[redacted] **HYDROSURGERY SYSTEM**

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DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

EXECUTIVE SUMMARY

Introduction

Wound bed preparation (wound debridement) is the process of managing a wound to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures. A wound bed may be prepared by various non-surgical debridement techniques such as autolytic debridement facilitated by interactive dressings, larval therapy using sterile maggots, and enzymatic debridement with ointments containing papain, urea or collagenase mixture. These are all effective in selective wounds but are time consuming and may be unpredictable.

The [redacted] Hydrosurgery System uses pressurized streams of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The device provides cutting, irrigation and evacuation in the same tool. The stream of fluid simultaneously washes the tissue surface and removes foreign material from the wound or surgical site, including contamination and infected as well as necrotic tissue from the wound. The fluid acts to ablate the surface of the tissue and propel excised tissue and debris out of the surgical site. The debris and fluid are directed immediately within the instrument into a flexible tube, which carries the effluent to the drain or a collection canister.

Objective/Aim

The objective of this technology review was to assess the safety, effectiveness and cost-effectiveness of [redacted] Hydrosurgery System for wound debridement.

Results and Conclusions

There was limited but fair to good level of evidence to show that Versajet™ Hydrosurgery System for wound debridement was safe and effective. The device has a 510(k) approval by the United State Food & Drug Administration (USFDA) and CE mark in 2006.

There was no retrievable evidence to show the cost-effectiveness of Versajet™ Hydrosurgery System for wound debridement. However, there was an article on potential cost saving associated with this device. Versajet consoles and single use hand-units cost £[redacted] to £[redacted] and £[redacted] to £[redacted] respectively.

Methods

Electronic databases were searched, which included PubMed, Medline, Journal @ Ovid full text via OVID, OVID EBM Reviews - Cochrane central register of controlled trials, EBM Reviews - Cochrane database of systematic review, Horizon scanning databases - Centre, Birmingham, Australia and New Zealand Horizon scanning (ANZHSN), FDA website, MHRA website and from non scientific database - Google search engine. In

addition, a cross-referencing of the articles retrieved was also carried out accordingly to the topic. Relevant articles were critically appraised and evidence graded using US / Canadian Preventive Services Task Force.

[redacted] HYDROSURGERY SYSTEM

1.0 INTRODUCTION

Wound bed preparation (wound debridement) is the process of managing a wound to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures. A wound bed may be prepared by various non-surgical debridement techniques such as autolytic debridement facilitated by interactive dressings, larval therapy using sterile maggots, and enzymatic debridement with ointments containing papain, urea or collagenase mixture. These are all effective in selective wounds but are time consuming and may be unpredictable.[1]

Physical debridement uses whirlpool treatments to slough off necrotic tissues from the wound. Surgical debridement may create a very clean wound but it is not selective. Hydrosurgery ([redacted] combines both physical and surgical debridement techniques. It creates a Venturi effect that selectively removes the necrotic tissues. It is claimed to minimise the amount of normal tissue that is accidentally removed by surgery and, in most cases, the wound bed is ready for immediate skin grafting.[1]

This technology review was conducted following a request from the Senior Principle Assistant Director of Surgery and Emergency Unit, Medical Development Division, Ministry of Health Malaysia following the proposal to introduce this technology to Ministry of Health facilities.

2.0 OBJECTIVE/AIM

The objective of this technology review was to assess the safety, effectiveness and cost-effectiveness [redacted]™ Hydrosurgery System for wound debridement.

3.0 TECHNICAL FEATURES

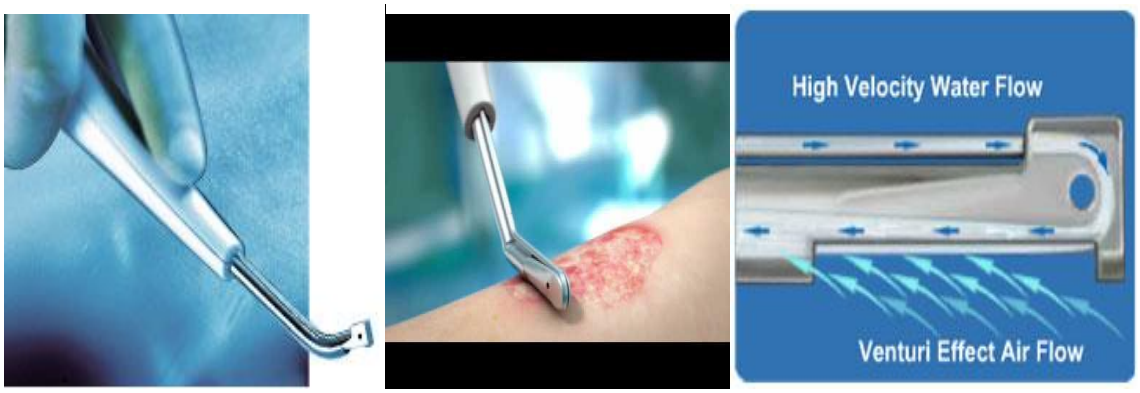

Figure 1: The handpiece and Venturi effect

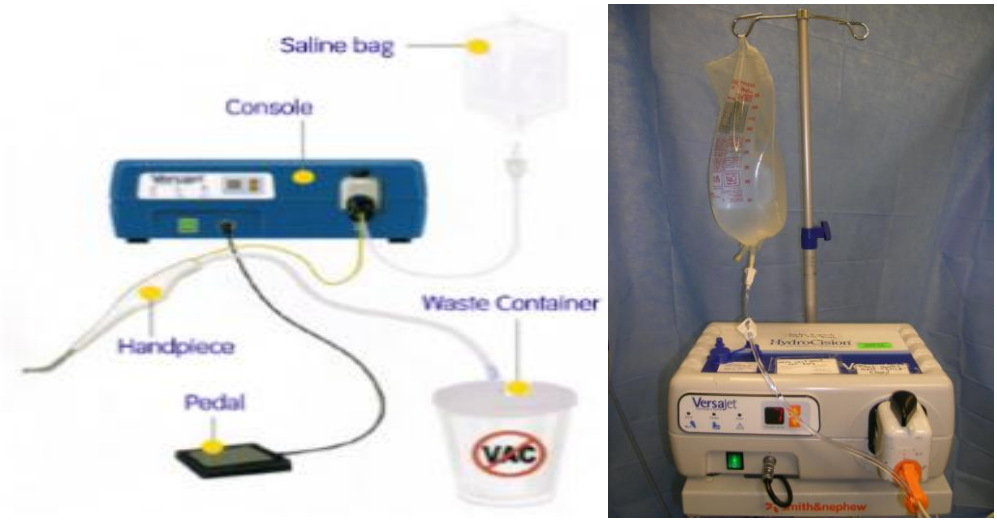

Figure 2: The Versajet components

The [redacted]™ Hydrosurgery System developed by the [redacted] has been brought into clinical use [redacted], Hull, England. The system consists of five components: [2]

1. Handpiece which is a sterile, disposable unit that can be used to debride and clean wounds
2. Power console which creates the fluid jet that enables the handpiece to work
3. A pedal switch which allows single-handed usage
4. A saline bag
5. Waste container

Mechanism of action: [2]

i. The unit is activated by using the pedal
ii. Sterile saline flows through low-pressure tubing to the power console where it is pressurised
iii. Pressurised saline is forced under very high pressure through a tiny jet nozzle at the end of the handpiece, producing a high velocity stream, and creating a vacuum
iv. This saline stream is directed backwards across the operating window and into the evacuation collector tube in the handpiece, which also collects any debris or contaminants created by the procedure
v. The saline and debris are collected in a waste container

The [redacted]™ Hydrosurgery System uses pressurized streams of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The device provides cutting, irrigation and evacuation in the same tool. The stream of fluid simultaneously washes the tissue surface and removes foreign material from the wound or surgical site, including contamination and infected as well as necrotic tissue from the wound. The fluid acts to ablate the surface of the tissue and propel excised tissue and debris out of the surgical site. The debris and fluid are directed immediately within the instrument into a flexible tube, which carries the effluent to the drain or a collection canister.[3]

4.0 METHODOLOGY

4.1. Searching

Scientific databases such as PubMed, Medline, OVID EBM Reviews - Cochrane central register of controlled trials, EBM Reviews - Cochrane database of systematic review, EBM Reviews - HTA databases, Horizon scanning databases - Centre, Birmingham, Australia and New Zealand Horizon scanning (ANZHSN), FDA website, MHRA website and from non scientific database - Google search engine were searched for evidence of safety, effectiveness and cost-effectiveness of [redacted]™ Hydrosurgery System for wound debridement.

The following keywords were used either singly or in combinations: [redacted] hydrosurgery, debridement, wound, burn, waterjet, cost*, safe*, adverse event.

4.2. Selection

All published articles related to safety, effectiveness and cost-effectiveness of [redacted] Hydrosurgery System were included. Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and evidence was graded according to US/Canadian Preventive Services Task Force (Appendix 1).

5.0 RESULTS AND DISCUSSION

The search strategies yielded an article on the United State Food & Drug Administration (USFDA) related to [redacted] Hydrosurgery System. There were four articles related to both safety and effectiveness and two articles related to only the effectiveness of this technology. There was only an article on potential cost saving associated with this device.

5.1 Safety

The [redacted]™ Hydrosurgery System is cleared for marketing by the USFDA in 2006 for wound debridement, soft tissue debridement and cleansing of the surgical site; and received CE mark for removing tissue and material from wounds in various surgical procedures, including wound debridement.[3]

Gravante G *et al*. 2007 conducted a randomised controlled trial (RCT) study to compare the [redacted] system ([redacted]) versus hand-held dermatome escharectomy for burn debridement involving 87 patients. The end points were the assessment of postoperative pain (evaluated with the visual analog scale), adverse effects, complete healing times, and contractures rate (after 6 months) using both device. The study showed that there was no significant difference for postoperative pain were reported. No patient reported a thermal effect with the [redacted] procedure. The authors concluded that Versajet is a safe technique.[4 Level I]

A randomised controlled clinical trial in 41 patients comparing hydrosurgery debridement with conventional surgical debridement in lower extremity ulcers was conducted in 2008 by Caputo WJ *et al*. The occurrence of any adverse events and whether they were related or unrelated to the Versajet device was recorded. The study demonstrated that five out of 22 (23%) patients in the Versajet group reported serious adverse events, which included amputation of the study leg below the knee

(contributory factor: peripheral vascular disease) and uncontrolled bleeding from study wound. Two out of 19 (10.5%) patients in the conventional group reported three serious adverse events, which included gangrene secondary to severe peripheral vascular disease which involved the study wound.[5 Level I]

Mosti G *et al*. 2005 conducted a controlled trial on 167 patients hospitalised for chronic, hard-to-heal leg ulcers, at the inflammatory phase. Sixty-eight out of 167 (41%) were treated with Versajet. The other 99 (59%) patients were treated only with traditional moist dressings who were considered as the control group. The procedure was performed in the ward at the patient's bedside. The study demonstrated that the pain caused by Versajet was acceptable to the majority of patients by adjusting the power level according to the patient's tolerance, although some form of anaesthesia was given to patients complaining of very painful ulcer. The pain, evaluated using the visual analog scale (VAS) in all the patient was 4.3 ± 1.6. In five out of 68 (7%) patients, the procedure was painful (level 8 in the VAS), despite local anaesthetic infiltration in two of them. No patient reported a thermal effect due to the procedure. The authors concluded that the pain caused by Versajet was well-tolerated by the majority of patients when it was used with the recommended pump speed.[6 Level II-1]

Rennekampff HO *et al*. evaluated the Versajet system used for 17 patients with burn wound areas of between 0.5% and 5% total body surface area (TBSA) involving the face, arm, hand, leg and foot. The study revealed that no complications were observed in this subgroup. There were no post-operative infections or complications.[7 Level II-3]

5.2. Effectiveness

Gravante G *et al*. 2009 conducted a study on 87 patients admitted over the course of one year at the Burn Centre of S. Eugenio Hospital, Rome. All patients were recruited and randomly assigned to Versajet or hand-held dermatome escharectomy for burn debridement. They evaluated the time for complete debridment and the efficacy of Versajet in reaching the correct dermal plane. Forty-two patients (48.3%) were treated with the Versajet system and 45 (51.7%) with classic escharectomy. There were 50 men (57.5%) and 37 women (42.5%) and the mean age was 48 years (±17 years SD). The study showed that an adequately debrided wound bed was achieved in all patients with both techniques. Fifty-nine out of 87 (68%) patients needed only one operative procedure, 20 out of 87 (23%) patients required two steps and 8 out of 87 (9%) patients required three steps because of a large TBSA. Considering operative times, the Versajet system had similar results to the classic hand-held dermatome. However, when the analysis was restricted to areas that required extra-attention (ie, hands, face, genitals), the Versajet system was shorter (13 ± 7, P=0.02), whereas when restricted to large areas (trunk, arms, legs) it was longer (21 ± 5, P=0.01). The authors concluded that Versajet ia a feasible, simple, and safe technique that hastens surgical debridment of burns and adds more precision to the procedure.[4 Level I]

Caputo WJ *et al*. 2008 conducted a study comparing Versajet with conventional surgical techniques in the debridement of lower extremity ulcers in 41 patients with mean age of 68 years (range 33 to 95 years) to assess the impact on time and resources for debridement. Operating room (OR) sessions were randomised to Versajet (n=22) or conventional debridement with scalpel plus pulsed lavage (n=19). Procedure time and utilisation of consumables were recorded. Wound areas were monitored for 12 weeks. The study revealed that there was significant difference in debridement time (10.8 min) using Versajet compared to conventional debridement

(17.7 min) P<0.008; a mean saving of 6.9 minutes (39%). A significant reduction in the use of pulsed lavage and saline (P<0.001) was observed with Versajet. Overall, clinical efficacy of the shorter debridement procedure was similar: median time to wound closure was 71 days (Versajet) versus 74 days (conventional) (P=0.733).[5 Level I]

Mosti G *et al*. 2005 conducted a study comparing 68 patients with 118 leg ulcers who underwent Versajet debridement and 99 patients with 159 ulcers had moist dressing. They demonstrated that in the majority of Versajet-treated cases 68% had an adequately debrided wound bed with one operative procedure; two and three procedures were required in 25% and 7% patients, respectively. This procedure is quick (the mean time per hydrosurgical procedure was 5.8 ± 3.6 minutes) when compared with a traditional treatment with moist dressing. The average time to obtain the wound bed clean decreased from 6.1 ± 5.2 days in the control group (treated only with moist dressing) to 1.4 ± 0.6 days in the patients treated with Versajet allowing an equivalent reduction in the hospitalisation time. The bacterial burden decreased from 106 to 103 cfu/cm^2 in approximately 42% of patients in the hydrosurgey group. The authors concluded that the Versajet has several advantages over the standard surgical scalpel debridement such as it can be done in the ward, less aggressive and more selective, and also it can prevent the diffusion of microbial contamination deeper into the wound. Versajet also seemed to induce minor bleeding but is less painful.[6 Level II-1]

Rennekampff HO *et al*. evaluated the clinical efficacy of debridement of burn wounds in 17 patients with the Versajet system (face, arm, hand, leg and foot). They reported that superficial partial thickness burn wounds were successfully debrided with a single pass of the Versajet system (pressure setting from 3 to 5). Mid-dermal level burns were also effectively debrided. Higher settings (5 to 7) were needed to obtain complete debridement and several passes were required. These wounds were successfully treated with skin substitute (Biobrane) and healed without sequelae. For deep partial thickness wounds, they reported that multiple passes with setting from 5 to 8 were required to attained complete debridement. Microbiological analysis demonstrated that of the four wounds that had pre-debridement bacterial load, two exhibited no bacterial growth and one demonstrated a reduction of bacterial load post-Versajet debridement. On the other hand, of the three wounds with no pre-debridement bacterial growth, one exhibited growth post-debridement. The authors concluded that the Versajet system demonstrated some particular advantage in the surgical treatment of superficial to mid-partial thickness burns in areas like the face, hand and foot. It also indicated that the Versajet is capable of reducing or clearing bacteria from the wound.[7 Level II-3]

A cross-sectional study conducted by Klein MB *et al*. 2005 utilised the Versajet in 44 patients as an adjunct to Watson and Guilian knives (sharp debridement) or electrocautery for burn excision in a variety of anatomic areas (e.g. eyelids, fingers and web spaces). No patients required repeat grafting as a result of inadequate excision with the Versajet. In addition, no patients experienced graft loss due to excessive tissue excision. The authors concluded that the Versajet is a useful adjunct in burn wound excision and reduces the risk of inadequate debridement and unnecessary damage to critical and fragile anatomic structures. However, it was found not to be suitable for the debridement of large areas due to the small nozzle.[8 Level II-3]

Granick MS *et al*. 2006 retrospectively reviewed 40 patients with 45 wounds whose wounds were debrided with the Versajet system and compared them to 22 control patients with 22 wounds who underwent conventional sharp debridement at

University Hospital, Newark, New Jersey over a 12 month period in 2003. Information was obtained from the hospital medical records and physician charts on patient characteristics, wound characteristics, and details of the debridement procedure. Both treatment groups were comparable with regards to gender, age, admitting diagnosis and wound type. However, the control group had a significantly larger median wound area (p=0.0016). Multiple regression analysis revealed that there was no evidence of statistically significant differences for debridement time after adjusting for patient age and wound area (mean time for pooled sample was 65 minutes). However, the mean number of surgical procedures was significantly less in the Versajet group (p=0.0002), which required 1.18 procedures per wound. In contrast the control patients required 1.91 procedures per wound.[9] Level II-2

5.3. Potential cost saving

From the same study conducted by Granick MS *et al*. 2006, potential cost savings associated with Versajet system was evaluated. Billing records at University Hospital listed all of the resources associated with each patient episode (including individual operative procedures), together with hospital charges. Detailed information was available for 55 separate debridement operations at University Hospital during the study period. Applying the relevant cost-to-charge ratio for 2002/2003, the mean cost per operative procedure was USD $[redacted]. However, a reduction in the mean number of procedures from 1.91 to 1.18 represents a potential net cost saving of USD $[redacted] per patient. The authors concluded that this saving was a result of the reduction in the number of debridement procedures needed per patient.[9] Level II-2

Versajet consoles and single use hand-units cost £6,000 to £7,000 and £220 to £240, respectively. These costs may be offset by the reduced number of procedures, reduce hospital stay and improved wound healing reported by the use of hydrosurgery.[10]

6.0 CONCLUSION

6.1. Safety

There was limited but fair level of evidence to show that [redacted] Hydrosurgery System was safe. The device has a 510(k) approval by the USFDA and CE mark in 2006.

6.2. Effectiveness

There was limited with a range of fair to good level of evidence to suggest the effectiveness of Versajet™ Hydrosurgery System for wound debridement.

6.3. Cost-Effectiveness

There was no retrievable evidence to show the cost-effectiveness of Versajet™ Hydrosurgery System for wound debridement. However, there was an article on potential cost saving associated with this device.

7.0 REFERENCES

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8.0 APPENDIX

8.1 Appendix 1

DESIGNATION OF LEVELS OF EVIDENCE

I Evidence obtained from at least one properly designed randomized controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)