
Clinical Report

Recall after total intravenous anaesthesia due to an equipment misuse

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Purpose: To present a case of recall after total intravenous anaesthesia (TIVA) with propofol-alfentanil infusions to point out an uncommon misuse of the Bard InfusOR syringe driver.

Clinical features: A healthy patient underwent diagnostic dilatation and curettage and laparoscopy for lysis of peritoneal adhesions. After induction, anaesthesia was maintained with propofol-alfentanil infusions using the Bard InfusOR syringe drivers. Ten minutes into maintenance, the patient was moving. The flashing green light confirmed the delivery of the medication and the alarms were not activated. However, the latch of the movable lever in the propofol syringe driver was found to be improperly positioned at the top of the plunger and only a small amount of propofol had been delivered. Postoperatively, the patient could recall the abdomen being touched during laparoscopy. An explanation was given and the patient was satisfied.

Conclusion: The Bard InfusOR syringe driver is not designed to detect a malposition of the lever on the syringe plunger. The anaesthetist must ensure proper placement of the lever and visual confirmation of medication delivery in order to prevent awareness due to this particular problem.

Objectif : Rapporter un incident de rappel consécutif à une anesthésie exclusivement intraveineuse (AEM) réalisée avec une perfusion de propofol-fentanyl dans le but d'attirer l'attention sur l'emploi incorrect d'un pousse-seringue Bard InfusOR.

Éléments cliniques : Une patiente en bon état subissait une dilatation avec curetage pour fin diagnostique et une laparoscopie pour lyse d'adhérences péritonéales. Après l'induction, l'anesthésie était maintenue à l'aide d'un pousse-seringue Bard InfusOR. Dix minutes plus tard, la patiente bougeait. Le clignotant vert lumineux confirmait l'administration de la médication et aucune alarme n'était activée. Cependant, on constatait que le loquet du levier mobile du pousse-seringue était mal placé sur la tête du piston et que seulement une petite quantité de propofol avait été reçue. En postopératoire, la patiente se rappelait qu'on lui avait touché l'abdomen. Après explications, la patiente s'est déclarée satisfaite.

Conclusion : Le pousse-seringue Bard InfusOR n'est pas conçu pour détecter le placement incorrect du levier sur le piston de la seringue. L'anesthésiste doit s'assurer que le levier est en bonne position et que la médication est reçue dans le but de prévenir un rappel causé par ce type de problème.

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THE incidence of recall is stated to be approximately 1% and the incidence has not declined in recent years.¹ Most episodes of awareness can be attributed either to faulty technique (70%) or to failure of equipment (20%).² The equipment failures commonly cited are empty vaporizer, empty nitrous oxide cylinder, entrainment of air by a ventilator and oxygen bypass being left switched on.¹ There are few reports of awareness and recall after total intravenous anaesthesia (TIVA).³ We present a case of recall after TIVA with propofol-alfentanil infusion to point out an uncommon misuse of the Bard InfusOR syringe driver.

Case Report

A 41-yr-old, 66-kg woman in good health presented for diagnostic dilatation and curettage and laparoscopy for lysis of peritoneal adhesions. In the operating room, intravenous access and routine anaesthetic monitoring were established. Initial blood pressure was 120/80 mmHg and heart rate was 80 beats·min⁻¹. After preoxygenation, anaesthesia was induced with 1 mg midazolam, 1300 µg alfentanil, 130 mg propofol and a priming dose of 0.5 mg vecuronium. With loss of consciousness, a further 3.5 mg of vecuronium were given. The trachea was intubated uneventfully. The intubation was immediately followed by a propofol infusion of 150 µg·kg⁻¹·min⁻¹ and an alfentanil infusion of 1.0 µg·kg⁻¹·min⁻¹. Two Bard InfusOR syringe drivers were used with the 60-ml Becton Dickinson (B-D) syringes. Both syringes were filled with the appropriate medications, purged of air and secured into position. The infusion rate, body weight of the patient and bolus dose were entered on the corresponding dials. No alarm was activated. Haemodynamic variables after induction remained stable with a blood pressure of 100–110/60 mmHg and a heart rate of 70–80 beats·min⁻¹. Ten minutes after induction, the patient was moving her toes. This was accompanied by increases in blood pressure to 130/80 mmHg and in heart rate to 100 beats·min⁻¹. There was no other autonomic sign of light anaesthesia. The blood pressure and heart rate gradually settled with 40 mg bolus of propofol and 500 µg bolus of alfentanil. An additional 0.5 mg vecuronium was given. The syringe drivers were reexamined. The green light was flashing indicating proper delivery. The latch of the moveable lever in the propofol syringe driver, however, was found to be improperly positioned (Figure 1). Instead of clamping onto the end of the plunger, the latch was positioned on top of the plunger. The amount of propofol delivered was noticed to be less than expected but the exact amount was not noted. The problem

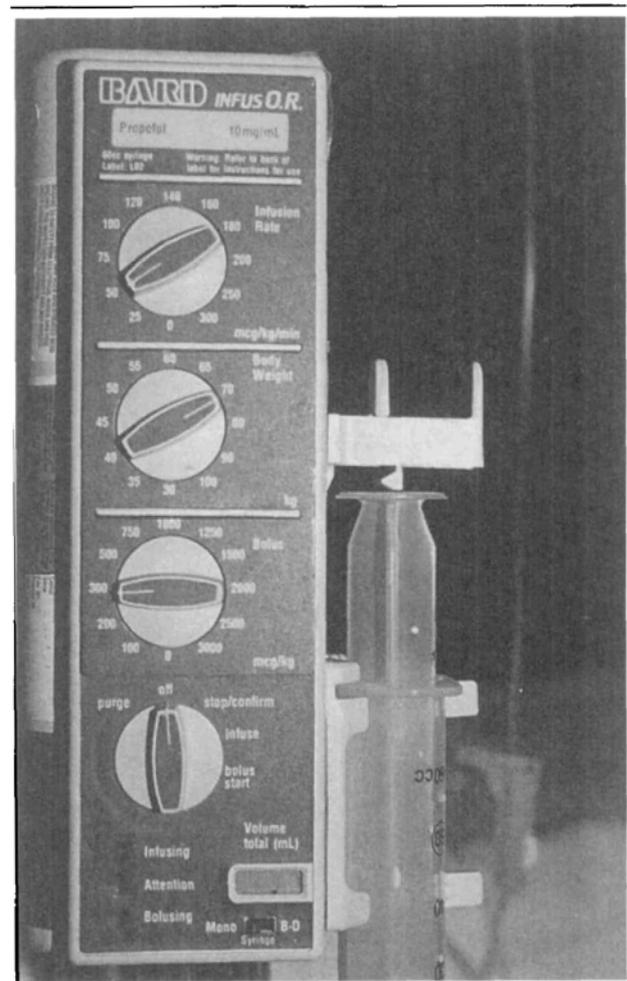


FIGURE 1 Malposition of the lever and latch on top of the syringe plunger.

was immediately corrected. The remainder of the intraoperative course was uneventful. The duration of the anaesthesia was 45 min. The total infusion dose of propofol and alfentanil was 230 mg and 4500 µg respectively.

The postoperative course was uneventful. The patient was interviewed by the attending anaesthetist two hours after the operation. The patient could recall the abdomen being touched during the laparoscopy for a very brief period but could not recall any verbal remarks made by the operating room personnel. An explanation of the incident was given. The patient was reassured concerning future anaesthesia and was satisfied with the anaesthetist's approach.

Discussion

Awareness is a state in which a patient is conscious of events occurring during intended general anaesthesia. Recall (or explicit memory) is the ability of a patient

to remember events which occurred during intended general anaesthesia. Liu⁴ cited a 0.2% incidence of recall after interviewing 1000 patients who underwent non-obstetric and non-cardiac surgery. Higher risks of recall are observed with obstetric (7–28%),⁵ major trauma (43%)⁶ and cardiac surgery (23%).^{1,7,8} Severe intraoperative awareness occurred only after the introduction of muscle relaxants in 1942.¹ With balanced anaesthesia, the dose of volatile and intravenous anaesthetics have been reduced while muscle paralysis obliterates the somatic signs of consciousness. Given our poor understanding of the complex levels of consciousness during anaesthesia⁹ and our inability to assess the depth of anaesthesia accurately,^{10–5} it is not surprising that awareness still occurs.

The reasons for intraoperative awareness can be traced to the following: interpatient pharmacokinetic and pharmacodynamic variability, selection of an anaesthetic technique that makes little provision for prevention of awareness and failure to maintain adequate plasma drug concentrations, for example, in critically ill patients when light anaesthesia is maintained for medical reasons or when there is a failure/misuse of equipment.

In this case, we used the Bard InfusOR syringe driver. It is a positive displacement syringe pump capable of delivering a wide variety of drugs by means of a series of electromagnetic templates. The templates modify the control of internal delivery mechanism.¹⁶ It is compatible with both the 20 or 60 ml syringes from B-D or Monoject. Drug delivery is in a controlled manner by means of a threaded lead screw rotated by a miniature motor. The speed of the motor is controlled by a microprocessor which also controls the display and alarm systems. The front panel of the infuser has four rotary switches, a five character liquid crystal display (LCD) and three small lights: A continuously flashing green light confirms the pump is infusing, a second green light flashes with the delivery of a bolus and a red light alerts the operator that a problem has arisen. The upper three rotary switches enable the anaesthetist to enter the patient's weight (kg), size of the bolus ($\mu\text{g}\cdot\text{kg}^{-1}$) and rate of infusion ($\mu\text{g}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$). The fourth rotary switch is a function switch which has separate settings for purging the system, bolus injection, infusion and stop. The LCD panel has a double function. During normal operation, it displays the cumulative delivered dose but, in the event of an alarm, it displays the cause of the problem. This is accompanied by an audible alarm and a flashing red light which can only be cancelled by ceasing the infusion or correcting the fault. The alarm is activated by line occlusion, low battery, an empty

syringe, improper switch position or internal fault. An internal fault can result from three conditions: syringe manufacturer selector switch moved during operation, templates missing or removed during operation, or internal electronic failure. The syringe is loaded into the pump with the barrel held in a moulded clamp and the plunger of the syringe being attached to a moveable lever. The lever has an anti-siphon latch to prevent the syringe from emptying under the force of gravity alone.^{17–8}

In our situation, we had not purged the system to confirm visually the delivery and the latch was not clamped onto the plunger, instead the lever was found positioned just above the plunger. We conjectured that the lever must have been positioned at a small distance above the end of the plunger at the start of the anaesthesia. The small gap made the error difficult to detect and the green light was flashing continuously, falsely indicating the infusion of the medication. No alarm was activated. The lever travelled the distance of the gap without delivery of the medication until the lever came into direct contact of the end of the plunger. Therefore, an inadequate dose of propofol was given. An inquiry was made with the quality control division and the representative of the Bard InfusOR, Baxter. They confirmed that the syringe driver was not designed to sense the different pressures exerted on the lever. The Bard InfusOR manual recommends visual confirmation of proper delivery on purging before use. The green light would flash continuously and no alarm would be activated even when no syringe was inserted. The reported incidence of this error is very low. According to the Baxter quality control division in Canada, this is the first report that came to their notice.

The other problem with this syringe driver is the occurrence of stiction,¹⁹ which is the tendency at low injection rate for the rubber end of the syringe plunger to stick to the inside of the syringe barrel and then to lurch forward. This impediment was found to be particularly troublesome when used with a very low infusion rate ($<5\text{ ml}\cdot\text{hr}^{-1}$), a small syringe and a viscous injectate. When stiction occurs, the continuous infusion acquires the characteristics of an intermittent bolus administration regimen. The fluctuating anaesthetic concentration may lead to awareness. Again, there is no activation of the alarms in this situation.

The use of a microprocessor in anaesthetic devices allows greater flexibility in equipment design but this flexibility is often coupled with complexity and more elaborate user-device interaction.²⁰ Devices that appear simple because they lack many controls may, in fact, be more complicated to use as multiple, discrete

devices are incorporated into a single shell under a supervisory software. Disciplined approach to design should avoid assigning multiple functions to single controls, hiding system states from user view, and using complex and arbitrary control sequences. Dynamic evaluation, with laboratory and field testing, is essential. The purpose of the evaluation is not to assess whether the device performs in ideal conditions. Rather, the evaluation seeks to map out device performance under the widest possible conditions of operator interaction.²⁰ Poor user-device interaction creates latent failure in the anaesthetic care system and predisposes the system to critical incidents when there are other simultaneous system faults. In this case, the human error in positioning the lever.

Intraoperative awareness and recall carry clinical and medicolegal consequences. From the clinical aspect, a number of authors have alleged that sleep abnormalities and psychological changes have resulted from intraoperative awareness, even when patients were amnesic for intraoperative events.^{21,22} Some patients suffered from a post-traumatic neurotic syndrome marked by anxiety and irritability, preoccupation with death, repetitive nightmares and reluctance to discuss symptoms. In most cases, the neurosis was ameliorated or cured if the patients were assured that the memory was real.²¹⁻²⁴ From the medicolegal aspect, the analysis from the American Society of Anesthesiologists (ASA) closed claims project involving awareness during general anaesthesia showed that of the 2,400 claims, 45 (2%) claims represented complaints of awareness.²⁵ This incidence is similar to that of respiratory distress syndrome, back pain or hepatic dysfunction following anaesthesia.²⁵ This testifies to its importance as a source of litigation and the trend of litigation following awareness is rising.²⁶

Anaesthetists should be alert to the possibility that patient may be aware and high risk patients should be forewarned. Whenever possible, patients should receive an agent or a combination of agents providing amnesia. Anaesthetists must reexamine their interactions with equipments to ensure proper use. For example, knowledge and access with regard to instruction manuals should be improved. This could be achieved by attaching manuals to the equipment. Clinicians should maintain a high index of suspicion for intraoperative awareness and its postoperative detection. Surgical colleagues and nurses need to be educated with regard to the possibility of patient awareness and its postoperative manifestations. In the event of intraoperative awareness and recall, accurate documentation of the details of the awareness episode is recommended. The anaesthetist should visit the

patient early in the postoperative period.¹ Careful and sympathetic discussion of the episode with the patient is essential.^{18,21} The experience should be acknowledged as real. The circumstances leading to the awareness episode should be reviewed and the patient should be reassured concerning future anaesthetics.^{18,21} Maintenance of personal contact with the patient is necessary. All discussion should be witnessed and well documented.^{18,21} In some cases, psychotherapy may be necessary. Referral for a psychiatrist or a psychologist should not be delayed if it becomes apparent that the patient continues to experience symptoms of traumatic neurotic syndrome.²⁷

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