Ramathibodi Instill-Soak-Suction System (RISS System) for Negative Pressure Wound Therapy with Instillation

Preedee Saeheng MD*, Chalermpong Chatdokmaiprai MD*

** Division of Plastic and Maxillofacial Surgery, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand*

Background: *Negative pressure wound therapy with instillation combines sub-atmospheric pressure with a topical irrigation solution. The antiseptic solution is delivered to the wound, soaked for a period of time, and negative pressure is applied to cleanse the wound. Cycles are then repeated. It has been reported as a novel effective adjunctive wound treatment for infected or contaminated wound with positive clinical outcomes. The commercial device has not been available in Thailand.*

Objective: *The present study is to evaluating safety and effectiveness of the system, instillation soaking and suction in wound therapy. In addition, previous the study also the information in clinical use.*

Material and Method: *An automatic device for controlling cycles of negative pressure wound therapy with instillation was designed and built. The Ramathibodi Instill-Soak-Suction system (RISS system) was created by using the device with basic hospital supplies. The system was tested with multiple artificial wound models to confirm safety and consistent function. Then it was applied to two patients who had positive aerobic culture traumatic wound. The data collected from the patients were reported.*

Results: *RISS system tested with the wound models could work properly throughout seven days of trial period without any mechanical failure. The good distribution of instillation solution was seen over the surface of artificial wound models. The clinical use in two patients with colonized traumatic wounds showed improvement of aerobic culture from wound beds and reduction in wound sizes with no complications caused by the device or system failure.*

Conclusion: *We invented a reliable automatic device and developed the RISS system that can provide negative pressure wound therapy with instillation as an adjunct local wound therapy. The preliminary use in two clinical cases showed improvement of aerobic culture results and reduction in wound surface area.*

Keywords: *Negative pressure wound therapy*

J Med Assoc Thai 2017; 100 (Suppl. 9): S25-S31
Full text. e-Journal: *http://www.jmatonline.com*

Negative pressure wound therapy (NPWT) or vacuum-assisted closure is being used to effectively treat a spectrum of wounds worldwide for decades[1-5]. However, the recommendation is to avoid using in contaminated or infected wounds[6]. NPWT with instillation combines sub-atmospheric pressure with a topical irrigation solution. It has been developed to be used for these types of wounds[7,8]. The cycles consist of three phases; (1) instillation, topical wound treatment solution is delivered to wound bed, (2) soak, the solution is held in the wound bed for a period of time, and (3) NPWT, the solution, wound exudates, and infectious materials are removed as negative pressure is delivered. Then the cycles are repeated[9]. The instilled solutions enhance wound fluid viscosity then exudates, infectious materials, and wound debris are cleansed from the wound during NPWT[10,11].

The appropriate instillation solutions that can be used are Lavasept, Prontosan and Microsyn/dermacin[12]. Duration of each phase, volume of instillation and duration of therapy varies. Furthermore, this also varies between studies[13].

Much of the literature reported NPWT with instillation as a novel effective adjunctive treatment of a wide variety of wounds[6,13-18]. In consensus document by expert panel, NPWT with instillation can be used in acutely and chronically infected wounds, contaminated wounds, diabetic wounds, traumatic wounds, decubitus wounds, wounds with exposed bone, wounds with underlying osteomyelitis, infected wounds in the presence of orthopedic hardware or joint implants, or wounds that are a bridge between staged/delayed amputation[13]. It has been reported to reduce time to

Correspondence to:
Chatdokmaiprai C, Division of Plastic and Maxillofacial Surgery, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, 270 Rama 6 Road, Ratchathewi, Bangkok 10400, Thailand.
Phone: +66-2-2011527 ext. 242, Fax: +66-2-2011316
E-mail: cjod@hotmail.com

wound closure, length of hospital stays, culture improvement, reduce number of operative visits, increase percentage of wound closure before discharge[12], clinical infection cleared[16], reduce rate of amputation[15], and reduce recurrence of infection[6].

Commercially NPWT devices with instillation are made available with pad, tube set, and foam dressing but the daily cost of use is quite high (about $194.80/day)[19]. These devices are not available in Thailand.

Objective

The first objective of this study is to invent the automatic device controlling cycles of instillation of topical irrigation solution, soak, and suction.

The other objective is to create RISS system that combines the invented device with basic supplies in hospital, such as gauze dressing, nasogastric tube, infusion catheter set, Ioban, canister and wall suction to provide NPWT with instillation as adjunctive treatment for patient with contaminated or infected wound in Ramathibodi Hospital.

Material and Method

The device for controlling cycles of NPWT with instillation was designed. It was invented by medical instrument technician and maintenance crew of Ramathibodi Hospital.

The device is designed as an acrylic box (Fig. 1) containing 220V AC to 12 V DC voltage transformer.

Motor with relay: to control occlusion arm that compress infusion set catheter externally to control fluid flow in instillation phase.

Solenoid valve: to control negative pressure phase from negative pressure generator by open/close valve.

Timer circuit kits: to control time in each phase of cycles and displays the count of seconds, minutes, hours on front LED. Instill, soak, and negative pressure time can be programmed from 1 second to 99 hours by separate buttons. The cycle will repeat automatically.

The approximate cost of the device is 6,500 baht.

The RISS system (Fig. 2) consists of the invented device connected to the instillation solutions drip via infusion set connected with nasogastric tube No. 14 to the wound bed. The infusion set is placed in a rack that is controlled by the motor with an occlusion external arm (keep the solution in sterile condition). Another nasogastric tube is placed on the wound bed to drain the fluid and exudates after soak time to 1.5 liter CRD or the canister that is connected to the device and wall suction as a negative pressure generator. The negative pressure duration is controlled by a solenoid valve. Gauze dressing is applied at wound defect and sealed with Ioban as conventional NPWT in Ramathibodi Hospital (Fig. 3).

The RISS system was tested and evaluated using six artificial wound models created by stucco (Fig. 4). The artificial wound models consisted of shallow wound, deep wound, wound with tunnel, and wound with undermining edge. They were used to confirm that the system can work properly, timers function normally, the fluid can be distributed all over the wound surface and cavity, and detect any mechanical problems such as leakage, failure of dressings, temperature, and noise. Temperature was measured by digital

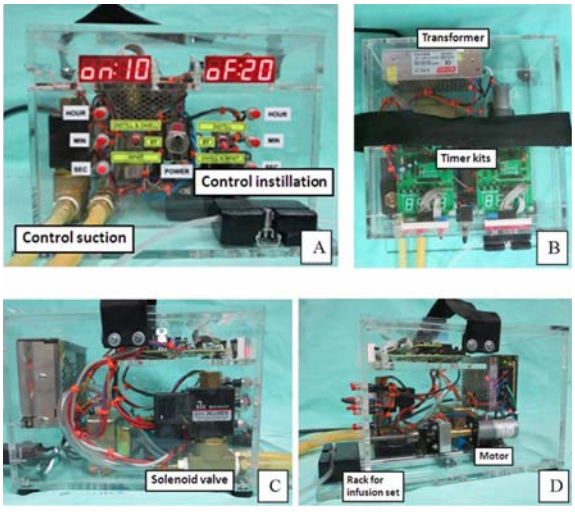

Fig. 1 A-B) Front view and superior view of the device. C) Lateral view shows the solenoid valve. D) Lateral view shows motor control occlusion arm.

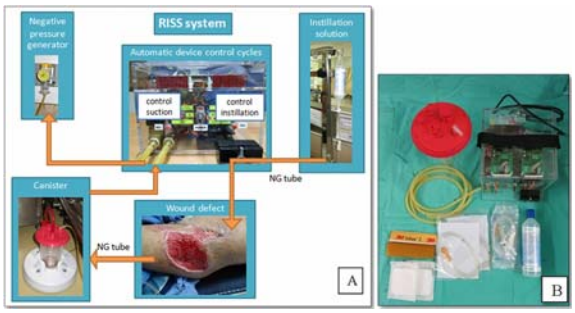

Fig. 2 A) Diagram of the RISS system. B) Supplies for the RISS system.

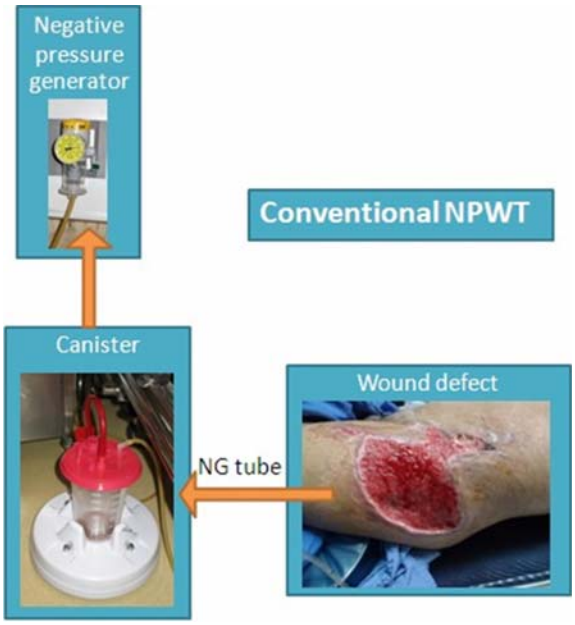

Fig. 3 Diagram of conventional NPWT.

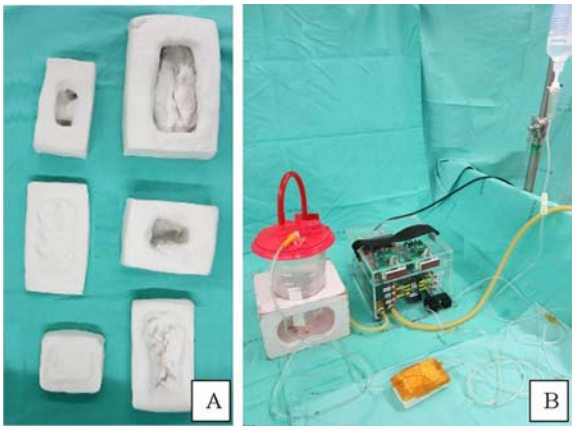

Fig. 4 A) Artificial wound models. (B) Wound models with RISS system.

thermometer during the trial period.

Protocol for test the RISS system with wound models was using tap water as test fluid, instill time was duration until the dressing was fully soaked, soak time was six minutes, negative pressure (-125 mmHg) time was three hours thirty minutes. The trial was continued for seven days with water replacement when depleted.

After testing the RISS system with the wound models, the clinical use in patients who had positive aerobic culture from wound bed was conducted. Because the set-up is not the portable, it needs wall suction to create negative pressure, the patients that have limit activities only on bed during the period of study were selected. All patients provided written informed consent before participation. Protocol for clinical use was similar to wound model, except Prontosan® (polyhexanide plus 0.1% betaine; B. Braun, Inc.) 350 ml was used as instillation solution. The dressing was changed every three days and continued for seven days. The surface areas of wounds were calculated by photography based method using OAWA program in smartphone with a reference frame. Aerobic culture was obtained from wound bed before and after use of RISS system. The patients were followed-up until final wound closure.

The project has been reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital Mahidol University, based on the Declaration of Helsinki.

Results

RISS system tested with artificial wound models could work properly throughout the trial period for seven days without any mechanical failure (Fig. 5). Neither leakage of irrigation fluid nor loss of negative pressure during the NPWT phase was detected. Low noise was created. Temperature of the device was 27 to 31 degrees Celsius. The distribution of instillation solution, seen on wet area at base of wound models, revealed that nearly all of the surface contacted with gauze dressing and can be soaked with instillation fluid during repeated cycles of instillation (Fig. 6).

The following cases show the preliminary experience using RISS system on patients with contaminated traumatic wounds.

Case 1

A 48-year-old man presented with pelvic fracture, avulsion wound at left hip, and nearly amputated right leg after he was hit by a minibus. Percutaneous screw fixation and above knee amputation of right leg was performed after two debridement operations and subsequent dressings of the avulsion wound at left hip with NPWT for a period of time. Moderate Proteus mirabilis and few Acinetobacter baumannii were isolated (105 CFU/g tissue). The patient showed no systemic signs of infection. The RISS system was applied for local adjunctive wound management as protocol and carried out for seven days. The initial wound surface area was 131.18 cm^2. There

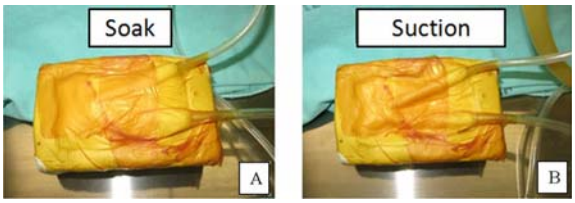

Fig. 5 A) Wound model in soak phase. B) Wound model in suction phase.

Fig. 6 Good distribution of instillation solution on wound models.

were neither leakage nor failure of the dressings, so the dressings can be changed as planned every three days. Follow-up aerobic culture showed few Proteus mirabilis (<103 CFU/g tissue). The wound was more shallow and wound surface area at seven days after using RISS system was 123.16 cm^2. The wound defect was completely healed by Split-thickness skin graft (STSG) coverage (Fig. 7).

Case 2

A 58-year-old man presented with open comminuted fractures at base of the first to fourth left metatarsal bones, proximal and distal phalanges of first toe, cuboid, and navicular bone after his foot was crushed under a crane. Debridement and K-wire fixation and external fixator was applied. Wound defect was seen at dorsum of left foot after multiple debridement. Few Staphylococcus coagulase-negative was isolated (<103 CFU/g tissue). The RISS system was applied as protocol. Initial wound surface area was 61.9 cm^2. Follow-up aerobic culture showed no bacterial growth. The wound surface area was decreased to 57.7 cm^2. After clearance of bacterial colonization, NPWT was applied until there was no bare tendon exposure. The wound was completely healed by STSG coverage (Fig. 8).

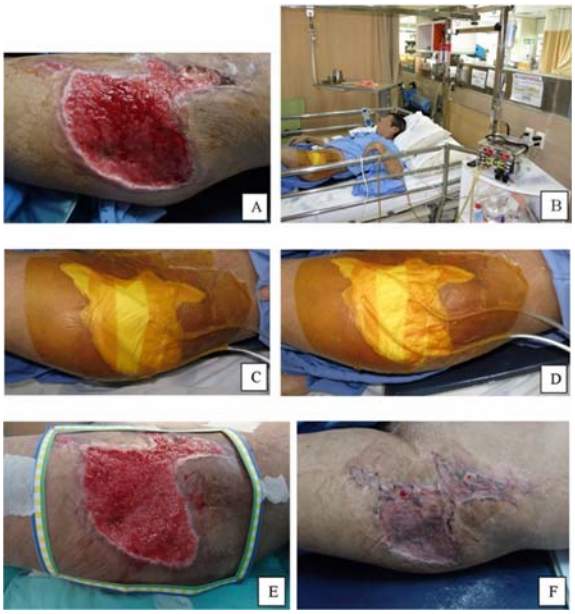

Fig. 7 A) Wound defect at left hip. B) The RISS system was applied. C) Soak phase. D) Suction phase. E) Defect after 7 days. F) After STSG coverage.

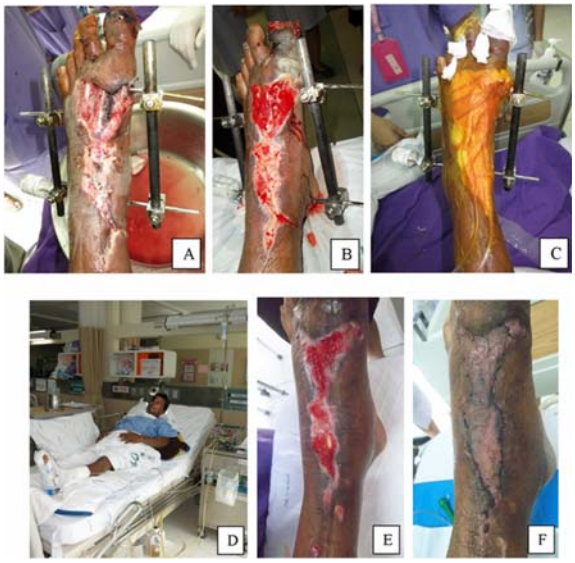

Fig. 8 A) Wound defect at dorsum of left foot with tendon exposure. B) After multiple debridements. C,D) The RISS system was applied. E) Defect before skin grafting. F) After STSG coverage.

Discussion

Successful use of NPWT with instillation was first published by Fleischmann et al[7]. Generations of commercially NPWT devices with instillation have been developed since 2003. The published literature

by many authors supports NPWT with instillation as an option to treat many types of colonized wound, infected wound, and wounds that not responded to conventional NPWT with positive clinical outcomes[6,11,12,15,16,18].

We invented the automatic device and created the RISS system using the concept of NPWT with instillation, which can be applied safely in patient with contaminated or infected wound. The approximate cost of the invented device is 6,500 baht and the basic supplies used in the RISS system are at an affordable price when compared to the commercial one.

Prontosan® (Polyhexanide plus betaine) contains antimicrobial and surfactant, has shown broad spectrum antimicrobial activity and ability of biofilm eradication[20-22]. The protocol used in this study is based on recently published retrospective, cohort, controlled study that reported positive results on hospital stays, time to final surgical procedure, culture improvement, and percentage of wound closure before discharge[12].

In our study, the pilot clinical use of RISS system in two patients with colonized traumatic wound showed improvement of aerobic culture results and reduction in wound size with no complications caused by failure of the device or the set-up.

Limitations of our study are (1) we have no commercial device as a gold standard for NPWT with instillation (VAC Instill® Therapy Unit, VAC VeraFlo™; KCI USA, Inc.) to compare with our invented device and set-up. (2) The invented device and set-up is not a portable design and need wall suction to create negative pressure. Therefore, only the patients that are unable to ambulate during the study period (above knee amputation of right leg in case 1 open fracture s/p external fixation of left foot in case 2) were selected in this study so that the patients had no activity limitation caused by the device and set-up. (3) Distribution of instillation solution was assessed by subjective method.

The favorable preliminary results may warrant further use of the RISS system in patients with various wound type in other subspecialty field such as orthopedic surgery, spine surgery, visceral surgery, thoracic surgery, vascular surgery, or pediatric surgery as reported in the literature[15,16,23-26]. Future prospective comparative trials can be conducted regarding other types of instillation solutions, duration of soak time, and duration of negative pressure. A portable device may be designed for ambulatory and patients with normal daily activity.

Conclusion

We designed the automated motor-solenoid timer device and developed a RISS system that can provide NPWT with instillation as an adjunct local wound therapy. The preliminary use in two clinical cases showed improvement of aerobic culture results and reduction in wound surface area.

What is already known on this topic?

There are many reviews for the benefit of using negative pressure wound therapy with instillation (NPWTi) and dwell time for adjunctive treatment in selected complex wounds.

With the scientific background, wound cleansing by instillation will be combined to negative pressure wound therapy in effective management of wound bed in terms of cleansing, soaking, and removing excessive exudate.

What this study adds?

This study adds simplified automated system of device that can generate cycle of instillation, dwell, and sucking out in specific period of time. The device is made of simple electronic circuit regulating input and output to the wounds and is safe, even after a lengthy use. This automated device is a prototype device that can be used in the indicated wounds and patients.

Acknowledgements

The authors would like to thank Vichai Srimuninnimit MD, Kachin Wattanawong MD, Sukit Laohachareonsombat MD, Noratep Kulachote MD for multidisciplinary care and permission to use the RISS system with their patients. We are grateful to DKSH (Thailand) Limited for providing Prontosan® solution.

Potential conflicts of interest

None.

References

1. Fleischmann W, Strecker W, Bombelli M, Kinzl L. Vacuum sealing as treatment of soft tissue damage in open fractures. Unfallchirurg 1993; 96: 488-92.
2. Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg 1997; 38: 563-76.
3. Armstrong DG, Lavery LA. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled

trial. Lancet 2005; 366: 1704-10.
4. Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg 1997; 38: 553-62.
5. Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg 2003; 17: 645-9.
6. Gabriel A, Shores J, Heinrich C, Baqai W, Kalina S, Sogioka N, et al. Negative pressure wound therapy with instillation: a pilot study describing a new method for treating infected wounds. Int Wound J 2008; 5: 399-413.
7. Fleischmann W, Russ M, Westhauser A, Stampehl M. Vacuum sealing as carrier system for controlled local drug administration in wound infection. Unfallchirurg 1998; 101: 649-54.
8. Jerome D. Advances in negative pressure wound therapy: the VAC instill. J Wound Ostomy Continence Nurs 2007; 34: 191-4.
9. Lessing MC, James RB, Ingram SC. Comparison of the effects of different negative pressure wound therapy modes-continuous, noncontinuous, and with instillation-on porcine excisional wounds. Eplasty 2013; 13: e51.
10. Wolvos T. Wound instillation with negative pressure wound therapy. Ostomy Wound Manage 2005; 51 (2A Suppl): 21S-6S.
11. Brinkert D, Ali M, Naud M, Maire N, Trial C, Teot L. Negative pressure wound therapy with saline instillation: 131 patient case series. Int Wound J 2013; 10 (Suppl 1): 56-60.
12. Kim PJ, Attinger CE, Steinberg JS, Evans KK, Powers KA, Hung RW, et al. The impact of negative-pressure wound therapy with instillation compared with standard negative-pressure wound therapy: a retrospective, historical, cohort, controlled study. Plast Reconstr Surg 2014; 133: 709-16.
13. Kim PJ, Attinger CE, Steinberg JS, Evans KK, Lehner B, Willy C, et al. Negative-pressure wound therapy with instillation: international consensus guidelines. Plast Reconstr Surg 2013; 132: 1569-79.
14. Wolvos T. Wound instillation-the next step in negative pressure wound therapy. Lessons learned from initial experiences. Ostomy Wound Manage 2004; 50: 56-66.
15. Timmers MS, Graafland N, Bernards AT, Nelissen RG, van Dissel JT, Jukema GN. Negative pressure wound treatment with polyvinyl alcohol foam and polyhexanide antiseptic solution instillation in posttraumatic osteomyelitis. Wound Repair Regen 2009; 17: 278-86.
16. Raad W, Lantis JC, Tyrie L, Gendics C, Todd G. Vacuum-assisted closure instill as a method of sterilizing massive venous stasis wounds prior to split thickness skin graft placement. Int Wound J 2010; 7: 81-5.
17. Lehner B, Fleischmann W, Becker R, Jukema GN. First experiences with negative pressure wound therapy and instillation in the treatment of infected orthopaedic implants: a clinical observational study. Int Orthop 2011; 35: 1415-20.
18. V.A.C. instill therapy - indications and technical applications. Abstracts of the First V.A.C. Instill Symposium. Heidelberg, Germany. November 21, 2008. Infection 2010; 37 (Suppl 1): 3-45.
19. Gabriel A, Kahn K, Karmy-Jones R. Use of negative pressure wound therapy with automated, volumetric instillation for the treatment of extremity and trunk wounds: clinical outcomes and potential cost-effectiveness. Eplasty 2014; 14: e41.
20. Sibbald RG, Coutts P, Woo KY. Reduction of bacterial burden and pain in chronic wounds using a new polyhexamethylene biguanide antimicrobial foam dressing-clinical trial results. Adv Skin Wound Care 2011; 24: 78-84.
21. Minnich KE, Stolarick R, Wilkins RG, Chilson G, Pritt SL, Unverdorben M. The effect of a wound care solution containing polyhexanide and betaine on bacterial counts: results of an in vitro study. Ostomy Wound Manage 2012; 58: 32-6.
22. Romanelli M, Dini V, Barbanera S, Bertone MS. Evaluation of the efficacy and tolerability of a solution containing propyl betaine and polihexanide for wound irrigation. Skin Pharmacol Physiol 2010; 23 (Suppl): 41-4.
23. Lehner B, Bernd L. V.A.C.-instill therapy in periprosthetic infection of hip and knee arthroplasty. Zentralbl Chir 2006; 131 (Suppl 1): S160-4.
24. D'Hondt M, D'Haeninck A, Dedrye L, Penninckx F, Aerts R. Can vacuum-assisted closure and instillation therapy (VAC-Instill therapy) play a role in the treatment of the infected open abdomen? Tech Coloproctol 2011; 15: 75-7.
25. Hofmann HS, Neu R, Potzger T, Schemm R, Grosser C, Szoke T, et al. Minimally invasive vacuum-assisted closure therapy with instillation (Mini-VAC-Instill) for pleural empyema. Surg Innov 2015;

22: 235-9.
26. Schreiner W, Oster O, Stapel P, Sirbu H. V. A. C. INSTILL(R) therapy - new option in septic thoracic surgery. Zentralbl Chir 2013; 138: 117-20.

ระบบ Instill-Soak-Suction (RISS system) สำหรับการรักษาแผลแบบสุญญากาศร่วมกับการหยอดสารละลาย

ปรีดี แซ่เฮ้ง, เฉลิมพงษ์ ฉัตรดอกไม้ไพร

ภูมิหลัง: *รายงานของการรักษาแผลแบบสุญญากาศร่วมกับการหยอดสารละลายโดยมีวงจรคือ การหยอดสารละลายที่มีฤทธิ์ฆ่าเชื้อโรคสู่บาดแผลและแช่ไว้ในระยะเวลาหนึ่งตามด้วยสุญญากาศที่จะดูดสารละลายและน้ำคัดหลั่งออก เป็นการทำให้บาดแผลสะอาดขึ้น เพียงแต่ในประเทศไทยยังคงขาดวัสดุที่มีการตั้งวงจรดังกล่าวในรูปแบบเชิงพาณิชย์จึงยังไม่มีการนำมาใช้*

วัตถุประสงค์: *เป็นการศึกษาและประเมินความปลอดภัย ประสิทธิภาพของระบบการรักษาแผลแบบสุญญากาศร่วมกับการหยอดสารละลาย โดยมีวงจรคือการหยอดสารละลายแช่ทิ้งไว้ และดูดออกด้วยแรงสุญญากาศ และยังต้องมีข้อมูลการนำอุปกรณ์ระบบนี้ไปใช้จริงทางคลินิก*

วัสดุและวิธีการ: *อุปกรณ์อัตโนมัติที่ควบคุมวงจรการรักษาแผลแบบสุญญากาศได้รับการออกแบบและสร้างขึ้น โดยใช้ชื่อว่า ระบบ Instill-Soak-Suction (RISS system) โดยใช้อุปกรณ์พื้นฐานที่สามารถหาได้ในโรงพยาบาลทั่วไปและได้รับการทดสอบกับบาดแผลเทียม เพื่อให้เกิดความมั่นใจว่า มีความปลอดภัยในระบบไฟฟ้าและมีความแม่นยำในการทำงานทั้งการหยอดสารละลายแช่ไว้และดูดสารละลายออก จึงได้นำไปทดลองใช้ในผู้ป่วยที่มีแผลอุบัติเหตุและมีการเพาะเชื้อแบคทีเรียชนิด aerobic ให้ผลบวกจำนวน 2 ราย*

ผลการศึกษา: *หลังการทดลองใช้พบว่าระบบ RISS system มีความเสถียรในการทำงานตลอด 7 วันติดต่อกันโดยไม่มีข้อผิดพลาด พบการกระจายของสารละลายบนพื้นผิวบาดแผลเทียมได้อย่างทั่วถึง เช่นเดียวกับ การนำมาทดลองใช้ในผู้ป่วยที่มีบาดแผล 2 คน แสดงให้เป็นการลดลงของปริมาณเชื้อแบคทีเรีย aerobic ที่ได้จากการเพาะเชื้อบาดแผลมีขนาดลดลงและไม่มีภาวะแทรกซ้อนใด ๆ เกิดขึ้นจากอุปกรณ์*

สรุป: *RISS system ที่ได้รับการสร้างขึ้น เป็นทางเลือกที่ใช้ทำความสะอาดบาดแผล จากการหยอดสารละลายแช่ไว้และดูดออกตามเวลาและช่วยทำให้จำนวนเชื้อแบคทีเรียจากบาดแผล และขนาดของบาดแผลลดลง จึงเป็นทางเลือกสำหรับบาดแผลที่มีการติดเชื้อ*
