin syringe filled with oxytocin so that the surgeon or the assistant can push it after baby delivery thereby de-burdening the anaesthetist of administering the drug which is ideal; because the surgeon is better aware of the PPH and he never delays to administer it. The lesser blood loss in Group A may be attributed to the faster acting due to SIMI of oxytocin than IV/IM as it takes 3-4 minutes to travel from injection site to the heart and thence to the uterus via the uterine arteries that to a portion of it majority being distributed to other organs. The time thus saved may contribute towards faster surgery and save some blood from oozing into the site. Studies show that intramyometrial route of oxytocin administration could significantly reduce excessive bleeding after caesarean delivery compared to intravenous oxytocin, the current standard method of active management of the third stage of labor. The intramyometrial route also significantly reduced the occurrence of inherent drug adverse effects such as nausea and vomiting when evaluated against the intravenous route of oxytocin administration. These were noted despite the greater dose of oxytocin used in the intravenous route than the intramyometrial group (20 IU versus 5 IU, respectively).

Conclusion

Intramyometrial oxytocin reduced hemorrhage but not significant when we compared with intravenous oxytocin. SIMI of oxytocin for 3rd stage management may be as good as or a better a method than IV/IM oxytocic administration. There is suggestion on the benefit of using intramyometrial oxytocin in the prevention of excessive bleeding in women delivering via caesarean section, but this can only be accurate with larger randomized controlled trials of high methodological quality.

References

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