Sterility Verification of Innovative Pressurized Carbon Dioxide Lavage for Bone Surface Preparation in Cemented Knee Arthroplasty

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Objective: *To verify sterility of innovative pressurized carbon dioxide (CO_2) lavage for bone surface preparation in cemented knee arthroplasty.*

Material and Method: *Twenty-five 500 L. air samples from the innovative pressurized CO_2 lavage were laboratory tested to verify the presence or absence of either bacteria or fungi in microbial air samplings taken in a biological safety cabinet. CO_2 gas was delivered though a pressure regulator, a sterile delivery tube, a hand piece, and a microbial air filter with a pressure level of 50 psi, according to the medical standard. Contamination samples for bacteria and fungi were taken by using Tryptic Soy Agar and Sabouraud Agar as the culture media and were then analyzed at 48 hours and 10 days, respectively.*

Results: *Twenty-five samples of microbial culture showed no bacterial or fungal growth on either Tryptic Soy Agar or Sabouraud Agar.*

Conclusion: *The sterility of the innovative pressurized carbon dioxide lavage was confirmed by laboratory test results and was approved for application for bone surface preparation in cemented total knee arthroplasty.*

Keywords: *Carbon dioxide lavage, Cemented, Knee arthroplasty, Sterility*

J Med Assoc Thai 2014; 97 (Suppl. 9): S108-S111
Full text. e-Journal: *http://www.jmatonline.com*

Total knee arthroplasty is an operation that potentially offers substantial benefits to the patient. In successful operations, patients are satisfied because this procedure can reduce pain, correct deformity, and provide improved range-of-motion (ROM) in the knee. However, the long-term success of cemented total knee arthroplasty is largely dependent on the mechanical integrity of the bone-cement interface. The fixation strength of the interface between prosthesis and cancellous bone depends on the depth of cement penetration, as well as the cleanliness and dryness of the resected bone surface at the time of cementation[1-4].

Previous studies have demonstrated that using carbon dioxide (CO_2) gas pressure to clean and dry the resected bone surface can significantly deepen cement penetration into the cancellous bone, as compared with using pulsatile saline lavage[5]. The additional depth of cement penetration may enhance bone-cement interface strength, thereby causing increased implant longevity.

At present, available instruments to clean and dry the resected bone surface are prohibitively expensive, because they have to be imported from abroad. Any device that can improve long-term procedure success rates and that can also reduce costs will deliver added value to both patients and physicians. A reduction in orders for expensive instruments from abroad, like those described here, could save Siriraj Hospital at least 3,500,000 baht per year. The aim of this study was to determine the effectiveness and verify the sterility of innovative pressurized carbon dioxide lavage for preparation of bone surface in cemented total knee arthroplasty.

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Material and Method

Material

The innovative pressurized carbon dioxide lavage instrument consists of the following:

A) Standard carbon dioxide cylinders with a pressure regulator, which has a 25-kilogram capacity

with pressure of 800 pounds per square inch (psi). The pressure regulator controls carbon dioxide gas, which flows from the tank at a pressure of 50 psi (Fig. 1). This pressure is acceptable for its medical purpose (50-55 psi). The resulting flow rate is 25 liters per minute (LPM).

B) A flexible stainless steel carbon dioxide delivery tube that is 8 millimeters in diameter and 2 meters in length, which has a connector to attach it to both the pressure regulator of the carbon dioxide tank and a reusable sterile hand piece. The lowest temperature resistance of the delivery tube is -200°C and the highest is 600°C. The tube can be cleaned at temperatures not exceeding 600°C.

C) A reusable sterile hand piece, which has a high-quality, gun-shaped, finger activated sprinkler to control gas flow.

D) A microbial air filter (Covidien®), which is fixed at the end of sprinkler to assure the sterility of the CO_2 gas (Fig. 2). It has the potential to filter more than 99.99% of bacteria and viruses[6] by electrostatic filters made of a hydrophobic non-woven polypropylene material. The mechanism of electrostatic filtration can be likened to magnetism with opposites attracting each other. Each fiber has a bipolar charge, positive on one side and negative on the other. Bacteria and viruses, which have a superficial electrical charge, are attracted to oppositely charged sites on the fibers and trapped within the filter membrane. Filters of this variety are normally used in anesthesiology to prevent infection through the intubation tube.

All instruments were sterilized using sterile technique procedures according to medical standards for sterilization.

Fig. 1 Pressure regulator.

Fig. 2 Reusable sterile hand piece and microbial air filter at the end of the sprinkler.

Fig. 3 Microbial air sampler and active air samplings in biological safety cabinet.

Material and Method

First, the sterile stainless steel CO_2 delivery tube and hand piece were cleaned by sterile technique procedure, according to standard sterilization methods for surgical instruments. Next, gas from the CO_2 tank was delivered through the pressure regulator, which was set to control gas pressure at a level of 50 psi, in accordance with the medical standard. CO_2 gas was then delivered through the sterile stainless steel CO_2 delivery tube, the sterile hand piece, and the microbial air filter. All active air samplings, the collection of CO_2 gas from the innovative pressurized CO_2 lavage instrument, were taken by using a microbial air sampler (AES Chemunex®). The suction volume was set to 500 L. per sample in a biological safety cabinet (Purifier®), located at the Department of Microbiology, Faculty of Medicine Siriraj Hospital (Fig. 3).

Laboratory methods

Contamination results of aerobic bacteria, anaerobic bacteria, and fungi were ascertained using Tryptic Soy Agar plates and Sabouraud Agar, according to standard techniques[7]. Tryptic Soy Agar has the potential to culture a wide variety of microorganisms,

including anaerobic and aerobic bacteria. These plates were incubated at an average temperature of 35±2°C for 48 hours. Sabouraud Agar has the potential to culture fungi. These plates were incubated at an average temperature of 30°C for 10 days. These two types of agar are generally acceptable and widely used in scientific studies. All research activities relating to this study were performed at the Department of Microbiology, Faculty of Medicine Siriraj Hospital, which has Hospital Accreditation (HA) in accordance with ISO 15189: 2007 for clinical specimens.

Data collection

For active sampling, 25 samples of CO_2 gas from the innovative pressurized CO_2 lavage instrument were collected at a volume of 500 L. per sample, consistent with standard laboratory testing procedures for gas verification and similar to methods used in previous studies. All specimens were evaluated for microbial contamination.

Data analysis

Specimens collected in Tryptic Soy Agar were evaluated at 48 hours, while those collected in Sabouraud Agar were evaluated at 10 days.

Results

The number of active air samplings for bacteria and fungi were 25 for each. The volume of CO_2 gas collected was 500 L. per sample. The sample was collected through the agar by the microbial air sampler in the biological safety cabinet. All samples of microbial culture showed no growth of either bacteria or fungi on either Tryptic Soy Agar or Sabouraud Agar at 48 hours and 10 days, respectively.

Discussion

Aseptic loosening of components remains a major cause of failure in total knee arthroplasty[8]. Micro-motion at the cement-bone interface can add to the generation of wear particles. From the findings of previous studies, better cement penetration increases the tensile and shear strength between cement and bone[9]. In addition, cement mantle integrity also provides resistance to osteolysis after knee arthroplasty[10]. Inappropriate cementation techniques play a significant role in the incidence of radiolucent lines at the bone-cement interface, which can be an indicator of aseptic loosening after total knee arthroplasty.

To improve cement penetration into interstice of cancellous bone, a good technique for bone surface preparation is required to achieve a clean and dry interface before cementation[4]. Pressurized carbon dioxide lavage appears to be a sound and effective technique.

Conclusion

The present study demonstrated that an instrument composed of a carbon dioxide tank, a pressure regulator, a sterile carbon dioxide delivery tube, a sterile hand piece, and an antimicrobial air filter with high efficiency in filtering bacteria and viruses at the end of the system produced an aseptic flow of carbon dioxide. The results of laboratory testing showed no evidence of contamination. This instrument can, therefore, be applied safely in clinical practice. In addition, the sterile hand piece and the stainless steel carbon dioxide delivery tube are reusable, which may contribute to reducing operational costs.

Potential conflicts of interest

None.

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การตรวจสอบสภาพปลอดเชื้อของนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์สำหรับเตรียมพื้นผิวกระดูกก่อนการใส่ซีเมนต์ในการผ่าตัดเปลี่ยนข้อเข่าเทียม

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วัตถุประสงค์: *เพื่อตรวจสอบสภาพปลอดเชื้อของนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์สำหรับเตรียมพื้นผิวกระดูกก่อนการใส่ซีเมนต์ในการผ่าตัดเปลี่ยนข้อเข่าเทียม*

วัสดุและวิธีการ: *ตัวอย่างก๊าซจากนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์จำนวน 25 หน่วยทดสอบถูกนำไปเพาะเชื้อแบคทีเรียและเชื้อราผ่าน microbial air sampler ภายใต้ห้องสุญญากาศโดยใช้ก๊าซปริมาตร 500 ลิตรต่อ 1 หน่วยทดสอบ ก๊าซคาร์บอนไดออกไซด์จะถูกลำเลียงผ่านเครื่องควบคุมความดัน ท่อส่งก๊าซ ปืนฉีดก๊าซ และตัวกรองอากาศปลอดเชื้อโดยความดันของก๊าซได้ถูกควบคุมให้อยู่ที่ระดับ 50 psi ตามมาตรฐานทางการแพทย์ ประเมินผลการเพาะเชื้อแบคทีเรียและเชื้อราโดย Tryptic Soy Agar และ Sabouraud Agar ที่เวลา 48 ชั่วโมงและ 10 วันตามลำดับ*

ผลการศึกษา: *ไม่พบสภาวะปนเปื้อนของแบคทีเรียและเชื้อราจากการเก็บตัวอย่างอากาศไปเพาะเชื้อทั้ง 25 หน่วยทดสอบ*

สรุป: *ก๊าซจากนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์ได้รับการตรวจสอบสภาวะความปลอดเชื้อ โดยวิธีการมาตรฐานในห้องปฏิบัติการสามารถนำไปใช้เพื่อเตรียมพื้นผิวกระดูกก่อนการใส่ซีเมนต์ในการผ่าตัดเปลี่ยนข้อเข่าเทียมอย่างปลอดภัย*