Safety and performance of intravenous pumps and syringe drivers in hyperbaric environments

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Abstract
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Introduction: Critically ill patients require continuation of their care when receiving hyperbaric oxygen treatment. This care may be facilitated via portable electrically powered devices such as intravenous (IV) infusion pumps and syringe drivers, which may create risks in the absence of a comprehensive safety evaluation. We reviewed published safety data for IV infusion pumps and powered syringe drivers in hyperbaric environments and compared the evaluation processes to key requirements documented in safety standards and guidelines.
Methods: A systematic literature review was undertaken to identify English language papers published in the last 15 years, describing the safety evaluations of IV pumps and/or syringe drivers for use in hyperbaric environments. Papers were critically assessed in relation to the requirements of international standards and safety recommendations.
Results: Eight studies of IV infusion devices were identified. There were deficiencies in the published safety evaluations of IV pumps for hyperbaric use. Despite a simple, published process for evaluating new devices, and available guidelines for fire safety, only two devices had comprehensive safety assessments. Most studies focused only on whether the device functioned normally under pressure and did not consider implosion/explosion risk, fire safety, toxicity, oxygen compatibility or risk of pressure damage.
Conclusions: Intravenous infusion (and other electrically powered) devices require comprehensive assessment before use under hyperbaric conditions. This would be enhanced by a publicly accessible database hosting the risk assessments. Facilities should conduct their own assessments specific to their environment and practices.

Introduction

Comprehensive hyperbaric facilities are capable of providing in-chamber intensive care to patients who are critically ill from a wide range of causes.[1] In such facilities, hyperbaric oxygen (HBO) treatment may be delivered to critically ill patients suffering from necrotizing fasciitis, gas gangrene, arterial gas embolism, decompression sickness or carbon monoxide poisoning, among other indications.[2,3] Much of the supportive care provided to such patients is facilitated via portable electrically powered devices such as intravenous (IV) infusion pumps and syringe drivers which are essential for the delivery of certain medications at precise infusion rates.[4] Depending on the complexity of the critical care needed, patients may require infusions via multiple devices to maintain physiological stability.

The Undersea and Hyperbaric Medicine Society (UHMS) has published recommendations for assessing the safety of portable devices before their use in the hyperbaric environment.[5] These require that all portable medical electrically powered equipment taken into hyperbaric chambers: (i) are not at risk of explosion or implosion; (ii) do not pose a fire risk; (iii) contain no toxic material; (iv) are oxygen compatible; (v) will not be damaged by pressure; and (vi) must function normally under pressure.[5–7] Equipment is deemed safe and serviceable only if it conforms to these criteria and can successfully perform its intended function under expected conditions, including the required pressure and oxygen concentration, and does not produce excessive heat or contain ignition sources. Specifically, the National Fire Protection Association (NFPA) 99 Health Care Facilities Code, 2021 Edition, Chapter 14, details requirements for portable patient care devices (Section 14.2.9.3.16) for both battery-operated and cord-connected devices, categories under which IV pumps and powered syringes fall as therapeutic patient-related electrically powered equipment.[8]

In order for critically ill patients to safely receive HBO treatment, it is imperative that IV infusion pumps and syringe drivers must be safe and able to deliver accurate doses of medication and maintain appropriate flow rates in a pressurised environment. Most available infusion pumps

are not approved for hyperbaric applications, although there are exceptions. Most have not undergone independent hyperbaric safety assessment, even if approved by the Food and Drug Administration (FDA) in the USA.[9] Moreover, some pumps may not function at all under hyperbaric conditions or might experience technical problems affecting their accuracy.[10]

According to a preliminary review of the literature, very early papers on this topic focused primarily on pump function and physical integrity or registration rather than safety, for example, assessment of electrical and fire risk received limited attention.[10–12] One study assessed the function of 29 pumps under hyperbaric conditions, but did not propose a process for safety risk assessment prior to chamber entry.[10] Another study noted that only one syringe pump used in European hyperbaric chambers had received *Conformité Européene* (CE) certification indicating that it complied with the safety standards outlined by the European Medical Device Directive (MDD 93/42).[11]

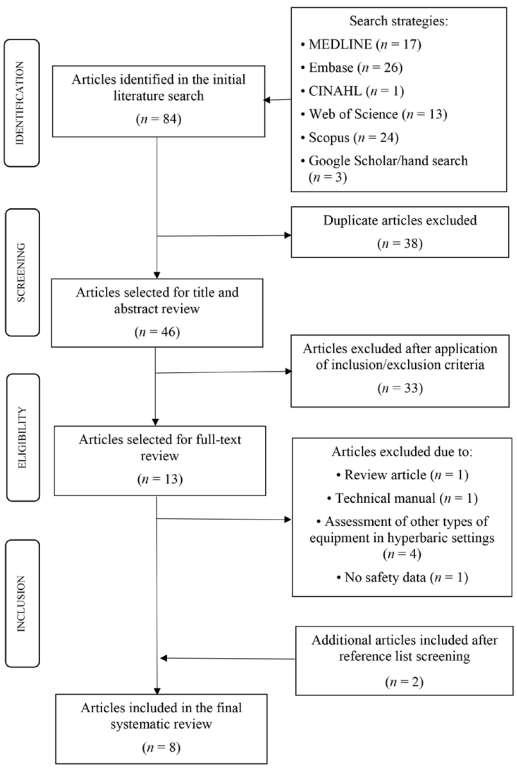
This paper aimed to review published safety data for IV infusion pumps and powered syringe drivers in hyperbaric environments and to compare the safety evaluation processes to key guidelines found in the Australian and New Zealand Standards 4774.2, UHMS processes, NFPA 99 Health Care Facilities Code and NFPA 53 recommended practice for oxygen-enriched environments.[6–8,13,14]

Methods

A systematic literature review was undertaken to identify papers describing the assessment of IV pumps and/or syringe drivers for use in hyperbaric environments, focusing primarily on safety and mitigation of fire risk. The review was conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[15] The inclusion criteria consisted of all full-text articles published in English over a 15-year period between May 2006 and April 2021 and describing the safety assessment of powered IV syringe drivers and infusion pumps in hyperbaric environments. Only experimental studies were considered eligible for inclusion. Technical manuals, manufacturer-funded reports and review articles were excluded from the analysis.

A literature search was conducted of the MEDLINE® (National Library of Medicine, Bethesda, Maryland, USA), Embase® (Elsevier, Amsterdam, the Netherlands), SCOPUS® (Elsevier), Cumulative Index to Nursing and Allied Health Literature (CINAHL; EBSCO Information Services, Ipswich, Massachusetts, USA), Web of Science (Clarivate Analytics, Philadelphia, Pennsylvania, USA) and Google Scholar (Google Inc., Mountain View, California, USA) databases. The following search terms were employed in various combinations: "*hyperbaric oxygen*", "*hyperbaric critical care*", "*intravenous pumps*", "*infusion devices*", "*syringe drivers*", "*safety*", "*risk*", "*risk assessment*" and "*fire risk*". In addition, a hand search was conducted of relevant diving and hyperbaric medicine textbooks as well as the journal websites and workshop/conference proceedings of the South Pacific Underwater Medicine Society (SPUMS), UHMS, European Underwater and Baromedical Society (EUBS) and International Congress on Hyperbaric Medicine (ICHM).

Figure 1
Flow chart summarising the literature search



Following the literature search, the titles, abstracts and reference lists of retrieved articles were reviewed to identify relevant articles and remove any duplicate records. Full-text versions of the remaining articles were critically evaluated by two researchers to determine their eligibility for inclusion in the review. At this stage, the reference lists of the full-text papers were searched to identify additional relevant articles. For each selected article we reviewed the research objective, study design, methodology and results. The focus of the assessment was the safety and serviceability of the device in hyperbaric clinical practice. Finally, technical documents for the NFPA publications 99 and 53 and Australian and New Zealand Standards 4774.2 were reviewed to determine the safety requirements for portable patient care-related electrically powered equipment usage in oxygen-enriched environments and hyperbaric facilities.[8,13,14]

Results

A flow chart summarising the literature search is outlined in Figure 1. The raw data resulting from the search strategies are provided in Appendix 1.

Table 1

Characteristics of studies describing the safety assessment of intravenous pumps and/or syringe drivers for use in hyperbaric environments; *Denotes device without electrical components; FDA – Food and Drug Administration; HBO – hyperbaric oxygen; NiMH – nickel-metal hydride; O_2 – oxygen; PRBCs – packed red blood cells; Ref – reference number

Ref	Device name	Type of device	Methodology	Chamber type and pressure	Type of safety assessment	Summary of outcomes	Remarks
16	Baxter elastomeric LV10 Infusor™	*Elastomeric IV infusion pump	Delivery of various antibiotic solutions measured by weight. Flow rates assessed at different pressures and intervals.	Multiplace 101.3 (sea level), 203, 243 and 284 kPa	Function under pressure	• Flow rate affected by pressure changes. • Could not confirm elastomeric infusion pumps are always safe.	• Choice of antibiotic (ceftazidime vs. flucloxacillin) could affect flow rate.
17	Hospira Plum A+(Hb) infusion pump	IV infusion pump	Flow accuracy evaluated at various rates (1, 100, 250 and 999 ml·h^{-1}), viscosities (normal saline vs. PRBCs at 100 ml·h^{-1}), pressures and volumes. Occlusion alarm settings adjusted to assess battery life.	Mono and multiplace Monoplace: 86.1, 202.7 and 304 kPa Multiplace: 202.7 and 304 kPa	Function under pressure	• Pump functioned within manufacturer limits during multiplace trials. • Delivery variations in monoplace trials. • Battery life insufficient for a clinical HBO session at higher flow rates.	• Pump approved by the FDA but has since been retired. • Uses a self-contained lead acid rechargeable battery. • Tubing pliability may affect delivery, especially at low flow rates.
18	Carefusion Alaris PC infusion pump (model 8015 PC unit and 8100 large volume pump module)	IV infusion pump	Standardised experiment to assess basic suitability, inspect internal components and assess performance. Volume delivery assessed using 0.9% normal saline at 10, 50, 125 and 500 ml·h^{-1}	Multiplace Basic suitability: Up to 304 kPa at 10 kPa·min^{-1} Performance: 283.7 kPa at 30 kPa·min^{-1}, up to 405.3 kPa at 180 kPa·min^{-1}	Implosion Explosion Fire O_2 compatibility Pressure damage Function under pressure	• Pump posed no additional ignition risk. • Battery posed minimal risk of fire or explosion. • Pump performance within specifications for flow rate and occlusion alarms.	• Testing limited to expected conditions. • Locking pins installed due to ignition risk. • Spare units recommended in-chamber in case of device failure.
19	BBraun Perfusor Space syringe	Peristaltic syringe driver	Three different brands of 50-ml syringes delivering 0.9% saline assessed at ambient and increased pressure. Tested for force generation, pump flow accuracy at 1, 5, 10 and 40 ml·h^{-1} and occlusion alarm parameters.	Multiplace Compression to 284 kPa at 30 kPa·min^{-1}, continued for 30 minutes at 284 kPa, decompression at 30 kPa·min^{-1}	Implosion Explosion Fire O_2 compatibility Pressure damage Function under pressure	• Performance depended on syringe type and flow rate. • Syringe deformation during compression. • Two brands showed unacceptable stiction upon compression to 284 kPa.	• Potential to under-deliver during compression and over-deliver during decompression. • Testing using internal NiMH battery pack. • Powered by a stepper motor.

Table 1 continued.

20	Zyno Medical Z-800F, CME BodyGuard 323 ColorVision™ and Baxter Flo-Gard® 6201	Infusion pumps	Pumps connected to chamber pass-through with rigid small-bore tubing. Saline infused at 1–100 ml·h^{-1}.	Monoplace 86.1–304 kPa	Function under pressure	• Pumps functioned within manufacturer limits. • At low flow rates, tubing pliability affected fluid delivery.	• Occlusion pressure adjusted to 304 kPa. • None of the pumps were cleared by the FDA for HBO use at time of testing.
21	Unknown	Infusion syringe	Twenty 60-ml syringes filled with 20 ml of red food dye-coloured water. Volume assessed at various pressures.	Multiplace 243.2 kPa over 2 minutes, continued for 1 minute to 283.7 kPa	Function under pressure	• Over-delivery of fluid during decompression due to expansion of air. • Degree of effect dependent upon compression rate.	• Pressure changes during treatment may affect fluid delivery at low infusion rates.
22	Baxter elastomeric LV10 Infusor™	*Elastomeric IV infusion pump	Groups of 10 pumps assessed using either antibiotics or dopamine over 2-hour intervals (one group under normobaric and the other under hyperbaric conditions). Fluid delivery and flow rates determined by measuring fluid volume and weight.	Multiplace Control group: 101.3 kPa (sea level) Hyperbaric group: Compression over 10 minutes, continued at 243 kPa for 90 minutes, decompression for 20 minutes	Function under pressure	• Hyperbaric group delivered non-statistically larger volumes. • Both groups gradually delivered less fluid over time. • Neither group attained the manufacturer specified flow rate.	• Both groups tested at similar temperatures (22–23°C). • No statistical difference between groups in flow rate; however, a significant difference in flow rate based on fluid type (antibiotics vs. dopamine).
23	On-Q Pain Pump	Elastomeric pain ball infusion pump	0.2% ropivacaine delivered at 14 ml·h^{-1}. Fluid output measured by fluid volume and weight under normobaric and hyperbaric conditions.	Monoplace 101.3, 202.7, 243.2, 283.7 and 304 kPa for 9 minutes, compression/ decompression over 7 minutes	Function under pressure	• Fluid output stayed within acceptable limits (± 10–20%). • No statistical differences between groups in terms of output.	• Both groups showed gradual decrease in fluid output with time. • Potential delivery variations due to fluid viscosity.

Eighty-four papers were identified during the initial literature search, of which 38 were excluded due to duplication. The remaining 46 papers underwent abstract and title screening to determine their eligibility according to the inclusion and exclusion criteria. A total of 33 papers were excluded at this stage, with the remaining 13 articles selected for full-text review. The reference lists of these papers revealed two additional articles. Finally, seven papers were rejected for the reasons described in Figure 1. Thus, a total of eight studies were found that assessed different IV pump and syringes in hyperbaric environments.

All eight papers included in the final analysis were experimental studies assessing infusion equipment in hyperbaric settings.[16–23] An overview of the studies is presented in Table 1. Of the studies, six evaluated infusion pumps,[16–18,20,22,23] and two assessed syringe drivers.[19,21] The majority of the studies were conducted under multiplace hyperbaric conditions.[16,18,19,21,22] Of the remaining studies, two were conducted under monoplace conditions, and one was conducted under both multiplace and monoplace chamber conditions.[17,20,23]

Three studies assessed elastomeric devices, while the remaining five studies evaluated electrically powered infusion devices. The electrically driven devices potentially offer several routes of medication administration, including IV, intra-arterial, subcutaneous or epidural routes. For clarity, one of the studies in Table 1 assessed an unnamed syringe driver device to determine the effect of air spaces on syringe function in a hyperbaric environment.[21]

Two of the eight studies documented a more comprehensive safety evaluation, both from the same centre.[18,19] There is sufficient detail in these published papers to demonstrate that the majority of the UHMS assessment criteria were considered, apart from toxicity.[5,6,18,19] Six of the eight studies focussed primarily on the performance of the equipment in hyperbaric settings, particularly flow rate function and accuracy.[16,17,20–23] These studies did not consider fire safety, oxygen compatibility, ignition sources or toxicity.

Three studies revealed that the tested infusion pumps performed to the manufacturer's specifications, including occlusion alarm testing.[17,18,20] Three studies indicated that flow rates were not significantly impacted by increases in ambient pressure.[16,18,22] However, one study offered evidence to suggest that flow rate might be affected by choice of antibiotic; as such, the authors could not categorically determine that elastomeric infusion pumps are safe in hyperbaric settings.[16] Similarly, one study reported significant differences in flow rate depending on the type of medication being infused.[22]

One study noted that flow rates at low infusion rates (10 $ml \cdot h^{-1}$) fell below performance specifications, although this finding may be related to measurement methods.[18] Another also observed variations in fluid delivery during monoplace trials, particularly during the compression and decompression phases. The authors concluded that tubing compliance may affect fluid volume delivery, especially when infusion rates are low during compression and decompression.[17,20] At higher flow rates (999 $ml \cdot h^{-1}$), the battery life of the Hospira PlumA+ (Hb) pump in multiplace trials appeared to be less than the duration of a standard clinical hyperbaric session.[17] Lewis et al. found that the volumes delivered by the elastomeric pumps under hyperbaric conditions were not significantly different to the normobaric control group, although pumps operated in either condition did not achieve the flow rate claimed by the manufacturer, and delivered declining volumes over time.[22] Tobias et al. similarly noted no significant differences in fluid output between elastomeric pumps operated in hyperbaric and normobaric conditions, with volume delivery remaining within acceptable limits; however, the researchers also observed a gradual decrease in fluid output over time, regardless of group allocation.[23]

Both studies assessing syringe drivers indicated that changes in pressure affected equipment performance.[19,21] In one, the syringe drivers performed to the manufacturer's specifications; however, the researchers warned that performance was contingent on syringe type and flow rates. Issues with syringe deformation during compression resulted in significant stiction in two out of three brands of syringes – an effect which worsened with increasing syringe size. As a result, the authors cautioned that the device may under-deliver during compression and over-deliver during decompression.[19] In the other study, compression of the air spaces within the syringe during normal HBO treatment resulted in statistically significant changes in fluid volume delivery, with the degree of effect dependent on the rate of compression. It was suggested that fluid delivery would decrease or even halt entirely during compression, while extra fluid would be delivered during decompression as the air spaces within the syringe re-expanded.[21]

Discussion

Most patients receiving HBO treatment do not require infusions. However, some emergency cases and critically ill individuals frequently require continuous infusions of various drugs, including vasopressors, sedatives, insulin or antibiotics.[24]

This project sought to systematically review current literature evaluating the hyperbaric safety of IV infusion pumps and syringe drivers and compare this guidance with key technical

Footnote: * Appendix 1 is available on DHM Journal's website: https://www.dhmjournal.com/index.php/journals?id=310

safety reference standards. Seven infusion devices assessed in these experimental studies were evaluated based on a single criterion of the UHMS recommendations, namely whether the device functioned normally under pressure.[5–7] These studies did not consider implosion/explosion risk, fire safety, toxicity, oxygen compatibility or risk of pressure damage, which is of significant concern. Sources of heat and ignition within equipment such as lithium-ion batteries and brushed motors could precipitate fire in the oxygen-enriched hyperbaric environment.

Section 3.9 of the Australian/New Zealand (ANZ) Standards 4774.2, which considers work performed in HBO facilities, states that: "*Portable electronic or electrical systems (e.g., entertainment units) shall have a risk assessment report completed by a competent person for risk of ignition and ability to support combustion prior to being taken into the chamber*".[13] Thus, only two of the identified studies attempted to conduct a risk assessment consistent with ANZ standards and considered all UHMS criteria except for toxicity.[5,6,18,19] Both were from the same centre.

One study conducted three additional phases of testing, including basic suitability testing, internal inspection and surface temperature measurement to determine fire risk, implosion risk, oxygen compatibility and pressure damage. The authors concluded that the infusion pump itself was not at risk of pressure damage or ignition.[18] Component surface temperatures reached a maximum of 74°C, which was below the maximum allowable (85°C) under NFPA99 Code.[8] Additional components were also found to present minimal risk of fire or explosion under conditions of expected use, including other potential sources of ignition such as the stepper motor, encapsulated lithium battery and lubricating grease. The authors identified a possible risk of spark ignition due to the design of the device which allowed electrical connection or disconnection of the modules during operation.[18] Another study documented the safety assessment process which preceded the evaluation of the BBraunPerfusor Space syringe.[19] This did not follow UHMS recommendations, but was locally developed and followed a local matrix.[19,25] There was sufficient description in the text to identify that issues of pressure deformity, fire, internal ignition source and oxygen compatibility had been evaluated. Unfortunately, the locally used matrix was never published other than in an abstract which lacked sufficient detail to be properly evaluated, although it was again referred to in Smale and Tsouras's paper.[18,25]

Overall, the majority of the tested infusion pumps conformed to the manufacturer's specifications, with reported flow rate and output variations falling within clinically acceptable ranges; however, there were several findings of note.

It is possible that different antibiotic solutions may affect flow rates. Four out of five infusions of ceftazidime were above the set range for clinically acceptable infusion (9–12 $ml \cdot h^{-1}$) whereas trials using flucloxacillin demonstrated flow rates within acceptable limits.[16] Similarly, significant flow rate variations could occur depending on choice of infused medication (antibiotics vs. dopamine).[22] In monoplace situations, the pliability of infusion pump tubing external to the chamber may affect fluid volume delivery, especially at low flow rates.[17,20] This occurs because the expansion of the tubing during compression results in a reduction in the amount of fluid delivered. Subsequently, when the internal chamber pressure decreases during decompression, the extra fluid in the expanded tubing is delivered in a single bolus, even if the pump is turned off. This occurred even with rigid, small bore tubing and would likely be amplified with normal medical-grade IV tubing.[17]

Both assessments of syringe infusion devices demonstrated significant variations in fluid delivery, especially at low infusion rates. In particular, the devices had the potential to release too much fluid during the decompression phase and not enough during compression, likely as result of the re-expansion and compression of pockets of air within the syringe.[19,21] In addition, syringe deformation and stiction occurred during pressurisation with both the Terumo and Becton Dickinson syringes.[19] Stiction refers to the occurrence of static friction between the plunger seal and the wall of the syringe which impedes the normal movement of the syringe, resulting in a jerky, start-and-stop type of motion. The subsequent flow irregularities and inadvertent boluses from this unintentional movement can be detrimental to critically ill patients.[26] The researchers were obliged to continue their experiments using the BBraun syringe, with which there was less lateral movement of the plunger due to the stiffer barrel and the increased distance between the plunger O-rings.[19]

Two studies evaluated the Baxter LV10 Infusor™, a large-volume, non-electronic, balloon-driven, elastomeric infusion pump.[16,22] Although not an electrically powered device, the documented assessments were detected by the literature search and included for analysis. We considered that elastomeric infusion devices should be subject to the same safety evaluation processes as any other equipment.

Depending on the type of hyperbaric chamber utilised, supportive devices such as infusion pumps may either be placed within the chamber itself, for instance in the context of multiplace chambers treating multiple people, or externally, in the case of monoplace chambers which only have room for a single patient. In the latter, infusions are provided through ports in the chamber hull.[24] Both chamber types pose challenges when operating infusion devices. Pumps placed outside of monoplace chambers have the advantage of keeping the electrically powered device outside the hyperbaric environment. However, they must work against a considerable pressure gradient to deliver fluids into the pressurised chamber. Many infusion pumps have a much lower default upper occlusion pressure setting

than is feasible in monoplace settings.[20] In contrast, pumps within multiplace chambers have no pressure differential to overcome but pose a greater risk due to their location within the hyperbaric chamber.[24]

Fire is a key risk for devices taken into multiplace hyperbaric chambers. These chambers are pressurised with air, but oxygen levels within the chamber may rise if not carefully monitored and controlled. Materials may ignite and burn more easily; moreover, because the chamber is pressurised and enclosed, rapid extinguishing of the fire or evacuation of the patient may be difficult, if not impossible.[27] Thus, there should be strong risk awareness and zero tolerance for devices that could cause a fire. Potential sources of ignition such as sparks must be eliminated (e.g., brushed electric motors or wire connections) and devices must not heat up when operating. Moreover, it is imperative that the devices should not support combustion; in other words, that they should be composed of oxygen-compatible materials with a low probability of ignition.[28,29]

Using a non-contact infrared thermometer, one study confirmed that the operating surface temperature of the internal components of the Carefusion Alaris PC infusion pump did not exceed 75°C, as per section 14.2.9.3.11 of the NFPA 99 Code.[8,18] However, their risk evaluation identified issues that could conceivably pose a risk of ignition in an oxygen-rich environment. Specifically, the device included electronic components, lubricating grease and an encapsulated lithium battery. The brushless stepper motor was considered low risk. This would not be the case for a brushed motor which can produce sparks. A key area of risk allowed for the electrical connection and disconnection of the large-volume pump module from the PC unit. This created a risk of electrical sparks but was controlled by preventing disconnection using locking pins. The researchers also recommended bringing two spare units into the chamber in case of device failure to avoid having to latch or unlatch the modules during operation or being forced to subject a new device to rapid changes in pressure and temperature due to transfer through the entrance lock. The lubricating grease applied to the door clamping mechanism was determined to be a stable phenylmethyl silicone-based grease which did not pose a risk of spontaneous ignition under expected hyperbaric conditions. The researchers confirmed the PC unit included a non-rechargeable, single-cell lithium battery encapsulated in a 0.4-mm nylon casing.[18]

Lithium-ion batteries have revolutionised portable electronic devices by facilitating reductions in equipment size and weight and allowing greater power output, longer endurance and the ability to supply voltage more effectively than previous battery technologies. Nevertheless, despite their extensive usage in medical devices, lithium-ion batteries are susceptible to thermal runaway and fire, with pressure exposure increasing failure risk.[30] One study has demonstrated damage to pump batteries when exposed to pressure, an event which could lead to an in-chamber fire.[12] Although the NFPA previously prohibited devices using lithium-ion batteries in hyperbaric chambers unless specifically qualified by the manufacturer or by a recognised testing agency, such restrictions have been lifted in recent editions.[8,14] Nevertheless, as noted by Burman, the code intends that power sources remain outside of the chamber.[31] It can be concluded that all providers using battery-operated electrically powered devices in an oxygen-enriched environment should ensure that the batteries are non-damaged, secure, contained in fully enclosed housings and under no circumstances allow charging of any battery type while in-chamber.[4,8,31]

Following a risk assessment, Smale and Tsouras deemed the battery in the Carefusion Alaris PC infusion pump to pose minimal risk of fire or explosion.[18] This determination was based on previous data confirming the oxygen compatibility of the encapsulated nylon at 12,000 kPa to be 200°C in a 99.5% oxygen atmosphere.[32] These conditions fall considerably outside the upper range of temperature and pressure expected in clinical hyperbaric settings.[18] Moreover, non-rechargeable, single-cell, low-voltage lithium batteries are considered preferrable in hyperbaric environments compared to larger, higher voltage or rechargeable batteries.[4] None of the other studies identified in this review assessed the ignition risk posed by the batteries of their tested infusion devices. One study reported that the life of the self-contained, lead-acid rechargeable battery in the Hospira Plum A+(Hb) infusion pump did not match the duration of a typical HBO treatment session at high pump flow rates.[17] Battery endurance is a key consideration for infusion devices proposed for use in multiplace chamber settings.[24] Historically, unsealed lead-acid batteries are discouraged in hyperbaric chambers due to the risk of spillage and hydrogen production during recharging, while nickel-metal hydride batteries (such as in the BBraunPerfusor space syringe driver[19]) are considered to be the most suitable type of rechargeable battery.[33]

Most IV infusion devices are used in 'off-label' fashion in hyperbaric facilities, signifying that their sale for use in hyperbaric chambers is unsupported by the manufacturer. In one study, none of the three pumps assessed had been cleared by the FDA for use in hyperbaric chambers.[20] Moreover, even those few devices which have been granted FDA clearance for hyperbaric use have not had a published risk assessment.[9] These devices appear to have a limited design life and may be discontinued by the manufacturer, as was the Hospira Plum A+ (Hb) infusion pump which was retired in June 2014.[17] Once a hyperbaric compatible device becomes unavailable, the search for, and risk assessment of appropriate replacements must recommence. The safety evaluation of electrically powered devices for hyperbaric use needs to be on-going and continuous across the entire hyperbaric medicine community.

In view of the near universal uptake of medical equipment incorporating lithium-ion batteries, coupled with their serious risk of thermal runaway and fire in hyperbaric environments, the authors strongly recommend that a thorough safety/risk assessment should precede any testing of IV pump integrity and function under pressure, covering – as a minimum – the six UHMS criteria. This recommendation would sensibly be extended to all portable electrically powered devices intended for use within the hyperbaric environment.

This review has demonstrated deficiencies in the published safety evaluations of IV pumps for use in the hyperbaric environment. Despite a simple, published process for evaluating new devices (UHMS), including NFPA codes and recommendations for fire safety, only eight studies of IV infusion devices were identified in this review, and only two had comprehensive safety assessments. It is of concern that most studies focused only on whether the device functioned normally under pressure. Given the widespread use of HBO treatment, it would be useful to establish a central database hosting comprehensive equipment risk assessment to permit quick reference by intending new users. Nonetheless, it is important to note that the burden of proof of safety for using an off-label and non-FDA-cleared device in a hyperbaric chamber, an intrinsically hazardous environment, remains the responsibility of the facility; as such, no study or risk assessment should be considered to bestow unilateral safety approval, either tacit or implied, as there are too many unknown variables at play. However, such a database could be useful for guidance.

LIMITATIONS

The search strategy may have missed key studies that were published outside of the medical literature. In addition, articles published in languages other than English could not be included in the systematic search. As such, it is possible that relevant studies published in other languages were not included in the final analysis.

Conclusions

A systematic review of published safety data describing the assessment of IV pumps and/or syringe drivers for use in hyperbaric environments revealed that many recent studies on this topic have concentrated primarily on the performance and function of devices and have missed many aspects of a comprehensive safety assessment. There is a need for facilities to conduct their own comprehensive safety assessments of IV infusion devices for use under hyperbaric conditions. This should include important criteria such as explosion or implosion risk, ignition and fire risk, toxicity, oxygen compatibility and pressure damage. This process could be enhanced by a publicly accessible database hosting the risk assessments to guide future hyperbaric practitioners in their selection of equipment. It would also be useful if manufacturers would support the development and assessment of infusion devices which conform to technical safety standards for use in hyperbaric chambers, although this may be unrealistic due to the limited market for such applications.

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