Dear Colleagues,

In August, HealthPACT held its first meeting to discuss the way forward as a sub-committee of the Clinical, Technical and Ethical Principal Committee (CTEPC). A work plan to be submitted through CTEPC to the Australian Health Ministers’ Advisory Council (AHMAC) will be prepared by the end of the year. HealthPACT will take a more active role in setting priorities for topics and is encouraging jurisdictions to submit topics of interest/importance for consideration. HealthPACT through the Chair will now report directly to CTEPC.

In association with the Victorian Department of Health, a workshop on Health Technology Disinvestment sponsored by Southern Health was held in August. This workshop coincided with the HealthPACT meeting held in Melbourne and some members took the opportunity to attend this workshop. Case studies of health technologies where the literature suggests no benefit compared with other therapies and in some circumstances may result in poorer outcomes were presented. This is a possible area that HealthPACT is considering in a future work plan.

This issue of the newsletter visits or revisits technologies now being trialled in the Australian settings.

1. Ultrasound ablation of uterine fibroids
2. Single incision laparoscopy in cholecystectomy
3. Veno-venous extra corporeal support for patients with respiratory distress – this technology has diffused with the H1N1 influenza season and may have saved many lives.

Professor Brendon Kearney
Chair, HealthPACT
Dynamic wound closure for the treatment of patients with fasciotomy wounds and infected sternal wounds

For most wounds, the normal wound healing process proceeds spontaneously without the need for anything more than conservative management. However, some wounds, particularly large or infected wounds, do not heal spontaneously and require treatment in order to achieve full closure. Dynamic wound closure is a technique that can be used to treat such wounds and to date has been used on infected sternal wounds and fasciotomy wounds.

HOW IT WORKS

The ABRA® Dynamic Wound Closure System is composed of adhesive anchors and elastic silicone cords called elastomers (Price et al. 2007). Anchors are placed on the skin on either side of the wound and, depending on the wound type, attached either with adhesive textile strips or small slits in the surrounding healthy skin. Elastomers are then connected between each pair of anchors and laced across the wound. The elastomers are then tightened every 3 to 4 days, which places constant tension on the tissues, until complete wound closure is achieved. A number of potential advantages of delayed wound closure over conventional methods of wound management have been identified, including versatile and straightforward bedside application, the ability to close large skin defects or defects that exhibit excessive tension, adequate and customised tensile strength, elasticity, and durability over a full range of motion (Taylor et al. 2003).

THE EVIDENCE

Four case series reported on the use of dynamic wound closure for the treatment of decompressive leg fasciotomy wounds. Eligible patients (n=11) were treated in a combat hospital in Iraq and had impending compartment syndrome of the leg or a recent fasciotomy for compartment syndrome of the leg. Successful delayed primary closure of the lateral wound was achieved in 10 of the 11 patients (91%), and none of the patients required a split-thickness skin graft. Wound closure was achieved in an average of 2.6 days (range 2-6 days), with the initial wound size averaging 8 cm (range 7-12 cm). Post-treatment wound size averaged 2.7 cm (range 2-6 cm). One patient subsequently required bilateral above the knee amputation.

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Members of HealthPACT recently toured Melbourne’s Royal Women’s Hospital’s new MRI guided focussed ultrasound (MRgFUS) facility. MRgFUS offers women a non-invasive and uterine conserving option for the treatment of symptomatic uterine fibroids. The treatment involves no incision and no hospitalisation and most women are able to return to normal activity within 1-2 days. MRgFUS was identified by horizon scanning in May 2007 and was a technology of great interest to HealthPACT members. Leasing and recurrent operating costs for the system is partially offset by funding provided by the New Technology Program via the Victorian Department of Health. As of August 2009, a total of 14 treatments have been conducted, with all bar one patient reporting a positive outcome. Currently the Royal is committed to treating Victorian women. Other jurisdictions, however, are watching the results of this trial with interest, especially as the technology may have other applications including the treatment of breast tumours.

Dynamic wound closure for the treatment of patients with fasciotomy wounds and infected sternal wounds

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The largest case series study conducted by Reimer et al (2008) evaluated the use of dynamic wound closure for the management of open abdominal wounds. A total of 23 patients treated for open abdomens that could not be primarily closed more than 7 days after the cause for primary surgical intervention had resolved were included. The primary pathology of the included patients was trauma (n=3), cardiovascular (n=5), gastrointestinal (n=10) and abdominal compartment syndrome (ACS) (n=4). The average time between creation of the open abdomen and application of the device was 18 days. Successful delayed primary closure of wounds was achieved in 14 of the 23 patients (61%). Complete wound closure was achieved in all trauma and ACS patients, 40% of cardiovascular (2/5) and gastrointestinal (4/10) patients. In those patients who achieved successful wound closure, the device was applied for an average of 40 days. In the 9 patients in whom complete wound closure was not achieved, the wound area decreased by an average of 87% during the treatment period. A number of factors were strongly associated with a lower likelihood of wound closure, prolonged treatment with ABRA and gastrointestinal disease. The rate of hernia formation was reported to be 26% (6/23), while the rate of enterocutaneous fistulisation was 9% (2/23).

FUTURE STEPS

It appears that dynamic wound closure is a feasible, potentially effective and cosmetically acceptable treatment for patients with fasciotomy wounds and infected sternal wounds, but the long-term safety and efficacy of this procedure are yet to be established. Considering its ease of use and potential diffusion, HealthPACT have recommended that this technology be monitored for further information in 12-months time.

Written by Prema Thavaneswaran (ASERNIP-S)

REFERENCES

Cholecystectomy, the surgical removal of the gallbladder, is the main treatment for symptomatic gallstones. When surgery is not immediately feasible, small stones may be dissolved through ingestion of bile acid. For critically ill patients, drainage of pus from the gallbladder may be used to stabilise the patient before cholecystectomy is performed (Heuman et al 2006).

**HOW IT WORKS**

Conventional laparoscopic (keyhole) surgery typically uses three or four small incisions to allow the insertion of operating ports through which a camera and instruments are fed (Keus et al 2009). Using the recently developed single-incision laparoscopic cholecystectomy technique the gallbladder is removed through the belly button (umbilicus). This technique aims to provide the benefits of NOTES, such as fewer incisions and less visible scarring, without requiring additional specialist training beyond that required for standard laparoscopic cholecystectomy (Hodgett et al 2009).

**THE EVIDENCE**

One non-randomised prospective comparative study compared single-incision laparoscopic cholecystectomy with conventional multi-port, multi-incision laparoscopic cholecystectomy (Hodgett et al 2009). The most recent case-series, published in the last two years, with the largest patient cohorts (n ≥ 20), were also included in the full HS summary, details of which may be accessed via the HS web site.

Hodgett et al (2009) performed single-incision laparoscopic cholecystectomy on 29 consecutive patients, 76% had chronic cholecystitis. The concurrent comparative group consisted of 28 patients who underwent conventional multi-incision laparoscopic cholecystectomy. Seventy-two percent of patients in this group had chronic cholecystitis. The same surgeon performed all operations for both groups. There were no significant differences between the groups in terms of age, sex, body mass index, or gallbladder pathology. Two patients undergoing LESS cholecystectomy required placement of additional trocars away from the umbilicus to facilitate exposure and none of the patients required conversion to an open operation. The mean operative time was 74 ± 17.3 minutes for the LESS cholecystectomy compared to 71 ± 16.3 minutes for the conventional laparoscopic cholecystectomy (p =0.46). All patients in both groups had less than 100 cc of estimated blood loss. There was no significant difference between the mean length of hospital stay for both groups (1 ± 0.61 vs 1 ± 0.51 days, p=0.81). No biliary injuries or major postoperative complications occurred in any patients. Two patients in the LESS group required extended post-operative stays for pain control, and one patient in the LESS group required catheter insertion for urinary retention. There were no reported complications in the conventional multi-incision laparoscopic cholecystectomy.

**FUTURE STEPS**

There is insufficient comparative evidence currently available to establish any substantial clinical benefits of single-incision laparoscopic cholecystectomy over the conventional laparoscopic technique. Given the fact that a number of new randomised studies are currently being conducted on single-incision laparoscopic cholecystectomy, HealthPACT have recommended that this technique be monitored for further developments and reassessed in 12-months.

**REFERENCES**


The Novalung: Pumpless extracorporeal lung assist system for the provision of pulmonary support to patients suffering from acute respiratory distress syndrome

This technology was first identified by HS in 2006 and has been updated for further information in 2007, 2008 and now 2009. See the HS web site for details.

Acute respiratory distress syndrome (ARDS) is a life threatening breathing dysfunction associated with a variety of conditions including pneumonia, shock, sepsis, trauma, fluid overload, narcotic overdose and burns (Anatomica 2001). ARDS causes both lungs to become inflamed. Often the inflammation is severe, resulting in damage to alveoli and surrounding capillaries that affects their ability to exchange oxygen and carbon dioxide (Ware and Matthay 2000). This leads to fluid leaks from capillaries (oedema), which causes the alveoli to collapse or fill with fluid and further reduces the capacity of the lungs for gaseous exchange. Continued inflammation leads to fibrosis as the lungs attempt to heal themselves (Ware and Matthay 2000). The result is a life threatening condition marked by respiratory failure.

Providing sufficient oxygen to and removing carbon dioxide from the blood of an ARDS patient is a crucial part of treatment.

HOW IT WORKS

Extracorporeal lung assist (ECLA) devices can be used to complement mechanical ventilation and reduce the risk of ventilator-associated lung injury during ARDS treatment. ECLA devices are an invasive alternative that work by establishing either a venovenous or venoarterial shunt comprising a roller or pump, a membrane for gaseous exchange and a heat exchanger to maintain blood temperature (Liebold et al. 2002). However, this technique also has drawbacks. In particular, the significant blood trauma caused by ECLA devices can lead to haemolysis and coagulation disorders.

In an attempt to overcome many of the limitations of conventional pump driven ECLA devices, the pumpless extracorporeal interventional lung assist (iLA) device was developed. The iLA acts as an extra-pulmonary gas exchange system that uses the patient’s arteriovenous pressure gradient as the driving force for the extracorporeal circuit, thus eliminating the need for a pump (Liebold et al. 2002; Zimmermann et al. 2006)

The system is implanted by inserting cannulae into the femoral artery and femoral vein. These are connected to the membrane apparatus and blood allowed to flow from the artery, through the apparatus and then into the venous cannula (Zimmermann et al. 2006). An oxygen supply line is connected to the membrane apparatus to provide oxygen for gaseous exchange, and a bidirectional ultrasound sensor is attached to the venous cannula to monitor volumetric blood flow. The iLA system is easy to handle and does not require continuous support from technical staff. Once implanted the entire system can be placed anywhere that is convenient but this is most often between the patient’s legs.

THE EVIDENCE

Three case series were identified for inclusion in this HS update of Novalung. Only the results from the largest case series is reported here. Results of the other two case series may be found in the full summary found on the HS web site.

Effectiveness

Florchinger et al (2008) reported their 10 year experience using the iLA device in patients suffering from acute lung failure. A total of 159 patients were included including 112 diagnosed with ARDS, 45 with pneumonia and two patients with cystic fibrosis. Prior to treatment with the iLA these patients suffered from severe hypoxia (PaO₂/FiO₂ ratio < 80 mmHg) or hypercapnia (PaCO₂ > 70 mmHg) despite the use of aggressive mechanical ventilation.

Patients received treatment with the iLA for a mean of 7.0 ± 6.2 days (range 0-33 days) requiring an average of 1.3 membrane oxygenators each. Treatment with the iLA led to significant improvements in oxygenation with the fraction of inspired oxygen (FiO₂) improving from a mean 0.96 ± 0.09 prior to treatment to 0.48 ± 0.13 (p = 0.001) at the time prior to termination (and resumption of conventional mechanical ventilation) and remaining stable until the following day. Similarly, the partial pressure of oxygen (PaO₂) improved from 66 ± 24 mmHg prior to treatment to 91 ± 17 mmHg prior to treatment termination (p = 0.001). The severe hypoxia previously experienced by patients prior to treatment (PaO₂/FiO₂ ratio 72 ± 37 mmHg) improved to 203 ± 61 mmHg prior to termination and remained stable to the following day.
The Novalung: Pumpless extracorporeal lung assist system for the provision of pulmonary support to patients suffering from acute respiratory distress syndrome

Hypercapnia levels ($\text{PaCO}_2$) also improved from $67 \pm 24$ mmHg to $39 \pm 17$ mmHg ($p = 0.001$). Blood pH values also improved as a result of iLA treatment from $7.25 \pm 0.13$ to $7.43 \pm 0.07$ however no statistical significance was reported. Despite the improvements noted, tidal volumes were not changed throughout the treatment period. Eighty-three patients (52.2%) were successfully weaned from treatment after meeting the criteria of $\text{PaO}_2 > 80$ mmHg and $\text{FiO}_2 < 0.45$ mmHg for more than 24 hours.

Both device and clinically related adverse events were reported. As reported above, a mean of 1.3 were used. Thrombus formation ($n = 27$) and retention of air bubbles ($n = 22$) were the main reason for oxygenators being changed (a mean of 1.3 oxygenators per patient). Additionally, eight patients experienced thrombosis of the entire system with consecutive no-flow (four patients were inadequately anticoagulated, two patients suffered heparin induced thrombocytopenia type II and two patients experienced device failure). Percutaneous placement of the femoral cannula proceeded uneventfully in all but six patients who required open surgical insertion. Two patients who had extremely small femoral vessels underwent cannula insertion by means of Dacron prosthesis. Other adverse events reported included ischaemia for the lower limb in 13 patients and compartment syndrome with necessary fasciotomy in four patients (one patient required lower leg amputation).

Seventy-five patients died during treatment and 29 patients died after treatment. The overall survival rate was 34.6% (55 patients). The main causes of death included multi organ failure ($n = 50$), septic shock ($n = 38$), and low cardiac output failure ($n = 13$). Various patient characteristics including age, body mass index and duration of iLA treatment were noted to be significantly ($p < 0.05$) lower in survivors compared to non survivors.

**FUTURE STEPS**

Members acknowledged that there was a significant demand for ECMO machines since the H1N1 pandemic, and therefore deliberated over the need for an in-depth assessment on all ECMO devices. It was also noted that diffusion of this device was probable, particularly since the devices were much simpler to use, and a surgeon was not required to connect the machine.

Written by Luis Zamora (ASERNIP-S)

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**REFERENCES**


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**Other New and Emerging Technologies**

The following additional technologies were considered by the Health Policy Advisory Committee on Technology (HealthPACT) in August 2009.

- Minimally invasive robot-assisted unicompartmental knee arthroplasty
- Intra-abdominal vagal blocking for obesity
- Mini-cardiopulmonary bypass system [evidence update]
- Percutaneous aortic valve replacement (PAVR) [evidence update]

Further information on the health technologies included in the Bulletin can be accessed on the following link: [http://www.horizonscanning.gov.au](http://www.horizonscanning.gov.au)
**NEWS FLASH**

A recent presentation to the European Society of Cardiology Congress in Barcelona reported that healthy adults at low-risk of a cardiovascular event who took a daily aspirin for up to eight years did not significantly reduce their risk of a heart attack or stroke, but did increase their risk of stomach bleeding. These findings cast doubt on the "blanket prescription" of aspirin for the over-50s or as part of a polypill, a multi-drug tablet being developed to help prevent heart problems. The initial aim of the study was to find out whether aspirin could cause a greater than 25% reduction in cardiovascular events. Asymptomatic adults aged between 50 and 75 who were considered at risk of heart disease were enrolled in the study (n=3,350) and randomised to a group taking aspirin or the placebo arm. There was no statistically significant difference in primary endpoint events between subjects in the two groups (Hazard Ratio = 1.03, 95% CI [0.84, 1.27]) with heart attacks and strokes occurring in equal numbers in the aspirin (n=181) and the placebo arms (n=176). However, two per cent of people in the aspirin arm were hospitalised due to gastrointestinal bleeding, a known side-effect of the drug, compared with only 1.2 per cent of the placebo group.