Occlusion of multi-holed catheters used in continuous wound infusion in open gynecologic surgery: A pathological study

ABSTRACT
Background: Continuous wound infusion (CWI) with local anesthetics is useful as a method of pain management after abdominal surgery. However, there have been no studies regarding the obstruction of multi-holed catheters in this application.
Methods: We conducted from July to November 2015. In the first portion of the study, we obtained 34 catheters used postoperatively with open gynecologic surgery, and evaluated the status of each hole in vitro. Each catheter had eight holes, and we investigated the number of open holes after the removal of the catheter. In the second portion of the study, we reviewed pathological specimens from four occluded catheters. Statistical analysis was performed using the statistical software MedCalc™ (MedCalc, Ostend, Belgium), and intergroup comparisons were made with independent sample t-test. Data are expressed by mean and standard deviation.
Results: In each catheter, the number of remaining open holes was 0–7, and there were no catheters with all eight holes still open. Although the occlusion may be occurred after the end of infusion, 38.2% (n = 12) did not have any open holes remaining in our investigation. The composition of the emboli in the catheters was clotted blood and plasma, with a mass of fibrin and possibly some inflammation around the embolus.
Conclusions: Occlusion of these catheters occurs at a very high rate, and the catheter embolus might be composed of clotted blood, plasma, and/or fibrin.

Key words: Blood clot with plasma component; continuous wound infusion; occlusion

Introduction
Although continuous wound infusion (CWI) with local anesthetics has become increasingly popular, there have been some reports indicating complications associated with CWI.1-4 One of the major complications associated with CWI is the occlusion of multi-holed catheters. In the previous studies, catheters were found to be occluded in 2.9–8.6% patients undergoing cesarean section.3-6 In regards to epidural catheters, the causes of catheter occlusion were divided into four factors: (1) anatomical factors such as the migration of the catheter; (2) technical factors from inserting...
the catheter; (3) catheter-based problems such as kinking, knotting, and occlusion by blood-clot or tissue debris; and (4) patient factors such as obesity and a deep epidural space.⁷⁻⁹ To our knowledge, however, large studies have not been published regarding the frequency and cause of occlusion of the multi-holed catheters used in CWI.

This study was meant to evaluate the cause and frequency of occlusion in multi-holed catheters used for CWI among patients who have undergone open gynecologic surgery. We also investigated a hypothesis that there having many open holes in the catheter during postoperative period provided better postoperative pain management. In addition as second study, we also investigated any occlusions in these multi-holed catheters pathologically.

**Methods**

There were two portions to our study: The first was to consider the frequency of occlusions in vitro and the second was to evaluate the embolus of the catheter pathologically. Our study was approved by the Ethics Committee of the studied Hospital (27-19 and 349). Informed consent was obtained from the patients in the form of opt-out on the hospital website.

In the first portion of our study, the population consisted of 34 patients with the American Society of Anesthesiologists physical status (ASA-PS) of 1-3, who underwent open gynecologic surgery (total abdominal hysterectomy, radical abdominal hysterectomy, or bilateral salpingo-oophorectomy) under general anesthesia. General anesthesia was performed according to our standardized protocol of anesthesia as follows: Propofol was injected intravenously, followed by rocuronium, after which the patient was intubated via the trachea. Anesthesia was maintained via continuous intravenous infusion of remifentanil along with intermittent intravenous administration of fentanyl and rocuronium. The dose of sevoflurane was adjusted to maintain bispectral index values between 40 and 60, and the rate of continuous infusion of remifentanil and the dose of fentanyl were adjusted to maintain hemodynamic stability at the discretion of the attending anesthetist. At the end of the surgery, a 15 cm multi-holed catheter (PAINCLINIC™, Hakko, Tokyo, Japan) was inserted subcutaneously or subfascially (when achievable) by the surgeon after peritoneum closure. After skin closure, 20 mL of 0.75% ropivacaine was injected from the catheter as the initial dose, the infusion pump containing 0.2% ropivacaine was connected via the patient controlled analgesia (PCA) pump (CADD Legacy™, Smith Medical Japan, Tokyo), and the wound was infused at a rate of 5 mL/h. When the patients pushed the purge button, 4–6 mL of analgesic solution was injected, not more than once every 30 min.

After surgery, almost all of the patients were admitted into the high care unit. Patients were treated according to a gynecology clinical pathway in our hospital. When patients complained of moderate to severe pain, even after using patient controlled analgesia with the wound infusion catheter, non-steroidal anti-inflammatory drugs (NSAIDs) or pentazocine was prescribed by attending gynecologists. Per the clinical pathway, the multi-holed infusion catheter was removed three days after surgery.

In the first portion of our study, we collected 34 multi-holed catheters which were used from July to November 2015. First, we injected 50 mL of air into the catheter in order to remove any remaining substances. Then, we connected the catheter to syringe pump (Terumo, Japan), injected colored water at a rate of 5 mL/h [Figure 1], and then investigated any remaining open holes.

From the patients’ medical records the following study parameters were recorded: Age, height, weight, type of surgery, operation and anesthesia time, amount of blood loss, location of the inserted catheter, PCA pump volume used until the morning the day after surgery, and effective demand frequency until completion of the PCA pump. Assessment of pain was performed at 24 h after surgery, and was assessed via the Prince Henry Pain Scale (PHPS), providing a score from 0 to 4 (0 - no pain; 1 - feeling pain with a deep breath; 2 - feeling pain with coughing; 3 - feeling pain but don’t need an analgesic; 4 - feeling pain and need an analgesic). Complications associated with wound catheter placement were also recorded.

In the second portion of our study, we pathologically evaluated any occlusions found in the catheters. As we previously explained, we first assessed the status of the occlusion just after the catheter was removed from patients. If the catheter was occluded, a paraffin block was made from the occlusion and fixed in formalin and stained with

![Figure 1: Outflow of colored water from side holes of catheter. This catheter have 8 side holes every 2 cm from the place of 1 cm from the end tip. In the first study, we initially flushed with 50 mL of air and infused with colored water at 5 mL/h by a syringe pump to check the number of open holes (blue arrow)
hematoxylin and eosin (HE), Masson-Trichrome (MT), and phosphotungstic acid hematoxylin (PTAH). A pathologist from our hospital assessed 4 specimens from 4 occluded catheters.

Statistical analysis was performed using the statistical software MedCalc™ (MedCalc, Ostend, Belgium), and intergroup comparisons were made with independent sample t-test. Data are expressed by mean and standard deviation. A value of \( P < 0.05 \) was considered statistically significant.

**Results**

We analyzed the data obtained from patients from July to November 2015 in our hospital. The background of the patients is shown in Table 1. One patient had not appraised her ASA-PS before surgery. And we could not visit first postoperative day to evaluate postoperative pain for another one patient. We reviewed the site of placement of the indwelling catheters. Twenty six patients’ medical records showed the placement of the catheter put whether subfascial or subcutaneous [53.8% (\( n = 14 \)] were subfascial]. The indwelling time was 2 or 3 days in most cases.

In clinical settings, we reviewed the medical records to find complications associated with catheters. Of the 34 cases reviewed, the pumps sounded an occlusion alarm in 2 cases, and the catheters were removed earlier than expected due to this reason. In one case, there was a leakage of ropivacaine and a reinforcement suture was needed. There was one case in which incision edema appeared after the removal of the catheter. Furthermore, in one case, the amount of subcutaneous drainage was more than usual, and the catheter was the suspected cause of the additional drainage.

Next, we considered whether postoperative pain control was affected by the occlusion of the catheter [Table 2]. We excluded one patient who could not evaluate her postoperative pain from this investigation. No statistical differences were observed between the number of open holes and postoperative pain level on the morning of the first day post-surgery.

When we compared the higher (≥3) PHPS group with the lower (≤2) PHPS group on day 1, there were no statistically significant differences in age, height, weight, and use of NSAIDs. There were, however, significant differences in operation time, anesthesia time, amount of blood loss, dose of pentazocine used postoperatively, and amount of CWI use until the morning after surgery. Likewise, the number of requests for rescue analgesic drugs, effective bolus, and the amount of analgesic drugs in CWI were increased in the lower PHPS group than in the higher PHPS group.

| Table 1: Backgrounds of patients of first study |
|-----------------------------------------------|
| Demographic Characteristic                     |
| Summary Statistic                              |
| Age (year)                                     | 58.8±14.0 |
| Height (cm)                                    | 153.8±5.7 |
| Weight (kg)                                    | 55.7±14.2 |
| Operation time (minute)                        | 292±32    |
| Anesthesia time (minute)                       | 349±132   |
| Amount of bleeding (ml)                        | 1257±1474 |
| ASA-PS 1/2/3 (a)                               | 6/19/8    |
| Indwelling place (b) Subfascial/Subcutaneous   | 14/12     |
| Number of holes opened 0/1/2/3/4/5/6/7/8       | 13/4/6/4/0/1/0 |

ASA-PS: American Society of Anesthesiologists physical status. Values are expressed as mean±standard deviation of 34 patients or the number of patients. (a): n=33, ASA-PS was not evaluated in patient, (b): n=26, Site of the wound infiltration catheter was unknown in 8 patients.

| Table 2: The characteristics of patients with low (≤2) and high (>3) Prince Henry Pain Scale 24 h after surgery |
|---------------------------------------------------------------|
| n | PHPS ≤2 | PHPS >3 | P |
|---|---------|---------|---|
| Open hole (number) | 2.1±1.9 | 1.4±1.5 | 0.35 |
| Age (years) | 64±12 | 54±14 | 0.48 |
| Height (cm) | 155.6±5.8 | 152.3±5.5 | 0.82 |
| Weight (kg) | 54±12.3 | 54±8.6 | 0.18 |
| Operation time (minute) | 320±163 | 267±89 | 0.02 |
| Anesthesia time (minute) | 379±161 | 322±91 | 0.03 |
| Amount of bleeding (ml) | 1438±1793 | 1086±1097 | 0.07 |
| Amount of CWI use until the morning of 1 POD (ml) | 46.5±18.6 | 82.1±43.3 | 0.002 |
| NSAIDs (times) | 2.1±2.9 | 6.8±2.1 | 0.232 |
| Pentazocine (mg) | 3±6 | 15±21 | <0.001 |
| Effective demand frequency | 3.9±4.8 | 15.9±13.5 | <0.001 |

PHPS: Prince Henry Pain Scale, CWI: Continuous wound infusion, NSAIDs: Non-steroidal anti-inflammatory drugs.

Figure 2: Magnified image of occluded catheter side hole fixed by formalin in second study (Unstained)

For pathological considerations, we found red blood cells, nuclei, and plasma components in all of the occluded specimens [Figures 2 and 3a, b]. Because the specimen size was relatively small, we could not identify what the nuclei was
composed of, although it could be from leukocytes, fibroblasts, or endothelial cells. In another specimen, we did identify some eosinophils and neutrophils with red blood cells.

Discussion

Nowadays, the use of postoperative CWI with local anesthetics has been applied for multimodal analgesia, and has gained popularity as a means for postoperative analgesia as well. Some benefits were observed for using CWI in patients undergoing obstetric and gynecological surgery, including improved analgesia, reduced opioid use, and side effects, increased patient satisfaction, and reduced hospital stay.\(^{[7]}\)

Delayed wound healing due to incision infection was detected in 2.5% and postoperative incision edema occurred in 4.2% of patients.\(^{[1]}\) In another study, a few patients mentioned that the wound and dressings became unpleasantly wet.\(^{[4]}\) There was also a 17.2% rate of catheter-related complications, including leakage of local anesthetics and catheter dislodgement.\(^{[2]}\) It was reported that there was a 15–17% rate of catheter dysfunction, such as accidental retrieval or occlusion.\(^{[3]}\) In our study, it was demonstrated that catheters were occluded very frequently in vitro.

For pathological considerations, the hole of catheter was possibly occluded by blood clot, plasma, and/or fibrin. There was no evidence that tissue debris or adipose tissue contributed to the occlusion of the catheter. With regard to epidural catheters, there were some case reports in which the occlusion of epidural catheters due to blood clots in clinical settings was discussed,\(^{[8,9]}\) although to our knowledge there were no case reports about the occlusion of catheter used in CWI. It was not clear whether leukocytes were from blood, however it was suggested that the embolus might be blood clot in this case. In MT staining, high-power magnification showed the plasma component was colored red. In PTI staining, there was a predominance of fibrin that was colored purple under high-power magnification. The embolus of the catheter is possibly blood clot with plasma, and/or a mass of fibrin, and there may be some inflammation around the embolus. A multi-holed CWI catheter is placed directly in the surgical wound, and an injury to the skin immediately initiates clotting cascades, which provide a temporary fibrin blood clot plug to the injury site.\(^{[10]}\) Therefore, a CWI catheter may occlude more easily than an epidural catheter.

As we have shown, about 40% of the catheters did not have any remaining open holes in the first portion of our study, and the PCA pump occlusion alarm was activated in 5.9% of the clinical cases. In a previous study, the catheter occlusion was found in 2.9–8.6% of patients undergoing cesarean section.\(^{[3,5,6]}\) The other relating factor for catheter occlusion was the duration after the completion of the infusion, and this result was easily anticipated. In this study, the CWI catheter was removed during patient rounds by gynecologists, and thus, the catheter was removed at varying times passed after the completion of wound infiltration.

With regard to the site of placement of the indwelling catheter, there was no significant difference in the rate of occlusion between of catheters placed below the fascia and subcutaneously. Several studies have concluded that placing the catheter below the abdominal fascia is more effective because a deeper catheter placement reduces leakage of analgesic fluid.\(^{[2]}\) It is possible that placing the catheter below the abdominal fascia is more beneficial since the percentage of occlusion is almost the same.

Whether many holes of catheter were occluded or not may not be important in terms of the management of postoperative pain at next morning of surgery. One reason for this is that if some of the holes were occluded, local anesthetics flowed out of the other holes. Another reason is that the occlusion of the catheter occurred after it was used in clinical settings. This explanation was supported by the fact that the PCA pump occlusion alarm of was activated in only 2 cases, although about 40% of the catheters didn’t have all holes open in vitro. The last, and most important reason showing partial CWI catheter occlusion does not affect the outcome of postoperative pain management is based on the PHPS. The other method of pain management, such as pentazocine, had enough effect to relieve pain, even if the occluded catheter had little effect for patients. It has been reported that infusion of the wound with local anesthetics could provide suitable postoperative analgesia in association with multimodal system analgesia.\(^{[3]}\)

There were some limitations in our study. First, this study was done in a single center, and the study population was relatively small. Second, the time between infusion completion and removal of the catheter from the wound varied. And the duration between removal of catheter and examination is also varied. We took days to evaluate the
open holes for some catheters. This duration may affect the results. Further studies regarding catheter occlusion will be necessary to maximize the effectiveness of local anesthetics and to decrease catheter-related complications. For example, we may develop the current catheter into more a specialized one for CWI, such as adding a heparin coating in order to prevent blood clot formation in the lumen.

**Conclusions**

We considered the frequency of catheter occlusion during CWI when used in patients who underwent open gynecologic surgery. The rate of occlusion of catheter may be high. More studies are needed in order to reveal the mechanism of occlusion and potential solutions or preventative measures.

**Declaration of patient consent**

We obtained written informed consent from all the patients that we studied. In the form the patient(s) has/have given his/her/their consent for his/her/their clinical information and images of catheter used for him/her/them to be reported in the journal. The patient(s) understand that his/her/their private information such as name(s) and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.

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