Title: Compartment Pressure Monitoring for Fasciotomy

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Context and policy issues:
Compartment syndrome is caused by raised pressure in a closed fascial space \(^1,2\) It can compromise circulation to other compartments \(^1,2\) and result in muscle and nerve damage if pressure is not relieved promptly.

Compartment syndrome can be caused by many factors. Orthopedic fractures, both open and closed, are the most common cause.\(^1,2\) Vascular injuries, soft tissue injuries and other iatrogenic injuries may result in compartment syndrome as well.\(^1,2\)

Patients with compartment syndrome often present with pain disproportionately more pain compared to the size of the injury.\(^1,2\) Compartment pressure should only be taken when the clinical signs are unclear, in an unconscious or uncooperative patient\(^1,2\) or in a young child due to the invasiveness of the procedure.\(^1\)

While compartment pressure monitoring is used by some physicians, it is not practiced in all Canadian hospitals. This report will investigate the comparative effectiveness of the Stryker pressure monitoring system with other available pressure monitoring systems.

Research questions:
What is the comparative clinical effectiveness of the Stryker pressure monitoring systems and other devices used for measuring compartment pressure in orthopedic surgery?
Methods:
A limited literature search was conducted on key health technology assessment resources, including PubMed, CINAHL, The Cochrane Library (Issue 2, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI’s HTAIS, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2002 and the present, and are limited to English language publications only.

Summary of findings:
Two reports were identified that compared three devices that measure compartment pressures: Stryker Intracompartmental Pressure Monitoring system (a hand held monitor), a manometer, and the Whiteside apparatus.

In the report by Boody et al.\(^3\), the three devices were compared to a muscle compartment model with a known standard pressure. In addition, three different methods of injection were compared: side port needle, straight needle and slit catheter needle. The Stryker device with a side port needle consistently underestimated the pressure, but the difference was not statistically significant (p=0.264). When used with a straight needle, the Stryker device significantly overestimated pressure (p<0.001). When used with a slit catheter, the Stryker device significantly underestimated the pressure (p<0.001).

The arterial line manometer with a side port needle significantly underestimated pressure (p<0.001). However, when used with a straight or slit catheter needle, pressure was significantly overestimated (p<0.001 and p=0.004, respectively). The Whitesides apparatus demonstrated the largest standard errors and showed significant overestimates with the side port and slit catheter needles (p=0.01 and p=0.009, respectively), but a non-significant underestimate with the straight needle (p=0.119).

Overall, the authors concluded that the side port and slit catheter needles were more accurate than the straight needles. The arterial line manometer was the most accurate, but the Stryker device was also very accurate. The Whiteside apparatus had unacceptable precision for clinical use.

The second study by Uliasz et al.\(^4\) compared the Stryker Quick Pressure monitor, manometric IV pump and the Whiteside apparatus. It is unclear whether the Stryker device used here is the same as the device tested by Boody et al above.

A muscle compartment model using a water column was constructed and pressure readings from the three devices were each compared to the model’s standard pressure. This study reported similar results as Boody et al. Uliasz et al. reported that both the Stryker and the IV pump methods were accurate in comparison to the standard pressure. However, the IV pump method demonstrated lower standard deviations and ranges in measurements compared to the Stryker device; thus deemed to be more accurate. The authors were unable to obtain consistent pressure reading using the Whitesides method; pressure reading fluctuated by more than 10-20 mmHg.

The authors commented that both the Stryker and IV pump methods were easy to use. They suggested that even if the Stryker device is available, the IV pump method could be used as a double check to confirm the measurement, especially given the consequences of failing to identify a compartment syndrome. The authors also note that the Stryker device costs US$1575 and US$66 for the disposable unit per use. Although the IV pump can also have a high cost, they are normally readily available in hospitals as they are also used for IV infusion monitoring.
In the study by Harris et al.\textsuperscript{5}, the effect of continuous compartment pressure monitoring in acute tibia fractures was compared to “non-monitoring”. In this study, 200 patients were randomized to receive continuous compartment pressure monitoring for 36 hours with the Stryker compartment pressure monitor or “non-monitoring” with only usual post operative observations. In alert patients, the diagnosis of compartment syndrome was made clinically, regardless of compartment pressure; whereas, in unconscious patients, a difference between compartment pressure and diastolic blood pressure (\(\Delta p\)) of less than 30 mmHg was the criterion for suspected compartment syndrome and consequently, for fasciotomy. At six months, patients were assessed for late complications of compartment syndrome such as sensory loss, muscle weakness, contracture and toe clawing.

The follow-up rate was 89%. At six months, there were five cases of compartment syndrome in the non-monitored group and all underwent fasciotomy. There were no cases of compartment syndrome in the monitored group, although one fasciotomy was performed prophylactically. The late complication rates between the two groups were not significantly different. In the monitored group, of the patients with \(\Delta p\) less than 30 mmHg (\(n=18\)), none developed compartment syndrome or late complications.

The authors found that clinical diagnosis alone did not lead to cases of missed compartment syndrome. They concluded that compartment pressure monitoring is not indicated in alert patients who are adequately monitored.

There were two studies identified that compared a Stryker device to the EBI Non-invasive Compartment Evaluator. The EBI device quantitatively measures the hardness of the compartment, defined as the ratio of pressure applied to the volume displaced.\textsuperscript{6} Although orthopedic surgeons have subjectively measured hardness by palpating limbs suspected of having compartment syndrome, it is not common practice.\textsuperscript{6} According to the Medical Devices Active License Listing database, the EBI device is not available in Canada,\textsuperscript{7} and therefore, only the general findings of these studies are presented below.

In the study by Dickson et al.\textsuperscript{6}, pressure measurements were made using the Stryker STIK electronic pressure measuring device and hardness measurements were made using the EBI Non-invasive Compartment Evaluator. Both devices are hand held. Dickson found that the EBI device was less accurate compared to the invasive pressure measuring device in making a correct diagnosis. The sensitivity of the two devices were similar (EBI 0.68, Stryker 0.66), however the specificity was significantly less with the EBI device (EBI 0.82, Stryker 0.96). Overall, the authors did not recommend the device for clinical use.

In the study by Steinberg \textsuperscript{8}, the same EBI device was compared to the Stryker electronic intracompartmental pressure monitoring device. Eighteen volunteers had their intracompartmental interstitial pressures elevated by applying a tourniquet. Comparison between the interstitial pressure and the hardness measurement showed a strong linear relationship (i.e. as interstitial pressure increases, hardness increased proportionally).

Conclusions and implications for decision or policy making:
Compartment pressure monitoring is not adopted in all Canadian hospitals. However, there is consensus that it is necessary when the clinical signs of compartment syndrome are unclear, in unconscious or uncooperative patients, in young children or when the signs and symptoms are unequivocal.\textsuperscript{1,2}
Of two reports that compared the Stryker device to a manometer pressure device and the Whiteside apparatus, the manometer pressure device was the most accurate, but the Stryker device was also highly accurate. The Whiteside was considered inappropriate for the clinical setting because of its inconsistency on measurements.

Both the manometer and the Stryker device are invasive. Since the IV manometer is also used to measure IV infusion monitoring, it is readily available in hospitals. The Stryker device is commercially available and uses a disposable unit for each use.

Adequate training should be considered for monitoring compartment pressure devices, as different thresholds have been used to diagnose compartment syndrome and clinical monitoring must also be performed regularly. Regardless of whether compartment pressure devices are used, it is essential that patients with compartment syndrome be treated promptly as it may lead to muscle and nerve damage.

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